DEPARTMENT OF THE ARMY
HEADQUARTERS, US ARMY MEDICAL RESEARCH AND MATERIEL COMMAND
810 SCHREIDER STREET
FORT DETRICK, MARYLAND 21702-5000

REPLY TO ATTENTION OF

OCT 17 2016

Freedom of Information/
Privacy Act Office

Mr. John Greenewald
John Greenewald [john@greenewald.com]

Dear Mr. Greenwald:

This is in response to your Freedom of Information Act (FOIA) requests dated June 13, 2016 for "1) a copy of the most recent administrative report on the activities of the U.S. Army Medical Research and Materiel Command; 2) a copy of the most recent budget justification document for the U.S. Army Medical Research and Materiel Command; 3) a copy of the most recent administrative report on the activities of the U.S. Army Medical Material Agency; 4) a copy of the most recent budget justification document for the U.S. Army Medical Material Agency. We agreed to provide the 2014 Annual Historical Report.

Your request was processed in accordance with the Freedom of Information Act (FOIA), 5 United States Code (U.S.C.) § 552.

The USAMRMC Headquarters Electronic Reading Room posts records of interest that have been released in response to written requests for information under the FOIA and have been redacted per FOIA guidelines. The 2014 Annual Historical Report can be found at our website at https://mrmc.amedd.army.mil/ Freedom of Information Act and then click on Reading Room. Please review the website for the records you have requested.

Redactions made to the 2014 Annual Historical Report include redactions according to:

- (b)(3)(b) specifically exempted from disclosure by statute (other than section 552b of this title), provided that such statute (A) requires that the matters be withheld from the public in such a manner as to leave no discretion on the issue, or (B) establishes particular criteria for withholding or refers to particular types of matters to be withheld;

- (b)(4) trade secrets and commercial or financial information obtained from a person and privileged or confidential;

- 5 U.S.C. § 552(b)(6): Records have been redacted or withheld where the disclosure of information would represent a clearly unwarranted invasion of personal privacy;

Because your request has been partially redacted you are advised of your right to appeal this determination to the Secretary of the Army. If you decide to appeal at this time, your appeal must be submitted within 90 days of the date of this notification. In your appeal, you must state the basis for your disagreement with the partial denial and the justification for the release of information associated with your request for this command. Your appeal should be addressed to: CDR U.S. Army Medical Command, Attention: Freedom of Information/Privacy Acts Office (MCPA), 2748 Worth Road, JBSA, Fort Sam Houston, Texas 78234-6021, for forwarding, as appropriate, to the Office of the Secretary of the Army. Please enclose a copy of this response along with your Appeal. To ensure proper processing, the letter and the envelope should both bear the notation, "Freedom of Information Act Appeal."

You are also advised of your right to seek dispute resolution services pertaining to your concerns from the MEDCOM FOIA Public Liaison Officer, Ms. Emily D. Hall at (210) 221-4233 or email: emily.d.hall5.civ@mail.mil

Should you have any questions pertaining to this response I may be reached at USArmy.Detrick.MEDCOM-USAMRMC.List.FOIA-MRMC@mail.mil

Fees associated with the processing of your request are waived in this instance.

Sincerely,

Sandra Rogers

Sandra J. Rogers
Freedom of Information/Privacy Act Officer
U.S. Army Medical Research and
Materiel Command

FISCAL YEAR 2014

ANNUAL HISTORICAL REPORT

U.S. ARMY MEDICAL RESEARCH AND MATERIEL COMMAND

FOUO (For Official Use Only)

Section 1

Fiscal Year 2014
Annual Historical Report

G1 – Deputy Chief of Staff for Human Resources

Mission

Provide World Class Human Resources (HR) support to MRMC. Develop integrated strategies and refine business processes to efficiently manage the full spectrum of HR programs, policies, and human capital assets. Institutionalize change management. Take care of Soldiers and DA Civilians.

Staff

LTC (b) (6), G1/DCSHR
(b) (6), Secretary, G1/DCSHR

Functions

A. Office of the Deputy Chief of Staff for Human Resources

1) Responsible for administration and management of human resources in the specialized areas of military and federal civilian personnel for USAMRMC.
2) Formulates local HR plans and policies and executes DoD military and federal HR policies based on regulation, guidance, and law, ensuring military and federal civilian HR programs are effectively and efficiently implemented and monitored.
3) Principal staff advisor to the Commanding General on HR matters, reporting to the Chief of Staff.
4) Performs duties and responsibility as the Troop Commander for the USAMRMC, and serves as rater/mentor for HQ Commander, supervising unit level operations, health and welfare, discipline, readiness, and training.
5) Coordinates as required with USAMEDCOM, OTSG, US Army Human Resources Command (USAHRC), US Army Civilian Human Resources Agency (USACHRA), US Army Reserve Command, the Army G-1, OASA (ALT), and HQDA on HR matters.
6) Directs and supervises HR operations in the areas of strength management, hiring actions, readiness, personnel management and actions, awards, evaluations and civilian appraisals, PROFIS, special pay, and finance.
7) Supervises and manages the G-1 staff, providing direction and oversight to all military HR functions.
8) Manages the AMEDD military and civilian acquisition workforce programs, to include acquisition career development management.
9) Serves as a member of the working Program Budget Advisory Council.
10) Responsible for the HR roles in the implementation and daily maintenance of DMHRSi.

Military Personnel Management Division

Staff
(b) (6), Chief Military Personnel
(b) (6), Operations Specialist
(b) (6), Human Resource Specialist
(b) (6), Human Resource Specialist
(b) (6), Human Resource Specialist
SFC (b) (6), NCOIC G1/DCSHR

SGT (b) (6) Human Resource Sergeant

A. Significant Accomplishments

1) The MPD staff continues to conduct training and manage the Army Disaster Personnel Accountability and Assessment System (ADPAAS) for the headquarters and subordinate units. USAMRMC has an approved ADPAAS Policy Guidance.
2) Exceeded DA & MEDCOM Standards of 95% for timeliness of OERs and NCOERs for the past 4 quarters with a 99% error free processing rate.
3) Coordinated training on the new Revised Officer Evaluation Report prior to implementation. All officers, supervisors of USAMRMC and tenant units on Fort Detrick were trained in order to meet the CSA directive.
4) Exceeded MEDCOM standard of 95% with a 100% fill-rate for the past 4 quarters on the PROFIS Deployment System.
5) Exceeded personnel strength (Officers) at 90% above DA & MEDCOM standards of 80% with a 90% manning rate.
6) Responsible for the HR roles in the implementation and daily maintenance of DMHRSi.

CORPS	AUTH	ASG	HCDP	% ASG/AUTH
IMM	20	19	20	95%
MS	212	204	204	96%
AN	30	27	27	90%
MC	102	72	72	71%
DC	6	6	6	100%
SP	10	9	9	90%
VC	61	61	61	100%
Total	441	398	399	90%

Civilian Personnel Management Division 1 Oct 2013 – 30 Sep 2014

Staff

(b) (6), Program Advisor (HR)
(b) (6), Program Advisory Specialist (HR)
(b) (6), Program Advisory Specialist (HR)
(b) (6), Program Advisory Specialist (HR)
(b) (6), Program Advisory Specialist (HR)

A. Accomplishments:

1) Participated in the MRMC-wide implementation of DMHRSi. The implementation entailed training attendance (11-12 September 2014), ensuring civilian personnel were properly aligned, and assisting subordinate units with their DMHRSi challenges. Participated in recurring MEDCOM Workforce 2020 working group meetings.
2) Established a ST approval process with MEDCOM and Civilian Senior Leader Management Office August 2014.
3) Established an Office of Workers' Compensation Programs (OWCP)/Federal Employees' Compensation Act Working Group that is meeting quarterly; first meeting was held 24 July 2014.

4) Improved acquisition management by higher certification compliance percentage.

5) Established a Request for Personnel Action (RPA) Flow Process to reduce RPA time within HQ; CoS approved 21 April 2014.

6) MEDCOM Placement Program (MP2) implemented MRMC-wide August 2014.

7) 7Consolidated the TAPES Base System employees rating cycle with the TAPES Senior System employees (GS-9 through GS-12) rating cycle. This consolidation reduced the number of rating cycles within the TAPES system as a whole from multiple cycles to two, and improved tracking appraisal completions.

8) Two Science, Mathematics, and Research Transformation (SMART) Defense Education Program sponsored students completed degrees, and started/returned to full-time work at their respective MRMC units

9) Staff completed the 16th successful Personnel Demonstration Project (PDP) appraisal and performance payout cycle where all payouts were completed within the strict timelines of the mass process.

10) Updated the 15 PDP policies to revise language and bring them into compliance with the current processes. Developed a new PDP policy that established procedures for the review of DB positions (engineering or scientific) by the unit's Lab Science Director or Senior Civilian Scientist to help ensure the Command's workforce capabilities align with required competencies that, because of the current environment, are also dynamic, a greater degree of scrutiny over scientific and engineering hiring practices is required.

11) Developed the first OPORD for the MRMC PDP Pay for Performance Management System End of Cycle Process, which was published May 2014. On 17 June 2014, the DCSHR conducted training for the unit Pay Pool Managers and Quality Control team to explain the payout process, quality control expectations, and the roles and responsibilities of all parties involved in the mass process. An After Action Report was issued on 29 September 2014.

12) Completed Site Assistance Visits/Organizational Inspection Program to subordinate units Institute of Surgical Research, Institute of Chemical Defense, Institute of Environmental Medicine, and the Medical Materiel Development Activity.

13) Provided TAPES training to the Defense Centers of Excellence (DCoE) for Psychological Health and Traumatic Brain Injury on 14 May 2014; DCoE was newly transitioned to MRMC.

14) Consolidated the prior MRMC telework policies (one for the HQ, one for the subordinate units) into one MRMC Telework policy, which was published 12 August 2014. Updated the Alternative Work Schedules policy for the subordinate units and the Regular and Alternative Work Schedules policy for HQ; both were published 5 September 2014.

15) The HQ USAMRMC processed 124 civilian personnel recruitment actions for FY 2014.

16) Coordinated 74 civilian honorary awards.

17) Coordinated the recruitment effort and approvals of selectees to fill two additional ST positions with CSLMO and MEDCOM.

Civilian Workforce Composition

Personnel Systems	
MRMC Demo	1,422
GS/WG	468
Local National	342
ST	4
SES	2
IPA	23
Consultants	3
DCIPS	6
TOTAL	2,270

Tenure*	Totals
Permanent	2,024
TERM	211

*Does not include IPAs or Tempis

	# Units	Unions	Demo	Non-Demo
CONUS	14	3	10	4
OCONUS	2	1	0	2

Acquisition	MRMC	Other	Total-AMEDD
Critical- Mil	63	35	98
Critical – Civ	56	33	89
Non-Crit-Mil	83	38	121
Non-Crit-Civ	266	250	516
Totals	468	356	824

LTC (b) (6) CI Troop Ca (b) (6) UNCLASSIFIED 8

HQ Company

Headquarters and Headquarters Detachment

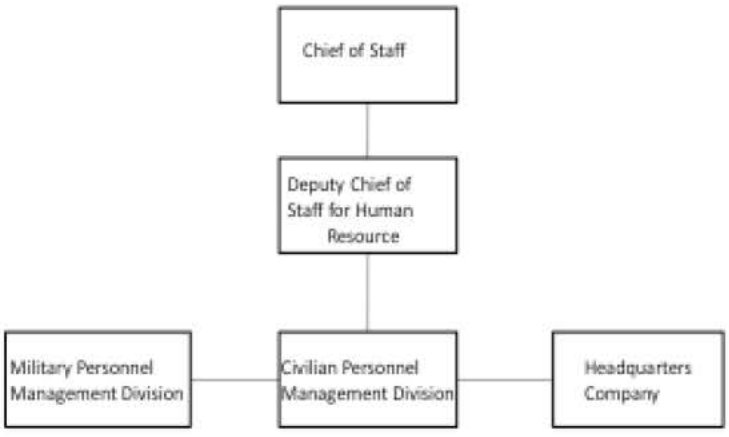
The mission of Headquarter and Headquarters Detachment (HHD) is to provide command and control, training, readiness, administrative support, discipline, and moral and welfare support to the Soldiers assigned/attached to HHD, US Army Medical Research and Materiel Command.

Staff
CPT (b) (6), Company Commander
SFC (b) (6), 1SG
(b) (6), Human Resource Specialist
(b) (6), Military Human Resources Manager

A. Significant Accomplishments

1) HHD USAMRMC established an active Family Readiness Group to support military and civilian personnel. The FRG hosted the first annual Thanksgiving Potluck for all USAMRMC employees and family members.
2) Completed the semi-annual APFT in during 21-25 October 2013 and 21-25 April 2014, with an average score of 240.
3) Completed all EO and SHARP training with 90% of personnel trained; no EO or SHARP complaints filed.
4) All personnel were transferred into the DMRSi program as mandated by MEDCOM.
5) 100% of personnel completed IPerms personnel records review by 30 September 2014.
6) Unit personnel were 100% complete on the annual SRP requirement before 30 September 2014.
7) Hosted the EO observance on 29 April 2014 for Holocaust Remembrance on Fort Detrick; coordinated an EO trip to the National Holocaust Museum on 25 April 2014 open to all personnel on Fort Detrick.
8) Assisted with the planning, coordination and set up of the MRMC Organizational Day on 15 August 2014 for all MRMC employees.

Deputy Chief of Staff for Human Resources



Section 2

Fiscal Year 2014
Annual Historical Report

G3 – Deputy Chief of Staff for Operations

Staff Operations and Training Management Division (G3)
LTC (b) (6) - DCSOP
SGM (b) (6) – G3 SGM
(b) (6) -Plans and Operations Officer
(b) (6) -Emergency Manager
MSG (b) (6) - NCOIC
SFC (b) (6) – OPS NCO
SSG (b) (6) - OPS NCO

Security and Intelligence Management Division (G2) Staff
(b) (6) - OPSEC Officer
(b) (6) – Overseas Travel Officer
(b) (6)
(b) (6)
Administrative Support Staff –VACANT
Security Officer – VACANT
OIP Coordinator - VACANT

OPERATIONS MISSION:

A. Deliver a broad range of functional and operational support and services to USAMRMC, USAMEDCOM , OTSG, Army , DoD, and Federal Agencies .

B. Assess, develop, and produce all USAMRMC operational, mobilization, and contingency plans to include supporting documents .

C. Coordinate with USAMEDCOM and USAMEDCOM MSC staffs to facilitate and support operational planning and taskings.

D. Serve as chief liaison between USAMRMC Operations and USAMEDCOM Operations Division staff for all planning, deployment , and tasking requirements.

E. Coordinate, prepare, staff, and deliver the quarterly USAMEDCOM Readiness Report (MRR) and Defense Readiness Reporting System-Army (DRRS-A) .

F. Receive, coordinate , manage, and ace for all IJSAMRMC personnel taskings received from USAMEDCOM for CONUOCONUS operational mission requirements and deployments .

G. Operate the Emergency Operations Center as directed by the Chief of Staff.

H. Manage the USAMRMC 68W Sustainment Program.

I. Manage the USAMRMC Professional Filler System (PROFIS) Training and Readiness Program.

J. Responsible for Command Incident Reporting and coordination to include Commanders Critical Information Requirements and Serious Incident Reports.

K. Monitor the USAMRMC Special MEDCOM Response Capabilities (SMRC) Team assets to include training management, financial support requests, and command and control between USAMRMC and USAMEDCOM Plans Division.

L. Responsible for the USAMRMC Command Inspection Program to include Organization Inspection Program and Staff Assistance Visits .

M. Responsible for all USAMRMC command ceremonies to include, but not limited to, changes of command , retirement/retreat ceremonies, and command- sponsored events.

N. Responsible for the implementation and over-site of the Biological/Chemical Security Program for all of MRMC.

Significant Accomplishments:

A. **Continuity of Operations Program:**
Conducted 13 COOP exercises to include 6 subordinate commands and 10 sub directorates of the HQ
Assisted in the development and evaluated 12 subordinate command COOP plans and exercises

B. **Organizational Inspection Program:**
Conducted 10 Organizational Inspections around the world

C. **Emergency Management:**
Evaluated seven Subordinate Command exercises.
Conducted 14 no notice Emergency Alert Notification exercises.
Participated in the HQDA National Level Exercise.
Participated in and evaluated the USAG annual exercise.

D. **Civilian Training:**
Trained and instructed 15 Subordinate Command and HQ MRMC POCs in development of Individual Development Plans.
Encouraged and enforced the completion of Supervisor Development Course resulting in 87% completion rate from 36% the year prior.
Submitted and registered over 60 training opportunities for civilian career advancement in the form of SF 182s .
Advised, monitored and tracked the Civilian Education System Course completion for the Command.

E. **Security Operations:**
Executed 53 conference site security risk (criminal and threat) assessments ensuring the security of over 2800 conference attendees.
Conducted 607 Operations Security reviews of documents.
Processed 222 foreign national visit requests.
Performed 143 Antiterrorism and Operations Security contract reviews.
Participated in 2 Vulnerability Assessments of subordinate units.
Reviewed and provided response to 6 Freedom of Information Act (FOIA) requests

Overseas Force Protection Operations

A. Manage the Overseas Travel and Force Protection program which requires the coordination and processing of Country/Theater/Special Area clearances for over 7,000 personnel which includes HQ, USAMRMC and subordinate units/commands as well as other entities with support agreements.

B. Verify security clearances for al overseas travelers and ensure their foreign travel is captured in the Case Adjudication Tracking System portal. Verify all personnel information provided on the

USAMRMC Form 55-46 to include: Name, Rank, Positon DOB, POB, Citizenship, Security clearance information and passport information.

C. Ensure all overseas travelers have received Level I Antiterrorism training, Survival, Evasion, Resistance & Escape (SERE) training, Human Rights training, Isolated Personnel report (ISOPRES/PRO-FILE) and any other required theater-specific area of responsibility training.

D. Provide all HQ MRMC personnel their overseas pre-travel Area of Responsibility (AOR) and intelligence threat briefings and ensure all other travelers have received their appropriate briefings before travel departure and de-briefings upon return.

E. Provide guidance in the preparation of the Antiterrorism/Force Protection Recovery Plans, AFRICOM Statement of Preparedness document (STOP), Synchronized Planning Operational Tracking System (SPOT), PACOM Travel Tracker/Individual Antiterrorism Plan and any other required tracking system.

F. Provide message traffic communication for the Commanding General, USAMRMC and subordinate commands through the All Message Handling System (AMHS) and the Aircraft and Personnel Automated Clearance System (APACS).

G. Continual update of the USAMRMC OCONUS Travel website link.

H. Personnel Recovery Mission software Program management for the command, responsible for validating PRO-FILE's on each traveler before they depart.

I. Responsible for update and management of applicable regulations, directives, Executive Orders, and pamphlets for OCONUS Travel, Force Protection, Personnel Recovery as well as other inter-related areas.

J. Responsible for SIPERNET training, control, and coordination with G6 for command users.

Significant Accomplishments:

Managed over 1,200 Overseas Travel Force Protection packages, pre-travel training requirements, and Area of Responsibility threat briefs in support of USAMRMC's Worldwide mission.

Section 3

Fiscal Year 2014
Annual Historical Report

G4 – Office of the Deputy Chief of Staff for Logistics

In FY14 the Office of the Deputy Chief of Staff for Logistics (ODCSLOG) was challenged with a 30% staff turnover, resulting in cross leveling of duties of departed individuals. A System Analyst position was created, allowing the capability of the US Army Medical Research and Materiel Command (USAMRMC) to be less dependent on other Commands for the Defense Medical Logistics Standard Support (DMLSS) system assistance. The USAMRMC's General Service Administration (GSA) Fleet saw a 29% reduction with a cost avoidance of $821K. The ODCSLOG procured a centralized medical equipment maintenance and a facility operation and maintenance contracts with a cost avoidance of $1M; providing efficiency across the Command. With its continuous aggressive approach, the Wide Area Work Flow-Receipts and Acceptance (WAWF-RA) program significantly reduced USAMRMC's late interest penalties with only paying $51K of late penalties of a total of $275M disbursed. In collaboration with Medical Command (MEDCOM), ODCSLOG coordinated training for the Command's logistics, resource management and contracting professionals, training 410 staff; saving MEDCOM over $600K by centralizing training at Fort Detrick.

Mission

The ODCSLOG provides logistics management oversight, training, strategic, and operational logistics support to Headquarters (HQ), USAMRMC, twelve (12) subordinate commands and laboratories, and five (5) executive agencies that are globally dispersed. Support and oversight includes management of logistics automation systems, property accountability, supply and services management, transportation, medical equipment maintenance management, facility planning and management, life-cycle equipment management, and acquisition and logistics management. Additionally, the ODCSLOG develops and implements logistics policies, strategies, and business practices for management throughout USAMRMC.

Vision

The ODCSLOG's, vision is to enhance readiness by providing high quality logistics support in a timely, integrated, comprehensive, and cost effective manner.

Function

The ODCSLOG provides the following core competencies: coordinates and synchronizes the full spectrum of strategic and operational logistics, facility operations, medical maintenance management, and acquisition support; provides strategic and operational logistics policy guidance and training; serves as the Lead Agent for the Command Property Accountability Campaign ensuring accountability and supply discipline compliance in accordance with (IAW) regulatory guidance; oversees and manages the life-cycle (planning, engineering, execution, sustainment, and disposal) of USAMRMC capital investments; serves as the Army Site Lead and the Medical Command (MEDCOM) Regional Group Administrator for WAWF – RA program and Miscellaneous Pay; and serves as a mentor to the Command logistics and facility staff.

Personnel

A. Staffing: The ODCSLOG currently consists of twenty-two (22) teammates: six (6) military, thirteen (13) civilians, and three (3) contractors.

B. ODCSLOG Staff:

1. The ODCSLOG has been under the leadership of COL (b) (6) since August 2012. Under her leadership, the ODCSLOG has established an aggressive Temperature Sensitive Medical Products program, Standardization, and GSA Fleet Reduction program.

2. The ODCSLOG welcomed (b) (6) as the Office Administrator for ODCSLOG in December 2013. (b) (6) comes to us with 15 years of Government Service.

3. The ODCSLOG NCOIC, MSG (b) (6), continues to provide outstanding support to the ODCSLOG and provides special projects for the USAMRMC Command Sergeant Major. MSG (b) (6) has taken on several new major initiatives to include serving as the USAMRMC Master Resiliency Training trainer, conducting training at Fort Detrick and the Defense Center of Excellence (DCoE).

4. The ODCSLOG welcomed COL (b) (6) to serve as ODCSLOG's Reserve Officer. COL (b) (6) comes to ODCSLOG with 30 years of service

C. The Logistics, Plans and Readiness Division:

1. LTC (b) (6) transferred to USAMMA in July 2014. LTC (b) (6) was replaced by MAJ (b) (6), serving as the Chief, Logistics Plans and Readiness Division. MAJ (b) (6) comes to ODCSLOG with 18 years of Military experience.

2. (b) (6), Medical Equipment Specialist, continues to manage the Command Medical Maintenance Program and (b) (6), Logistics Management Specialist, continues to manage the Command's GSA fleet, serve as the Transportation Coordinator, manage the Financial Liability Investigation of Property Loss (FLIPL) program, and update USAMRMC policies.

D. Equipment Management Division:

1. MAJ (b) (6) continues to serve as the Chief, Equipment Management Division. (b) (6), departed ODCSLOG in April 2014. ODCSLOG welcomed (b) (6) in September 2014, as ODCSLOG's new Material Handler.

2. (b) (6), Supply Management Specialist and Property Book Officer, retired in January 2014 after serving in the Equipment Management Division for 27 years. ODCSLOG welcomed (b) (6) in April 2014 as the new Supply Management Specialist and Property Book Officer. (b) (6) is supported by SPC (b) (6) who serves as Hand Receipt Manager. ODCSLOG welcomed (b) (6) in March 2014 as the new Supply Technician and Government Purchase Card (GPC) holder.

E. Facilities Transformation, Engineering, and Management Division (FTEMD): (b) (6) continues to serve as the FTEMD Director. (b) (6) is supported by the following staff members: Facility Space Management Analyst, (b) (6); Facility Engineer, (b) (6) and two Facility Integrators: (b) (6), and (b) (6). The FTEMD is also supported by three outstanding contractor's (b) (6), (b) (6), and (b) (6), who was welcomed in ODCSLOG in November 2013. In July 2014, (b) (6) departed ODCSLOG for a Facility Manager position with the Federal Emergency Management Agency Training Campus. In September 2014, (b) (6) departed ODCSLOG for Chief of Facilities position with the Cumberland and Ohio Canal National Park.

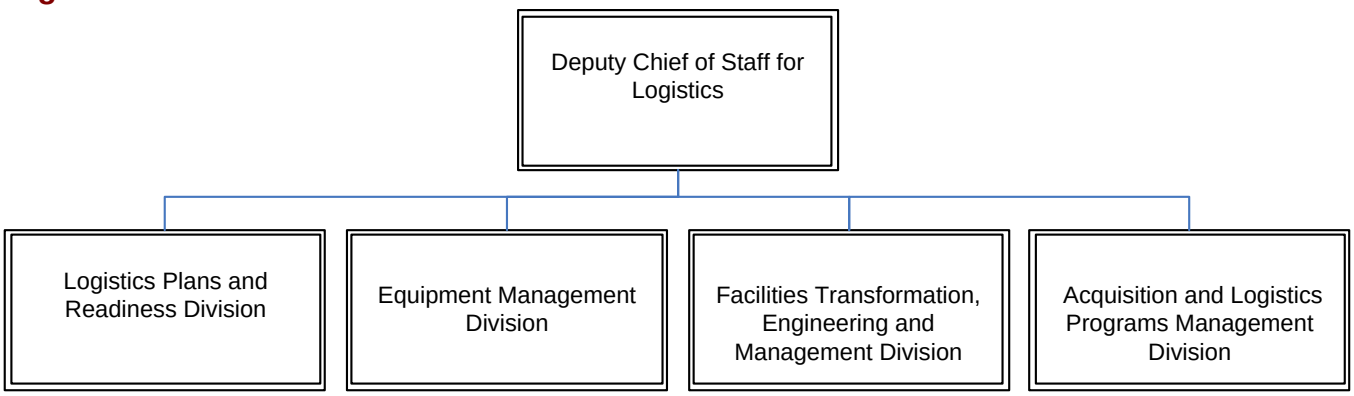
F. Acquisition and Logistics Programs Management Division: (b) (6) continues to provide outstanding leadership as the Director, Acquisition and Logistics Programs Management Division. (b) (6) serves as the Command Alternate Group Administrator (GAM) for WAWF-RA and as the HQ's, USAMRMC Primary GAM. ODCSLOG welcomed (b) (6) as the new USAMRMC System Administrator in April 2014.

G. Training: The ODCSLOG staff completed all required Army training, preparing the staff for positions of greater responsibility. All personnel within the ODCSLOG have been encouraged and afforded the opportunity to take as much applicable training in their respective career fields. In FY14 a (b) (6)

completed facilities engineering certification, and LTC (b) (6) and (b) (6) completed their program management certification. Additional, specialized training and conferences/symposiums included:

1. Defense Acquisition University (DAU) courses
2. Civilian Education Courses
3. General Fund Enterprise Business System (GFEBS) and GFEBS Power User Training courses
4. GSA International Products and Services EXPO Training
5. Facility Management Workshop
6. Test Measurement Diagnostic Measurement (TMDE) training for all USAMRMC subordinate commands
7. Equipment Management (Hand-Held Terminals) for all USAMRMC subordinate commands
8. Property Management (Hand Receipt Holder) training for all USAMRMC subordinate commands
9. WAWF-RA Training
10. Senior Medical Logistician Workshop

Organization



A. Logistics Plans and Readiness Division.

(1) The Logistics Plans and Readiness Division serves as the ODCSLOG's proponent for strategically developing and coordinating all USAMRMC applicable regulations, policies, Standing Operating Procedures (SOP's), Command Policy Memorandums and Pamphlets. The Division is also responsible for monitoring logistics readiness for USAMRMC subordinate commands to ensure they are within regulatory compliance with the Organizational Inspection Program (OIP), Staff Assistance Visit (SAV), Command Supply Discipline Program (CSDP), and property accountability statistical data.

(2) In FY13, the Commanding General directed the ODCSLOG to lead a multi-functional Tiger Team of subject matter experts (SME's) to the Armed Forces Research Institute of Medical Science (AFRIMS). ODCSLOG developed a three (3) phase plan that began in November 2013 for phase one and deployed the SAV Team back in February 2014 for phase two. Phase three, the official OIP, has been scheduled for July 2015.

(a) The purpose of the Tiger Team visit was to:

(i) Conduct an assessment of business processes in the areas of Medical Maintenance, Property Management, GPCs, and perform hands-on DMLSS training.

(ii) Perform follow-on review and provide additional training and support in the areas of Information Assurance, Resource Management, Facility Operations and Maintenance (FO&M), Logistics Management, and Supply Management.

(iii) Continue to train and assist AFRIMS personnel in providing best business practices and assist in developing a business strategy to transition from a decentralized to a centralized oversight/management business process in the functional areas of Logistics, Information Management, and Resource Management.

(iv) Conduct DMLSS System Administration and end user training focused on the Customer Assistance Inventory Module, Inventory Management, System Services, and Customer Support.

(3) In FY14, USAMRMC was directed by MEDCOM to reduce the Command's GSA Fleet. The ODCSLOG began the process with an inventory of the USAMRMC fleet, determining the optimal fleet required to meet MEDCOM's mission requirements, and identifying resources necessary to operate the fleet effectively and efficiently. The ODCSLOG determined the most effective criteria to justify mission essential vehicles was the mileage utilization rate. Vehicles that did not meet the utilization of 833 miles per month were required to submit a justification to retain their vehicle/s or turn them in. Through a collaborative effort with the Fort Detrick Transportation Motor Pool and USAMRMC's subordinate commands, the fleet was reduced by 29% with a cost avoidance saving of over $821K annually.

(4) The Logistical Readiness Division prepares the Financial Liability Investigation of Property Loss (FLIPL) for HQ's, USAMRMC. In FY14 the USAMRMC maintained a stellar record with no FLIPL resulting in no financial deficient to the federal government.

(5) OIPs/SAVs:

(a) OIPs were conducted at the following units: The United States Army Medical Research Institute of Chemical Defense (USAMRICD) and the United States Army Medical Materiel Medical Activity (USAMMDA). Detailed reports describing the findings and providing recommendations for each inspected area were delivered to these commands in accordance with USAMRMC Regulation 1-201, Organizational Inspection Program. These inspections resulted in an improved understanding of regulatory guidelines and adherence to written policies and procedures by logistics divisions staff.

(b) As part of the ODCSLOG team, the Logistics Readiness Division completed three (3) SAVs at AFRIMS in November 2013 and February 2014, and USAMMDA in July 2014.

(6) The following regulations and policies were updated: USAMRMC Regulation 700-6, Loan of Command Property, USAMRMC Regulation 700-14, USAMRMC Regulation Personal Use Policy, and USAMRMC Regulation 750-1, Equipment Maintenance Management.

(7) Bio-Medical Equipment:

(a) In 2012 USAMRMC established a new **prime maintainer contract** to assist subordinate commands with their medical maintenance program. The purpose of the prime maintainer contract was to manage the scheduled and unscheduled "Calibration, Preventive Maintenance, and Repair" services of specialized equipment beyond the capabilities of assigned Biomedical Equipment Specialists through the use of original equipment manufacturers and third-party organizations. The prime maintainer contract provides a command level, firm fixed price, maintenance contract to service/repair equipment and reduce the need to manage or negotiate multiple service contracts with the various subordinate activities. The prime maintainer contract entered the second of four option years on 1 August 2014. Activities utilizing the contract were required to submit a Service Contract Approval Form and to fully fund their portion of the service contract. The following USAMRMC laboratories currently utilize this contract for maintenance of 1,300 equipment items: The United States Army Institute of Surgical Research (USAISR), Walter Reed Army Institute of Research (WRAIR), United States Army Medical Research Institute of Infectious Diseases

(USAMRIID), USAMRICD, Armed Forces Medical Examiner Services (AFMES), and National Museum of Health and Medicine (NMHM). In addition, the United States Army Research Institute of Environmental Medicine (USARIEM) will be added to the contract 1 April 2015. As the contracting officer representative for the prime maintainer contract, (b) (6) was responsible for ensuring all issues associated with the contract were resolved.

(b) OIPs/SAVs:

(i) OIPs. The Bio-Medical Equipment Maintenance Section performed OIP inspections at USAMRICD, and USAMRIID. Detailed reports describing findings and providing recommendations for each inspected area were delivered to these commands in accordance with USAMRMC Regulation 1-201, Organizational Inspection Program. These inspections resulted in an improved understanding of regulatory guidelines and adherence to written policies and procedures by maintenance activities.

(ii) SAVs. As part of the DCSLOG team, the Biomedical Equipment Maintenance Section completed two (2) SAVs to AFRIMS, November 2013 and February 2014. This SAV identified numerous deficiencies and provided recommendations to the maintenance manager in framing an action plan to correct noted deficiencies.

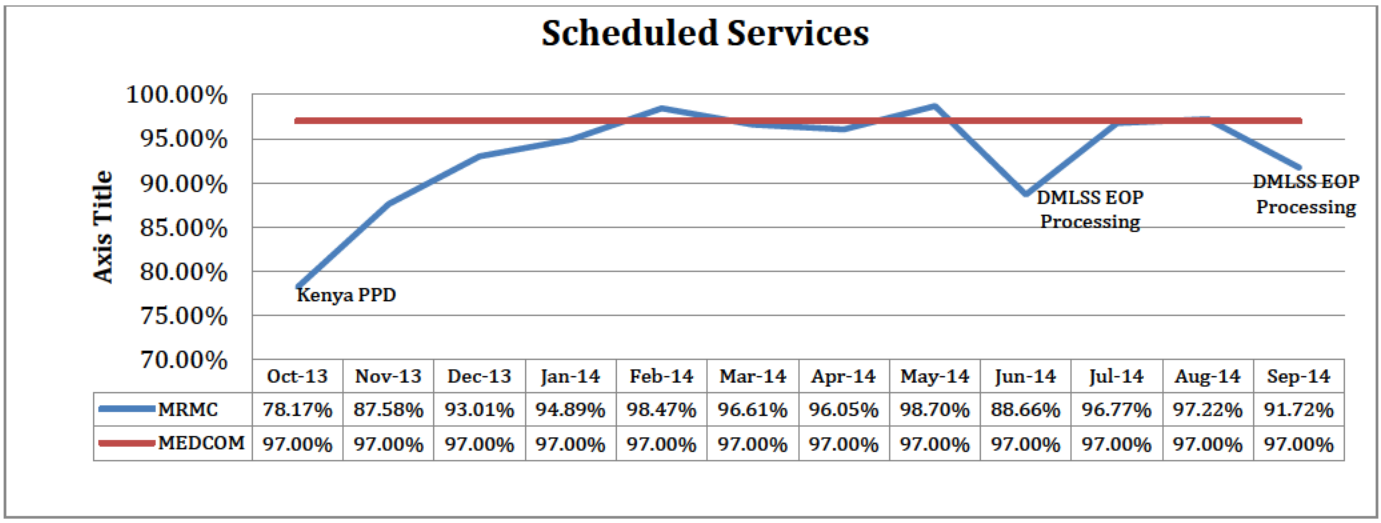
(c) Government Purchase Card (GPC) Billing Official/GFEBS:

(i) As the GPC Billing Official (BO) for the ODCSLOG GPC program during FY14, the Bio-Medical Equipment Section reconciled 12 monthly statements with US Bank; approving a total of 172 GPC transactions, totaling $123,633.29. In addition, after the DMLSS system process for purchase cards was activated by MEDCOM, 12 monthly statements have been processed using the Inventory Management module of DMLSS.

(ii) The GFEBS review and approval process for Purchase Requests (PR) is twofold. First, a file containing the request for purchase is reviewed for an appropriate justification and any documentation supporting the purchase. If suitable documentation is received, the BO signs the reports, indicating the PR has been reviewed and approved. The second part of the process involves electronic or email notification to the BO that a PR has been entered into GFEBS and is awaiting release. Once notification is received, the BO must access GFEBS, review the PR, the short text description, valuation, and contact person for accuracy. If correct, the BO releases the PR. In 2014 the Biomedical Equipment Section released 172 purchase requests in GFEBS totaling $123,633.29.

(d) Command Maintenance Program: On a monthly basis, the USAMRMC maintenance activities report work order completion percentages to the Bio-Medical Equipment Section. These reports included work order completion percentages for preventive maintenance, inspections, calibrations, and scheduled parts replacement on their medical equipment. This information comes from the DMLSS Maintenance Management Report. The report is reviewed, tracked, and updated on a monthly basis. The report also allows ODCSLOG and the Bio-Medical Equipment Maintenance SME to analyze the Command's trends or problem areas that may require assistance or corrective action.

Figure 1 FY14 USAMRMC Maintenance Statistics



	Oct-13	Nov-13	Dec-13	Jan-14	Feb-14	Mar-14	Apr-14	May-14	Jun-14	Jul-14	Aug-14	Sep-14
MRMC	78.17%	87.58%	93.01%	94.89%	98.47%	96.61%	96.05%	98.70%	88.66%	96.77%	97.22%	91.72%
MEDCOM	97.00%	97.00%	97.00%	97.00%	97.00%	97.00%	97.00%	97.00%	97.00%	97.00%	97.00%	97.00%

Figure one provides an average of medical maintenance performance statistics throughout the fiscal year. Overall, USAMRMC maintenance performance has increased over previous years however, because of a change in the way scheduled services were documented by USAMRIID, averages were not as high as expected.

Figure 2 FY14 USAMRMC Scheduled Service Performance by Command

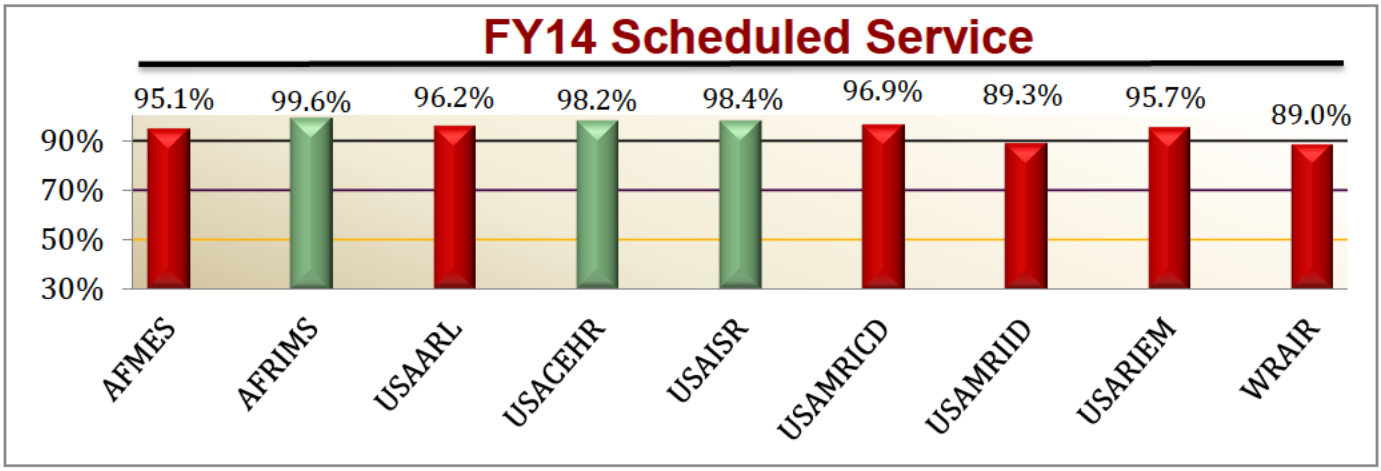


Figure two shows scheduled service completion percentages by command. The MEDCOM performance standard for scheduled services is 97%. Activities shown in red were unsuccessful in obtaining the MEDCOM standard for the following reasons: AFMES has been experiencing connectivity issues with the DMLSS system and has been unable to update work order status. The DMLSS system End of Period (EOP) processing ran early in June 2014, directly affecting USAARL and USARIEMs ability to process completed work. Scheduled service work orders remaining open for contractor support and the early EOP processing were the main reasons for USAMRICD not meeting standards. Several factors contributed to USAMRIID not reaching the minimum performance levels prescribed by MEDCOM. First, early EOP processing in June; next DMLSS end of year processing on 25 September 2014 and finally contractor completion of scheduled services. Many factors contributed to WRAIR not

meeting the standard. These included a TDY to Kenya was postponed in October 2013, leaving 350 scheduled service work orders open; the closure of the maintenance activity for several days due to severe weather conditions in December 2013, and the DMLSS End of Year processing schedule.

(e) Medical Materiel Quality Control (MMQC) Messages: When MMQC messages are received, they are immediately reviewed by the Bio-Medical Maintenance section to determine if the subject equipment item is in the USAMRMC inventory. This is accomplished by accessing each DMLSS server within USAMRMC and searching the equipment database for the particular item. If the equipment item is located, an email message is sent to the maintenance manager of the activity with a copy of the MMQC message, the equipment record, and a suspense date for an action taken response. This information is then logged into the MMQC Message Tracking File. If a response is not received within the allotted timeframe, reminder messages are sent to the activity. Two hundred forty one MMQC messages were researched during 2014. This process ensures USAMRMC maintenance activities are aware of potential equipment related hazards and the safety of equipment operators.

B. Equipment Management Division

(1) The Equipment Management Division serves as the lead agent for HQ, USAMRMC for the Army's

Campaign on Property Accountability, ensuring property accountability and supply discipline, are IAW AR 710-2, AR 710-2-1, and AR 735-5. HQ, USAMRMC property book is valued at $12M with 6,355 items. The Equipment Management Division consistently managed and maintained oversight, conducted training, provided guidance and mentorship to 14 subordinate command property books, with a combined property book value of $422M and 78K items (see Figure 3). In FY14, 44 inventories were conducted semi-annually throughout HQ, USAMRMC using Hand-Held Technology (HHT) IAW AR 735-2 and DODI 5000.64, 6.1.1. Also, six (6) items were laterally transferred throughout USAMRMC, valued at $92K. In FY14, over $1.6M of excess equipment was turned-in to Defense Logistics Agency Disposition Services (DLA – DS) in support of EXORD 259-10, Campaign on Property Accountability.

Figure 3 FY14 Property Listings

Unit Identification Code (UIC)	Activity	DODAAC	Property Book Officer	PB Value	Equipment Records
W03JAA	HQ, USAMRMC	W23RYX	(b) (6)	$12,923,305.28	6355
W03K06	AFMES	W56DNJ	(b) (6)	$23,154,798.00	4301
WDCYAA	6th MLMC	W90UF5	(b) (6)	$1,410,774.47	428
W03J22	DcoE	W56SQA	LCDR (b) (6)	$3,859,345.98	2230
W03YAA	USAARL	W31BM8	(b) (6)	$39,981,106.92	4483
W03SAA	USAISR	W45MW3	(b) (6)	$39,900,611.02	8106
W05JAA	USAMMA	W80DLM	(b) (6)	$19,102,641.14	3930
W4QFAA	USAMMDA	W806YH	(b) (6)	$2,539,807.76	1037
W4PZAA	USAMRAA	W81XWH	(b) (6)	$1,218,941.48	1381
W4D7AA	USAMRICD	W23MEX	(b) (6)	$42,293,532.07	6422
W4GPAA	USAMRIID	W23MYC	(b) (6)	$95,253,437.74	11604
W03WAA	USARIEM	W81NLC	(b) (6)	$21,233,539.80	3326
W4D705	USACEHR	W23MWK	(b) (6)	$6,221,683.32	852
W03KAA	WRAIR	W74MYF	(b) (6)	$74,961,439.54	13052
W2DRAA	AFRIMS/ Thailand	W2DR01	SSG (b) (6)	$24,060,788.11	5707
W0CCAA	USAMMC-E	WK4F5E	(b) (6)	$11,183,495.35	3907
W6R1AA	USAMMC-K	W8120U	(b) (6)	$2,941,037.56	1325
			TOTAL:	**$422,240,285.54**	**78446**

(2) OIPs/SAVs:

(a) OIPs. The Equipment Management Division performed two (2) OIP inspections at USAMRICD, May 2014 and USAMMDA, July 2014. Detailed reports describing the findings and specific recommendation to address the findings were provided to each of the commands in accordance with USAMRMC Regulation 1-201. These inspections resulted in an improved understanding of regulatory guidelines and adherence to written policies and procedures by the equipment management staff

(b) SAVs. The Equipment Management Division performed three (3) SAV visits at AFRIMS, November 2013 and February 2014, and USAMMDA January 2014. The focus of these SAVs was to provide DMLSS training on the Equipment Management module. In addition to the SAVs, the Equipment Division assisted the WRAIR property management staff in preparing for a MEDCOM Command Logistics Review Team inspection, which resulted in no findings.

(3) Item Unique Identification (IUID). USAMRMC, surpassed the MEDCOM IUID standard of 95% to 98% in FY14. This achievement was a slow start but the trend remained consistent and positive for each quarter (see Figures 4 and 5 below).

Figure 4 IUID Statistics for 1st Quarter FY14

MRMC 1st QTR FY14	Records With UII/IUID Assigned	Records Requiring a UII/IUID	Records Requiring User Update	Equipment Requiring Labels	Equipment Physically Labeled (CALCULATED FIELD)	Percent of Equipment Physically Labeled (CALCULATED FIELD)
HQ USAMRMC	575	577	2	0	575	100%
AFMES	548	559	11	0	548	98%
USAMRIID	2283	2301	18	0	2283	99%
USAARL	458	481	23	0	458	95%
USAISR	1334	1334	0	10	1324	99%
USAMMA	0	506	506	506	0	0%
USAMMDA	72	74	2	2	70	95%
USAMRAA	42	44	2	2	40	91%
USAMRICD	956	968	12	0	956	99%
USARIEM	446	481	35	274	172	36%
USACEHR	147	148	1	0	147	99%
WRAIR	1716	2091	375	0	1716	82%
USAMMC-E	445	457	12	0	445	97%
USAMMC-K	125	125	0	0	125	100%
AFRIMS	90	883	793	2	88	10%
6TH MLMC	86	86	0	0	86	100%
Total	9323	11115	1792	796	9033	81%

Figure 5 IUID Statistics for 4th Quarter FY14

MRMC 4th QTR FY 14	Records With UII/IUID Assigned	Records Requiring a UII/IUID	Records Requiring User Update	Equipment Requiring Labels	Equipment Physically Labeled (CALCULATED FIELD)	Percent of Equipment Physically Labeled (CALCULATED FIELD)
HQ USAMRMC	840	840	0	0	840	100%
DCOE	30	43	13	13	30	90%
AFMES	543	543	0	0	543	100%
USAMRIID	2082	2099	17	17	2082	99%
USAARL	663	633	0	0	633	100%
USAISR	1655	1658	3	3	1655	100%
USAMMA	529	529	0	0	529	100%
USAMMDA	77	78	0	0	78	100%
USAMRAA	37	37	0	0	37	100%
USAMRICD	1516	1531	15	185	1346	88%
USARIEM	486	492	6	0	492	100%
USACEHR	167	170	3	1	169	99%
WRAIR	2167	2170	3	1	2169	100%
USAMMC-E	4083	461	0	1	460	100%
USAMMC-K	133	133	0	0	133	100%
AFRIMS	887	887	0	0	887	100%
Total	15895	12304	60	221	12083	98%

(4) The current EXORD 259-10, Campaign on Property Accountability, is a comprehensive approach in which the objective is an enduring campaign to achieve and sustain accountability for all property. The campaign addressed re-establishing a culture of supply discipline and property accountability by accounting for supplies, materiel, equipment, and reintegrating excess equipment into the supply system to enhance overall readiness. The objective was to provide renewed vigor to the CSDP within USAMRMC. The ODCSLOG reinforced property accountability at all subordinate command levels by conducting training to Leaders/Directors, Primary Hand Receipt Holders (PHRH), and Sub Hand Receipt Holders (SHRH) such as, FLIPL processes with legal, DMLSS reconciliation, and Managing Medical Equipment. In FY14, ODCSLOG turned-in 745 items to DLA-DS, valued at $1,636,799.95.

(5) Property accountability and GPC training was provided to all subordinate commands via the classroom setting, and one-on-one. A total of 28 hand receipt holders and ten (10) GPC holders were trained in FY14. The training consisted of basic knowledge of policies and procedures, DMLSS applications, and regulatory guidance to newly appointed GPC holders.

(6) The ODCSLOG maintained the GPC accounts for HQ, USAMRMC. The ODCSLOG staff completed 172 purchases of supplies and equipment valued at $123,633.29. In addition, the total number of rebates received from the US Bank was valued at $1,689.10.

C. FTEMD:

(1) In FY14, the FTEMD developed, inspected, recommended, and oversaw the implementation of Command policies, procedures, and initiatives in all areas of facility planning, engineering, acquisition, transformation, and management.

(2) Management of Real Property Assets. The FTEMD staff maintained oversight of more than 4M square feet of facilities assigned to the USAMRMC units worldwide. The maintenance endeavors included successful command oversight of sustainment, repair project implementation, operations and maintenance programming and facility staff management of these diverse and unique facility assets.

These facilities included a vast array of state-of-the-art unique medical research labs, vivarium's, general warehouses, leased office spaces, administrative buildings, utilities, forensic labs, industrial waste water buildings, medical warehouses, and mission specific simulators. Figure 6 below provides a list of the facility square footage for USAMRMC.

Figure 6 FY14 USAMRMC INVENTORY OF FACILITIES

		DHP		IMCOM		RDTE		
Subordinate Unit	Subordinate Component	Number of buildings	Total Square Footage	Number of buildings	Total Square Footage	Number of buildings	Total Square Footage	Total Square Footage
USAMMC-K				11	104,977			104,977
USAMMC-E				39	847,837			847,837
MRMC-HQ				7	102,255			102,255
	TATRC	5	45,662					45,662
	CDMRP			3	19,303			19,303
USAARL		5	195,043	2	4,240			199,283
USARIEM		2	82,473					82,473
USAMRIID		9	587,383	3	31,205			618,588
USAMRICD		4	171,808	10	36,933			208,741
	USACEHR	1	44,638	1	2,137			46,775
USAISR		4	354,701					354,701
WRAIR		5	640,552					640,552
	AFRIMS					11	164,121	164,121
	KENYA					21	91,476	91,476
USAMRAA				8	60,124			60,124
USAMMA				5	126,422			126,422
USAMMDA				1	17,214			17,214
NMHM		2	87,619					87,619
AFMES		1	117,000					117,000
TOTAL FACILITIES		**38**	**2,326,879**	**90**	**1,352,647**	**32**	**255,597**	**3,935,123**

(3) Funded Facility Construction Projects. In FY14, there were four (4) active Military Construction (MILCON) facility construction projects totaling 1,356,700 square feet; valued at $881,459 that were in progress. These projects included the recapitalization of the USAMRICD facility, the recapitalization of the USAMRIID facility and the USARIEM medical warehouse facility (see Figure 7). The FTEMD is still developing a construction project for the USARIEM Pikes Peak Laboratory of 3,000 square feet with an approved funding amount of $3.6M. The FTEMD also successfully acquired funds of $2.0M in the Unspecified Minor MILCON program for the AFMES warehouse addition with a programmed amount of 6,200 square feet (see Figure 7).

Figure 7 USAMRMC FACILITIES UNDER CONSTRUCTION OR DESIGN

Activity	Project Title	Facility Size (SF)	Award Cost ($K)	Estimated Completion Date	Location
USAMRIID	Recapitalization	835,000	$597,752	2018	Fort Detrick, MD
USAMRICD	Recapitalization	509,800	$279,800	2015	Aberdeen Proving Grounds, MD
USARIEM	Medical Warehouse	5,700	$1,907	2014	Soldier System Command – Natick, MA
AFMES	Medical Warehouse	6,200	$2,000	2014	Dover Air Force Base, DE
	TOTAL	**1,356,700**	**$881,459**		

(4) Future Facility Construction Projects. The FTEMD continuously plans and programs in the Program Objective Memorandum (POM) construction projects for future funding. There are nine (9) projects estimated at 752,393 square feet and $499M of future medical funded MILCON projects or lab revitalization projects being actively pursued (see Figure 8). There are two (2) projects estimated at 179,908 square feet and $80M of future Army funded Military Construction Army (MCA) projects actively being pursued (see Figure 9).

Figure 8 FUTURE USAMRMC MEDICAL MILCON FACILITY CONSTRUCTION PROJECTS

Project Title	DD1391	Program Amount ($000)K	New Footprint Scope (SF)	Program
WRAIR 511 Addition	87025	$4,000	5,300	Lab Revit
USARIEM 42 Addition	86440	$4,000	8,393	Lab Revit
Pikes Peak High Altitude Laboratory Replacement	51639	$3,000	1,500	MED MILCON
WRAIR Decompression Medical Laboratory Facility	77247	$170,000	165,000	MED MILCON
USARIEM Research Institute Recapitalization	61837	$121,198	110,200	MED MILCON
WRAIR Pilot Bioproduction Facility	65727	$50,000	42,000	MED MILCON
AFRIMS Recapitalization	62130	$90,000	190,000	MED MILCON
WRAIR Clinical Trials Center Building	77250	$7,700	10,000	MED MILCON
USAARL Medical Research Laboratory Recapitalization and Renewal	72386	$50,000	220,000	MED MILCON
	TOTAL	**$499,898**	**752,393**	

Figure 9 FUTURE USAMRMC ARMY MILCON FACILITY CONSTRUCTION PROJECTS

USAMRMC Priority	Project Title	DD1391	Program Amount ($000)K	New Footprint Scope (SF)
1	USAMRAA	55839	$20,000	65,000
2	US Army Research Support Operations Center	55840	$60,000	114,908
		TOTAL	**$80,000**	**179,908**

(5) The FTEMD provides subject matter expertise and strategic advice to USAMRMC and subordinate commands on facility programs to include life-cycle management, repair, restoration and renewal, transformation planning and coordination, space utilization management program, facility systems and training, and other associated support programs.

(6) Design Reviews. The FTEMD staff performed multi-discipline design reviews. These reviews useda teaming approach that effectively identified numerous issues that required redesign and clarification in order to meet the requirements of the Army and the users. The following significant projects were reviewed by the FTEMD staff:

(a) WRAIR Bldg 503 South and East Wing Flood Damage Repairs

(b) WRAIR Bldg 503 Repair Fire Control Panel and Addressable System

(c) WRAIR Bldg 503 Waterproofing Repairs

(d) WRAIR Campus Boiler Repairs

(e) WRAIR Provide Ventilation to Generators and Conduct Power Study

(f) WRAIR Repair Campus Base Automation System

(g) WRAIR Bldg 501 Repair Roof and Air Handler Units

(h) WRAIR Bldg 511 Repair Cagewash and Heating, Ventilation, and Air Conditioning

(i) WRAIR Bldg 503 Combustion Air Unit Repairs

(j) WRAIR Bldg 503 Repair Freezer Farm

(k) WRAIR Bldg 503 Repair Bio-Safety Level (BSL) 3 Lab3N50

(l) NMHM Bldg 178 Renewal

(m) NMHM Bldg 178 Repair Generator

(n) USARIEM Construct Medical Warehouse

(o) USARIEM Bldg 42 Mechanical

(p) USACEHR Bldg 568 Vivarium Repairs

(q) USACEHR Bldg 568 Second Floor Laboratory Repairs

(r) USACEHR Bldg 568 Construct Elevator

(s) USAMRIID Bldg 1425 Repair Breathing and Mechanical Air Systems

(t) USAMRIID Bldg 1425 Repair Air Handler Units

(u) USAMRIID Bldg 1425 Repair BSL-4 Lab AA5

(v) USAMRICD Bldg E2909 Miscellaneous Repairs

(w) AFMES Bldg 115 Miscellaneous Repairs

(x) AFMES Bldg 115 Warehouse Addition

(7) Engineering Studies, Regulation, Policies and Reports. The staff directed, participated in, and reviewed the following studies, policies, reports and projects:

(a) USAMMC-E Relocation Planning

(b) Maher Memorial High Altitude Laboratory, Pikes Peak, CO Design Charrette

(c) AFMES Bldg 115 HVAC Engineering Study

(d) USAMRIID Bldg 1425 Reuse Study

(e) WRAIR Bldg 501 Facility Survey

(f) USAMRAA MILCON Planning

(g) NMHM Bldg 2500 HVAC Study

(h) NMHM Bldg 178 Waterproofing Study

(i) NMHM Bldg 178 Generator Sizing Study

(j) MEDCOM RMC/MTF OIP Checklist

(8) Construction Management. The FTEMD participated and was instrumentalin providing valuable input to construction management meetings for USAMRMC MILCON, and the Major Repair and Renewal (MRR) projects to ensure the user and Command's needs were addressed. The FTEMD participated in the construction meetings for the following significant projects:

(a) USAMRICD Replacement Facility, Aberdeen Proving Grounds, MD

(b) USAMRIID Replacement Facility, Fort Detrick, MD

(c) USAMRIID Steam Sterilization Plant (SSP), Fort Detrick, MD

(d) USARIEM Planning for the Maher Memorial High Altitude Laboratory, Pikes Peak, CO

(e) Senior Executive Review Boards between Commanding General and Corps of Engineers leadership on recently completed facilities such as the SSP, AFMES and NMHM.

(9) Operations & Maintenance (O&M). In FY14, the FTEMD continued to corporately align maintenance activities to follow recommendations from a comprehensive maintenance study completed in late FY10. The FTEMD expended over $14M in O&M funding to USAMRMC medical labs analyzed by this study. These funds were used for a combination of in-house maintenance operations and contract maintenance operations. An annual FTEMD centralized O&M contract was awarded which included support for WRAIR, USACEHR, TATRC, USAARL, AFMES, NMHM, and the US Navy Medical Research Lab – Fort Detrick, MD. USAMRIID continued to use both in-house staff and contracted O&M support. USAMRMC attained partial possession of the new USAMRICD and awarded an O&M contract that supported the existing USAMRICD facilities and the partial acceptance area of the new facility. USAISR/BHT continued to rely on support provided by the Brooks Army Medical Center central maintenance contract. USARIEM continued to use a stand-alone maintenance contract.

(10) Space Utilization Management. The FTEMD developed a secure, online, quarterly reporting process for tracking space utilization inventory data, providing ease of accessibility to customers. Additionally, a webpage was designed and published on the USAMRMC intranet site as a resource for HQ, USAMRMC and subordinate commands located at Fort Detrick. This webpage provides access to a full range of space related regulatory guidance, templates and forms (https://usamrmc-ext.amedd.army.mil/SUM/index.cfm). The FTEMD coordinated space validation processes for inclusion in the Manpower Program Budget Advisory Council review to ensure space is available and planned for prior to hiring actions. In 2014 conceptual space planning diagrams were generated by the FTEMD to support a comprehensive on-post relocation project for USAMRAA; diagrams were also provided as a bid package tool. Ultimately, the move will allow Fort Detrick US Army Garrison (USAG) to dispose of WWII failing wooden structures, as well as trailer structures, and provide site space to move forward with master planning projects. Regular, collaborative, joint space meetings continued with Fort Detrick, USAG, to address space issues which needed prompt and ongoing coordination with USAG. The FTEMD collaborated with USAG in compiling and publishing a shared conference room online resource listing, saving the Government valuable time and funds. The FTEMD continued to be active providing services and support to determine space utilization needs, transition space requirements, and planning for HQ, USAMRMC and subordinate commands located at Fort Detrick.

(11) In FY14, the FTEMD participated in the US Army, MEDCOM, and USAMRMC directed initiatives and inspections which included:

(a) GFEBS implementation and training of power users

(b) OIP of USAMRICD and USAMMDA

(c) DMLSS Facility Module training

(d) SAV for AFRIMS and Georgia Medical Laboratory

(e) Builder Facility Assessment Deployment

(f) Defense Health Agency (DHA) reorganization

(12) The FTEMD represented the Command in various forums involving multi-organization and/or tri-service meetings such as the Fort Detrick Integrated Coordinating Committee, Installation Real Property Planning Boards, transformation meetings, project team meetings, MEDCOM Facilities Board of Directors, MEDCOM Support Team Project Line Item Reviews, Contract Advisory Committee, facility contract source selection boards, Army Corps of Engineers/Health Facility Planning Agency MILCON meetings, and DHA meetings.

(13) The FTEMD managed the Defense Health Program (DHP) Facility Funds for all DHP supported facilities for Sustainment Restoration and Modernization (SRM). The FTEMD also coordinated and directed the preparation of programming documents for input to the MILCON Program and provided corporate input to the POM process. The FTEMD was also successful in procuring a stand-alone USAMRMC regional facility SRM Multiple Award Task Order Contract through Mobile Corps of Engineers.

(14) Funds Execution. The FTEMD awarded approximately $24.3M in SRM project contracts in FY14.

The funding types used for facility expenditures included DHP, O&M Army, Research Development and Technology P6 funds, and Initial Outfitting and Transition funds. The following figures show the facility contracts awarded during FY14. Figure 10 lists the 12 contracts/task orders funded with a value over $500K and Figure 11 lists the 31 contracts funded with a contract/task order value under $500K.

Figure 10 FY14 USAMRMC FUNDED FACILITY CONTRACTS EXCEEDING $500K

PROJECT	ACTIVITY	DMLSS#	PROJECT	COST ($K)
1	USAMRAA	14MRHQ039	USAMRAA Bldg 1504 Renovations	511.00
2	USAMRICD	14RICD001	E2909 Relocate Pulmonary Mechanics, e2909 tem/sem room mod, f2401 xray imaging, dry sprinkler n2 generation	719.74
3	NMHM	12MRHQ001	Bldg 178 Back-Up Power Repairs	781.31
4	USAMRIID	14RIID003	Bldg 1425, Suite AA-5, BSL-4 Lab Repairs	971.70
5	USAISR	12RISR005	Bldg 3611 Fire Alarm and Mass Notification Repairs	1127.59
6	WRAIR	13WRAI042	503 South Wing Flood Repairs	1132.99
7	HQ,MRMC	NA	Command Wide Demand Maintenance	3,500.00
8	WRAIR	14WRAI002	503 Repair BSL3 Lab 3N50	1219.97
9	WRAIR	11WRAI010	503 Back-up Power Repairs	1676.35
10	USAMMC-E	14USAMCE001	Prepare KAD facilities for USAMMC-E Relocation	2739.80
11	WRAIR	12WRAI003	503 Reheat Coils	3101.90
12	WRAIR	11WRAI003	503 and 501 BAS Repairs	6861.94
			TOTAL	**24,344.30**

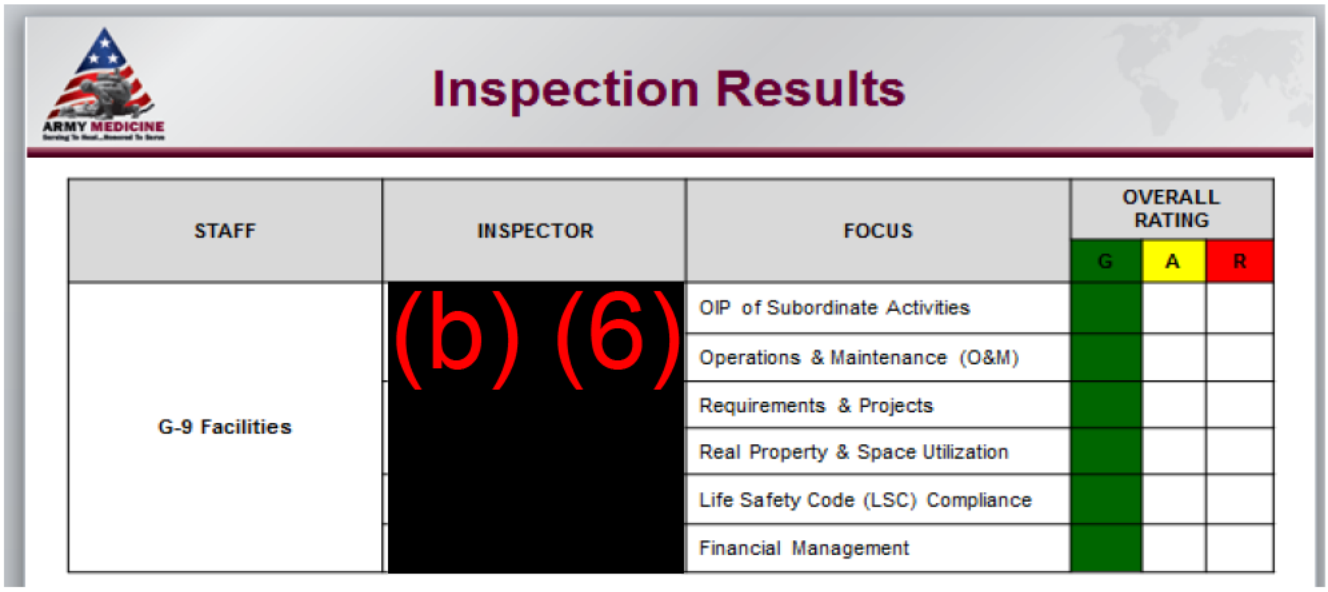
Figure 11 FY14 USAMRMC FUNDED FACILITY CONTRACTS BELOW $500K

PROJECT	ACTIVITY	DMLSS#	PROJECT	COST ($K)
1	USAMMC-K	14USMK058	Bldg 710 Install Faucet	0.07
2	USAMMC-K	13USMK021	Bldg 734 Paint & Caulking	0.45
3	USAMMC-K	13USMK020	Bldg 710 Relocate AC Units	0.50
4	USAMMC-K	13USMK013	Bldg 710 Generator Shed	1.99
5	USAMMC-K	13USMK031	Bldg 710 Hallway Painting	3.00
6	USAMMC-K	14USMK076	711 Repair Optical Lab Fume Hoods	3.50
7	USAMMC-K	13USMK006	Multiple Buildings Heaters	4.50
8	NMHM	na	178 Electrical Engineer Generator Sizing	6.00
9	NMHM	na	178 Waterproofing Assessment	6.00
10	USAMMC-K	14USMK046	Bldg 710 Kitchen Hoods	6.60
11	USAMMC-K	13USMK017	Bldg 710 Install 6 lights under roof and install guard rail and cement pad behind building	7.00
12	HQ,MRMC & USACEHR	12MRHQ004	568 Gas Service Supply Line Repairs	10.37
13	USAMMC-K	14USMK077	Remove Cement Stairs next to O2 cage on Building 709	11.69
14	NMHM	na	NMHM HVAC Survey	15.00
15	WRAIR	na	511 Steam Line Jumper	18.00
16	USAMMC-K	14USMK053	Bldg 709 Grating	19.27
17	AFMES	14AFME003	Bldg 115 Stair Tread Repairs	19.54
18	WRAIR	na	Campus Boiler Commissioning Purchase Order	19.79
19	USAMRIID	na	ABM SSP VESSEL CERTIFICATION	24.00
20	WRAIR	13WRAI044	503 Mechanical room heater repairs	26.33
21	AFMES	na	Canopy Repairs	35.47
22	USAISR	14RISR0011	Bldg 3610 Rm 164-1 Site Prep for Digestion System Equipment	61.68
23	AFMES	13AFME018	Bldg 115 Server Room Dry Fire Suppression	69.14
25	USARIEM	na	USARIEM Pikes Peak MILCON NEPA	105.00
26	WRAIR	14WRAI003	503 Renovation of Lab Space	207.10
27	USAMMC-K	13USMK014	709 Install back-up generators	251.89
28	USAISR	13RISR0028	Bldg 3611 Repair Doors and Hardware	274.15
29	USAARL	13USAR0014 & 14USAR0032	6901 Repair Rooftop Exhaust and Supply Fans & 6901 Install ADA Compliant Signage	313.77
30	AFMES	14AFME001	Bldg 115 Glasswash and Bathroom Repairs	342.57
			TOTAL	**1864.39**

(15) OIPs. The MRMC assisted MEDCOM G9 with the development of two (2) comprehensive OIP checklist to ensure that all MEDCOM facilities and regions facility programs were consistently inspected the same.

(16) In FY14, the FTEMD was inspected by the MEDCOM G9 Facilities and received a perfect score without any negative findings for the six (6) categories comprised of OIPs of subordinate commands; O&M; Requirements & Projects; Real Property & Space Utilization; Life Safety Code Compliance; and Financial Management. Figure 12 shows the summary of results.

Figure 12 USAMRMC FTEMD OIP SUMMARY OF RESULTS



(17) Staff Training. The FTEMD staff completed all required Army training as directed. The staff has also completed training to retain their various Acquisition Work Force credentials. Examples of the FTEMD staff training include:

(a) Facility Engineering 301 – DAU

(b) Miscellaneous DAU training development courses

(c) National Facility Technology and Management Conference Course Curriculum

(d) DMLSS-FM Training

(e) Mobile Corps of Engineers Contract Officer Representative Training

(f) US Army Contract Officer Representative Training

(g) Miscellaneous Civilian Service Training

(h) Intermediate Medical Acquisition Course Training

(i) OIP Training

(j) Energy Star Database Training

(k) Builder Facility Survey Database Training

(l) NeoCon East "New Space Solutions", Space Management Curriculum

(18) Data Call Submissions. The FTEMD staff completed all requests for data tasks within the specified time constraints. A sampling of FY14 completed tasks are provided in Figure 13.

Figure 13 FY14 TASKERS COMPLETED BY THE FTEMD

Number	Organization	Title
Internal	MCMR-LM	PN 55839 Due-outs
1311061	MCMR-PPA	POM 16-20 DHP O&M Requirements
Internal	MCMR-LM	Review MEDCOM Pamphlet 40-18
Internal	MCMR LM	Updates on facility loss at WRAIR
Internal	MCMR-LM	MEDCOM OIP Inspection of HQ,USAMRMC
1312041	MCMR-PPA	FY16-20 DHP O&M Issue Nominations
1403086	MCMR-LM	MILCON review within last 5 years. Note any RDTE projects in PB for FY 15 or in POM for FY 16-FY20
1403078	MCMR-LM	Information paper on the current status of the AFRIMS Facility
1404040	MCMR-LM	Construction Activity Update
Intern25al	MCMR-LM	Develop information paper about differences between the Army/DHA/TMA facilities sustainment
1404095	MCMR-OP	Identify building manager for building manager forum
1404092	MCMR-LM	Space Utilization Inventory
1404089	MCMR-LM	MRMC FY15 Facility Initial Outfitting and Transition Fund Data call
1403079	MCMR-LM	Asia Pacific Trip-Determine Recapitalization Courses of Action for AFRIMS Facility
1404143	MCMR-RT	USAMRMC Infrastructure list
1406058	MCMR-LM	Space Request Form for Bldg 1520
1405028	MCMR-RTM	Review of CBDP Infrastructure Implementation Plan
1408112	MCMR-LM	Space Utilization Inventory
1404074	MCMR-LM	FY15-18 MRR Program
1409034	MCMR-LM	FY2021 MILCON Program Development
Internal	MCMR-LM	NHMH Bldg 178 water issues
1409111	MCMR-SGS	CG Trip book for USAMMA
1409112	MCMR-SGS	CG Trip book for WRAIR/DCoE
Internal	MCMR-LM	FY14 Projects over $500K
Internal	MCMR-LM	Natick program for design review
1410046	MCMR-SGS	CG Prep for USAMRIID
1410144	MCMR-SGS	CG Prep for USAISR
Internal	MCMR-IT	BIA Review
1410047	MCMR-LM	CG Prep for USAMRICD visit
1410145	MCMR-SGS	CG Prep for AFMES visit
1410146	MCMR-LM	CG Prep for USACEHR
Internal	MCMR-LM	Prepare for Balance Score Card Brief
1410147	MCMR-SGS	CG Prep for USAARL
1410048	MCMR-SGS	CG Prep for USAMMC-K, AFRIMS
Internal	MCMR-LM	MILCON IPT
1412023	MCMR-LM	Review Submit concurrence/non-concurrence with OPORD 15-XX Mandatory Data Management in DMLSS
1412021	MCMR-PPA	FY17-21 DHP O&M Issue Nominations
1404092	MCMR-LM	Space Utilization Inventory
1404146	MCMR-LM	Request for Updates for Conference Room Roster
1412093	MCMR-LM	Space Management Information (HQ MRMC)
1412094	MCMR-LM	Space Management Information (Ft Detrick Subordinate Units)

D. Acquisition and Logistics Program Management Division:

(1) WAWF-R&A Program: As the Army Site Lead, the MEDCOM GAM, and USAMRMC's Program Manager for the WAWF-RA Program, the Division is preparing the Command WAWF-RA program for an Army Audit by reviewing over 1,100 customer profiles and supporting documentation required for system access. The Division coordinated and conducted an internal command audit of over 1,100 user profiles that achieved 100% successful rate during the inspection of WAWF-RA accounts. Our aggressive business processes resulted in USAMRMC paying only $51K of interest penalties out of $275M disbursed. With effective planning, communication and coordination, training was provided to over 410 financial, contracting and logistics managers, GAMs, Contracting Officer Representatives and GPC holders in support of the Command integrated mission requirements. The Division was able to save the Command over $600K by centralizing the required training at Fort Detrick.

(2) DMLSS Program: The Supply System Analyst (SA) serves as the single point of contact between the Regional Medical Command and the subordinate commands regarding issues pertaining to medical logistics systems such as the DMLSS and GFEBS Systems. The SA successfully coordinated with the Joint Medical Logistics Functional Development Center and DMLSS Senior Service Representative in deploying DMLSS build 3.1.2.0.893.893, 3.1.2.0.893.895, 3.1.2.0.894, 3.1.2.0.893.896, and 3.1.2.0.893.897 to all DMLSS clients/servers. He also created and distributed five (5) DMLSS guides/workbooks to include a SA SOP throughout USAMRMC.

(3) Standardization Program: (b) (6) was appointed as the Command Senior Logistician to createand establish the Command Standardization Committee and program that will oversee and manage the Command GPC, medical supply and equipment standardization purchases. Currently, the committee is in the process of finalizing a charter and working closely with the Defense Medical Material Program Office to synchronize and leverage medical logistics capabilities in support of the Military Health Systems.

(4) GPC Program: In support of the OTSG's operations order 14-88 (Increase Visibility of Medical Treatment Facility Purchases with the Government Purchase Card), the division was able to identify and reduce the Command GPCs from 185 to 170. While assisting USAMRIID, USAMRICD and WRAIR in converting their GPC purchases to the electronic catalogue (ECAT), ODCSLOG was able to identify a potential savings of $2.6M.

(5) USAMRMC Information Management & Information Technology (IM/IT) Management Review and Advisory Council (MRAC): As a member of the Command's newly established MRAC, the Division assisted in the development of the first charter and reviewed over 30 software applications. The Division assisted in establishing the designated membership, duties and responsibilities for the USAMRMC IM/IT Executive Governance Board, MRAC, and the Technical Review and Advisory Board.

(6) Budget/Table of Distribution and Allowances (TDA)/Support Agreements/ Taskers: As ODCSLOG's Budget Officer, the Acquisition and Logistics Division effectively managed and executed ODCSLOG FY14 $2.1M Army RDT&E operational budget. The Division provided oversight of ODCSLOG's two (2) GPC holders with expenditures in excess of $35K. As an Approving Official for the Defense Travel System, the Director reviewed and certified 65% of ODCSLOG's travel requests and vouchers. The Personnel Strength Management System was updated and the Activity Base Costing report was prepared and submitted for FY14. As the custodian of ODCSLOGs TDA, the Division established and submitted requirements for the FY15 TDA. The Division also prepared, consolidated, and submitted all required ODCSLOG documents

for the MEDCOM Manpower Study and reviewed and approved over 20 Support Agreements and service contracts for USAMRMC. The Division also reviewed and completed over 35 external and internal taskers.

(7) Management Internal Control/Acquisition: Working closely with the other director's, the Acquisition and Logistics Division completed the FY14 Army Management Internal Control assessments of the following areas within ODCSLOG: Property Management, GPCs, Equipment Medical Maintenance, Material Management, and Facility Engineering.

(8) Contracts: The Acquisition and Logistics Division is responsible for overseeing the management, execution, and renewal of ODCSLOGs $50K snow removal contract, $10K in automation equipment purchase and $8K in Test, Measurement, and Diagnostic Equipment calibration support agreement. This oversight led to the sidewalks being cleaned and the safety of ODCSLOG employees, strict life cycle management for automation equipment and proper calibration of the Command's medical equipment.

(9) OIPs: The Division provided two SME and inspectors during the OIPs at USAMRICD, WRAIR, and USAMMDA. In preparation for the Federal Information System Controls Audit Manual inspection, the Division reviewed all WAWF-RA and DMLSS user profiles and business processes to ensure regulatory compliance.

(10) Training: The Division Chief received his Level III in Facility Engineering. (b) (6) attended and completed the following courses: the Medical Logistics Systems Management Course, Writing Skills (HBS 444), Purchase Card Online System (CLG 005), DoD Government Purchase Card (CLG 001), GFEBS Overview (L101E), Integrated Process Overview (L201E), and Navigation and Reports (L303E).

The point of contact for this report is (b) (6) **, at DSN** (b) (6) **or** (b) (6)

(b) (6)
COL, MS
Deputy Chief of Staff for Logistics

Section 4

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G8 – Deputy Chief of Staff for Resource Management

General

A. DCSRM, LTC (b) (6) .

B. Staff. Two Army Officers, 18 Department of the Army civilians, and two support contractor personnel. The office consisted of the DCSRM, LTC (b) (6) , and her administrative personnel, Financial Reporting, Manpower and Management, and Budget divisions. The Chief, Financial Reporting, was (b) (6) ; Chief, Management and Manpower, Vacant; and Budget Officer, CPT (b) (6)

Mission

A. Operational manager of USAMRMC's fiscal and manpower resources and related business practices. The DCSRM represents the Commanding General (CG) in exercising directional authority over the management and control of total USAMRMC resources.

B. Provides executive-level insight, guidance, assistance, and direction for financial management issues.

C. Serves as the Command's integration hub, providing the resource management system and framework for sound and timely business and program decisions.

D. Directs and supervises the Headquarters (HQ) resource management support functions, consisting of manpower documentation, USAMRMC support agreements, Activity-Based Costing (ABC), and Defense Travel System.

E. Responsible for issuing funds, recommending fiscal policy, monitoring execution of all USAMRMC funds, and preparing fund utilization reports.

F. Responsible for assisting with and reviewing financial information for the Defense Business Certification (DBC) process for all business systems in USAMRMC.

G. Provides the HQ staff with technical advice on budget cycle and execution matters, budget analysis, and obligation and disbursement rate performance.

H. Principal staff advisor to the CG on all fiscal matters.

I. Reports to the Chief of Staff.

Focus Areas.

A. **Office of the DCSRM:**

1) Executes Department of Defense fiscal policies based on regulation, guidance, and law.

2) Principal advisor to CG on all fiscal matters.

3) Directs and supervises the development of Command fiscal and manpower policies.

4) Coordinates resource management matters with the US Army Medical Command (USAMEDCOM), Office of The Surgeon General (OTSG), Office of the Assistant Secretary of Defense for Health Affairs (OASD(HA)), and the Office of the Assistant Secretary of the Army for Acquisition, Logistics, and Technology (OASA(ALT)).

5) Serves as the Executive Secretary of the Manpower Program Budget Advisory Council and Chairperson of the Manpower Working Program Budget Advisory Council.

B. **Financial Management and Reporting Division:**

1) Interprets financial guidance on statutory policy and regulatory issues. Develops Command policies, procedures, and guidance for fiscal support services.

2) Plans and manages the execution of financial and manpower resources.

3) Recommends Command budget execution business practices.

4) Interfaces with USAMEDCOM, OTSG, OASD(HA), OASA(ALT), the HQ staff, and subordinate commands on fiscal/financial policy.

5) Responsible for assisting with and reviewing financial information for the Defense Business Certification (DBC) process for all business systems in USAMRMC.

6) General Fund Enterprise Business System (GFEBS) – Responsible for assisting USAMRMC HQ and subordinate units with GFEBS system issues and day-to-day work processes (help desk type support for HQ and all subordinate as required). Coordinate as necessary with USAMEDCOM and GFEBS Program Manager (PM) to resolve issues and/or get additional direction in order to achieve Army objectives as they relate to medical RDT&E programs and unique funding streams and processes.

7) Responsible for all financial reporting external to USAMRMC to include execution reviews as required.

8) FY14 funds were distributed as shown below. FY13 and FY12 are shown for comparative purposes only:

USAMRMC TOTAL FUNDING - DIRECT & REIMBURSABLE ($000)			
APPROPRIATION	FY 12	FY 13	FY 14
RESEARCH, DEVELOPMENT, TEST AND EVALUATION, ARMY (2040.0000)	521,635	435,379	436,913
OTHER PROCUREMENT, ARMY (2035.0000)	48,105	46,312	52,535
DTRA CBDP, ARMY (0400.2601)	117,756	100,745	93,834
DHP R&D, ARMY (0130.1831)	717,973	646,267	1,021,915
DHP, O&M, ARMY (0130.1881)	334,203	319,492	362,736
DHP, PROCUREMENT, ARMY (0130.1871)	32,000	61,472	71,495
OPERATION AND MAINTENANCE, ARMY (2020.0000)	228,587	191,863	170,057
OPERATION AND MAINTENANCE, ARMY, SECY ARMY REPRESENTATION FUNDS (2020.0012)	8	16	4
FAMILY ASSISTANCE PROGRAM, ARMY (0100.6041)	0	0	0
RELOCATION ASSISTANCE PROGRAM, ARMY (0100.6091)	0	0	0
DARPA, ARMY (0400.1301)	0	0	0
DHP ENHANCEMENT, R&D, ARMY (0130.18N1)	213,829	207,500	331,241

MILITARY PERSONNEL ARMY (2010.0000)	1	2	0
GLOBAL HEALTH PROGRAMS (1031.18Q1)	701	9,292	12,085
DOD ACQUISITION WORKFORCE (0111.6161)	0	0	1157
TOTAL	2,214,798	2,018,340	2,553,972

C. **Management/Manpower Division:**

1) Activity Based Costing (ABC) – Provides ABC policies, objectives, and procedures. Develops and maintains ABC models and standard activity definition; and provides Command-wide cost and process analysis to identify potential opportunities for process improvements and savings in time and dollars utilizing all appropriate analysis techniques. Developed numerous process maps and business rules for deployment of a Command-wide cost management process. Continue to develop ABC models for several units and use the models to derive HQ research support rates per appropriation.
2) General Fund Enterprise Business System (GFEBS) – Provided General Fund Enterprise Business System cost management implementation policies, objectives, and procedures.
3) Lean Six Sigma – Assists the Lean Six Sigma project team in determining the type of financial benefit (savings, cost avoidance, or revenue generation) that the project is expected to generate.
4) Managers' Internal Control Program - Administers the Command's Management Control Program and keeps the Commander and managers informed on internal control matters.
5) Manpower Management - Develops manpower policy, objectives, and procedures based on guidance received from the HQDA and major changes to mission funding, workload, and availability of manpower assets.
6) Support Agreements - Manages the USAMRMC Inter/Intra Service Support Agreement, Memoranda of Understanding, and Memoranda of Agreement programs.
7) Request for Services Contract Approval - Administers and ensures compliance with the in-sourcing policy and guidance for civilian workforce management and service contracts.
8) Automated Time, Attendance, and Production System (ATAAPS) - Administers Civilian Payroll Management. Enters new employees and removes departed employees from the ATAAPS system; close each pay period; resolve pay issues; enter Defense Civilian Pay System (DCPS) input. Assisted with the development of GFEBS Internal Orders to support the cost management process and assist MRMC in analyzing costs of activities.
9) Conference/Travel Coordination - Administers and oversees the routing of Conference/Travel Coordination for approval by USAMRMC Manpower Program and Budget Advisory Committee, MEDCOM and Army. This responsibility transitioned to the HQ, USAMRM, Chief of Staff Office in October 2014.
10) Defense Medical Human Resources System - Internet (DMHRSi) – Administers maintenance of DMHRSi and the Position Control Roster as the MEDCOM Manpower System of Record to identify mission priorities and to align the workforce and funding with enduring mission requirements.

D. **Budget Division:**

1) Obtains, controls, and accounts for funds necessary to conduct the Medical Research, Development and Acquisition and Logistics missions and assigned functions.

2) Coordinates and monitors compliance with resource planning guidance during execution of the intramural and extramural research programs.

3) Develops statistical reporting procedures, financial controls for resources, and finance and accounting reports.

4) Directs the annual formulation of the Command Budget Estimate for core Research and Development programs.

5) Monitors the execution of the current-year budget, receives and issues funds, and reports on the utilization of those funds to USAMEDCOM, ASD(HA), and ASA(ALT).

6) Responsible for daily execution of funds management tasks GFEBS to include establishing funded programs and work breakdown structures (WBS), monitoring status of funds and resolving interface errors. Develops new business practices in accordance with MEDCOM directives.

7) Responsible for the accuracy and updating of all Standard Finance System (STANFINS) master files and daily/monthly STANFINS reports.

8) (Interfaces with the Defense Finance and Accounting Service (DFAS) to ensure the accuracy of all budgetary information and detailed accounting records. Provides DFAS feedback regarding deficiencies identified in review of the monthly status of funds report.

9) Maintains the Commitment Accounting Disbursement System database that interfaces with the STANFINS for legacy budgetary and accounting information and the Extramural Research Management System database for legacy contractual information.

10) Facilitates issuing of travel credit card and monitors payments.

11) Facilitates issuing of Government Travel Charge Card and monitors payments.

12) Facilitates establishment and payment of Government procurement cards and assists the Agency/Organization Program Coordinator with surveillance of assigned accounts.

Significant Accomplishments.

A. **Office of the DCSRM:**

1) (b) (6) retired as Chief, Management and Manpower during August 2014 and his position was still vacant as of 31 December 2014. (b) (6) retired with 35 years of Federal service.

2) LTC (b) (6) name was on the O-6 promotion list in October 2014.

3) CPT (b) (6) name was on the O-4 promotion list in November 2014.

B. **Financial Management and Reporting Division:**

1) Monthly execution reviews were implemented by the Assistant Secretary of the Army for Acquisition, Logistics, and Technology (ASAALT) in October 2011. Reviews were completed through July 2014 pausing for fiscal year end and reinstated during December 2014 for the core Science and Technology program. Detailed charts have been required to include obligation and disbursement plans and actual obligations and disbursements. Allowable variances to Office of the Secretary of Defense obligation and expenditure goals were 5% and 10% respectively, otherwise explanation was required.

2) Execution information to include funding, obligations, and disbursements are provided to the Principal Assistants for Research and Technology and Acquisition. Monthly budget meetings continue to take place with the Principal Assistant for Acquisition. Obligation rates have improved and disbursement rates are still being assessed for additional areas of improvement. The meetings are key in correcting execution issues at the HQs, Research Area Directorates, laboratories, as well as USAMRAA, USAMMA, and USAMMDA.

C. **Management Analysis and Manpower Division:**

1) The USAMRMC manpower strength for FY14 is as follows:

   a. Military – 1,234 Required; 1,101 Authorized; and 1,068 Actual

   b. Civilians – 2,269 Required; 2,112 Authorized; and 2,346 Actual

   c. Contractors – 0 Required; 1,587 Authorized; and 3,188 Actual

2) The actual strength figures were extracted from the USAMRMC monthly strength report as of 30 September 2014, and the required and authorized figures were extracted from the DA Approved FY15 Tables of Distribution and Allowances for USAMRMC.

3) Table of Distribution and Allowances (TDA) Documentation. Effective with the FY15 DA-approved TDAs, all manpower requirements above authorizations, as well as all contractor positions, were removed from the TDAs. As civilian, military, and contractor manpower requirements are earned and validated, either from approved Concept Plans or from approved manpower studies, they will then be documented on out-of-cycle TDAs.

4) USAMRMC Manpower Study. The USAMEDCOM manpower analysts continued their review of the Baseline Submission Packages that were submitted by each USAMRMC activity. Four studies were completed in 2014: Army Medical Research Institute of Chemical Defense, U.S. Army Medical Materiel Development Activity, U.S. Army Institute of Surgical Research, and U.S. Army Aeromedical Research Laboratory. The analyses by USAMEDCOM and the U.S. Army Manpower Analysis Agency (USAMAA) for all remaining activities are currently on-going. The final manpower study results are expected to be documented on FY16 out-of cycle TDAs.

5) USAMRMC submitted an in-sourcing proposal to in-source seven contract positions to civilian positions within the Joint Trauma Analysis for Prevention of Injury in Combat Program Management Office. The proposal is pending approval of the Assistant Secretary of the Army (Manpower and Reserve Affairs).

6) Implemented use of the Position Control Roster (PCR) in the Defense Medical Human Resources System - Internet (DMHRSi) to identify faces to spaces to funding within USAMRMC activities with the goal of using DMHRSi as the system of record, which includes Civilians, military, and contractors. DCSRM coordinated with the DMHRSi program office, MEDCOM manpower and human resources, to provide face-to-face, hands-on training for manpower and human resources personnel from all MRMC activities, including in Korea and Germany. DCSRM monitored and reported completion of the alignment of personnel to the Table of Distribution and Allowances

(TDA) in the DMHRSi through production of PCRs which are representative of each entire activity and associated personnel, to meet the MEDCOM Chief of Staff direction for initiation of this Workforce 2020 project.

7) Management Controls: In FY14 99% of the scheduled Internal Control Evaluations were completed (406 of 410) and 79% of planned Risk Assessments were completed (26 of 33). Three new material weaknesses were identified and reported in the FY14 Annual Statement of Assurance:
   a. Overhead Reimbursement Charges (HQMRMC)
   b. .ORG and CAC Authentication (WRAIR AFRIMS)
   c. Assessment of .ORG Systems (WRAIR AFRIMS)

8) During 2014, 793 Service Contract Approval Forms (SCAF) were completed. Completion defined as signed by CG or SES. The SCAF, now to be referred to as Request for Service Contract Approval (RSCA) was modified by ASA (M&RA) twice, in May 2014 and Oct 2014. Training was provided on use of the new forms.

9) Automated Time, Attendance, and Production System (ATAAPS) transitioned from hosting and support by USAMITC to DISA. In addition, all Leave and Premium Time transitioned to being requested and approved through ATAAPS.

10) Developed and deployed business rules for a Command-wide cost management process with follow-up inspections (OIP) to determine adherence to policy.

11) Developed Command-wide Dashboard that interlaced data from ATAAPS, GFEBS, and TDA. This dashboard allows senior leadership to quickly visualize the status of these databases and identify corrective actions.

12) Obtained approval for the deployment of a Command-wide Cost Formulation and Estimation Tool (CFET). This application allows the units to easily develop their research proposals and gives them a centralized database of proposals to analyze their costs (overhead, comparison of projected versus actual, etc.)

13) A total of 471 agreements were negotiated for both internal and external customers.

D. **Budget:**

1) Managed successful fiscal year closeout across three financial systems (SOMARDS, STANFINS, and GFEBS).

2) Managed over 11 single and multiple year appropriations totaling more than $2B; each with its own unique management requirements.

2. Point of contact for this action is COL (b) (6)

(b) (6)
COL, MS
Deputy Chief of Staff
Resource Management

Section 5

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International Affairs

Mission

USAMRMC/MEDCOM International Point of Contact (IPOC), manage International Agreements and Exchange Programs from inception to finalization, manage and provide guidance and policy concerning international agreements, and personnel exchange, develop, staff and implement new international agreements, maintain and manage existing international agreements, develop an annual International Affairs Book, Coordinate with MEDCOM, OTSG, ASA(ALT), and DASA(DE&C), and update and manage input to the International Online (IOL) database. USAMRMC HQs Foreign Disclosure Officer (FDO).

Organization and Personnel:

1 DA Civilian; (PAO insert)

Statistical Data:

Maintain the 13 (2 additional pending/in process) official government-to-government international agreements, 6 exchange personnel (3 additional/potential in process), received 36 OCONUS Trip Reports, processed numerous international visits requests.

Healthcare Delivery:

N/A

Veterinary Services:

N/A

Training and Education:

Foreign Disclosure Officer

Research and Development:

A new Project Arrangement (PA) was signed into effort between USARIEM and Canada, as well as our Singapore Data Exchange Agreement (DEA) extended for an additional 5 years. Received Technology Information Paper (TIPs) requests for distribution around the command for possible collaboration interest as well as access to the TIPs database. During the course of the year, respond routinely to Taskers from ASA(ALT) and DASA(DE&C) identifying potential areas of collaboration in various countries/medical research topics and help update senior leadership on the hundreds of international activities, agreements, etc. that MRMC is involved in. Continued interest in personnel exchanges, which help advance research and development for each country and overall cooperation. International Affairs Book was completed with input throughout the command on current international activities.

Resource Management and Budget:

N/A

Information Management:

N/A

Operations:

N/A

Modernization:

N/A

Logistics:

N/A

Construction:
N/A

Health and Environment:
N/A

Other:
N/A

Appendices:
N/A

Section 6

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Office of Research Protections

Mission

The primary mission of ORP is to oversee USAMRMC supported research and Army Medical Department clinical investigations involving human subjects, human anatomical substances, cadavers, or animals, to assure these activities are conducted in accordance with Federal, DoD, Army, USAMRMC, and international regulatory requirements. ORP comprises an administrative core and four branch offices, each with mission-specific responsibilities. These branches include the Animal Care and Use Review Office (ACURO), the Institutional Review Board Office (IRBO), the Human Research Protection Office (HRPO), and the Clinical Investigation Regulatory Office (CIRO), and their unique roles are summarized as follows:

A. ORP. ORP's director serves as principal staff officer for all aspects of Command operations in the areas of human subjects protection and animal care and use review. ORP develops Command policy and guidance and manages resources and action in these areas, and interfaces with staff throughout DA, DoD, other Federal, and civilian agencies and organizations on the topic of research protections. ORP reviews, approves, and maintains active compliance oversight of DA-conducted and –supported "sensitive uses" of cadavers.

B. HRPO. HRPO oversees the Headquarters (HQ) USAMRMC Human Research Protection Program and provides human subjects protection review and approval of USAMRMC conducted, contracted, sponsored, supported, or managed extramural and selected intramural research proposals and protocols. HRPO's director serves as principal advisor to the Command for human subjects protection, provides subject matter expert consultation and staff assistance visits to USAMRMC laboratories and institutes, and administratively supports the HQ USAMRMC Research Ethics Advisory Panel. HRPO activities include the development and implementation of human subjects protection policies and regulations, assistance with Freedom of Information Act requests, and maintenance of the USAMRMC Volunteer Registry Management System. By agreement, HRPO also provides intramural and extramural oversight and staff assistance to other Army and DoD organizations.

C. IRBO. IRBO supports the HQ USAMRMC Institutional Review Board (IRB) and serves as the primary IRB for HQ and several USAMRMC subordinate laboratories and activities. IRBO also supports many DoD and Army institutions that do not have their own IRB, and has the ability to serve as a central IRB for DoD studies conducted at multiple sites. IRBO provides determinations for activities that do not meet the regulatory definitions of research or human subjects, and for human subjects research protocols that are exempt from regulatory requirements. IRBO performs post-approval compliance monitoring and oversight at the direction of the IRB Chair or the Director, ORP.

D. CIRO. CIRO oversees compliance for all human research conducted at Army Medical Treatment Facilities (MTFs). This includes conducting pre-approval reviews of studies that involve medical products to ensure compliance with FDA regulations. CIRO also provides instrumental staff assistance to clinical investigation programs throughout the Army by facilitating an education series, conducting Staff Assistance Visits, and serving as a real-time resource for MTFs encountering challenges or problems. CIRO serves as principal advisor to the Command regarding clinical investigation program (CIP) research and has approval authority for cooperative agreements that support CIP research throughout MEDCOM.

E. ACURO. ACURO serves as the principal advisor to the Command regarding the use of animals in RDT&E, education or training throughout the Army, and is the MEDCOM, and DA point of contact for all supported organizations on animal care and use matters. ACURO assists in developing responses to FOIA requests concerning animal use in DoD-supported activities. ACURO reviews research proposals and protocols involving animal use supported by MEDCOM, DA or other DoD organizations to assure they are conducted IAW Federal, DoD, Army, USAMRMC, and international regulatory requirements. This includes oversight for Army Combat Trauma Training involving live animals. By agreement, ACURO additionally provides intramural and extramural support and oversight to other DoD organizations. ACURO sponsors and administers the US Army Laboratory Animal Medicine Residency Program and provides a member to the DoD Animal Working Group.

Organization and Personnel

The structure of ORP, including branch offices, is illustrated in Figure 1, *ORP Diagram*. Appendix 1, *ORP Organization Chart*, is a complete organization chart for the ORP as of 3 September 2014. ORP collectively includes 59 staff members as described in Table 1, *ORP Personnel*. Key leaders and leadership changes are summarized below:

TABLE 1: ORP Personnel

Military	Civilian	Contractor	Student	Total
4	22	31	2	**59**

A. ORP.

1) Director, (b) (6), RN, PhD

2) ORP experienced no key leadership changes in FY14.

B. HRPO.

1) Director, (b) (6), RN, PhD

2) New staff arrivals included Deputy Director, (b) (6), PhD, CIP, and Special Projects Scientist/Intramural Laboratory Liaison, (b) (6), PhD, CIP.

C. IRBO.

1) Director, (b) (6), MS, CIP

2) New staff arrivals included Deputy Director, (b) (6), MA, CIP.

D. CIRO.

1) Director, LTC (b) (6) & Deputy Director, LTC (b) (6)

2) CIRO experienced no key leadership changes in FY14.

E. ACURO.

1) Director, COL (b) (6) & Deputy Director, (b) (6), DVM

2) Outgoing staff included Executive Officer LTC (b) (6), who transferred to her next assignment at the Walter Reed Army Institute of Research. ACURO also prepared for the retirement of (b) (6), the ACURO Deputy Director and Executive Director for the Army's Laboratory Animal Medicine Residency Program, at the end of FY14.

3) New staff arrivals included LTC (b) (6), serving as the Executive Officer of ACURO.

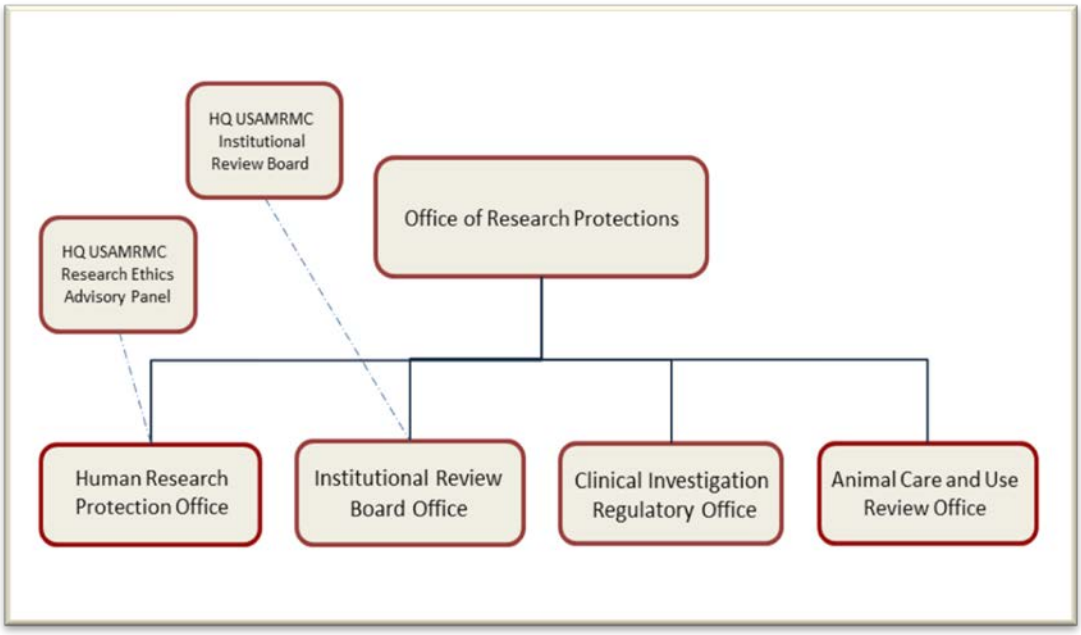

FIGURE 1: ORP Diagram

Statistical Data (Activities and Workload)

A. ORP.

1) In 2014, ORP offices provided oversight for research activities conducted by 1697 institutions in 67 countries. Workload and notable accomplishments of each office are summarized below:

2) Supported over 55 DoD organizations.

3) Managed an operating budget of $4.8M and all personnel actions for 4 military and 18 federal civilian personnel. Director, ORP co-chaired the Defense Health Agency Human Research Protections Work Group that produced recommendations for improvements and economies in DoD human research protections.

4) Director, ORP served as the senior human research protections advisor to the CENTCOM surgeon and supported the orderly and regulatory compliant conclusion of research activities in the Afghanistan theater of operations.

B. HRPO.

1) In 2014, HRPO and IRBO collectively maintained oversight for 4324 human research studies and received 1190 new protocols.

2) Negotiated Secretary of the Army waivers of the advanced informed consent provision of 10 US Code 980 that allowed the use of DoD funds for two DHP-funded FDA-regulated studies conducted under the "Exception from Informed Consent for Emergency Research" regulation 21 CFR 50.24. The Army remains the only Service Component with this Secretarial waiver authority.

3) Completed 4666 protocol approval or determination actions.

4) Implemented the Metrics and Measures Performance Improvement Initiative which was designed to improve the efficiency of the initial protocol review process resulting in outcomes that established a standardized system for documenting process milestones, identified process barriers, and formulated mitigating strategies to overcome barriers.

5) The HRPO completed human subjects research administrative review services for the DoD Joint Program Manager-Medical Countermeasures Systems for the following global multi-site pivotal Phase III influenza treatment trials:

   a. During the Northern and Southern Hemisphere Influenza seasons of the fiscal year (1 Oct 13-30 Sep 14), reviewed and approved 184 sites in the US and Canada and 76 sites in Central and South America to conduct the pivotal trial, "A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study Evaluating the Efficacy and Safety of Favipiravir in Adult Subjects with Uncomplicated Influenza (T705aUS317)."

   b. During the Northern and Southern Hemisphere Influenza seasons of the fiscal year (1 Oct 2013-Sep 14, reviewed approved 115 sites in the European Union, Russia and Ukraine and 65 sites in South Africa, Australia and New Zealand, and 6 in the United States to conduct the pivotal trial, "Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study Evaluating the Efficacy and Safety of Favipiravir in Adult Subjects with Uncomplicated Influenza (T705aUS316)."

C. IRBO.

1) IRBO continues to provide some level of IRB services to over 50 different institutions.

2) In FY14 IRBO completed an extensive revision of the HQ USAMRMC IRB research protocol template and corresponding guidance document for principal investigators. These changes streamline and clarify the requirements for IRB review and approval and were well received by researchers.

3) IRBO established a system on behalf of the Office of the Undersecretary of Defense for Personnel and Readiness (OUSD(P&R)) to provide Human Research Protection Official (HRPO) administrative reviews and determinations for OUSD(P&R)'s human subjects research portfolio. In close coordination with the Acting Director, OUSD(P&R) Research Regulatory Oversight Office, IRBO refined and improved processes for responsive HRPO reviews. Approximately 70 initial and lifecycle reviews were completed by IRBO on behalf of OUSD(P&R) during the reporting period.

4) IRBO functioned as the primary interface between deployed Joint Combat Casualty Research Team (JC2RT) Director, Deputy Director, and team members, and the USCENTCOM Human Protections Administrators to provide critical guidance and assure smooth coordination of theater protocols reviews, closures, and withdrawals during the April 2014 draw-down, redeployment of the JC2RT, and conclusion of research activities in Afghanistan.

D. CIRO.

1) In FY14, CIRO maintained oversight for over 1100 MTF protocols.

2) CIRO participated in three DoD Assurance Audit visits in during the reporting period, and served as Audit Team Lead. Most notably was CIRO's lead of the assurance assessment audits of the two National Capital Region Directorate (NCR-D) institutions, Walter Reed National Military Medical Center (WRNMMC) and the Ft. Belvoir Community Hospital (FBCH), on behalf of OUSD(P&R) and the Army Human Research Protections Office (AHRPO).

   a. CIRO personnel were responsible for overall project management and coordination of a large audit team with representatives from all three offices, as well as Human Research Protections Program (HRPP) staff from MTFs.

b. Assessments included protocol level audits of over 60 studies and evaluation of the institutions' entire HRPPs, including the WRNMMC IRB and the WRNMMC and FBCH Departments of Research Programs.

3) CIRO conducted post approval compliance monitoring of three protocols at NCR-D institutions that led to strengthened human subjects protections and provided valuable insights into considerations for research involving potentially vulnerable populations, such as Soldiers with traumatic brain injury and/or post-traumatic stress disorder.

4) CIRO's Federal Laboratory activities in support of the Army Military Medical Research community remained robust throughout FY14, and involved execution of approximately 90 Cooperative Research and Development Agreements with a total value of over $5.8 million.

E. ACURO.

1) In FY14, ACURO maintained oversight for over 300 animal use projects. ACURO continues to experience growth in workload. In Calendar Year (CY) 2014, 1131 new protocols were received; this represents a 20% increase over 2013. Over 1000 lifecycle actions on active projects were received in FY14.

2) ACURO staff conducted compliance inspections to six DoD laboratories and conducted seven site visits to extramural institutions conducting DoD sponsored research.

3) ACURO has contributed significantly to the efforts at the Assistant Secretary of Defense for Research and Engineering (ASD(R&E)) to standardize animal care and use within the DoD, specifically through two mechanisms.

a. The Department of Defense Animal Working Group was chartered by ASD(R&E) to optimize the collaboration and use of animal models in RDT&E and training throughout the DoD.

b. The Department of Defense Live Animal Use in Medical Education and Training was chartered by ASD(R&E) and the Assistant Secretary of Defense for Health Affairs (ASD(HA)) to optimize medical education and training while refining, reducing, and appropriately replacing the use of the animal model.

c. ASD(R&E) discontinued the DoD Animal Care and Use Program Reports (i.e. the data call).

Healthcare Delivery

A. IRBO and the HQ USAMRMC IRB Chair worked closely with representatives from the US Army Medical Materiel Development Activity Force Health Protection Division and Landstuhl Regional Medical Center (LRMC), Germany, to support administration of intravenous artesunate under the FDA's emergency use IND provisions to two critically ill Service Members cared for at LRMC.

Veterinary Services

N/A

Training and Education

A. In FY14, IRBO established the Lunch and Learn program to provide ORP staff members a monthly forum for continuing education on topics of broad interest. This program has been well received by staff, and has included presentations from various USAMRMC Institutions and Laboratories.

B. CIRO continued to organize and host the Clinical Investigation Program (CIP) educational webinars via Defense Connect Online (DCO), conducting approximately one hour-long session every six weeks with a cumulative attendance of more than 300 participants during the FY. These CIP DCO sessions cover a

broad range of research topics, have robust attendance, receive positive feedback, and benefit participants beyond the Army CIP.

C. The ACURO-managed US Army Laboratory Animal Residency had one successful candidate who challenged the American College of Laboratory Animal Medicine board examination and seven successful candidates who challenged the American College of Veterinary Preventive Medicine board examination.

D. In 2014, one ACURO staff member successfully completed the Certified Professional IACUC Administrator (CPIA) board examination.

Research and Development

N/A

Resource Management and Budget

ORP receives funding for its $4.8 million budget through Army RDT&E, DHP RDT&E, DHP O&M, and eight reimbursable sources (DARPA, DTRA, USAISR, DVBIC, USAMMDA, JPC-MCS, ARO, and Hearing CoE). This is illustrated in Table 2, *ORP Funding*.

TABLE 2: ORP Funding

Office	Army RDT&E	DHP RDT&E	DHP O&M	Reimbursables	Total
ORP	$425,045	-	-	-	**$425,045**
HRPO	$1,100,977	$893,222	-	$394,908	**$2,389,107**
IRBO	$273,846	$140,587	-	$429,129	**$843,562**
CIRO	-	-	$437,264	$135,188	**$572,452**
ACURO	$313,394	$32,928	-	$225,634	**$571,956**
Total	**$2,113,262**	**$1,066,737**	**$437,264**	**$1,184,859**	**$4,802,122**

Information Management

A. HRPO created new processes for electronic document management and review systems for global phase III study using the following systems: central mailbox for electronic submissions; dedicated admin support for intake; excel logs for tracking; standard operating procedures for secure electronic file set up and staffing the review actions; and electronic review and approvals by HRPO approval authorities.

B. HRPO and ACURO mapped all current workflow processes that utilize a paper-based system in conjunction with a manual entry electronic Information Management System (IMS) in preparation for transitioning to a paperless document system in EGS.

Operations

N/A.

Modernization

HRPO and ACURO began the transition from a paper-based system that requires manual entry into IMS to a paperless information management system in EGS. Maps of current workflow processes were modified to exploit

the efficiencies of a paperless system. These offices worked with the EGS Information Technology Team to adapt workflow processes to the EGS environment.

Logistics
N/A.

Construction
N/A.

Health and Environment
N/A.

Other
N/A.


Funding Source
Office of Research
Organizati
imal Care & Use
iew Office
Insti
nal Review Board C
CUR
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Animal Use
VACANT
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Section 7

Fiscal Year 2014
Annual Historical Report

Plans, Programs, Analysis and Evaluation Directorate

Mission

A. PPA&E vision is to be the US Army Medical Research and Materiel Command's (USAMRMC's) most trusted facilitator. PPA&E responsively and responsibly shapes and protects the military medical investment for the development and delivery of healthcare solutions.

B. PPA&E serves as an experienced team composed of biomedical science and acquisition personnel who combine their talents and knowledge to support the leadership of the USAMRMC.

C. PPA&E integrates medical Research, Development, and Acquisition (RDA) processes for full life-cycle management of medical materiel in the Army.

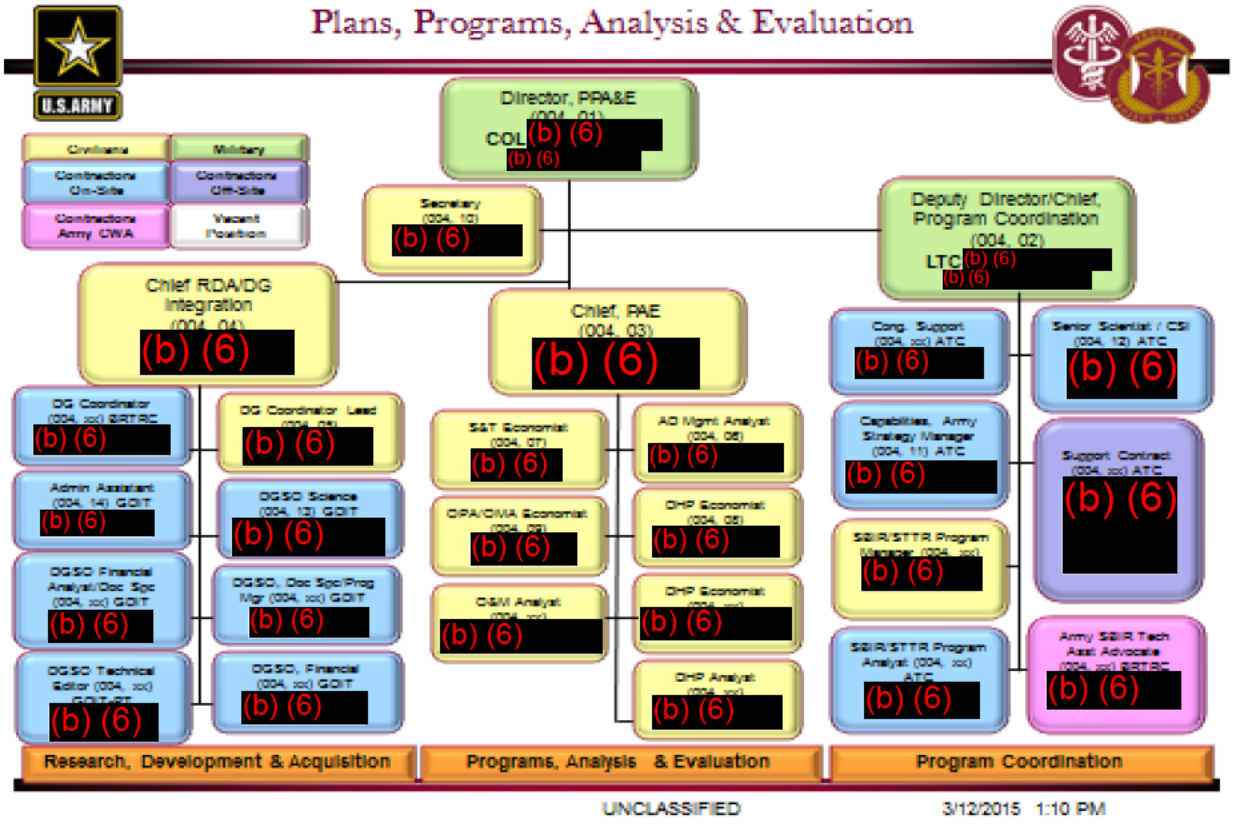
D. PPA&E successfully integrates complex processes across many organizations that facilitate the delivery of safe and effective medical solutions for Military Service Members, their Families, and beneficiaries.

E. PPA&E manages the following six program initiatives:
   1) Coordinates and analyzes Research, Development, Test & Evaluation (RDT&E) budget planning with DoD and Army requirements.
   2) Manages and analyzes the Planning, Programming and Budgeting process for Army RDT&E, Operations & Maintenance (O&M) and Procurement, and Defense Health Program (DHP) RDT&E and O&M.
   3) Supports the RDA process by managing the Command's Decision Gate and providing acquisition/program management support to the Integrated Product Teams (IPTs).
   4) Manages communications and engagements with Congress, analyzes congressional language and facilitates integration of Army and DHP RDT&E Congressional Special Interest (CSI) medical research programs.
   5) Manages the Army medical and DHP Small Business Innovation Research (SBIR) and the Small Business Technology Transfer (STTR) Programs.
   6) Conducts scientific and strategic reviews to support the medical research efforts of the USAMRMC.

F. PPA&E works with the Office of the Assistant Secretary of the Army for Acquisition, Logistics, and Technology (ASA(ALT)), the Office of The Surgeon General (OTSG), Headquarters, Department of the Army (HQDA) G-8, Army Office of the Chief of Legislative Liaisons (OCLL), the Army Medical Department Center and School (AMEDDC&S), and the U.S. Army Training and Doctrine Command (TRADOC) to coordinate our research efforts with current and future warfighter needs and outcomes. Additionally, PPAE engages with the Office of the Assistant Secretary of Defense for Health Affairs, the other Services, and other DoD organizations to optimize medical RDA solutions.

G. PPA&E reports to the USAMRMC Chief of Staff.

ORGANIZATION AND PERSONNEL



STATISTICAL DATA

Office Administration. The PPA&E Directorate processed, analyzed and coordinated over 240 taskings for the Headquarters elements from the SGS office and other external activities. The taskings are related to the primary mission areas of the Directorate including tasks for other Army and Defense RDA efforts, awards, future programming, strategic development, and policy issues.

Programs, Analysis and Evaluation Division (PAE)

The PAE division handles the Program Objective Memorandums (POM) for multiple appropriations across twelve Army Management Decision Packages (MDEPs); across Defense Health Program (DHP) Army RDTE named programs, DHP Guidance for Defense of the Force (GDF); and finally DHP Operations & Maintenance (O&M) programs at US Army Medical Research and Materiel Command (USAMRMC). In addition, PAE staff oversees the Board of Directors (BOD) budget review, Command Budget Estimate (CBE) review, Program Integration Advisory Committee (PIAC) reviews, DHP near and mid-term reviews, R and P Form development, issue paper development, and POM and budget taskings from the Office of the Surgeon General (OTSG).

Below highlights some of the more critical taskings carried out by the PAE division in fiscal year 2014:

A. Medical Command (MEDCOM) Commander's Program Assessment (CPA)

1) PAE prepared four of MEDCOM's seven funding issue descriptions for the CPA. These issues included:
    a. Joint Trauma Analysis and Prevention of Injury in Combat (JTAPIC) program environmental sensor data critical unfunded requirement (CUFR)
    b. Armed Forces DNA Identification Laboratory (AFDIL) funding shortage to meet the FY2010 National Defense Authorization Act (NDAA)
    c. US Army Medical Materiel Center Europe (USAMMCE) relocation costs
    d. Medical Potency and Dated Supply Readiness program

B. Planning USAMMCE Transition (PUT) Working Group
1) In January of 2014, USAMRMC formed a working group called the PUT to plan the move and develop the cost strategy for USAMMCE to relocate from Pirmasens to Kaiserslautern Army Depot (KAD) in Germany.
    a. In 2014, the Secretary of Defense approved the move based on a European Infrastructure Consolidation Review by the US Army-Europe and Installation Management Command-Europe.
    b. PAE participated on the PUT and developed the relocation estimate for MEDCOM's portion. The bill across FY14-20 was estimated at $24.8M.
    c. US Army Health Facility Planning Agency (HFPA) agreed to be the bill payer to provide the DHP initial outfitting and transition (IO&T) funding for the project.

C. Combating Antimicrobial-Resistant Bacteria (CARB) Initiative
1) In 2014, the White House provided budget guidance for Countering Biological Threats Resources. DHA responded by finding trade space to include CARB initiatives that will be carried out within USAMRMC. PAE coordinated with Walter Reed Institute of Research (WRAIR) staff to gather and report the requirements to DHA and OTSG. Requirements involved both DHP O&M and RDTE.

D. Under Execution Drills Summer 2014
1) PAE managed the coordination and response to OTSG's and MEDCOM's FY14 under execution drills. The impact of under execution would result in severe program decrements. PAE wrote impact statements and issue papers with information gathered from USAMRMC's subordinate organizations, MRMC Resource Management, and MEDCOM.
    a. Due to PAE efforts, Army MDEPs under review were removed from under execution lists. This includes MDEPs: FL8D (OPA, RDTE), and RL03 (RDTE).
    b. The Defense Centers of Excellence (DCoE) projected under execution in FY14 was $20M and DHA reduced DCoE's DHP O&M funding controls in POM16-20.

E. Assistant Chief of Staff for Installation Management (ACSIM) Housing Tasker
1) In September 2014, PAE was tasked for the first time by ACSIM, to officially provide Army housing POM data. PAE staff coordinated with MEDCOM and then collected and reported OCONUS labs housing requirements for POM 17-21.

F. Executive Agent (EA) Cost of Analysis (COA) on Transitioning to DHA
1) In April of 2014, USAMRMC requested PAE and RM participation in a working group to review and improve the EA briefs that presented each EA's analysis of moving to the DHA or staying with MEDCOM/USAMRMC. PAE attended meetings and provided input on improvements to each of the 5 slide decks.

G. FY15-17 Funds Distribution (CBE) and Army Near-Term Program Planning
1) The PAE Division over saw the execution of the Near-Term Program Planning Board of Directors (BOD) meeting held on 4 June 2014. Oversight included the development of guidance, templates, internal and external staff coordination, review and analysis of briefing data, coordination of meetings, and the staffing of documents. The BOD briefing covers task plans for the upcoming execution year and subsequent two years. PAE supported preliminary senior leader review followed by the BOD review of plans and unfunded POM requirement (UFR) lists. The FY15 plan is the basis for funds distribution to the laboratories, subordinate commands, and extramural participants. The approved plan and UFR list are used by the Deputy Chief of Staff for Resource Management to manage execution year funding. An FY15 UFR list was provided separately after the BoD meeting.

H. FY15-17 DHP Near-Term Planning
   1) The PAE Division managed the development of the DHP Near-Term Planning effort that began in April 2014. The three years evaluated and analyzed were FY15, the upcoming current year, and the two budget years of FY16 and FY17. Management included the development of guidance, templates, training, internal and external staff coordination, review and analysis of briefing data, coordination of meetings, and the staffing of documents. Document management was controlled through the use of the Electronic Document Management System (EDMS). Senior USAMRMC leadership was supported in the development of the program and UFR lists. A PIAC meeting was held in July 2014 to review the Near-Term Plan and provide a recommendation to the Director, RDA. Final approval was received from HA, thus becoming the investment plan for FY15-17.

I. FY15 President's Budget (PB) and FY16 BES R and P Form Congressional Summaries
   1) For the Army, the PAE Division prepared the data call to the Research Area Directorates (RADs), the United States Army Medical Materiel Development Activity (USAMMDA) and the United States Army Medical Materiel Agency (USAMMA) project managers requesting updates to the R-Form Congressional summaries for Army RDT&E and Procurement. PPA&E also analyzed and reviewed the R-Form updates to ensure consistency with current planning prior to forwarding to ASA(ALT).
   2) For the DHP, the PAE Division coordinated and analyzed input from the Joint Program Committee (JPCs), PA(R&T), PAA, RDA Directorate, and HA, and other special program areas, to prepare R-Forms for the FY16 BES and FY14 PB. The EDMS again supported document revision and control. The Defense Technical Information Center XML R-Form database system continues to be used to upload DHP R-Form data for DHA to be incorporated into the overall DHP budget submission.

J. FY17-21 Army POM
   1) The PAE Division oversaw the execution of the Mid-Term Program Planning meeting held in June 2014 to support the upcoming POM 17-21 submission. Oversight included the development of guidance, templates, internal and external staff coordination, review and analysis of briefing data, coordination of meetings, and the staffing of documents. Decisions from BOD meetings are approved by the CG and guide development of the upcoming POM.
   2) PAE prepared and analyzed POM briefing materials with Research Area Directorate (RAD) input for POM 17-21 in October-November 2014.
   3) PAE prepared and analyzed POM briefing materials with the Advanced Development PMs input for POM 17-21 in August-September.
   4) PAE prepared and analyzed POM briefing materials with the United States Army Medical Materiel Agency (USAMMA) on the Other Procurement, Army (OPA) and Operations and Maintenance, Army (OMA) funding.

K. PAE prepared, reviewed, and presented briefings on all other OMA funded MRMC programs both to senior leaders at MRMC and externally to OTSG and respective DA Headquarters staff. FY16-20 DHP POM and DHP Mid-Term RDT&E Program.
   1) For DHP O&M, the PAE Division collected, analyzed and presented a list of 18 DHP O&M unfunded requirements to USAMRMC senior leaders. They approved 13 issues to move forward to OTSG and removed 5 from consideration.
      a. The DHP O&M UFRs across the POM totaled over $94M.
      b. PAE submitted 5 issues (4 pharmaceutical products and 1 Rapid Diagnostic Device) to OTSG to include in the DHP O&M formulary POM as these products transition out of Army Advanced Development and are to be administered at brick and mortar Medical Treatment Facilities (MTFs).
      c. PAE developed cost analysis sheets and issue papers for the remaining 8 issues to detail the unfunded requirements. PAE added a last minute facility submission for a total of 9 issues submitted.
      d. Only the Multidrug-Resistant Organism Repository and Surveillance Network (MRSN) issue was vetted through DHA's issue team process and was the only USAMRMC DHP O&M UFR submission funded across the POM.

2) The PAE Division also oversaw the execution of a Mid-Term RDT&E Program review that began in November 2013 in support of the FY16-20 POM. Oversight included the development of guidance, templates, training, internal and external staff coordination, review and analysis of briefing data, coordination of meetings, and the staffing of documents. The USAMRMC's senior leadership, and the PIAC reviewed the packages making program recommendations and addressing proposed UFRs, Change Proposals, and other RDT&E realignments to the Director, RDA for vetting within DHA and HA.

L. Army RDT&E Professional Staff Member Briefs

1) February 2014, PAE oversaw and coordinated the preparation of Professional Staff Member briefing packages for Congressional staffers from the House and Senate Armed Services Committees. Oversight included the development of guidance, templates, staff coordination, review and analysis of briefing data, coordination of meetings, and the staffing of documents.

M. Army Science and Technology Management Information System (ASTMIS)

1) Updated the Project Cost (FY11-15) data, cross walked ASTMIS tasks to Long-Range Investment Requirements Analysis (LIRA) Advanced Development Tasks, and FY15 ASTMIS major efforts. In all cases templates/spreadsheets were forwarded to each of the Research Area Directors (RADs) and System Biology POCs. The data was consolidated and submitted to ASA(ALT).

N. DHP RDT&E Funding Profile Workbook

1) Updated the DHP RDT&E Funding Profile Workbook (AKA the Horseblanket) at each funding milestone within the FYDP cycle. Funding is based on the official positions of the PB or POM/BES at the JPC, Task, and Topic levels for prior, current, and FYDP years. This document assists in evaluation of historical and development of new JPC investment plans.

O. SMART Goals and Objectives

1) Per the Principal Assistant for Research and Technology PA(R&T), PAE conducted research into SMART goals and objectives. A briefing and templates were developed and presented and approved by the PA(R&T). An official tasking was initiated to have the RADs and Systems Biology staff to develop SMART goals aligned to the new task structure. PAE analyzed and made improvement recommendations to the RADs. The subsequent SMART goals were approved by the PA(R&T). PAE established a subsequent follow on process for the development of SMART Objectives against the approved goals.

P. DASC Parade Smart Charts

1) Developed PowerPoint overview charts as a follow-up to the FY15 President's Budget P-Form submittal to ASA(ALT). These charts provide additional program detail and status on our Combat Support Medical and MEDEVAC MEP OPA programs for the Congressional Professional Staff Member overseeing these programs.

Program Coordination Division

A. Congressional Communications, engagement management and Congressional Special Interest (CSI) Coordination. The PPA&E Directorate, acting as the Command point of contact for the Army Office, Chief of Legislative Liaison (OCLL), the Office of the Assistant Secretary of the Army (Financial Management and Comptroller), OTSG Congressional Affairs Coordination Officer and the Defense Health Agency RDT&E for programs executed through the USAMRMC, managed the coordination of information and correspondence relating to Congressional inquiries, review of Congressional language, preparation of senior leader testimony, and preparation of Congressional briefings/meetings for the President's Budget core programs and for CSI medical RDT&E programs. PPA&E also facilitated the central assignment of USAMRMC execution managers for CSI appropriations. The office also assisted in data gathering for certain Government Accounting Office and Office of Management and Budget analyses.

B. The CSI programs are not included in the President's Budget, but are added by Congress in response to constituents, advocacy groups and member interests. These programs are leveraged to facilitate the core Army and DHP medical research missions where appropriate. The CSI programs are managed to meet the intent of Congress, to comply with current ethical and regulatory standards of practice, and to fund good science. This office was assigned the responsibility for CSI coordination for the Command in FY01. Since that time, these CSI programs grew rapidly through FY10 and declined in FY11 in number of projects and quantity of funds due to a moratorium on earmarks. In FY 14 medical RDT&E CSIs executed thorough USAMRMC were approximately $896 million across 31 appropriation titled programs. During FY2014, PPA&E staff prepared or assisted in the staffing of approximately 446 inquiries, visits, and analyses regarding the execution of the FY14 DoD appropriations, the lack of a completed FY14 DoD appropriation, and monitored the FY 15 legislative cycle congressional actions. The PPA&E Directorate Congressional communication and coordination activities are supported by 2 FTE contract positions for: a Senior Scientist/Congressional Advisor and a Science and Congressional Advisor position. A command policy for Congressional Engagements, 2014-97, was developed by PPA&E staff and signed on 14 May 2014 (See Item 16.A.).

C. Army RDT&E Congressional Briefs. PA&E oversaw and coordinated the preparation of 22 Congressional briefing packages for Congressional staffers or members of Congress from the House and Senate Armed Services Committees. Oversight included the development of guidance, templates, staff coordination, review and analysis of briefing data, coordination of meetings, and the staffing of documents.

D. SBIR/STTR. In FY14, the PPA&E Directorate coordinated the publication of 21 SBIR/STTR topics in DoD SBIR/STTR Solicitations. They received 312 SBIR/STTR proposals and conducted 186 debriefing requests. As a result of PPA&E coordination, USAMRAA awarded a total of 56 Phase I contracts in the amount of $7.3M, awarded 27 Phase II contracts in the amount of $21.0M, and awarded second year Phase II increments in the amount of $9.5M. PPA&E also helped facilitate SBIR Phase II Enhancements in the amount of $1.1M. PPA&E prepared and submitted the FY14 DHP SBIR Annual Report to the DoD SBIR Data Team. In addition, PPA&E maintains the Defense Health Program (DHP) SBIR website which includes the tracking of topics, proposal evaluations, and contract awards.

E. Competency Management Initiative. In FY14, PPA&E continued to work with the PART office to track the Competency Management Initiative for establishing manpower requirements tied to capabilities associated with core competencies. This effort establishes the manpower needs to meet the medical research capabilities designed to meet core research capabilities. This effort will allow MRMC laboratories to more effectively understand and manage the critical personnel to accomplish the research mission and to execute any adjustments to their manpower. This will also help MRMC (PPA&E) to plan adjustments to the POM by Program Element should funding adjustments be required.

F. TRADOC Capability Needs Analysis. The CNA process/review is conducted annually by the Army Capabilities Integration Center (ARCIC) of the Training and Doctrine Command (TRADOC). PPAE represents the U.S. Army Medical Research and Materiel Command (USAMRMC) for the materiel solutions portion of the medical review. The products resulting from the CNA process are a prioritized list of Army Critical Capability Gaps and a prioritized listing of Doctrine, Organization, Training, Materiel, Leadership, Personnel, and Facilities (DOTMLPF) solutions.
   1) The CNA 17 – 21 Critical Capability Gaps list contained 223 prioritized Tier 1 capability gaps. Tier 1 gaps are considered so critical that they must be fully solved or mitigated to ensure mission accomplishment. The medical capability gap, "The force at divisional level and below lack the ability to provide specialized advanced trauma management (far-forward damage control resuscitation at or near the point of injury to achieve a 100% survival rate for casualties with potentially survivable wounds." was priority number 11.

2) The CNA 17 - 21 DOTMLPF final solutions list contains 1421 prioritized total items from the entire Army. USAMRMC had a total of 43 material solutions on the list to include all 5 of our Initial Capability Documents (ICDs), 18 of our Capability Development Documents (CDDs) and 20 of our Capability Production Documents (CPDs). USAMRMC had 25 of 43 items placed in Tier 1; 11 items were placed in Tier 2 and the remaining 7 were placed into Tier 3. The actual number placement is not the critical factor; it is the Tier that is important. Items that are in Tier 1 (Items 1 - 568) are considered the highest risk to mission accomplishment and must be funded. Tier 2 (Items 569 - 852) are considered modest risk to mission accomplishment and will be funded once the highest risk solutions are funded. Tier 3 (Items 853 - 1421) are the lowest risk to mission accomplishment.

G. **Unified Quest 2015-16. PPA&E, in coordination with the Military Deputy of the PA(R&T), remains involved in the Army-wide Concept Development and Experimentation Exercise "Unified Quest." This annual Wargame is sponsored by the Army Chief of Staff. PPA&E and the PA(R&T) continued activities to ensure that medical materiel development considerations are included in future force planning for the Army. Unified Quest also enhances communication among the Army concept developers in TRADOC and the medical combat and materiel developers at AMEDDC&S and USAMRMC, respectively. PPA&E participation increased the USAMRMC's contribution to understanding medical combat learning demands to ensure material development concerns are addressed.**

H. Capability Documents. PPA&E worked closely with the RADs, Project Managers and the Directorate of Combat and Doctrine Development, AMEDDC&S to coordinate actions and needs for capabilities documents. During 2014, seven Capability Documents were approved.

I. Force 2025 and Beyond. PPAE participated in a number of forums that support the Force 2025 and Beyond effort. During FY14 we collaborated with the Army Medical Department Center and School and the USAMRMC's Office of the Principal Assistant for Research and Technology to provide a memorandum to the Commanding General, TRADOC outlining our Top 5 prioritized capability needs. The priorities include: 1) Brain Health and Fitness Optimization, 2) Infectious Disease Prevention, 3) Optimize Combat Casualty Care, 4) Tailored, Individualized Health and Performance Enhancement, and 5) Health and Performance Status Monitoring. This memo is designed to inform POM 17-21, the LIRA, as well as the Science & Technology strategy.

J. Science and Technology Objectives (STOs). PPAE coordinated the STO submission process. Three USAMRMC Science and Technology Objectives (STOs) were approved by the Warfighter Technical Council on 7 October, 2014. STOs are major efforts that address Army priorities, inform acquisition programs and/or future requirements. The Extended (Refrigerated) Platelet Storage and Availability STO will provide a safer, more effective, and less expensive platelet product with triple the shelf-life that allows forward use of this life-saving product. The Burn Wound Repair and Scar Mitigation STO will develop candidate products for transition that address severe extensive burn wound injury and associated scarring to improve Service member functionality and quality of life. The Optimizing Mental Acuity during Continuous and Sustained Military Operations STO is designed to provide actionable intelligence to optimize sleep and associated cognitive ability in the operational environment.

Research, Development and Acquisition Division

A. The Decision Gate (DG) Support Office was retitled the Research, Development, and Acquisition Support Office (RDASO) this year. The name change reflects the RDASO's broader mission to support both Army and DHA development efforts, as well as organizations and research, development, and acquisition (RDA)-related activities during all phases of the acquisition lifecycle. The primary functions of the RDASO is to ensure the successful execution of the Command's DG process, and to

provide project management and RDA support to USAMRMCIPTs and RDA leadership. The results of the RDASO's efforts can be seen in the Command's continued success in the development and fielding of critical medical products; production of high-quality program management plans and acquisition documentation; and successful program briefings and presentations.

B. Throughout FY14, the RDASO provided assistance to 48 different IPTs in the advancement of development efforts through the acquisition life cycle. The RDASO delivered 55 workshops (totaling 129 class hours) on 29 unique subjects. Workshops were conducted at Ft. Detrick, the US Army Institute of Surgical Research, the Walter Reed Army Institute of Research, and Ft. Belvoir. The total number of workshop participants increased from 539 in FY13 to 684 in FY14. The increase was due in part to the concerted effort to educate all IPTs on risk management and presenting a project management series of eight classes. The IPTs continue to utilize the RDASO staff to facilitate team building activities, and to provide IPT Chairs one-on-one coaching sessions. Over the last FY, the RDASO created or revised eight DG guides and templates; eight Cost Benefit Analyses and one Business Case Analysis; eight IPT acquisition documents; and four Microsoft Project schedules. Additionally, three DG Directives were finalized, and four were drafted. The RDASO website totaled 4,686 hits since May 2014, averaging 586 hits per month; major areas of interest being DG document reviews, upcoming workshops, DG guides, and DG directives. The feedback from DG customers regarding performance of the RDASO has been overwhelmingly favorable over the last year, with especially favorable comments regarding our staff, workshops, coaching activities, and our project management tools and documents available through the RDASO website.

C. Process-wise, the RDASO remained fully engaged in the coordination of DG activities. The RDASO coordinated annual DG in-progress reviews (IPRs), co-chaired by Dr. Bertram and Dr. Glenn, for every product development effort in DG. At the end of FY14, there were 48 development efforts in DG. Other important DG activities occurring in FY14 included the fielding of one product, the Burn Resuscitation Decision Support System – Mobile, four Milestone Decisions, and the start of four new capability development efforts (Materiel Development Decisions [MDD]). In addition to coordinating annual IPRs, Milestone reviews, and MDDs, the RDASO also facilitated the command-level review and approval of five Phase 1 and six Phase 2 clinical trials, and coordinated two strategic-level product portfolio reviews for the Commanding General. Reviews were conducted for the Rehabilitative and Restorative Products Portfolio and the Physiological & Physical Health Portfolio. The RDASO also provided direct support to the Milestone Decision Authority, Dr. Bertram, by coordinating monthly face-to-face training meetings with all IPTs in advance of their annual IPRs or milestone briefs. These sessions provided greater communication between the IPTs and the Command's RDA leadership, and facilitated the leveraging of knowledge to increase productivity despite declining resources. Lastly, the RDASO supported the Army, Navy, and US Air Force advanced development leads (Dr. Bertram-Army, (b) (6) – Navy, LtCol (b) (6) – USAF) by coordinating and overseeing the successful execution of three advanced development-focused reviews of Joint Program Committee 1, 2, and 5 funded development efforts. These reviews promoted visibility of potential products/capabilities in development, provided senior Acquisition Leaders the opportunity to identify and advise Execution Management Agents on potential roadblocks or acceleration pathways, and provided training and mentoring to those involved in the DHP product development process. These advanced development-focused reviews officially ended in FY14, with the increasing level of RDT&E oversight provided by DHA advanced developers.

Healthcare Delivery:

Does not apply to PPAE

Veterinary Services:

Does not apply to PPAE

Training and Education:
See Item 16.B.

Research and Development:
Does not apply to PPAE

Resource Management and Budget:
Does not apply to PPAE

Information Management:
Does not apply to PPAE

Operations:
Does not apply to PPAE

Modernization:
Does not apply to PPAE

Logistics:
Does not apply to PPAE

Construction:
Does not apply to PPAE

Health and Environment:
Does not apply to PPAE

Other:
Items of significance not covered in other categories such as impact of legislation/regulation on operations, support to combat/contingency operations.

Appendices:
Include copies of key supporting documents as an appendix to the report. Information papers, studies, and reports describing key events, activities, programs, operations, etc. are important documents which may be appended to the annual historical reports.

Section 8

Fiscal Year 2014
Annual Historical Report

The Principal Assistant for Acquisition

Mission

The Principal Assistant for Acquisition (PAA), a member of the Senior Executive Service (SES) reports directly to the Commanding General, US Army Medical Research and Materiel Command (USAMRMC), and acts as the Army Milestone Decision Authority (MDA) in executing the overall responsibilities for the life-cycle acquisition management of medical materiel. The Office of the PAA (OPAA) provides biomedical research, development, and acquisition, program goals, objectives, priorities, and policies consistent with Congressional, Department of Defense (DoD), Assistant Secretary of Defense (Health Affairs), Headquarters Department of the Army (HQDA), and Medical Command (MEDCOM) guidance, directives, strategic initiatives, and regulations. In this capacity, the OPAA provides oversight and technical support to the Project Managers (PjM) of the USAMRMC and two subordinate USAMRMC organizations. The OPAA manages the development and training of the Army Medical Acquisition Corps and Workforce and serves as mentor and guide for Integrated Product Teams (IPT) managing materiel solutions in the DoD Acquisition processes. As the proponent for the Intermediate Medical Acquisition Course (IMAC), the OPAA fosters and enhances acquisition knowledge and growth within the community. The OPAA develops policies and plans; as well as, integrates and coordinates execution of all functions, operations, and activities involved in providing support for the Command's Advanced Development program. The OPAA ensures that all DoD and Army advanced development requirements are fully integrated to achieve a balanced program and provides authoritative direction and guidance, which influences the organization, direction, and control of resources required to achieve Command objectives. The OPAA provides executive-level oversight and management of the USAMRMC's medical advanced development investment strategy in order to enable responsive and comprehensive planning, programming, budgeting, and sustainment of programs. The PAA also provides oversight and management authority over the 6.7 Defense Health Program (DHP) and supports the DHP Small Business Innovative Research (SBIR) Program within the USAMRMC in addition to providing recommendations to 6.1-6.5 DHP programs. Finally, the PAA serves as the Army Surgeon General’s Sponsor’s Representative to the Food and Drug Administration.

Organization and Personnel

The PAA reports directly to the Commanding General, USAMRMC. The PAA is the rater for the Commander for the United States Army Medical Materiel Development Activity (USAMMDA) and senior rater for the Deputy for Acquisition and all PjMs within the USAMMDA. He is also the senior rater for the Deputy for Acquisition and PjMs at the United States Army Medical Materiel Agency; as well as, for the PjMs for Human Immunodeficiency Virus Vaccine at the Walter Reed Army Institute of Research. Additionally, the PAA exercises oversight of the command wide advanced development program.

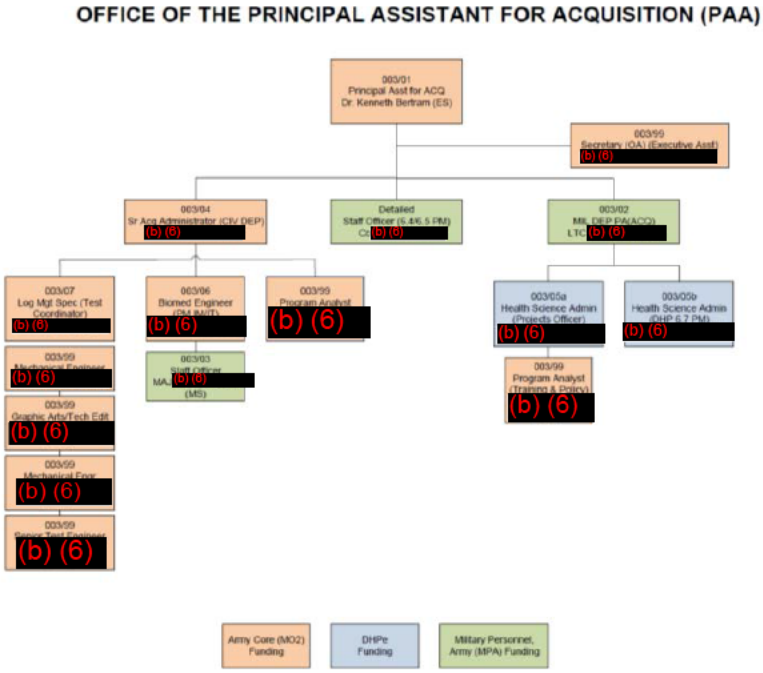


FIGURE 1: PAA Organization Chart

Statistical Data

The PAA, serving as the MDA, conducted 14 Integrated Product Review sessions that reviewed 48 product development efforts from October 2013 to September 2014. There were 4 Materiel Development Decisions: Burn Treatment Skin Repair, neuro-Cognitive Assessment Test, Extremity Injury Repair, and Platelet Derived Hemostatic Agent.

A. In addition, the MDA approved the following milestone Decisions:

1) Three Milestone Bs: Lab Assay for TBI, Cryopreserved Platelets, and Freeze Dried Plasma.

2) One Milestone C: Leishmania Rapid Diagnostic Device.

3) Three Full Rate Production (FRP) Reviews: Noise Immune Stethoscope, Burn Resuscitation Decision Support System-Mobile, and Oxygen Generator Field Portable.

4) Approved the transition of the Veterinary Services System Management Program into Sustainment.

B. The MDA also disapproved the Vector Trap Carbon Dioxide Generator Milestone B and sent the Coliform Analyzer to the tech base for tech watch.

Acquisition Workforce - The Army Medical Department (AMEDD) Acquisition Career Management Advocate (ACMA), PAA Civilian Deputy, represents over 907 Acquisition Workforce (AWF) Professionals within the AMEDD. The ACMA manages the Memorandum of Agreement that maintains a separate but equal AMEDD Military AWF; develops acquisition position and workforce policies for the MEDCOM and coordinates and advices AWF information at HQDA and DoD levels; advises and scopes AMEDD AWF and corps personnel and position management; obtains Defense AWF Development Management Funds funding and sponsors training and

education opportunities for the workforce; and challenges position assignments to broaden experience. The ACMA further coordinates medical personnel support to other Program Executive Office (PEO) requirements such as PEO, Chemical-Biological Defense. The OPAA has been instrumental in helping the AWF achieve a 98% completion rate for certification and training resulting in a 3% drop of delinquency from FY13. The OPAA also played a significant role in obtaining stellar AWF results; it is the first time in recent history that 100% of the workforce achieved 80 Continuous Learning Points. In addition, the FY16 TDAs were updated and out-of-cycle TDAs will include Acquisition Workforce designations in FY15.

Small Business Innovative Research (SBIR) - The OPAA led prioritization of the SBIR Phase II projects to enable matching of SBIR funds. During FY14 there were two solicitations – one for Army funding and one for DHP funding. For the DHP solicitation, there were 11 topics of which 28 projects were funded amounting to $4M. For the Army solicitation, there were 8 topics of which 18 projects were funded amounting to $1.8M. The InBios Leishmania Rapid Diagnostic Device received FDA clearance in FY14, which was noted by the Associated Press and published in the Washington Post; as well as, many other news outlets.

In addition, the Medical Technology Enterprise Consortium (MTEC) pre-solicitation was announced at the 2014 Military Health Systems Research Symposium. The solicitation notice was updated on FedBizOps detailing plans for a full solicitation release in March 2015.

Information Technology - OPAA continued to provide enterprise wide Information Technology (IT) support to the USAMRMC. During FY14, the eIT PMO delivered two key capabilities to the Electronic Document Management System. The first was the last in a series of workflows that provided additional capability and efficiency gains to the Command in support of the Program Objective Memorandum (POM) Development Process. The second was the high profile tool for Freeze Dried Plasma that allowed the USAMMDA's Division of Regulated Activities and Compliance (DRAC) to meet the FDA and Institutional Review Board (IRB) regulations for routine monitoring and approval of new Sub-Investigators for the Freeze Dried Plasma Clinical Study. The eIT PMO also successfully passed an audit by the United States Army Medical Research Institute of Infectious Diseases and the USAMRMC Quality Management Organization to ensure that the Electronic Data Capture Product met the requirements for being an FDA "validated" system. The eIT PMO also successfully upgraded all FDA compliance products to comply with the Army Cyber Command mandated server operating system upgrades. Finally, the eIT PMO oversaw the validation of compliance of the MeRITS portfolio and all security requirements in accordance with the DoD Information Assurance Certification and Accreditation Process.

Testing – The OPAA continued to provide equipment testing support to the USAMRMC and outside DoD activities including the US Air Force and the Georgia National Guard. Efforts during 2014 included upgrading the test facility, which included freeing up space for additional test capabilities and providing digitized test results. Items tested by the USAMRMC Test Branch in 2014 included:

A. Environmental Testing on seven different types of medical products:

1) IntuBrite™ Laryngoscope

2) Three Patient Monitors: ZOLL® Propaq® M; Philips IntelliVue MP5; and Remote Diagnostic Technologies, Inc. Tempus Pro™

3) Trauma Shears

4) Two Carbon Dioxide (CO_2) Generators: CUBE Technology, Inc. CO_2 Generator and TDA Research Chemical CO_2 Generator

5) Environmental Sentinel Biomonitor (ESB) System

6) BG Sentinel Mosquito Trap

7) AMPV Biologics Refrigerator (with performance characteristic testing)

B. Performance Characteristic Testing on four types of products:

1) Three Different HABCO TraumAid™ Chemical Oxygen Generators

2) O_2PAK™ Chemical Oxygen Generators

3) Ratchet Tourniquets Model TX-2" and Model TX-3

4) AMPV Biologics Refrigerator (with environmental testing)

C. Package Testing was conducted on the X Gauze Trauma Dressing and the Air Wrap Inflatable Bandage.

Healthcare Delivery

N/A

Veterinary Services

N/A

Training and Education

From October 2013 to September 2014 (FY14), the OPAA hosted multiple growth and knowledge enhancing activities to include Decision Gate (DG) IPT and IMAC training. The Office of the PAA complied with Army, MEDCOM, DoD Acquisition, and Civilian Senior Leader Management Office mandatory Military, Civilian, and contractor training requirements.

The OPAA continued direct training support to the AMEDD and the DoD by sponsoring six IMAC sessions for 140 students during FY14. Of these six sessions, three were local sessions and three were at USAMRMC subcommands including one USAMRMC Laboratory. The IMAC is certified by the Defense Acquisition University (DAU) as an equivalent course to the DAU's Acquisition 201B and has been instrumental in the AMEDD improving its compliance with the Defense Acquisition Workforce Improvement Act training requirements. Of all the attendees, 115 were from the DoD and 25 were participants from industries that support the DoD.

In addition, the OPAA obtained Defense Acquisition Workforce Development Funds (DAWDF) in FY14 to sponsor two Naval Postgraduate School Program Management courses at Ft. Detrick. There were 27 USAMRMC students who graduated and achieved Level 2 or Level 3 certification in DAU Program Management.

Research and Development

As the MDA, the PAA approved the fielding (post-FRP) of three products, which remained in the Decision Gate process: Noise Immune Stethoscope, Burn Resuscitation Decision Support System-Mobile, and Oxygen Generator Field Portable.

The PAA serves as the Chair of the Advanced Development Advisory Group to the Armed Services Biomedical Research Evaluation and Management (ASBREM). The ASBREM is a Community of Interest that was reorganized to enhance opportunities for collaboration and coordination of programs across all DoD stakeholders in order to save money and improve international recognition.

Resource Management and Budget

The PAA ensures that support is provided to the USAMRMC Project/Product Managers and resolves or recommends appropriate action concerning priorities between Project/Product Managers and subordinate Commands of the USARMMC having over 7,000 Military and Civilians, with an annual operating budget approaching $2.5B.

The OPAA managed approximately $11.9M* DHP 6.7 FY14 allocation, providing oversight for approximately 45 ongoing projects. The OPAA released a DHP 6.7 funding announcement in the first quarter of FY14 with two submission deadlines and review cycles. The OPAA formalized a review process to obtain JPC-level input on each proposal for consideration by the final selection panel. From November 2013 through September 2014, 109 solicitations for funding were received and reviewed. Of these solicitations, awards were made for 29 new projects amounting to approximately $4.9M in FY14 funds (total ~$9.2M FY14-16 funds). *Available for science, not President's Budget.

In FY14, the PAA was responsible for $52.5M Army 6.4/6.5 funding, $52.2M OPA funding, and $170.0M OMA funding. The Army funds were obligated at 83.9% and disbursed at 28.3%; the OPA funds were obligated at 99.9% and disbursed at 57.1%; and the OMA funds were obligated at 75.4%.

The PAA serves as The Surgeon General's representative to the Army Equipping (EE) Program Executive Group (PEG) and Sustainment (SS) PEG. The PEGs are a high-level review of the Program Objective Memorandums submitted by various Commands based on their basic organization structure (e.g., ammunition, aviation, mobility, science and technology, soldier).

Information Management

The ACMA team developed a SharePoint site to support the Acquisition Workforce. The MEDCOM ACMA SharePoint site is a resource for all of the MEDCOM Acquisition Workforce. The site provides information on certification requirements, Army Acquisition policies, and more.

Operations

The OPAA led a very successful Program Status Review (PSR) to the Assistant Secretary of the Army for Acquisition, Logistics, and Technology in June 2014. The purpose of the PSR was to inform the Honorable Ms. Heidi Shyu about the USAMRMC advanced development portfolio, industrial base issues, risks, and funds execution.

The OPAA assembled and led three major product presentations utilizing the combat support hospital facilities at the US Air Force Medical Evaluation Support Activity (AFMESA). This immersive presentation approach effectively provided a realistic chronological walk through medical support in the life of a Soldier, from accessions and training through deployment and point-of-injury, interacting with medical evacuation and emergency treatment, and concluding with follow-on definitive care efforts. In each station, displayed products served to segue to discussion of the USAMRMC's broader medical product programs and remind visitors of the Command's responsibility for total lifecycle management of medical materiel. The three visits were:

A. February 2014 – MG Dean G. Sienko, Commanding General, US Army Public Health Command, MG Richard W. Thomas, Director, Healthcare Operations, Defense Health Agency, Rear Admiral Bruce A. Doll, Deputy Chief, Navy Medicine Research and Development, Bureau of Medicine and Surgery (M2), Special Assistant for Department of the Navy Office of Research Protections, Bureau of Medicine and Surgery, and Commander, Naval Medical Research and Development Command, and Major General Brian C. Lein, Deputy Surgeon General/Deputy Commanding General, Operations, US Army Medical Command

B. April 2014 – Dr. David Smith, Deputy Assistant Secretary, Force Health Protection and Readiness, Office of the Assistant Secretary of Defense for Health Affairs

C. July 2014 – Mr. Thomas Mullins, SES, Deputy Assistant Secretary for Plans, Programs and Resources, Assistant Secretary of the Army for Acquisition, Logistics & Technology, Ms. Nancy Harned, SES, Executive Director, Strategic Plans and Program Planning

Modernization
N/A

Logistics
N/A

Construction
N/A

Health and Environment
N/A

Section 9

Fiscal Year 2014
Annual Historical Report

Directorate for Materiel

Mission

The Director for Materiel (DfM) is a special staff reporting to the Chief of Staff, providing strategic leadership and subject matter expertise for medical logistics and management. Primary functions include:

A. Principal to the Commanding General, MRMC on Medical Materiel

B. MEDLOG integration within the Life Cycle Management Command (LCMC)

C. MRMC integration and support to the Army Medical Logistics Enterprise (AMLE)

D. MRMC engagement with Defense Medical Logistics (DML), Defense Logistics Agency (DLA), and Defense Health Agency MEDLOG Division (DHA MEDLOG)

E. Army Medical Logistics Enterprise (AMLE) Office of Strategy Management (OSM)

F. AMLE Executive Committee (EEC) [Co-Chair]

G. AMLE Information Technology (IT) Executive Steering Committee (ESC)

H. AMLE Review and Analysis (R&A)

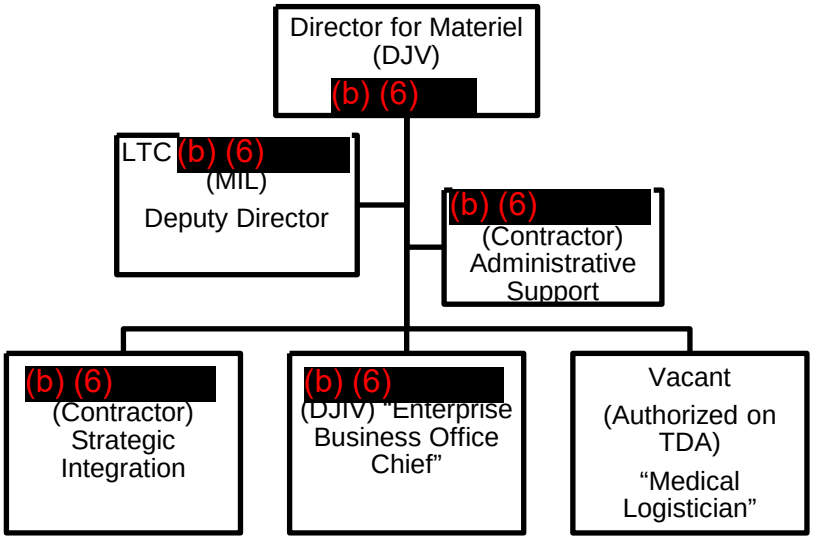
I. Integration with Defense Medical Logistics (DML) Enterprise and Joint logistics community

J. MRMC Decision Gate process (i.e. Logistics)

Organization and Personnel

During this report, LTC (b) (6) (Deputy, DfM) was reassigned and was replaced by LTC (b) (6). The DfM exercised the option years on both the Deloitte (b) (6) and GDIT (b) (6) contracts listed below on the DfM organization chart. The DfM organization Chart is depicted in Figure 1 below:

FIGURE 1: DfM Organization Chart



Statistical Data
N/A

Healthcare Delivery
N/A

Veterinary Services
N/A

Training and Education

The DfM assisted FORSCOM and subordinate Medical Logistics Commands with various Theater Enterprise-Wide Logistics System (TEWLS) training. Specifically, DfM assisted with writing an Operations Order (OPORD) for FORSCOM to task 6th Medical Logistics Management Center with training the 428th Medical Logistics Company (MLC) with their pre-deployment training.

Research and Development

Research and Development: The DfM continues to assist the Milestone Decision Authority (MDA) by serving on Product Lifecycle Review Committee (PLRC) and the Executive Management Committee (EMC). The DfM assisted the Joint Medical Logistics Functional Development Center (JMLFDC) with Research and Development (R&D) funding for medical logistics system changes such as the Common User Interface (CUI), which is an "Amazon" like shopping cart capability for non-medical logisticians to submit medical supply requests. The DfM assisted the US Army Medical Materiel Agency with various aspects of delivering new functionality in TEWLS Assembly Management (AM). The TEWLS-AM functionality requirements document was developed by the DfM and in FY 14 as the functionality was delivered, the DfM assisted with validating requirements against the capabilities delivered.

Resource Management and Budget

The DfM was adequately resourced to perform assigned missions. The DfM budget is displayed in Figure 2 below.

FIGURE 2: DfM Budget FY 14

Cost Center	OMA	Total
Civilian Pay and Benefits	$349,712	$1,188,559
Travel	$33,600	$33,600
Contracts	$550,246	$550,246
Supply	$2,000	$2,000
Equipment	$3,000	$3,000
Other Contracts	$250,000	$250,000
Total	$1,188,558	$1,188,558

Information Management

N/A

Operations

The DfM served as the MRMC lead for the Medical Logistics Line of Effort (LOE) in support of Operation United Assistance (OUA). The DfM assisted early on as the operation was unfolding with the coordination of Personal Protective Equipment (PPE) requirements, unit equipment and materiel shortfalls, Unit Deployment Package (UDP) fieldings, and medical supply distribution.

A. OUA Positive Impacts / Sustain:
    1) Coordination Between AML / MTF & USAMMA to Support Equipping Gaps
    2) CG MRMC Appointment of LOE Leads
    3) Structured Collaboration Among Logisticians Across Agencies with Clinical SMEs
    4) MEDLOG Communications Improved Over Time
    5) 6th MLMC and USAMMA DOC Coordination to Ship Critical Reagents
    6) MedLog Company Visit to USAMMCE to Receive MEDLOG Training

B. OUA Challenges / Improves:
    1) MEDLOG Communications
    2) HQDA Guidance on Deployment Days of Supply
    3) Ad Hoc ASL for MedLog Company
    4) MedLog Company Arrival Timeline
    5) Funding for UDP's Unclear Initially
    6) PPE Guidance Fluid Causing Unnecessary & Delayed Procurement
    7) Process to Support NIAID with MilAir Assets
    8) MEDLOG Information Technology (IT) Plan Unclear
    9) Delay of 6th MLMC Officer Arrival to AFRICOM ISO of MedLog Operations

Modernization

The DfM continues to assist OTSG / MEDCOM G4 with critical equipment and force design updates (FDU) such as the new materiel requirements in the Combat Support Hospital (i.e. Combat Support Hospital FDU).

Logistics

A. MRMC Reorganization: The DfM served as the MRMC lead for the reorganization of the command from a logistics perspective in support of OTSG's "Futures" concept. The DfM reviewed various courses of action to split the command as it relates to medical logistics. The DfM worked with the MRMC staff and the medical logistics commands to include USAMMA, USAMMCE, and USAMMC-K. Throughout this effort, the MEDLOG team explored options with moving the MEDLOG commands to various geographical headquarters and moving the DfM staff to DHA or OTSG G-4. Generally, the MRMC Commanding General briefed the CG, MEDCOM that the command to include MEDLOG would stay intact.

B. Army Medical Materiel Agreement (AMMA): The DfM attended multiple meetings with updating the AMMA agreement between DLA and OTSG/MEDCOM. This document defines the support the Defense Logistics Agency (DLA) provides the Army with DLA stocks in support of the military health system. Furthermore, this document addresses the controls necessary for the items in inventory receipt, order fulfillment, receivables and inventory management processes. The DfM provided background information, recommended changes and context to many areas within the document. This document was ultimately signed on 12 Nov 14.

C. Army Medical Logistics Enterprise (AMLE) Strategy:

1) Enterprise Executive Committee (EEC): The DfM Deputy serves as the AMLE Office of Strategy Management (OSM) lead. His task is to assist the AMLE with meeting the Mission and Vision of the Enterprise through the seven (7) AMLE Strategic Objectives. The seven AMLE objectives (i.e. Implement Enterprise Business Model, Model Fiscal Stewardship, Inform and Educate Stakeholders, Improve MEDLOG Services, Increase the Readiness of the Operating and Generating Force, Provide Full Lifecycle, and Talent Management) have twenty three (23) measures and eighteen (18) initiatives established in the Strategic Management System (SMS) using the Balance Score Card (BSC) methodology. The EEC meets monthly to review at least two objectives to understand the performance of the objective, progress or challenges. The EEC is also briefed monthly on emerging topics, opportunities and challenges. The EEC tracks open issues and tasks the Staff Action Group (SAG) assist with gaps identified through the monthly EEC engagement. During this period, the EEC process has struggled with the BSC process, which is mainly attributed to the lack of Initiatives aligned to various objectives.

2) Staff Action Group (SAG): The DfM Chief, Enterprise Business Office (EBO) facilitates the SAG meeting monthly. This meeting adjudicates AMLE business issues, emerging topics and strategic issues in support of the AMLE EEC. Issues are tracked and shared with the AMLE EEC for decisions or situational awareness.

3) Review and Analysis (R&A): The DfM EBO facilitates the quarterly AMLE R&A meeting. This meeting is done live in the Strategic Management System (SMS) including seven (7) broad topics to include Resource Management, Theater Lead Agent for Medical Materiel Supply Chain Management, Materiel Management, Services, Medical Maintenance Management Operating Force, Assembly and Production, and Theater Recap, Reuse, and Divesture of Class VIII Equipment. These seven topics have 43 measures representing both the operational and generating force. Many of these measures have improved based on emphases by leadership, business process reengineering or other related reasons. Some measures have not improved but continue to be monitored closely. The AMLE R&A meeting drives business process improvement, system change requests and resourcing for AMLE organizations.

4) AMLE Charter: The AMLE Charter is signed by the CG, MRMC. During this period, the AMLE Charter expired. The staffing process to update the Charter is still in staffing.

5) IT Executive Steering Committee (ESC): The ESC meeting is held twice per quarter. The DfM EBO assists the OTSG G-46 with the conduct of this meeting. This meeting focuses on our systems in support of Army Medicine Medical Logistics support. This meeting provides updates to the ESC on IT related topics, which informs business process changes and system change requests.

6) Centralized Medical Materiel Management (CM3) Business Case Analysis (BCA): The DfM serves as the co-lead for the contract in support of the CM3 BCA. The CM3 effort is a three-phased process in support of the Army Surgeon General's 2025 Campaign Plan. The CM3 initiative is a line of effort under the pending AMLE 2025 Program. The BCA phase started in September 2014 and will culminate with a decision brief in April 2015. The BCA is exploring options to consolidate medical materiel management regionally in support of MTF and CONUS MTOE unit supply chain support. The BCA will explore options to streamline the master data processes across MRMC and MEDCOM. The BCA will provide several options to the AMLE to move forward with this concept into phase 2 (Business Process Reengineering / BPR). The BCA will include data that shows a Return On Investment (ROI) or

otherwise. The BCA phase included travel to Fort Sam Houston, TX and Fort Hood, TX to meet with stakeholders to validate our hypothesis as well as receive input from various units in the supply chain. The core team also visited the DLA, Services and DHA for their input.

7) MLC TEWLS Pilot: The DfM EBO played a key role in the planning and execution of the MLC TEWLS Pilot at Fort Hood, TX in April 2014. The OTSG G-43 served as the lead for this Pilot while the MRMC EBO facilitated the weekly IPR's, task lists, and DOTMLPF-P assessment document. The Pilot occurred over a 4 day period with transactions conducted in TEWLS by both the MLC and TLAMM. The 1st Army MEDLOG warehouse at Fort Hood, TX was used to accommodate the exercise. This pilot included the 1st MED BDE staff and MLC, OTSG/MEDCOM, MRMC EBO, USAMMA, USAMMCE, AMEDD Center and School (DCDD Force Sustainment Division), and 1st Army. The objective of this Pilot was to validate the TEWLS system in support of the MLC would accommodate our MLC business processes while having a TLAMM conduct the CM3 activities. The deliverable of this Pilot was to conduct an assessment of the MLC business processes as well as the CM3 activities at the TLAMM in the DOTMLPF-P format. The major gaps identified during the Pilot included training, catalog, CM3 activity lead while in CONUS prior to a deployment, and doctrinal updates to the Combined Arms Training System (CATS) document.

8) Defense Health Agency (DHA):

   a. Defense Medical Logistics (DML) Metrics: With establishment of the Defense Health Agency (DHA), the DfM participated with other Services in development of metrics to monitor the performance of 'shared services' and business process initiatives intended to improve efficiency in delivery of medical logistics product lines. Metrics were addressed for three broad purposes: performance of DHA programs established for its Initial Operating Capability (IOC); performance of DHA and DLA in meeting responsibilities under a Performance Based Agreement (PBA), and 'Measures of Effectiveness' (MOA) related to DHA performance as a Combat Support Agency (CSA). Whenever possible common metrics were adopted for all three purposes. Challenges included harmonization of data from multiple data sources and Service-specific policies and business processes. By end of CY14, metrics have been adopted for medical materiel standardization, use of eCommerce, cost avoidance, and sourcing optimization associated primarily with support to the military direct care (DHP) system. Metrics for various aspects of medical materiel readiness and standardization in operating forces remain under development.
   b. Defense Medical Logistics Enterprise Solution (DML-ES): The DfM continues to assist DHSS/DHA/JMLFDC with improving and proliferating TEWLS across the Services and Army. The EBO ICW USAMMCE and USAMMA Business Support Office (BSO) conducts monthly meetings to improve the functionality and performance of TEWLS to include system improvements and master data.

2) Defense Logistics Agency (DLA) Supply Chain Assessment: The DfM participated in analysis of a Class VIII supply chain assessment (SCA) chartered by DLA and supported by the Defense Medical Logistics Medical Logistics Proponent Committee (DMLPC). This assessment is intended to satisfy a DoDD 5101.1 requirement for DoD Executive Agents to be assessed ≤ 3 years for continued need, currency, & effectiveness and efficiency in satisfying end user requirements. The DfM helped compile and interpret the survey results and prepared the briefing of preliminary results for the DML Staff Action Group (SAG). These preliminary results concluded that overall, the Class VIII supply chain is 'effective' with 18 of 19 assessed qualities rated at least 'somewhat effective'. Key areas for improvement included requirements determination, materiel standardization, system interoperability, and risk assessment.

3) DLA J3 Visit to USAMRMC: The CG, MRMC hosted the Director of Logistics Operations/J-3, Defense Logistics Agency (DLA), RADM Vincent Griffith, and the Commander, DLA Troop Support, BG Steven

Shapiro, at MRMC HQ on 1 December 2014. The meeting purpose was to discuss and renew the 14+ year partnership between Army and DLA which is critical for extending medical supply chain support to Army and joint medical forces worldwide. MG Lein provided an overview of MRMC as the Army's medical life cycle management command, followed by briefings covering Army Medical Logistics, Defense Medical Logistics, and medical logistics support to Operation United Assistance (OUA) in West Africa. The meeting was attended by the Chief, Medical Logistics Division, Defense Health Agency (DHA) and the Air Force and Navy Medical Logistics Chiefs. Following the meeting at MRMC, RADM Griffith and BG Shapiro visited the Defense Medical Logistics Center (DMLC) on Ft. Detrick.

4) Forces Command (FORSCOM) Visit: On 17 Oct 15 LTC (P) (b) (6) and COL (b) (6) (CDR, 6th MLMC) traveled to Fort Bragg, NC to brief the FORSCOM Surgeon (BG Providence) and FORSCOM G-4 on various AMLE topics and an overview on the 6thMLMC. This briefing included several AMLE topics to include an AMLE overview, AMLE General Officer Steering Committee (GOSC) concept, CM3 concept and BCA, MEDLOG Company TEWLS fielding, and readiness related issues. The FORSCOM Surgeon seemed on board with all topics briefed while the FORSCOM G-4 had some critical concerns about Army Medicine based on his recent experience in Korea with the 65th MED BDE.

5) USAMMC-K 90 Day Assessment: The new USAMMC-K commander (LTC Butler) provided a 90-day assessment briefing to the CG, MRMC on his organization. This assessment focused on resource gaps to transition to hostilities (TTH), organization alignment, mission command alignment, USAMMA Army Propositioned Stocks (APS) issue process/concerns, systems issues, personnel issues, Memorandum of Agreement issues with 65th MED BDE, and other concerns. These issues will be addressed during a meeting in Korea with personnel from the OTSG G-4, MRMC, Pacific Regional Medical Command, 8th Army, 65th MED BDE, and USAMMA.

Construction

US Army Medical Materiel Center Europe (USAMMCE) relocation and the European Infrastructure Consolidation (EIC) Review made significant progress in calendar year 2014. Throughout 2014, the DfM supported two primary work groups (medical and logistics) engaged in a SECDEF-directed EIC Review to validate whether Kaiserslautern Army Depot (KAD) is the optimal location to move USAMMCE. The KAD project has been an Army plan supporting its ongoing consolidation of USAREUR infrastructure, which requires closure of Husterhohe Kaserne (Pirmasens) where USAMMCE is currently located. The EIC analysis supported the KAD plan and included it in recommendations forwarded to SECDEF in Dec 2014 (approved by SECDEF in Jan 15). In Jan 2014, the DfM also began a comprehensive MRMC effort to plan the details of initial outfitting and transition (IO&T) associated with the USAMMCE move, including furnishing, warehouse design and equipping, information technology, and manpower costs necessary to execute the move without interrupting critical operations. Through collaborative staff work involving the MRMC DCSLOG, DCSIM, and DCSRM as well as MEDCOM counterparts and USAMMCE, these requirements were documented. A major break-through occurred in May 2015 when the USA Health Facilities Planning Agency incorporated these requirements into its funded IO&T program. This support ultimately included a MEDCOM contribution of $2M in Sep 14 to help cover an IMCOM-E funding shortfall to renovate a building for the optical fabrication lab. As of year-end, HFPA awarded a contract for on-site IO&T project management and USAMMCE's relocation appears on track for a move in late FY 16/FY17.

Health and Environment

N/A

Section 10

Fiscal Year 2014
Annual Historical Report

Military Infectious Diseases Research Program

MIDRP Overview

The Military Infectious Disease Research Program (MIDPR) annual historical report for FY 2014 will capture important events, accomplishments, lessons learned and organization changes.

MIDRP's Mission

A. To conduct for the Department of Defense (DoD) a focused and responsive world-class infectious disease research and development program leading to fielding of effective, improved means of protection and treatment to maintain global operational capability with minimal morbidity and mortality.

Organization and Personnel of MIDRP:

A. **Organization of MIDRP**

1) The Military Infectious Diseases Research Program (MIDRP) is managed by Research Area Directorate (RAD) 1 of the U.S. Army Medical Research and Materiel Command (USAMRMC) located at Fort Detrick, Maryland. MIDRP is the lead for planning, coordinating and overseeing a DoD Science and Technology (S&T) program that funds basic research leading to medical countermeasures for naturally occurring diseases affecting military operations. MIDRP is an intramural program executed through the Walter Reed Army Institute of Research (WRAIR) and the Naval Medical Research Center (NMRC), both located in Silver Spring, Maryland, the United States Army Medical Research Institute of Infectious Disease (USAMRIID), located in Fort Detrick, Maryland and at their affiliated OCONUS laboratories: the United States Army Medical Research Unit-Kenya (USAMRU-K) in Nairobi, Kenya; the Armed Forces Research Institute of Medical Sciences (AFRIMS) in Bangkok, Thailand; the Naval Medical Research Unit No. 6 (NAMRU-6) in Lima, Peru, Naval Medical Research Center-Asia (NMRC-A) in Singapore, Naval Medical Research Unit No. 2 (NAMRU-2) in Phnom Penh in Cambodia, and NAMRU-3 in Cairo, Egypt. Research Coordinators at WRAIR, NMRC and USAMRIID manage MIDRP's research programs and communicate with OCONUS researchers. MIDRP provides funds to both U.S. Army and U.S. Navy researchers for endemic disease research.

2) MIDRP's HIV program collaborates with National Institute of Allergy and Infectious Diseases (NIAID). MIDRP also collaborates with several companies and universities to develop and evaluate products.

3) MIDRP additionally executes a portion of the Defense Health Program enhanced (DHP) to intramural and extramural researchers in the areas of Rapid Screening of Fresh Whole Blood, Wound Infection Prevention and Management and Antimicrobial Countermeasures, Diagnostic Systems for Infectious Diseases (6.4 funding), Acute Respiratory Diseases and Innovative Immuno-chemo Prophylaxis Technologies.

B. **Military, Civilian and Contractor Personnel:**

1) Military:
   a. COL (b) (6), Ph.D. (Director, 01 OCT 2013 – 30 SEP 2014)
   b. LTC (b) (6), Ph.D. (Deputy Director, 01 OCT 2013 – departed Jun 2014 with no replacement)
   c. CDR (b) (6), Ph.D. MSM (Malaria Vaccines, Malaria Therapeutics, Flavivirus vaccine, Leishmania Topical Paromomycin IPTs Navy Liaison and Consultant , 8-Aminoquinoline Consortium Member, and Multilateral Integration Team member for PfSPZ malaria vaccine, and Navy Liaison to USAMRMC, 01 OCT 2013- 30 SEP 2014)
   d. CAPT (b) (6), MD (Infectious Disease Consultant, 04 FEB – 30 SEP 2014)

2) Civilian:
   a. (b) (6), Ph.D. (Director, Defense Health Programs, 01 OCT 2013 - 30 SEP 2014)

b. (b) (6), MD (Medical Officer, 01 OCT 2013- 30 SEP 2014)
c. (b) (6) (Civilian, Office Secretary, 01 OCT 2013 – 30 SEP 2014)

3) Contractors:
a. (b) (6) (Contractor, HIV and Adenovirus Vaccine Portfolio Manager, 01 OCT 2013-30 SEP 2014)
b. (b) (6) (Contractor, Malaria Vaccines and Malaria Therapeutics Portfolio Manager and Dengue Program Manager, and IV Artesunate, and Tafenoquine IPT Consultant) 01 OCT 2013- 30 SEP 2014)
c. (b) (6) (Contractor, Vector Identification and Control, Diagnostics Systems (including NGDS), and Lethal Viruses Portfolio Manager, SBIR Liaison and PPAE Liaison, 01 OCT 2013-30 SEP 2014)
d. (b) (6) (Contractor, MIDRP and DHP Budget Analyst, 01 OCT 2013-30 SEP 2014)
e. (b) (6) (Contractor, DHP Portfolio Manager, 01 OCT 2013-30 SEP 2014)
f. (b) (6) (Contractor, Diarrheal and Rickettsial Diseases Research Portfolio Manager, 01 OCT 2013- 30 SEP 2014)
g. (b) (6) (Contractor, DHP Budget Analyst) 01 OCT 2013- JUN 2014

4) Deployed – 0

Statistical data:
N/A

Healthcare Deliver:
N/A

Veterinary Services:
N/A

Training and Education:

A. COL (b) (6) visited Armed Forces Research Institute of Medical Sciences, Bangkok, Thailand 14-22 Mar 2014; Gates Foundations Meeting 21-26 Apr and Medical Health Sciences Research Symposium (MHSRS), 18-21 AUG 2014, Fort Lauderdale, FL.

B. LTC (b) (6) completed STM 202 and STM 303 and received Level 3 S&T Certification and received Level 3 S&T Certification and member of the Army Acquisition Corps.

C. CDR (b) (6) attended the American Society for Tropical Medicine and Hygiene (ASTMH), Washington, DC 13-17 NOV 2013. ASTMH, founded in 1903, is a worldwide organization of scientists, clinicians, and program professionals whose mission is to promote global health through the prevention and control of infectious and other diseases that disproportionately afflict the global poor. Attended MHSRS 18-21 AUG 2014 in Fort Lauderdale, FL. Attended Bio2014, 23-26 June 2014 in San Diego, CA. Attended 8-Aminoquinolone Consortium Meeting Apr 2014 in Oxford, MS.

D. (b) (6) attended MHSRS, 18-21 AUG 2014, Fort Lauderdale, FL.

E. (b) (6) - Fundamentals of Systems Acquisition Management AQ101 from DAU (Mar 2014), Intermediate Medical Acquisition Course at Fort Detrick (May 2014). Attended 8-Aminoquinolone Consortium Meeting Apr 2014 in Oxford, MS.

F. (b) (6) - Training GFEBS (7 different Modules); Hand Receipt Holders Single Card Training for Credit Card in GFEBS

G. (b) (6) - Attended International AIDS Vaccine Conference held on 7–10 October 2013 at the International Convention Center in Barcelona, Spain.

H. (b) (6) – Completed Level 1 Defense Acquisition Workforce Improvement Act Certification ; Attended 8-Aminoquinolone Consortium Meeting Apr 2014 in Oxford, MS.

I. (b) (6) - attended MHSRS, 18-21 AUG 2014, Fort Lauderdale, FL.

J. (b) (6) Decision Gate Fundamentals: MRMC (Oct 1st 2013), Fundamentals of the Analysis of Alternatives: MRMC (01/13/2014), Advancing Regulatory Science for High Throughput Sequencing Devices for Microbial Identification and Detection of Antimicrobial Resistance Markers: FDA (April 1st 2014), Navigating Medical Product Acquisition in the FDA - Regulated Space-Protecting the Development Effort, Completion of the IPT Checklist and Other Challenges: MRMC (May 1st 2014), Risk Management Workshop: MRMC (May 14th 2014), Small Business Innovative Research, Small Business Technology Transfer: MRMC (July 14th 2014), The Development of New Antibacterial Products- Charting a Course for the Future: FDA (July 30th -31st 2014), MHSRS (August 18th -21st 2014) and Intersciences Conference on Antimicrobial Agents and Chemotherapy (September 5th-9th 2014).

K. (b) (6) - Completed Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) FAC010 Section 889 from DAU (02/13/2014) and Improved Statement of Work CLM031 Section 890 from DAU (04/02/2014).

L. (b) (6) – Completed "MRMC's "Navigating Medical Product Acquisition in the FDA-regulated space" (05/01/2014) and MRMC's "Project Risk Management" (05/14/2014). (b) (6) attended a workshop entitled "Development of new antibacterial products: Charting a course for the future" jointly organized by the FDA and the NIH in July 2014. She also attended the 8th Vaccine and ISV Congress in Philadelphia in October 2014.

Research and Development:

A. MIDRP's objective is to protect deployed service members from infectious diseases common in the developing world that may interfere with operational readiness. MIDRP programs are focused on the discovery and exploration of innovative approaches to protect the health of military personnel against naturally occurring endemic and emerging infectious disease threats and to accelerate the transition of medical technologies into deployed products. All programs undergo a comprehensive internal and external peer review to ensure that only the "best" science is funded. The MIDRP has had notable successes as evidenced by its lead role in developing and fielding more than a dozen critical vaccines and drugs to prevent and treat endemic infectious diseases and in developing licensed vector and human diagnostic platforms for human diseases.

B. MIDRP programs are multifaceted and include highly effective inter-agency efforts that leverage all available resources (including academia, industry, U.S. Government and other partnerships) to maximize development and fielding of countermeasures to safeguard the Warfighter. In addition, since the FDA requires that pivotal clinical trials of products for infectious diseases be conducted in people living in endemic areas, the MIDRP's collaborative networks around the world (which include DoD overseas laboratories) also attract industry partners for accomplishing complex clinical trials. The recent success of this collaborative HIV vaccine research was acclaimed as a major medical breakthrough in HIV Vaccine development. The program continues to evaluate mechanisms of

protection in vaccinated volunteers through several new studies in collaboration with international academic and industrial partners. The Dengue vaccine development program spearheaded by MIDRP researchers also uses these international development assets as does the Military Malaria Vaccine Program - as evidenced by its recent (2011) success in co-developing the world's first malaria vaccine.

C. In OCONUS laboratories, MIDRP-funded scientists work in modern, well-equipped facilities with high-caliber foreign national scientists to develop diagnostic and detection tests, devices and assays applicable to the region (e.g. a dengue arthropod vector rapid detection device (AVRDD) developed in Thailand). These international scientific collaborations not only lead to products which benefit the US, but also to education and goods which benefit and are available to the host nation. MIDRP-funded scientists serve as goodwill ambassadors, and contribute to the development of health and science infrastructure in these developing countries - improving regional health and stability as well as potentially buoying US diplomatic and DoD relations.

D. Countermeasures and candidate solutions to combat infectious disease are studied through all phases of development including field testing. In addition to driving development of drugs and vaccines for naturally occurring infectious diseases of relevance to the military, MIDRP develops diagnostic products (including field worthy devices to diagnose human infections [e.g., scrub typhus] and to determine if humans are infected with pathogens transmitted by medically relevant arthropods, ie. mosquitos, ticks, sandflies, mites. Vector control products including personal protective devices (e.g., insect repellents, insecticides, and bed nets) to prevent mosquitoes, ticks, and sand flies from biting service members are also an important result of MIDRP funded research.

E. MIDRP's current research programs are focused on drugs to prevent and treat malaria, malaria vaccines, diarrheal vaccines, dengue vaccines, lethal virus countermeasures, scrub typhus research, treatment of cutaneous leishmaniasis, wound infection research, control of insect vector, diagnostics, and HIV research.

F. MIDRP managed the Defense Health Program Enhancement (DHP), a $200M program (FY10-19), that includes both intramural and extramural research projects spanning basic research through advanced development of military medical products. Joint Program Committee 2 (JPC-2) had program announcements in FY14 and has a few new project starts in Wound Infection Prevention and Management and Antimicrobial Countermeasures. DHP was established initially in FY10 based on GDF gaps. The objective is to accelerate the translation of advances in knowledge into new standards of care for injury prevention, treatment of casualties, rehabilitation, and training systems that can be applied in theater or in the clinical facilities of Military Health System (MHS). Five infectious disease DGP task areas include: Rapid Screening of Fresh Whole Blood (FSFWB), Wound Infection Prevention and Management (WIPM), Antimicrobial Countermeasures (AC), Diagnostic Systems for Infectious Diseases, Acute Respiratory Disease (ARD), and Innovative Immuno-Chemoprophylaxis Countermeasures. Primary focus for AC and WIPM is infections with one or more MDROs, particularly *Acinetobacter baumannii*, *Pseudomonas aeruginosa*, methicillin-resistant *Staphylococcus aureus*, extended-spectrum beta-lactamase producing *Enterobacteriaceae* (including *E. coli* & *Klebsiella pneumoniae*), and/or non-*Candida* invasive fungal (mold) pathogens.

G. The 2014 MHSRS was held 17-21 Aug 2014 in Fort Lauderdale, FL. There were 1534 attendees that included all services, other government agencies, international military, academia, and industry. This is an excellent venue to present the newest research in the areas of Combat Casualty Care, Traumatic Brain Injury, Joint Trauma System, Infectious Disease, Military Operational Medicine, Hyperbaric oxygen, Blast Injury, Clinical & Rehabilitative Medicine, Expeditionary & Sea Based Care & Global Disaster Response, and many other areas. This conference also served as a venue for many other sub-meetings to include media round tables, ASBREM, JPC and service specific meetings, etc. MHSRS received a record 1135 abstract submissions for the competitive oral/poster presentation process; only half of those were selected to speak or present their posters. MHSRS 2014 was the first time Infectious Disease was represented; received 120+ abstracts. Infectious Disease held two

breakout sessions on 21 August and due to the overwhelming response, two special lunch breakout sessions (20 and 21 August). Additionally, there was a media Infectious Disease Roundtable entitled "Fighting Wound Infections and Antibiotic Resistance" held 20 August and two infectious Disease oral presentations in the Plenary held 21 August. All sessions were well attended and attendees were very positive about seeing a continued presence of Infectious Disease topics in future MHSRS Meetings.

H. As part of the U.S.-Israel Data Exchange Agreement (DEA) and recommendations of the Executive Summary of Shoresh 2012, an Executive Session video teleconference was held on October 2, 2013. MIDRP provided semi-annual status of actions with their Israel Defense Force Co-Chair for the Infectious Disease working Group. MIDRP reported on 6 action items, completing 3 (Skin and Soft tissue Infection and bacterial diarrheal disease) of the 6; the remaining were ongoing in 2014.

I. Major Accomplishments in FY14 include:

1) MIDRP continues to enhance program focus and management to assure scientific merit and the mission / requirement alignment of proposed research prior to funding; in addition there is documentation of research outcomes after funding. Of 202 proposals submitted about 134 proposals were funded in FY14 which include both new and ongoing efforts. MIDRP also reviewed 14 MILVAX proposals and 5 were funded. MIDRP reduced the number of IIPT meetings to one (held APR 2014) and conducted no Scientific Advisory Boards due to the travel restrictions during the fiscal year. Other accomplishments include contribution of significant knowledge to the global scientific community for many tropical diseases, teaching and technology transfers, infrastructure improvements, and large clinical efficacy trials in the tropics.

2) There were no changes from 2013 historical report. MIDRP scientists and their USAMMDA collaborators continue to advance intravenous artesunate (IV AS) for the treatment of severe or complicated malaria. On average, 1500 cases of malaria a year are reported in the US, while 3.3 billion people (half of the world's population) live in areas at risk of malaria transmission. Approximately 10% of the reported cases develop into severe malaria, which have a significantly higher chance of death. Artesunate is recommended by the World Health Organization (WHO) for the treatment of severe malaria and has been used worldwide for many years. In 2007, the FDA approved an IND protocol for a new class of antimalarial medication which is available through the CDC for the first time as a replacement for intravenous Quinidine. The drug is provided to the hospitals, upon request and on an emergency basis, by the CDC Drug Service or by one of the CDC Quarantine Stations located around the country. In addition, Force Health Protection (FHP) has prepositioned IV AS in two overseas facilities that also handle other FHP products so that the drug is available to our military on an emergency IND basis. Average time from request to administration is seven hours. The treatment IND at the CDC under a MOA has treated over 154 patients through the end of 2012 with IV AS with no drug-associated serious adverse effects (SAEs). IVAS has shown high efficacy and rapid action for the treatment of severe and complicated malaria. IV AS was also donated to University of Tubingen/EDCTP/MMV for pediatric development. The study was completed in Gabon & Malawi with no SAEs related to study drug. A New Drug Application (NDA) is in preparation. Licensure in the U.S. by its commercial partner is expected in 2-3 years.

3) The new generation malaria prophylaxis drug, Tafenoquine, continues to advance in the licensure process with support by MIDRP as well. In collaboration with GlaxoSmith Kline and the Medicines for Malaria Venture, MIDRP Investigators are advancing Tafenoquine in radical cure indications as part of a growing global malaria eradication campaign with expected FDA licensure in 2018. Tafenoquine for a prophylaxis indication continues as well with licensure to follow the radical cure indication licensure. . MIDRP and USAMMDA investigators have initiated a CRADA with 60P Pharmaceuticals to accelerate development of a prophylaxis indication for Tafenoquine. The collaboration has targeted the Europe-US-Australia-Canada travelers market in a for profit business development effort. The collaboration will make use of the Glaxo-Smith Kline product,

manufactured by Piramal (India) and reformulated for the prophylaxis indication. It is anticipated that 60P will be able to generate sufficient revenue from global Tafenoquine malaria prophylaxis sales to be modestly profitable and enable its licensure by EU and FDA regulatory bodies. MIDRP Investigators also supported USAMMDA in efforts to obtain an NDA for the topical anti-leishmanial, WR279396 (Paromomycin + Gentamicin) for treatment of cutaneous leishmaniasis. A Phase 3 clinical trial in Latin America is underway to determine efficacy of Topical Paramomycin against New World Leishmania species also as part of the NDA submission and to expand its global market.

4) As part of a Joint Warfighter funded initiative (Congressional Special Interest supported by Congressionally Directed Medical Research Program), the MIDRP, Vaccine Research Center at National Institute of Health (NIH), PATH-Malaria Vaccine Initiative (PATH-MVI), Bill & Melinda Gates Foundation, Walter Reed Army Institute of Research (WRAIR) and Sanaria scientists have formed a global consortium to advance the first ever live attenuated malaria sporozoite vaccine to clinical trials around the world. Initial clinical trial data demonstrated >90% protection using this sporozoite vaccine that was administered intravenously. In follow on efforts, Navy and Sanaria scientists completed continued investigations into intravenous administration of irradiation attenuated sporozoites showing >85% protective efficacy from challenge by homologous (West African) parasites and 80% efficacy from a heterologous parasite challenge strain (Brazilian). This effort has also successfully reduced the number of IV immunizations from five to three while maintaining >80% protection. In an ongoing study, immunized volunteers who completed inoculations in November 2014 are being rested for six months post immunization and await challenge in April 2015 to assess duration of protection. Sanaria successfully competed for additional JWFRP funding ($7.6M) and awaits a funding determination from CDMRP in 2015 for a study to assess protection against a Plasmodium vivax challenge.

5) MIDRP management/co-management of SBIR's for FY14: 16 SBIR's (2 DHP Phase 1, 10 DHP Phase II, and 4 Army SBIR Phase II proposals) were managed by MIDRP with a total funding for Phase 1, 2 and enhancement funding of $11,75 million. The Phase I projects were initiated in the areas of Diagnostics Vector Pathogen Detection, and Adenovirus vaccine. Multiple Phase II awards were awarded in the areas of diagnostics, vector detection and hantavirus vaccine.

6) Within the MIDPR managed Defense Health Program:
   a. Rapid Screening of Fresh Whole Blood (RSFWB):
      ii. Continued development of RT2D2 that will serve as one of the many products developed to improve the safety of emergency blood collections by an orthogonal approach. This product will improve the use of more timely and accurate rapid donor blood screening by having FDA approved clinical diagnostic devices used during emergency blood drives. Multiplexed HIV, Hepatitis B (Surface Antigen) and HCV test will reduce the time and expense of performing rapid donor screening. Combined Milestone B/C will be held in FY 16.

      iii. Increment 2 Nucleic Acid Test (NAT) was reduced to tech watch.

   b. Next Generation Diagnostic Systems (NGDS):
      i. Biofire (Defense) was awarded the contract to develop the system to replace JBAIDS utilizing the FilmArray Platform. The awarded contract was held up in a contract protest which was settled in *November 2014. This system has multiple disease panels currently FDA approved.*

      ii. *The overall NGDS* program is envisioned to be a family-of-systems (FoS) providing modular orthogonal diagnostics capabilities across operational echelons (tactical, field confirmatory, and fixed facilities) and fielded over several acquisition increments.

Evolutionary acquisition program is to provide increments of capability across many echelons of care: Diagnostic and identification platform components; Point of Care diagnostics - hand held and single use components; Screening tools and enabling components.

c. WIPM and AC:

i. A phase II study at University of Pennsylvania in collaboration with Microbion Corporation, to evaluate the efficacy and safety of the use of BisEDT to treat postoperative infections following surgical stabilization of open fractures of the lower extremity is still on hold pending additional pre-clinical and clinical data required by FDA. The study recently received FDA qualifying infectious disease product designation that allows additional 5 years of market exclusivity and review fast tracking options. A pre-IND meeting with the FDA indicated that additional information was required on the part of Microbion Corporation to satisfy IND requirements. Microbion Corporation has been pursuing the resolution of outstanding pre-IND recommendations in order to submit the IND request.

ii. JPC-2 funded the Denver Health Medical Center in collaboration with the Denver VA Medical Center and Accer18 Technology for developing a diagnostic capability using advanced microscopy and bacterial culturing techniques. The researchers are developing the capability to identify bacteria and determine drug resistance profiles within six hours of receiving the specimen. Accer18 Technology has developed a prototype microscopy device that demonstrates the ability to detect real-time bacterial growth under various media conditions (with and without antibiotics). The team has achieved joint consensus with FDA on product development and clinical trial design for positive blood culture using the Accelerate identification /antimicrobial susceptibility testing (ID/AST) system. The success of the work so far indicates great potential for real-time microbiological diagnostics.

iii. With JPC-2 funding, Stratatech is developing a genetically enhanced human skin substitute that has sustained expression of cathelicidin—a naturally occurring, human-produced defense peptide with broad-spectrum antimicrobial properties that demonstrates effectiveness against multidrug-resistant bacteria and fungi. The FDA awarded Stratatech's human skin substitute orphan drug status in 2012. Initial preclinical studies have demonstrated effective antibacterial activity against multidrug-resistant *Acinetobacter baumannii*, one of the most common pathogens associated with combat wounds. More efficacy and toxicity studies required for Investigational New Drug submission are underway.

iv. JPC-2 funded invasive fungal infection research through the Infectious Disease Clinical Research Program (IDCRP). The Joint Trauma Service clinical practice guidelines for the identification and treatment of suspected invasive fungal infections (IFI) in war wounds were developed through this research. JPC-2 is currently funding IDCRP research aimed at investigating molecular methods to improve IFI diagnosis.

7) Within the MIDRP managed Wound Research Program, MIDRP researchers:

a. As in prior years, the amount of funding available to this research area is limited, effectively making this an idea and discovery program, suitable for attracting collaborations, partnerships, and other sources of funding.

b. Significant progress is being made in both the development of novel therapeutics for the treatment of MDR infections, and the characterization of genetic mechanisms of antimicrobial

resistance by various groups at the Walter Reed Army Institute of Research and Naval Medical Research Center in Silver Spring, MD.

c. In one of the projects funded under this research area, (b) (6) has optimized conditions for sufficient yield of *A. baumannii* OmpW2 (Ab*Omp*W2) and *K. pneumonia* (Kp*Omp*W) proteins for X-ray crystallography. In addition, docking studies of Ab*Omp*W2 and Kp*Omp*W with *E. coli* colicin S4 peptides are in progress. *In silico* screening of the National Cancer Institute database of small organic molecules has been conducted looking for candidates binding and inhibiting *Omp*W. 23 unique compounds for biological evaluations were selected for Kp*Omp*W, and an additional 20 to 25 compounds are expected to be selected after further analysis.

d. Viruses that infect and kill bacteria (bacteriophages) have shown promise in the treatment of a mouse wound infection model with *Acinetobacter baumannii*.

e. Genetic analysis of several MDROs obtained from both non-sterile polymicrobial sites (such as wounds) and sterile, monomicrobial cultures (such as blood) from the same patients did not reveal significant genetic differences, highlighting the need for continued study of the transmissibility and pathogenesis of these organisms.

f. Several articles were published detailing the analysis of several MDROs involved in clinical outbreaks or severe or fatal infections within the MHS, thereby contributing to the general medical knowledge of these organisms.

8) Within the Malaria Vaccine Research Program, MIDRP researchers:

a. Directly identified peptides expressed on the surface of infected human hepatocytes using mass spectrometry to search for protective liver stage antigens that could serve as targets for CD8+ T cells. Sequenced peptides from six different Plasmodium falciparum (Pf)-infected primary human hepatocyte samples derived from two different liver donors. Used partial sequences to identify at least one antigen that induced interferon-gamma (IFN-γ) ELISpot recall responses across a genetically diverse group of radiation attenuated sporozoite (RAS)-immunized research subjects. This lead to:

b. Continued to participate in the hypothesis-driven hepatic(pre-erthrocytic) antibody target identification consortium (HPATIC), a collaboration led by PATH MVI to characterize six novel P. falciparum sporozoite-surface-expressed antigens from USMMVP as well as antigens from other members of the consortium.

c. As part of a PATH-MVI funded antigen discovery project, we characterized the Immunological mechanisms underlying the previously reported (Limbach, Aguiar et al. 2011) consistent protection seen in outbred mice following DNA prime/adenovirus serotype 5 (Ad5) boost immunization with the P. yoelii orthologs of two novel P. falciparum liver stage antigens, Pf-UIS3 and Pf-falstatin, and examined their efficacy when combined with PyCSP. Immunization with the antigen combination induced high frequency effector CD8 T cells and high titer antibodies targeting the P. yoelii ortholog of Pf-falstatin, and protection was abrogated by depletion of CD8 T cells prior to challenge. Protection induced by the antigen combination was consistently higher than that induced by PyCSP, or by either antigen alone, in the prime-boost regimen, with up to 57% of mice protected from P. yoelii challenge.

d. Based on these and prior data, we are seeking to further develop these antigens in a subunit malaria vaccine capable of enhancing protection induced by RTS,S.

e. Confirmed protective activity, expressed as a reduction of liver parasite burden,of nine novel Plasmodium berghei liver stage antigens that have orthologs in P. falciparum, and hence are considered as potential vaccine candidates.
f. Continued collaboration with Seattle BioMed and the Bill & Melinda Gates Foundation to explore biomarkers of protection in humans immunized with *P. falciparum* sporozoites (spz) attenuated by radiation (RAS) via mosquito bite (IMRAS trial). Recruitment and immunization of cohort 1 started in FY14; controlled human malaria infection (CHMI) and hyperimmunization of cohort 1, and recruitment and immunization of cohort 2 will take place in FY15. Subjects are leukapheresed to collect large numbers of PBMCs and the tools of systems biology will be used to identify correlates of protection via an open aperture approach. This will be coupled with in-depth antigen-specific investigations, leveraged with funding from a MIDRP FY15 project developed jointly by WRAIR and NMRC investigators.

g. Generated 12 fully human monoclonal antibodies against *P.falciparum* sporozoites (Pfspz) and 39 fully human monoclonal antibodies against P. falciparum blood stages by immunizing two humanized mice (Wijayalath, Majji et al. 2014) with these stages and harvesting plasmablasts from spleen and bone marrow. These IFA-positive antibodies will be characterized in a MIDRP FY15 project. This work is relevant to antigen discovery as well as to characterizing immunological mechanisms of protection. It also opens the door to the exploration of protection by passive immunization.

h. Identified minimal epitopes of AMA1 recalling ELISpot and CD8T cell IFN-γ responses that appear linked to the sterile protection in volunteers immunized with the NMRC-M3V-D/Ad-PfCA vaccine (DNA prime/Ad5 boost) (Sedegah, Hollingdale et al. 2014). The potential relationship between the response to these and other epitopes and protection will be prospectively tested using tetramer technologies (Schwenk, Banania et al. 2013) with cells from subjects in a forthcoming repeat DNA/Ad clinical trial slated for FY15 in the NavOx collaboration, a partnership between NMRC and the University of Oxford funded by PATH-MVI and the United States Agency for International Development (USAID).

i. Demonstrated a new immune evasion mechanism in mice by which regulatory CD4+Foxp3+ T cells inhibit the ability of B cells to secrete antibodies and clear parasites from the blood. The studies highlight the need of generating vaccine candidates able to down-regulate and/or eliminate regulatory T cells in order to elicit protective immunity (Wijayalath, Danner et al. 2013).

j. Finalized a CRADA with the Childrens Hospital, University of Pennsylvania (b) (6) to generate Adeno-Associated-Viruses (AAV) encoding for neutralizing human monoclonal antibodies that will be tested in Aotus monkeys at the Naval Medical Research Unit No. 6 (NAMRU-6) in Lima, Perú for protection against P. falciparum malaria. The approach could lead to the development of new prophylactic and therapeutic intervention strategies against human malaria.

k. Demonstrated that humanized DRAG mice develop a functional human-immune-system and sustain the complete life cycle (liver-to-blood-to-mosquito) of *P. falciparum* upon intravenous challenge with *P. falciparum* sporozoites or bites of infected mosquitoes (Wijayalath, Majji et al. 2014). The humanized DRAG mice are protected by immunization with radiation-attenuated P. falciparum sporozoites and the level of protection is associated with the number of radiation-attenuated sporozoites used for immunization. The immunized mice elicited anti-Pfspz antibodies and their splenic CD4+ and CD8+ T cells secreted IFN-γ upon in vitro stimulation with Pfspz (Wijayalath, Danner et al. 2013). Our collaborators at the US Military HIV Research Program/WRAIR demonstrated that humanized DRAG mice reconstitute GALT (gut associated lymphoid tissues) and FTRALT (female tract associated lymphoid tissue) and

sustain HIV infection upon intravaginal challenge. Thus humanized DRAG mice represent a unique pre-clinical model for human malaria and HIV.

l. Developed a chimeric *P.berghei* containing the *P.vivax* repeat region that can serve as an in vivo model to downselect new *P. vivax* CSP-based vaccine candidates (Espinosa, Yadava et al. 2013).

m. Demonstrated that a soluble,near full-length PfCSP vaccine antigen induced cytophillic IgG2c antibodies that were the best correlate of CSP-based protection in in mice using trangenic P. berghei parasites that contain full length PfCSP (Schwenk, DeBot et al. 2014) . When the TLR4 agonist containing adjuvant GLA/SE was compared with TLR7/8 agonist containing adjuvants from 3M Corporation, GLA/SE induced a balanced IgG1:IgG2 response and was down-selected for testing in Rhesus monkeys. This study (Schwenk, DeBot et al. 2014) described the GMP manufacture of this CSP vaccine and described the immune correlates being considered for down-selection of PfCSP based vaccines in the mouse model.

n. Completed analysis of antibody responses to a GLA-SE formulated Pf-SAPN in rhesus monkeys. Results showed antibodies with protective ability were induced.

o. We evaluated the efficacy of the gorilla adenovirus vector,GC46, and Ad5 vectors expressing PyCSP, PyAMA1 and PyTRAP in the *P. yoelii*/mouse model. A DNA-Ad5 PyCSP vaccine, a DNA-Ad5 trivalent vaccine, a DNA-GC46 PyCSP vaccine and a DNA-GC46 trivalent vaccine protected 21%, 50%, 93%, and 78% of mice against a P. yoelii challenge, respectively. Eighteen weeks after the first challenge, the protected mice were re-challenged. None of the mice immunized with the DNA-Ad5 PyCSP vaccine, the DNA-Ad5 trivalent vaccine or the DNA-GC46 PyCSP vaccine were protected. However, 18% of the mice immunized with the DNA-GC46 trivalent vaccine were protected. These results indicate that the DNA-GC46 trivalent vaccine was still efficacious 5 months after the GC46 boost and suggest that the incorporation of multiple antigens can enhance the longevity of protection induced by a DNA-GC46 vaccine.

p. Continued collaboration with the Oregon Health and Sciences University to test the efficacy of replication competent rhesus cytomegalovirus (CMV) vectors expressing *P. knowlesi* antigens, (based on their successful induction of protection to SIV), as part of a multi-year MIDRP proposal. Preliminary results suggested that the CMV vectors induced potent immune responses.

q. WRAIR's pre-erythrocytic stage candidate, PfCelTOS(FMP012)/AS01B is currently in a first-in-human, clinical study with GSK's potent adjuvant system. Successful evaluation of this vaccine in the clinic will advance this candidate to further evaluations in combination with RTS,S/AS01B that is the only malaria vaccine shown to be safe in thousands of infants and children and adults. This work is highly leveraged and is a collaboration between these entities WRAIR/GSK/USAID/USAMMDA.

r. Continued to refine and optimize administration of RTS,S to achieve greater efficacy and longevity of protection. A 0 month, 1 month, 7 month schedule has achieved >80% protection to date.

s. NMRC and WRAIR in partnership with Sanaria are conducting a phase1 clinical trial with challenge testing the safety, tolerability, immunogenicity and efficacy of the PfSPZ Vaccine (cryopreserved radiation-attenuated sporozoites) administered by intravenous route. The vaccine was safe, very well tolerated; protection against homologous and heterologous strains of P. falciparum is being evaluated at 3 weeks and 24 weeks after the final immunization. This work has led to the submission of an FY15 MIDRP proposal to examine heterologous

protection, duration of protection, and an alternate route of immunization in a clinical trial leveraged with Joint Warfighter Medical Research Program funding.

t. Participated in a pre-IND meeting with the Food and Drug Administration for the NavOx clinical trial, which is designed to compare the safety, immunogenicity, and protective efficacy of DNA/ChAd63 and ChAd63/MVA regimens using PfCSP, PfTRAP and PfAMA1 in collaboration with University of Oxford with funding from PATH-MVI and the United States Agency for International Development (USAID).

u. Completed and published ananalysis of the immune response to DNA/Adenovirusprime- boost NMRC-M3V-D/Ad-PfCA and the adenovirus CSP alone NMRC-NV-D/Ad-PfC vaccines (Sedegah, Hollingdale et al. 2014)

v. A new batch of Pf3D7 parasites (300 vials) was manufactured under GMP conditions to support future CHMIs. Mosquito feeding experiments show the new GMP lot produces similar mosquito salivary gland infections as the previous lot.

w. Program Area F, Malaria Vaccine Research published 26 manuscripts in peer-reviewed journals (See Appendix A, Program Area F, Malaria Vaccine Publications, FY2014 Historical Report).

9) Within the Antiparasitic Drug Program, MIDRP researchers:

a. The triazine program was nominated a preliminary candidate, WR 909388.

b. Milestone: Full Patent Application (034047.059WO1) was submitted on 13MAR2014. Published: PCT Int. Appl. (2014), WO 2014159993 A1.

c. From triazine program area research initiative, a preliminary pre-clinical candidate has been selected from three analogs (WR647, WR388, and WR390). WR388 has the highest Rhesus plasma Cmax (903 ng/mL, compared to 623 ng/mL (WR390), and 662 ng/ml (WR647)); greatest Rhesus exposure (42 ug*hr/mL, compared to 31 ug*hr/mL for both WR390 and WR647) and demonstrated the lowest parasite count on Day 14 (77K) compared to WR647 (167K) and WR390 (130K). Pre-clinical candidate WR388 will next be assessed for genotoxicity (Ames test), general in vivo toxicity (IVT) in 14-day and 28-day rodent testing, CYP inhibition and in vivo micronucleus (if required).

d. Through collaborative work with the Malaria Vaccine Branch, Experimental Therapeutics discovered that primaquine, an 8-aminoquinoline (8AQ), requires metabolic activation by cytochrome P450 2D6 (CYP2D6) in order to be efficacious against relapsing malaria from *P. vivax* in humans (Bennett, et al.,2013). This CYP2D activation has also been shown to be necessary for PQ efficacy against the liver stage of *P. berghei* in mice (Pybus, et al., 2013) by assessing liver stage efficacy in CYP2D knockout mice. In addition, our team has demonstrated that other 8AQ compounds in late stage studies such as tafenoquine (Phase III) and NPC-1161B (pre-IND) also require CYP2D activation for liver stage efficacy.(Marcsisin, et al.,2014)

e. The pyrimidinylguanidine (PG) series transitioned from hit to lead to lead optimization in 2014. This program is leveraging CDMRP funding (FY12 $: CRADA with Geneva in place. Funding schedule: Year One- EFT done quarterly starting 9/30/13: $301,712.00; Year Two: $287,244.00; Year 3: $293,087.00. Additionally the program received $460K in UFR MIDRP FY13 funding. This UFR funding was used to help purchase a replacement NMR for analog characterization and an IVIS for in vivo testing.

f. During the reporting period, medicinal chemistry efforts were focused mainly on design, synthesis and assessment of phenyl derivatives [R1= Ph. 4-Cl-Ph, or 3-pyridyl] of 4-amidinoquinoline and 9-amidinobenzonaphthyridine (ABN) to research for compounds with optimal efficacy and better therapeutic index.

g. The overall strategy of the quinoline ester project has been to design and synthesize more soluble analogs of decoquinate (DQ) to improve the in vivo efficacy. Of the 39 new designed analogs that were assessed in the solubility assay: 9 compounds were no better than DQ (solubility <10 uM); 3 were between 10-200uM; 25 analogs were between 200-400uM and 2 >400uM.

h. The Next Generation Malaria Drugs (NGMD) IPT working group selected a prime candidate and two backup compounds for further development in Oct 2014. A proposal to develop the triazines from selection through preclinical development, Phase 0 microdose pharmacokinetic studies, a Phase 1 toxicity and pharmacokinetic study, and a Phase 2A efficacy human challenge malaria trial was successfully submitted through the Joint Warfighter Medical Research Program. Funding for this program will arrive in late spring 2015, and early preclinical testing will be completed using MIDRP funds.

i. The Next Generation Malaria Drugs IPT has been established and is currently working on advancing a triazine developmental candidate. Part of this IPTs charter is to conduct an analysis of alternatives against compounds that are similar to the triazine class with published Phase I data and Phase IIa trial data. There are a number of other drugs on market that may be possible alternatives to tafenoquine, which is USAMMDA¿s late developmental candidate. The drugs currently identified which have potential for weekly prophylaxis include chloroquine-azithromycin, dihydroartemisinin-piperaquine, and a dihydroorotate dehydrogenase inhibitor, DSM 265. . Legal agreements are in place with Pfizer and Sigma Tau, and ET will be participating in a Phase 2A challenge study with Seattle Biomed for DSM 265 A letter of support is in place with Pfizer.

j. Chloroquine-azithromycin has completed multicenter efficacy treatment trials in adults and pediatric patients. These and several pharmacokinetic and safety trials have been conducted under US FDA IND. Pfizer is currently collaborating with Medicines for Malaria Venture for a pregnancy indication. We have submitted a Peer Reviewed Medical Research Program proposal for a Phase 2A challenge study for chloroquine-azithromycin.

k. DHA-piperaquine recently received EU regulatory approval for malaria treatment. The US subsidiary is currently conducting a gap analysis for US FDA approval for the treatment indication. The company may be interested in collaborating with the US Army for a prophylaxis indication. One downside to this combination is the recent findings of widespread resistance to DHA-piperaquine in the border region between Cambodia and Thailand.

l. As Leishmania research has moved from active status to tech base status, current efforts for leishmania research are focused on minimal research to maintain existing competencies for leishmania in vitro and in vivo assays. Two partner proposals involving Experimental Therapeutics were accepted by the Peer Reviewed Congressionally Directed Medical Research Program in FY14. One proposal is a partner proposal with (b) (6) from OSU, and the second proposal is a partner project with Anacor Pharmaceuticals. Work begins on these projects in early FY15.

m. Program Area Q, Anti-parasitic Drugs published 27 manuscripts in peer-reviewed journals (See Appendix B, Program Area Q, Anti-parasitic Drugs Publications, FY2014 Historical Report).

10) Within the Diarrheal Diseases Vaccine Research Program, MIDRP (WRAIR/NMRC) researchers:
    a. Under NIAID support, two candidate second‑generation *S. sonnei* live, attenuated vaccines, WRSs2 and WRSs3 are being tested in a Phase 1 randomized, blinded, ascending dose clinical trial. The clinical stage of this trial was completed in Nov 2014 at the NIAID Vaccine Test and Evaluation Unit (VTEU) in Cincinnati.

    b. Two live attenuated *S. flexneri 2a* vaccine candidates have been manufactured under cGMP conditions, and *S. flexneri 3a* vaccines candidates have been developed, in support of the end goal of a trivalent *S. sonnei*, *flexneri 2a & 3a* live vaccine formulation.

    c. A pilot cGMP lot of the artificial *S. flexneri 2a* Invaplex (Invaplex$_{AR}$) vaccine has been manufactured, released and entered into a stability testing program. A pre‑IND meeting was held between WRAIR/NMRC investigators and the FDA in Aug 2014 and an IND submission is in the final stages of preparation for submission to the FDA. A Phase 1 clinical trial will begin in May 2015 in which Invaplex$_{AR}$ will be administered intranasally (IN) in escalating doses.

    d. In Jul 2014, a Phase 2b controlled clinical trial was completed, revealing preliminary evidence that ID vaccination with dscCfaE adhesin plus the LTR192G adjuvant confers protection against wild type CFA/I‑ETEC wild type challenge. In one of the two serial cohorts evaluated in the trial, the vaccine conferred 83% protective efficacy (p=0.015) against subsequent ETEC challenge, while in a second cohort the naïve control group failed to respond to challenge as anticipated, clouding the interpretation of results. This trial represents the culmination of a series of three early phase clinical trials that were initiated in 2011 testing the safety, immunogenicity and preliminary efficacy of prototype CfaE vaccines, and is serving as the basis for planning subsequent clinical evaluation of an ETEC adhesin‑based vaccine.

    e. Through an ongoing collaboration with Di Xia's structural biology laboratory at NCI, the CFA/I fimbria has been used as a model to elucidate the atomic structure of its component subunits and the structural basis of Class 5 fimbrial biogenesis.

    f. The major accomplishment of the *Campylobacter* research group in FY14 was the initiation of the first‑in‑human Phase 1 clinical trial of a monovalent capsular polysaccharide conjugate vaccine based on the HS23/36 capsule type. The clinical phase of this trial was completed at the end of Oct 2014, with data entry and immunology testing in progress at the time of this writing.

    g. The multiplex PCR capsule typing system for *Campylobacter* has been expanded from 14 capsule types to 35 capsule types that cover all 47 *C. jejuni* Penner serotypes. This system has been deployed to several overseas labs, and a provisional list of prevalent CPS types has been obtained from these data. Conversion to a more user‑friendly nested real time PCR method is also underway.

    h. Program Area D, Diarrhea Vaccine Program, published 4 abstracts, presented 2 talks and published 24 manuscripts in peer-reviewed journals (Appendix C, Program Area D, Diarrheal Vaccine Program Publications, FY2014 Historical Report).

11) Within the Flavivirus Vaccine Research Program, MIDRP researchers:
    a. WRAIR filed and IND for Heterologous Prime Boost. First in man trial start 8 Dec 2014. This clinical trial makes use of tetravalent live-attenuated or killed vaccines in a prime boost format. Human volunteers will be primed with either live or killed vaccines and boosted with the alternate produce at either day 28 or 180. Sera from these individuals will be tested for antibodies directed to a predicted protective virion quaternary epitope and to assay cellular

immune responses among peripheral blood mononuclear cells against predicted dengue virus T cell epitopes.

b. WRAIR investigators completed pre-clinical characterization of a GMP manufactured Dengue 1 strain for human infection model. Now qualified and validated, this first of four dengue test challenge strains was presented to Food and Drug Administration (FDA) by WRAIR/USAMMDA investigators as part of an IND meeting with FDA for the dengue 1 human infection model. A follow-on clinical trial briefing to the Principal Assistant for Acquisition (PAA) and Commanding General (CG) obtained final approval for execution of initial safety studies of attenuated dengue virus strains in humans with an anticipated study enrollment/initiation in Apr 2015. This effort consisting of collaborations among the Army, Navy and SUNY collaborators will utilize this qualified Dengue 1 challenge strain administered to human volunteers to determine how it mimics natural dengue infection in a safe controlled environment.

c. WRAIR continues successful collaboration with GSK to develop tetravalent purified inactive vaccine completing DPIV-001 in the US and in long term follow- up with DPIV-002 in Puerto Rico both trials showed a safe vaccine immunogenic vaccine in naïve and primed subjects. A phase 2 clinical trial is anticipated to assess protective efficacy of this vaccine in endemic regions in 2018.

d. The integrated Product Team IPT consisting of joint army and navy investigators down selected vaccine candidates eliminating a DNA based vaccine due to poor humoral immune responses and later initiated a CRADA with Takeda, Inc. to participate in its upcoming phase 2-3 dengue vaccine trail utilizing its chimeric dengue strain 2 chimeric construct engineered to contain epitopes from all 4 dengue strains.

e. AFRIMS continues to provide two sites for Sanofi Pasteur's Phase 3 clinical trial. Additionally, Navy efforts in the Philippines provided for a joint army navy contribution to this first phase 3 dengue vaccine clinical trial in collaboration with Sanofi-pasteur "The World's First, Large-Scale Dengue Vaccine Efficacy Study Successfully Achieved Its Primary Clinical Endpoint" (CYD14). 56% reduction of dengue disease cases, >10,000 volunteers from Asia. This initial trial also achieved >80% reduction in hospitalized cases and >67% reduction in dengue related hospitalizations. Discovery level efforts continue at AFRIMS and in the Philippines to assess cell mediated and humoral immune responses in study participants to monitor long term impact of the vaccine in Asia.

f. Program Area S, Flavivirus Vaccine Research Program published 32 manuscripts in peer-reviewed journals (Appendix D, Program Area S, Flavivirus Vaccine Research Program Publications, FY2014 Historical Report).

12) Within the Lethal Virus Countermeasures, MIDRP researchers:

a. Optimized M gene-based DNA vaccines against Choclo virus (hantavirus from Panama) and was constructed in FY13. This Choclo plasmid, and a Seoul M gene based plasmid, were used to produce neutralizing antibody controls in rabbits (T0138_14_RD).

b. Several animal experiments were performed using South American Arenavirus DNA vaccine technology. The findings from those experiments include: cocktails of polyclonal anti-JUNV, MACV, GTOV antibodies produced using DNA vaccines protected guinea pigs against lethal infection with JUNV or GTOV. Our strain of MACV was not lethal in guinea pigs; but the cocktail prevented infection with MACV (significant difference in neutralizing antibody titers after challenge, p.0006) (T0138_14_RD).

c. Anti-arenavirus neutralizing antibodies produced in geese DID NOT protect guinea pigs against JUNV, althought the time-to-death was delayed. This is consistent with reports in the literature that the Fc is required for antibody-mediated protection against JUNV (T0138_14_RD).

d. Additional CCHF DNA vaccine constructs were tested in hamsters in FY14; however, immunogenicity to-be-determined (T0134_14_RD).

e. An ID95 experiment was used to determine dose of CCHFV to be used in hamster infection model (T0134_14_RD).

f. Manuscripts and presentations: Three peer-reviewed publications attributed to Program Area T, including an important paper published in Science Translational Medicine demonstrating transchromosomal cows can be used to produce anti-viral polyclonal antibodies that are capable of protecting in animal models. The Kwilas paper demonstrated that PharmaJet disposable syringe jet injection is more effective than needle at delivering a DNA vaccine to nonhuman primates. Also, we reported a new model for hantavirus disease caused by Sin Nombre virus (this was the first animal model of hantavirus disease caused by Sin Nombre virus). We also had another patent issued (patent has same name as previously issued patent but it coverers additional claims). Lastly, we initiated the HFRS DNA vaccine Phase 2a clinical trial at WRAIR.

   i. Hooper JW, R. L. Brocato, S. A. Kwilas, CD Hammerbeck, MD Josleyn, M Royals, J Ballantyne, H Wu, J Jiao, H Matsushita, and E. J. Sullivan. DNA vaccine-derived human IgG produced in transchromosomal bovines protect in lethal models of hantavirus pulmonary syndrome. Sci Transl Med. 2014 Nov 26;6(264):264ra162. doi: 10.1126/scitranslmed.3010082
   ii. Kwilas S, Kishimori J, Josleyn M, Jerke K, Ballantyne J, Royals M, Hooper JW (2014).A Hantavirus Pulmonary Syndrome (HPS) DNA Vaccine Delivered using a Spring-Powered Jet Injector Elicits a Potent Neutralizing Antibody Response in Rabbits and Nonhuman Primates. Curr Gene Ther. Vol. 14, No. 3, 2014.
   iii. Brocato R, Hammerbeck CD, Bell TM, Wells JB, Queen LA, and JW Hooper (2014). A lethal disease model for hantavirus pulmonary syndrome in immunosuppressed Syrian hamsters infected with Sin Nombre virus. J Virol. 88:811-9.
   iv. Hooper, J. W. Title: Puumala Virus Full-Length M Segment-Based DNA Vaccine. United States Patent Number 8852598. Issued: Oct 7, 2014.

13) Within the US Military HIV Research Program (USMHRP) researchers:

a. MHRP, a Clinical Trials Unit for NIH HIV/AIDS Clinical Trials Networks, was selected to participate in follow-up vaccine studies related to RV144 in Mozambique and Tanzania. These trials will begin in 2015.

b. Johnson & Johnson has selected MUWRP in Uganda as a site for the planned HIV-V-A004 HIV Vaccine trial. A004 is a phase II study of an HIV candidate vaccine for prevention using Ad26 prime with MVA and protein boost. A0004 is the critical path study to down-select for a final regimen to advance to efficacy testing. In addition to contributing sites and collaboratively designing the study and development plans, MHRP provides the MVA to be tested in A004.

c. MHRP's large, long-term cohort study at multiple African sites called the African Cohort Study (AFRICOS) has enrolled 1,200 volunteers. This study is evaluating HIV prevention, care and treatment services it supports through local facilities, funded by the U.S. President's Emergency Plan for AIDS Relief (PEPFAR). A critical component of the study is the collection

of data regarding co-infections such as malaria and tuberculosis. TB/HIV co-infection rates are especially high in Kenya and Tanzania, two countries where MHRP conducts research with local partners.

d. MHRP began a new cohort study, RV363, to assess the incidence of HIV and the willingness of adults to participate in future HIV vaccine trials in Maputo Mozambique.

e. MHRP began a new cohort study (TRUST study) RV368 in high-risk populations in Nigeria in collaboration with the Institute of Human Virology (IHV) and Johns Hopkins University.

f. Two studies in the 19 March 2014 issue of *Science Translational Medicine* shed new light on the antibodies that appear to have played a role in decreasing the risk of HIV infection in the RV144 HIV vaccine trial. The results provide a better understanding of the immune response a vaccine may need to elicit in order to provide protection from HIV.

g. In a study published October 2013 in the journal *Cell*, a scientific team has shown that bioinformatically optimized HIV vaccine antigens known as “mosaic” antigens might be useful in the design of a global HIV vaccine.

h. A research team led by investigators at Beth Israel Deaconess Medical Center (BIDMC) in collaboration with MHRP demonstrated that the viral reservoir is established extremely early after simian immunodeficiency virus (SIV) infection of rhesus monkeys and before the virus can be detected in the blood. The findings appeared online on July 20 in the journal *Nature*.

i. At the HIV Research for Prevention Conference (R4P) in 2014, MHRP researchers gave nine oral presentations and eight poster presentations, in addition to two pre-conference symposium presentations. Research associated with the RV144 trial dominated the conference, and results were presented on the RV144 vaccine regimen safety in a trial in South Africa which showed it was safe and immunogenic.

j. MHRP had a major presence at the annual Conference on Retroviruses and Opportunistic Infections (CROI) in March, with ten posters and four oral presentations.

k. Developed a promising next-generation MVA vaccine in collaboration with the National Institutes of Allergy and Infectious Diseases (NIAID) Laboratory of Viral Diseases. It is being testing in combination with several vaccine candidates:

l. Demonstrated (the scientific team including MHRP researchers) that bioinformatically optimized HIV vaccine antigens known as “mosaic” antigens designed by the Los Alamos National Laboratory and Harvard University might be useful in the design of a global HIV vaccine. This very promising candidate, along with a novel, trimeric HIV envelope protein developed by Harvard, will enter clinical studies later this year with funding from NIH. Collaborators include Beth Israel Deaconess Medical Center, Harvard Medical School, Los Alamos National Laboratory, the Laboratory of Viral Diseases at NIAID and Crucell; published OCT 2013 in the journal *Cell*.

m. Continued in Uganda, Kenya, Tanzania and Thailand with a purpose of characterizing recruitment, retention, HIV prevalence, HIV incidence and biological characteristics of acute HIV infection in high-risk volunteers. RV217 has many unique elements including the acquisition of samples prior to HIV infection, the potential to acquire samples during the eclipse phase of infection prior to detectable HIV nucleic acid but after actual infection has occurred, and the collection of samples prior to peak viremia and the advent of antibody responses. The success of the study in collecting these unique samples has attracted world-

renowned scientists to work as collaborators on the analysis of samples. The first laboratory meeting was held in JAN 2014, and a manuscript is under development.

n. Identified the primary HIV infection attribution category in the Army for the first time since repeal of Don't Ask Don't Tell, which defines a very specific population most at risk for HIV that can now be provided with targeted preventive intervention activities.

o. Conducted medical economic analysis of a MHRP Hepatitis C infection (HCV) seroprevalence study of more than 17,000 recently deployed US military personnel which demonstrated that HCV screening of all applicants for military service will result in a net cost savings to the DoD in treatment cost avoided.

p. Tasked with conducting HIV DA Force Test Mission, May 2014.

q. MHRP investigators completed all phases of data collection for a sexual behavior and sexually transmitted infection risk survey of U.S. Navy personnel. The deployment phase of the study included data collection while underway and the survey included more than 2,000 Sailors on 11 U.S. warships. These data will generate knowledge products that identify specific targets for preventive intervention and will inform policy force health policy development, and adaptation of existing evidence-based best practices preventive interventions for use in U.S. military personnel.

r. MHRP's Department of Epidemiology & Threat Assessment and study team members from Fort Carson completed adaptation of existing evidence based HIV/STI interventions for use in military Service member and beneficiary populations. Evaluation of these intervention knowledge products was initiated in a focus group setting involving Soldier study volunteers at Fort Carson.

s. HIV Diagnostic and Reference Laboratory (HDRL) continued to conduct more than 1 million HIV-1 screening tests per year from personnel within the Army's active, reserve, and National Guard units, and from individuals applying for Army service.

t. US Military HIV Research Program (USMHRP) published 57 manuscripts in peer-reviewed journals (Appendix E, US Military HIV Research Program (USMHRP) publications, FY2014 Historical Report).

14) Within the Diagnostics Systems Division, MIDRP researchers:

a. Dengue

RHDD for NS1/IgM/IgG:

i. Following the RHDD IPT's recommendation for the prime vendor contract strategy to identify the best dengue RHDD alternative.
ii. Supported the development of Market Research, Analysis of Alternatives, and other briefing documents required for approval of this contract based acquisition strategy.
iii. An RFP is being prepared and will be posted to identify commercial partners. The timeline was accelerated for RHDD with the solicitation to go out ASAP with a Milestone A this summer, and ideally contract award in the fall.
iv. Received approval for the human use protocol covering all DoD sites for this study, so that following source selection and contract award, existing samples may be considered for expediting clinical evaluation of the new dengue rapid diagnostic device.

b. Rickettsioses

RHDD for scrub typhus IgM/IgG:

i. Established capability of using a 4-antigen-based IFA as the gold standard at NMRC.

ii. A pilot clinical study is planned to further evaluate an InBios prototype rapid test.
iii. Seeking commitment from InBios to fund the clinical study for the FDA 510(k) clearance.

c. Leptospirosis
RHDD for IgM/IgG:
i. The performance of 3 recombinant antigens was evaluated in ELISA individually. The combined ELISA results for IgM and IgG of 3 antigens is close to 90% based on the MAT.
ii. Further improvement will be needed to include additional antigens.

d. Reagent repository
i. Leptospirosis and rickettsioses: The acquisition of well characterized leptospirosis patient sera has greatly expanded the panel of clinical samples to be used for the evaluation of rapid tests. Polyclonal antibodies specific for typhus group rickettsiae have been produced. Modification of rickettsial recombinant antigens has proved to be essential for improving the performance of these recombinant antigens in serological assays.

e. Malaria
i. Portable cartridge reader: A sole source justification for the contract with MBio delayed the commencement. The goal is to develop a low cost, multi-analyte diagnostic device for malaria with enhanced sensitivity, quantitation capabilities, and automated data capture and transmission.
ii. Thermostable controls for RDTs: Encountered 6 months delay in obtaining malaria RDTs that are not licensed for sale in the US. Accessory reagents and incubators were procured for control preparation.
iii. LAMP for dengue, malaria and chikungunya: Optimized all wet assays except for dengue which ultimately failed. Primers for dengue are being redesigned. Freeze-dried assays using a proprietary freeze drying reagent provided by BioFire resulted one log loss of sensitivity. Working with PATH to use their new electricity free heating device along with primers and homebrewed detection dyes to bring the device to the field.

f. Diarrheal diseases
i. Comprehensive Dx: Initiated discussion with InBios for them to restart production of the prototype ICTs for various bacterial, viral and protozoan enteric pathogens. These prototype ICTs were developed under a previous SBIR contract and were partially validated.
ii. Once the ICTs have been received, PI will conduct in-house, independent evaluation of *Shigella Detect* prototypes using archived frozen stool samples from non-human primates infected with *Shigella.*

g. Manuscripts and presentations:
i. Program Area L, Diagnostic Systems for Infectious Diseases published 11 manuscripts in peer-reviewed journals and 20 abstracts (Appendix F, Program Area L, Diagnostic Systems Division Publications, FY2014 Historical Report).

h. Patents awarded:
i. US Patent 8685649, "RT-LAMP assay for the detection of pan-serotype dengue virus," Dauner A, Pal S, Wu S-J. (04/01/2014).

15) Within the Insect Identification and Control Program, MIDRP researchers assisted with:
a. Completed the Chikungunya Arthropod Vector Rapid Detection Device development and laboratory evaluation, now commercially available for purchase to provide field surveillance capability of Chikungunya disease in mosquito vectors that informs vector control operations and reduces incidence of disease.

b. Proved efficacy of Bayothrin© as a toxicant/spatial repellent in bench top lab trials against *Aedes aegypti* and *Anopheles stephensi*, paving the way for future product development and discovery of effective spatial repellents for use against any insect or tick vector.
c. Field tested five different insect vector surveillance systems at sites in Peru, Ghana, Liberia, and Thailand to identify capability gaps and requirements for the DoD's next generation flying insect trap for use in arthropod vector surveillance programs.
d. Created the first WRBU taxonomic key App - "Malaria vectors of Central America" to help technicians easily identify important Anopheles mosquitoes in the field.
e. Patented the first Deployable Human Lure System to be used in the field to help attract important biting arthropod vectors to traps.

16) Within the Rickettsial Research Program, MIDRP researchers:
a. Maintenance of the 12 infected mite lines at AFRIMS Department of Entomology, Bangkok, Thailand continued this year. The maintenance and production of these mites are critical to the development of DoD preventive measures against the militarily important scrub typhus.
b. The continued development and characterization of the only chigger challenge model (murine and NHP) available in the world to assess efficacy of scrub typhus vaccine candidates is on schedule and is providing exciting and important results. A manuscript describing the adaptation of *Orientia tsutsugamushi* Lc-1 to CD-1 outbred mice fed upon by naturally infected *Leptotrombidium chiangraiensis* chiggers from the AFRIMS mite colony was published (Lurchachaiwong W *et al*., J Med Entomol 2014;51:658-60).
c. In addition, a paper describing various genotypes of *Orientia tsutsugamushi* infecting *Leptotrombidium* mites in the AFRIMS mite colony and relating these genotypes to those found in other mites and vertebrate hosts was published (Takhampunya et al Am J Trop Med Hyg 2014;90:139-46).
d. Program Area WJ, Rickettsial Diseases published 4 manuscripts in peer-reviewed journals:
ii. Faulde, M.K., L.M. Rueda, B.A. Kaireh. 2014. First record of the Asian malaria vector Anopheles stephensi and its possible role in resurgence of malaria in Djibouti, Horn of Africa (Diptera, Culicidae).
iii. <http://www.mosquitocatalog.org/files/pdfs/WR492.pdf> Acta Tropica 139: 39-43.
iv. Huang, Y.-M. and L.M. Rueda. 2014. A Pictorial Key to the Species of Aedes (Ochlerotatus and Coetzeemyia) in the Afrotropical Region (Diptera: Culicidae). <http://www.mosquitocatalog.org/files/pdfs/WR447.pdf> Zootaxa 3754 (5): 592-600.
v. Leveraging arthropod-borne disease surveillance assays for clinical diagnostic use. Melanson VR, Scheirer JL, Van de Wyngaerde MT, Bourzac K, Wu SJ, Kochel T, McAvin JC. Mil Med. 2014 Nov;179(11):1207-11. doi: 10.7205/MILMED-D-14-00019. PMID: 25373042 [PubMed - in process].

17) MIDPR **supports Stability Operations** through multiple facets of its program; specifically through the overseas laboratories and through the safety/efficacy clinical trials for its candidate vaccines. The primary mission of the OCONUS laboratories as a major asset to MIDRP; the mission and function involves establishing field sites to conduct seroincidence, seroprevalence and disease burden assessments for future vaccine clinical testing. They also aid in development of long-term data in stable populations in accordance with recently published guidelines for testing of vaccine in endemic regions.

Resource Management and Budget:

A. In FY14, the Military Infectious Diseases Research Program managed $65.0M in Army funding in support of the core infectious disease and the US Military HIV Research Program.

B. The HIV program received additional funds managed by USAMRMC including an Army Congressional plus up of $15.0M for HIV research and an additional $17.7M in funds from the NIAID DAIDS program to support a variety of HIV/AIDS related research and development.
C. The office budget of $2,888,335 (Army $2,141,204 and DHP- $747,131) funds primarily contract support for external peer review, the program management website, office GS and contract staff, and travel.
D. Department of Health program funding for FY14 was $13.6 million to support research in identified gaps.
E. Congressionally Directed Medical Research Program – The programmatic review for the FY14 Defense Health Program Defense Medical Research and Development Program (DMRDP) Applied Research Award (ARA) and Clinical Trial Award (CTA) proposals that have completed peer review was held 27-28 Feb 2014 at the Congressionally Directed Medical Research Programs (CDMRP), Fort Detrick, Maryland. The goal of the DMRDP is to advance the state of medical science in those areas of most pressing need and relevance to today's battlefield experience. Approximately $22.5M of the DMRDP FY14-16 appropriations is available for funding the two award categories. Seven (7) infectious disease projects were funded (5 ARA and 2 CTAs) for $13.7M; four (4) projects were on the alternate list. CDR C(b) (6) and CAPT (b) (6) served as a programmatic reviewers representing Military Infectious Disease Research Program/Joint Program Committee 2 (JPC2).
F. Joint Warfighter Medical Research Program – For FY13, JPC2 projects were awarded $15.3M for 6.3 (4 projects and 3 tails) and $0 for 6.4 funding. Only 50M was available in appropriations to the Research Area Directorates. For FY14, prior awards under Peer-Reviewed Medical Research Program (PRMRP) are now eligible for funding in addition to those projects that had previously been funded with JWMRP dollars. A FY14 Vision Setting Meeting for Military Infectious Disease Research Program (MIDRP) was held 31 Jan 2014 at Building 722, Fort Detrick, Maryland. The primary objective was to determine what pre-proposals MIDRP supports to be added to the final list that will be requested for full proposal submission. Importantly, the JWMRP received $100 million (M) in appropriations for FY14, a two fold increase from previous years of funding. On 07 Aug, the FY14 JWP 6.4 programmatic review was held; On 25 Aug FY14 JWP 6.3 programmatic review was held. On 15 Sep 2014, Defense Health Agency approved the recommended funding strategy established at the FY14 JWMRP program Review. MIDRP Staff were involved throughout the process from pulling eligible proposals from PRMRP, looking at progress reports, and prioritizing the proposals submitted for MIDPR. COL (b) (6) and CDR (b) (6) (Navy Service Representative) served on the panel reviews. JPC-2 captured $15.14M for 6.3 funding (6 projects) and $10.29M for 6.4 funding (2 projects).
G. Peer-Reviewed Medical Research Program (PRMRP) – MIDRP and Navy Service Representative, CDR (b) (6), served as primary/secondary reviewer on the Joint Programmatic Review Panel (JPRP) and on the steering committee for the Congressionally Directed Medical Research Programs (CDMRP) FY13 Programmatic Review and FY14 Vision Setting Meeting held 12-14 February 2014. CDMRP reached out to the Research Area Directorates/Joint Program committees to get the word out and ask to provide military relevant gaps/recommendations for the relevant topic areas for JPC2. The relevant areas for FY14 are DNA Vaccine Technology to produce protective antibodies, malaria, and respiratory diseases. In the FY14 CDMRP process, the JPRP was asked to review/provide feedback for the Program announcements for the Clinical Trial, Discovery, Investigator-Initiated Research (including the Partnership Statement), Technology/ Development mechanisms, new Focused Program Award and the FY14 Gap Areas. Importantly, the PRMRP received $200 million (M) in appropriations for FY14, a four-fold increase from previous years of funding. CAPT (b) (6) joined the JPRP in Mar 2014. On 14 Jul, the FY14 PRMRP Focused Program Award pre-app screening teleconference was held. On 29 Jul, the FY14 PRMRP Clinical Trials and Technology/Therapeutic Development Awards pre-application screening teleconference was held. 25 Aug, the FY14 PRMRP Investigator-Initiated Research Award pre-application screening teleconference was held.

Information Management:

A. In FY14 Army continued to evolve General Fund Enterprise Business System (GFEBS) to manage Army funding. Some basic functions implemented include PM work order execution, funds management, PM annual planning and management of external contract support. Some basic functions implemented include PM work order execution, funds management, purchase requisitioning and approval workflow, purchase orders and contracts, PM annual planning and management of external contract support. Most of personnel from MIDRP took the training with different level of access. All intramural laboratories still have not embraced GFEBS such as WRAIR, USAMMDA, and NAVY.

1) **The MIDRP process is now fully managed through MIDRP website located at https://midrp.amedd.army.mil.**

Operations:

N/A

Modernization:

N/A

Logistics:

N/A

Construction:

N/A

Health and Environment:

N/A

Other:

A. Many researchers at both WRAIR and NMRC contributed to a publication concerning the military's medical infectious diseases research program which will appeared in Military Medicine in FY15.

Appendices:

None

Appendix A. Program Area F, Malaria Vaccine Publications, FY2014 Historical Report

Bartholomew N. Ondigo, James S. Hodges, Kathleen F. Ireland, Ng'wena G. Magak, David E. Lanar, Sheetij Dutta, David L. Narum, Gregory S. Park, Ayub V. Ofulla, Chandy C. John. 2014. Estimation of recent and long-term malaria transmission in a population by antibody testing to multiple Plasmodium falciparum antigens. JID, 210, 1123-32.
Lanar DE. and Burkhard P. Attacking Malaria. March 2014. International Innovation. 129, 39-41. http://www.research-europe.com/magazine/ISSUE/129/index.html.

El Bissati K, Zhou Y, Dasgupta D, Cobb D, Dubey JP, Burkhard P, Lanar DE, and McLeod R. (2014) Effectiveness of a novel immunogenic nanoparticle platform for Toxoplasma peptide vaccine in HLA transgenic mice. Vaccine. 32(26); 3243-8.

Bergmann-Leitner ES, Leitner WW. Adjuvants in the driver's seat: how magnitude, type, fine specificity and longevity of immune responses are driven by distinct classes of immune potentiators. Vaccines, 2014, 2: 252-296.

Bergmann-Leitner ES, Li Q, Caridha D, O'Neal MT, Ockenhouse CF, Hickman M, Angov E. Protective immune mechanisms against pre-erythrocytic forms of Plasmodium berghei depend on the target antigen. Trials Vaccinol.2014 Vol 3: e 6-10

Brando C, Richardson JH, Murphy J, Ockenhouse CF, Kamau E. Phenotypic characterization of Plasmodium berghei responsive CD8+ T cells after immunization with live sporozoites under chloroquine cover. Malar J. 2014 Mar 12;13:92. doi: 10.1186/1475-2875-13-92. PMID: 24620841.

Harris KS, Adda CG, Khore M, Drew DR, Valentini-Gatt A, Fowkes FJ, Beeson JG, Dutta S, Anders RF, Foley M. Use of immunodampening to overcome diversity in the malarial vaccine candidate apical membrane antigen 1. Infect Immun. 2014 Nov;82(11):4707-17. doi: 10.1128/IAI.02061-14. Epub 2014 Aug 25.

Kamau E, Alemayehu S, Feghali KC, Komisar J, Regules J, Cowden J, Ockenhouse CF. Measurement of parasitological data by quantitative real-time PCR from controlled human malaria infection trials at the Walter Reed Army Institute of Research.Malar J. 2014 Jul 28;13:288. doi: 10.1186/1475-2875-13-288. PMID: 25066459

Kester KE, Gray Heppner D Jr, Moris P, Ofori-Anyinam O, Krzych U, Tornieporth N, McKinney D, Delchambre M, Ockenhouse CF, Voss G, Holland C, Beckey JP, Ballou WR, Cohen J; Sequential Phase 1 and Phase 2 randomized, controlled trials of the safety, immunogenicity and efficacy of combined pre-erythrocytic vaccine antigens RTS,S and TRAP formulated with AS02 Adjuvant System in healthy, malaria naïve adults. RTS,S/TRAP Group. Vaccine. 2014 Nov 20;32(49):6683-91. doi: 10.1016/ j.vaccine.2014.06.033. Epub 2014 Jun 18. PMID: 24950358.

Kusi KA, Bosomprah S, Dodoo D, Kyei-Baafour E, Dickson EK, Mensah D, Angov E, Dutta S, Sedegah M, Koram KA. Anti-sporozoite antibodies as alternative markers for malaria transmission intensity estimation. Malar J. 2014 Mar 17;13:103. doi: 10.1186/1475-2875-13-103.

Kumar, R, Angov, E, and Kumar, N. Potent malaria transmission blocking antibody responses elicited by Plasmodium falciparum Pfs25 expressed in E. coli after successful protein refolding. Infect. Immun. Jan. 2014.

Krzych U, Zarling S, Pichugin A. Memory T cells maintain protracted protection against malaria. Immunol Lett. 2014 Oct;161(2):189-95. doi: 10.1016/j.imlet.2014.03.011. Epub 2014 Apr 5. PMID: 24709142.

Laurens MB; Coulibaly D; Ouattara A; Kone AK; Guindo AB; Traore K; Traore I; Kouriba B; Diallo DA; Diarra I; Daou M; Dolo A; Tolo Y; Sissoko MS; Niangaly A; Sissoko M; Takala-Harrison S; Lyke KE; Wu Y; Blackwelder WC; Godeaux O; Vekemans J; Ballou WR; Cohen J; Dube T; Soisson L; Diggs C; House B; Bennett JW; Lanar DE;

Dutta S; Heppner DG; Doumbo OK; Plowe C.; Thera MA (2014) Extended safety, immunogenicity and efficacy of a blood-stage malaria vaccine in Malian children: 24-month follow-up of a randomized, blinded phase 2 trial. PLoS ONE. Vol 8 (11). Nov 18, 2014. e79323

Kusi KA, Bosomprah S, Dodoo D, Kyei-Baafour E, Dickson EK, Angov E, Dutta S, Sedegah M, Koram KA. Anti-sporozoite antibodies as alternative markers for malaria transmission intensity estimation. Malar J. 2014 Mar 17;13:103.

Murphy JR, Weiss WR, Fryauff D, Dowler M, Savransky T, Stoyanov C, Muratova O, Lambert L, Orr-Gonzalez S, Zeleski KL, Hinderer J, Fay MP, Joshi G, Gwadz RW, Richie TL, Villasante EF, Richardson JH, Duffy PE, Chen J. Using infective mosquitoes to challenge monkeys with Plasmodium knowlesi in malaria vaccine studies. Malar J. 2014 Jun 3;13:215. doi: 10.1186/1475-2875-13-215.

Ondigo BN, Hodges JS, Ireland KF, Magak NG, Lanar DE, Dutta S, Narum DL, Park GS, Ofulla AV, John CC. Estimation of recent and long-term malaria transmission in a population by antibody testing to multiple Plasmodium falciparum antigens. J Infect Dis. 2014 Oct 1;210(7):1123-32. doi: 10.1093/infdis/jiu225. Epub 2014 Apr 15.

Pow-Sang L, Majji S, Casares S, Brumeanu TD. Long-term silencing of autoimmune diabetes and improved life expectancy by a soluble, pHLA chimera in a newly humanized NOD.DR4.hB7.1 mouse. Hum Vaccin Immunother. 2014 Mar;10(3):693-9.

Quispe AM, Pozo E, Guerrero E, Durand S, Baldeviano GC, Edgel KA, Graf PC, Lescano AG. Plasmodium vivax hospitalizations in a monoendemic malaria region: severe vivax malaria? Am J Trop Med Hyg. 2014 Jul;91(1):11-7.

Sedegah M, Hollingdale MR, Farooq F, Ganeshan H, Belmonte M, Kim Y, Peters B, Sette A, Huang J, McGrath S, Abot E, Limbach K, Shi M, Soisson L, Diggs C, Chuang I, Tamminga C, Epstein JE, Villasante E, Richie TL. Sterile immunity to malaria after DNA prime/adenovirus boost immunization is associated with effector memory CD8+T cells targeting AMA1 class I epitopes. PLoS One. 2014 Sep 11;9(9):e106241.

Schwenk R, DeBot M, Porter M, Nikki J, Rein L, Spaccapelo R, Crisanti A, Wightman PD, Ockenhouse CF, Dutta S. IgG2 antibodies against a clinical grade Plasmodium falciparum CSP vaccine antigen associate with protection against transgenic sporozoite challenge in mice. PLoS One. 2014 Oct 24;9(10):e111020. doi: 10.1371/journal.pone.0111020. eCollection 2014.

Spring M, Polhemus M, Ockenhouse C. Controlled human malaria infection. J Infect Dis. 2014 Jun 15;209 Suppl 2:S40-5. doi: 10.1093/infdis/jiu063. PMID: 24872394

Talley AK, Healy SA, Finney OC, Murphy SC, Kublin J, Salas CJ, Lundebjerg S, Gilbert P, Van Voorhis WC, Whisler J, Wang R, Ockenhouse CF, Heppner DG, Kappe SH, Duffy PE. Safety and comparability of controlled human Plasmodium falciparum infection by mosquito bite in malaria-naïve subjects at a new facility for sporozoite challenge. PLoS One. 2014 Nov 18;9(11):e109654. doi: 10.1371/journal.pone.0109654.

Terheggen U, Drew DR, Hodder AN, Cross NJ, Mugyenyi CK, Barry AE, Anders RF, Dutta S, Osier F, Elliott SR, Senn N, Stanisic DI, Marsh K, Siba PM, Mueller I, Richards JS, Beeson JG. Limited antigenic diversity of Plasmodium falciparum apical membrane antigen 1 supports the development of effective multi-allele vaccines. BMC Med. 2014 Oct 16;12(1):183. [Epub ahead of print]

Wijayalath W, Danner R, Kleschencko Y, Majji S, Villasante EF, Richie TL, Brumeanu TD, David CS, Casares S. HLA class II (DR0401) molecules induce Foxp3+ Treg suppression of B cells in Py17XNL malaria. Infect Immun. 2014 Jan;82(1):286-97.

Wijayalath W, Majji S, Villasante EF, Brumeanu TD, Richie TL, Casares S. Humanized HLA-DR4.RagKO.IL2RgammacKO.NOD (DRAG) mice sustain the complex vertebrate life cycle of Plasmodium falciparum malaria. Malar J. 2014 Sep 30;13:386.

Wijayalath W, Majji S, Kleschenko Y, Brumeanu T-D, Villasante EF, Vasta G, Fernández-Robledo JA, Casares S. Humanized HLA-DR4 mice fed with the protozoan pathogen of oysters perkinsus marinus (dermo) do not develop noticeable pathology but elicit systemic immunity. PLoS One. 2014 Jan 31;9(1):e87435.

Yadava A, Hall CE, Sullivan JS, Nace D, Williams T,. Collins WE, Ockenhouse CF, and Barnwell JW. Protective Efficacy of a Plasmodium vivax Circumsporozoite Protein-Based Vaccine in Aotus nancymaae is Associated with Antibodies to the Repeat Region. PLoS Negl Trop Dis 8(10) e3268. doi10.1371. 2014.

Appendix B. Program Area Q, Anti-parasitic Drugs Publications, 2014 Historical Report

WRAIR, AFRIMS, USAMRU-K, 27 PUBS TOTAL

Causal prophylactic efficacy of primaquine, tafenoquine, and atovaquone-proguanil against Plasmodium cynomolgi in a rhesus monkey model.

DiTusa C, Kozar MP, Pybus B, Sousa J, Berman J, Gettayacamin M, Im-erbsin R, Tungtaeng A, Ohrt C. J Parasitol. 2014 Oct;100(5):671-3. doi: 10.1645/13-480.1. Epub 2014 Apr 29. PMID: 24780070

Efficacy of two versus three-day regimens of dihydroartemisinin-piperaquine for uncomplicated malaria in military personnel in northern Cambodia: an open-label randomized trial.

Lon C, Manning JE, Vanachayangkul P, So M, Sea D, Se Y, Gosi P, Lanteri C, Chaorattanakawee S, Sriwichai S, Chann S, Kuntawunginn W, Buathong N, Nou S, Walsh DS, Tyner SD, Juliano JJ, Lin J, Spring M, Bethell D, Kaewkungwal J, Tang D, Chuor CM, Satharath P, Saunders D. PLoS One. 2014 Mar 25;9(3):e93138. doi: 0.1371/journal.pone.0093138. eCollection 2014. PMID: 24667662

The role of submicroscopic parasitemia in malaria transmission: what is the evidence?

Lin JT, Saunders DL, Meshnick SR. Trends Parasitol. 2014 Apr;30(4):183-90. doi: 10.1016/j.pt.2014.02.004. Epub 2014 Mar 15. Review. PMID: 24642035

Blackwater fever in an uncomplicated Plasmodium falciparum patient treated with dihydroartemisinin-piperaquine.

Lon C, Spring M, Sok S, Chann S, Bun R, Ittiverakul M, Buathong N, Thay K, Kong N, You Y, Kuntawunginn W, Lanteri CA, Saunders DL. Malar J. 2014 Mar 14;13:96. doi: 10.1186/1475-2875-13-96. PMID: 24629047

Randomized, double-blind, placebo-controlled clinical trial of a two-day regimen of dihydroartemisinin-piperaquine for malaria prevention halted for concern over prolonged corrected QT interval.

Manning J, Vanachayangkul P, Lon C, Spring M, So M, Sea D, Se Y, Somethy S, Phann ST, Chann S, Sriwichai S, Buathong N, Kuntawunginn W, Mitprasat M, Siripokasupkul R, Teja-Isavadharm P, Soh E, Timmermans A, Lanteri C, Kaewkungwal J, Auayporn M, Tang D, Chour CM, Prom S, Haigney M, Cantilena L, Saunders D. Antimicrob Agents Chemother. 2014 Oct;58(10):6056-67. doi: 10.1128/AAC.02667-14. Epub 2014 Aug 4. PMID: 25092702

Dihydroartemisinin-piperaquine failure in Cambodia.

Saunders DL, Vanachayangkul P, Lon C; U.S. Army Military Malaria Research Program; National Center for Parasitology, Entomology, and Malaria Control (CNM); Royal Cambodian Armed Forces. N Engl J Med. 2014 Jul 31;371(5):484-5. doi: 10.1056/NEJMc1403007. No abstract available. PMID: 25075853

Ex vivo activity of endoperoxide antimalarials, including artemisone and arterolane, against multidrug-resistant Plasmodium falciparum isolates from Cambodia.

Lanteri CA, Chaorattanakawee S, Lon C, Saunders DL, Rutvisuttinunt W, Yingyuen K, Bathurst I, Ding XC, Tyner SD. Antimicrob Agents Chemother. 2014 Oct;58(10):5831-40. doi: 10.1128/AAC.02462-14. Epub 2014 Jul 21. PMID: 25049252

KAF156 is an antimalarial clinical candidate with potential for use in prophylaxis, treatment, and prevention of disease transmission.

Kuhen KL, Chatterjee AK, Rottmann M, Gagaring K, Borboa R, Buenviaje J, Chen Z, Francek C, Wu T, Nagle A, Barnes SW, Plouffe D, Lee MC, Fidock DA, Graumans W, van de Vegte-Bolmer M, van Gemert GJ, Wirjanata G, Sebayang B, Marfurt J, Russell B, Suwanarusk R, Price RN, Nosten F, Tungtaeng A, Gettayacamin M, Sattabongkot J, Taylor J, Walker JR, Tully D, Patra KP, Flannery EL, Vinetz JM, Renia L, Sauerwein RW, Winzeler EA, Glynne RJ, Diagana TT. Antimicrob Agents Chemother. 2014 Sep;58(9):5060-7. doi: 10.1128/AAC.02727-13. Epub 2014 Jun 9. PMID: 24913172

Nanoparticle formulations of decoquinate increase antimalarial efficacy against liver stage Plasmodium infections in mice.

Wang H, Li Q, Reyes S, Zhang J, Zeng Q, Zhang P, Xie L, Lee PJ, Roncal N, Melendez V, Hickman M, Kozar MP. Nanomedicine. 2014 Jan;10(1):57-65. doi: 10.1016/j.nano.2013.07.010. Epub 2013 Jul 25. PMID: 23891618

Plasmodium falciparum field isolates from areas of repeated emergence of drug resistant malaria show no evidence of hypermutator phenotype.

Brown TS, Jacob CG, Silva JC, Takala-Harrison S, Djimdé A, Dondorp AM, Fukuda M, Noedl H, Nyunt MM, Kyaw MP, Mayxay M, Hien TT, Plowe CV, Cummings MP. Infect Genet Evol. 2015 Mar;30:318-22. doi: 10.1016/j.meegid.2014.12.010. Epub 2014 Dec 13. PMID: 25514047

Fighting the good fight: the role of militaries in malaria elimination in Southeast Asia.

Manning JE, Satharath P, Gaywee J, Lopez MN, Lon C, Saunders DL. Trends Parasitol. 2014 Dec;30(12):571-81. doi: 10.1016/j.pt.2014.10.002. Epub 2014 Nov 5. Review. PMID: 25455566

Plasmodium falciparum field isolates from areas of repeated emergence of drug resistant malaria show no evidence of hypermutator phenotype.

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Appendix E. US Military HIV Research Program (USMHRP) Publications, FY2014 Historical Report

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Asmelash A, Zheng Y, Kaloustian KW, Shaffer D, Sawe F, Ogwu A, Salata R, Currier J, Hughes MD, Lockman S. Predictors of suboptimal CD4 response among women achieving virologic suppression in a randomized antiretroviral treatment trial, Africa. BMC Infect Dis. 2014 Jun 17;14:331. PubMed PMID: 24938526; PubMed Central PMCID: PMC4083139.

Ousman Jobe, Sodsai Tovanabutra, Phil Ehrenberg, Kultida Poltavee, Kristina K. Peachman, Agnes-Laurence Chenine, Robert McLinden, Rasmi Thomas, Jerome Kim, Nelson L. Michael, Carl R. Alving, and Mangala Rao. Siglec-1 on Macrophages is a Major Infectivity Receptor for HIV-1: Differential Effects of GM-CSF and M-CSF on HIV-1 Entry and Replication. AIDS Research and Human Retroviruses 29 (11) A83; 2013.

Kristina K. Peachman, Erik Billings, Morgane Rolland, Robert McLinden, Agnes-Laurence Chenine, Sodsai Tovanabutra, Jerome H. Kim, Nelson L. Michael, Carl R. Alving, and Mangala Rao. V2 Peptide Binding to HIV-1 Variants and Interaction of HIV-1 with α4β7 Integrin Receptor. AIDS Research and Human Retroviruses 29 (11) A54; 2013

B. **Publications under Review, Revision and Preparation**

Bonnie M. Slike, *Shelly J. Krebs, Pasiri Sithinamsuwan, Matthew Creegan, Somporn Tipsuk, James L.K. Fletcher, Nittaya Phanuphak, Linda Jagodzinski, Jerome H. KIM, Jintanat Ananworanich, Mary A.

Marovich and Victor G. Valcour, on behalf of the SEARCH 011 study team, “Sex differences in soluble markers vary before and after the initiation of antiretroviral therapy in chronically HIV infected individuals”, to be submitted to AIDS in Dec. 2014

Adoro S, Cubillos-Ruiz JR, Chen X, Deruaz M, Vrbanac VD, Song M, Park S, Murooka TT, Dudek TE, Luster AD, Tager AM, Streeck H, Bowman B, Walker BD, Kwon DS, Lazarevic V and Glimcher LH, “Coupling of microRNA-29 induction in CD4 T cells to early HIV-1 control by IL-21”, Nature Immunology – under review.

Johnson S, Eller M, Maloveste SM, Schultz BT, Lu R, Oster AF, Soghoian DZ, Laurence-Chenine A, Alter G,Dittmer U, Marovich M, Robb M, Michael N, Bolton D and Streeck H, “Cooperativity of HIV-specific cytolytic CD4 T cells and CD8 T cells in control of HIV viremia, PLoS Pathogens” –prep. Revisions.

Schultz BT, Oster AF, Pissani F, Teigler J, Kranias G, Alter G, Marovich M, Eller MA, Dittmer U, Robb M, Kim J, Michael N, Bolton D and Streeck H, “Peripheral T Follicular Helper Cells with Universal Helper Activity in HIV infection”, -in preparation.

Eller MA, Goonetilike N, Tassaneetrithep B, Eller LA, Costanzo MC, Johnson S, Betts MR, Krebs S, Slike B, Jagodzinski L, Peel S, Nitayaphan S, Rono K, Maganga L, Kibuuka H, Tovanabutra S, Rolland M, Marovich MA, Kim J, Michael NL, Robb ML and Streeck H, “Expansion of inefficient HIV-specific CD8 T cells during acute infection” in preparation.

Hu H, Eller MA, Zafar S, Zhou Y, Gu M, Wei Z, Currier JR, Marovich MA, Kibuuka HN, Bailer RT, Koup RA, Robb ML, Michael NL, Kim JH, Ratto-Kim S. Preferential infection of human Ad5-specific CD4 T cells by HIV in Ad5 naturally exposed and recombinant Ad5-HIV vaccinated individuals. Proc Natl Acad Sci U S A. 2014 Sep 16;111(37):13439-44.

Silvia Ratto-Kim, Mark S. de Souza, Jeffrey R. Currier, Nicos Karasavva, John Sidney, Morgane Rolland, Anais Valencia-Micolta, Sirinan Madnote, Alessandro Sette, Sorachai Nitayaphan, Punnee Pitisuttuthum, Jaranit Kaewkungwal, Supachai Rerks-Ngarm, Robert O’Connell, Nelson Michael, Merlin Robb, Mary Marovich, Jerome H. Kim. Identification of immunodominant CD4-restricted epitopes co-located with antibody binding sites in individuals vaccinated with ALVAC-HIV and AIDSVAX B/E. Submitted to PLOSone

Steers NJ, Peachman KK, Alving CR and Rao M. Isolation and Purification of Proteasomes from Primary Cells. Current Protocols in Immunology. 107:16.4.1–16.4.20. doi: 10.1002/0471142735.im1604s107 (in press).

Lindsay Wieczorek, Shelly J. Krebs, Vaniambadi Kalyanaraman, Stephen Whitney, Sodsai Tovanabutra, Carlos G. Moscoso, Eric Sanders-Buell, Constance Williams, Bonnie Slike, S. Munir Alam, Sebastian Molnar, Agnes-Laurence Chenine, Tina Tong, Edgar L. Hill, Hua-Xin Liao, Michael Hoelscher, Leonard Maboko, Susan Zolla-Pazner, Barton F. Haynes, Michael Pensiero, Francine McCutchan, R. Holland Cheng, Merlin L. Robb, Thomas VanCott, Nelson L. Michael, Mary A. Marovich, Carl R. Alving, Gary R. Matyas, Mangala Rao, and Victoria R. Polonis, “Comparable antigenicity and immunogenicity of oligomeric forms of a novel, acute HIV-1 subtype C gp145 envelope for use in preclinical and clinical vaccine research” submitted: Sept 2014, JVI

Shelly J. Krebs, Sandeep Narpala, Adam Wheatley, Bonnie M. Slike, Michael Eller, Silvia Ratto-Kim, Victoria R. Polonis, Jerome H. Kim, Merlin L. Robb, Mary A. Marovich, Richard A. Koup, Barney S. Graham, Nelson L. Michael and Adrian McDermott; “Comparative Analysis of Binding Antibody Responses elicited by a Cross-Section of Human HIV-1 Vaccine Clinical Trials” In current preparation

Beck Z, Matyas G, and Alving C: Detection of Liposomal Cholesterol and Monophosphoryl Lipid A by QS-21 Saponin and Limulus polyphemus Amebocyte Lysate. BBA, (2014) submitted.
Ousman Jobe, Hung Trinh, Gufoen Gao, Sodsai Tovanabutra, Phil Ehrenberg, Kristina K. Peachman, Wadad Alsalmi, Rasmi Thomas, Jerome Kim, Nelson Michael, Carl R. Alving, Venigalla B. Rao, Mangala Rao. The effect of GM-CSF and M-CSF on Siglec-1 expression, HIV-1 Entry, and Replication in monocyte derived macrophages: The Importance of HIV-1 envelope V2 region. Ready to be submitted.

Monica Vaccari, Shari N. Gordon, Slim Fourati, Luca Schifanella, Mark Cameron, Brandon F. Keele, Xiaoying Shen, Georgia D. Tomaras, Erik Billings, Mangala Rao, Namal P.M. Liyanage, Diego A.Vargas-Inchaustegui, Steve Whitney,Melvin N. Doster, Nicolo Binello, Poonam Pegu, David C. Montefiori, Kathryn Foulds, David S. Quinn, Mitzi Donaldson, Frank Liang, Karin Loré, Mario Roederer, Richard Koup, Adrian McDermott, Zhong-Min Ma, Christopher J. Miller, Tran B. Phan, Donald N. Forthal, Matthew Blackburn, Francesca Caccuri, Guido Ferrari8, Marjorie Robert-Guroff, Silvia Ratto-Kim, Jerome H. Kim, Nelson L. Michael, Sanjay Phogat, Susan W. Barnett, James Tartaglia, David Venzon, Donald M. Stablein, Rafick-Pierre Sekaly & Genoveffa Franchini. Adjuvant dependent mucosal V2 responses and RAS activation in vaccine induced protection from SIVmac251 acquisition.

Atef Allam, Sai Majji, Kristina Peachman , Linda Jagodzinski, Jiae Kim, Silvia Ratto-Kim, Wathsala Wijayalath, Jerome H. Kim, Nelson L. Michael, Carl R. Alving, Sofia Casares and Mangala Rao. Human follicular helper T cell subsets are enriched in mucosal tissues of humanized DRAG mice with variable permissiveness to HIV-1 infection.

Kristina K. Peachman, Nicos Karasavvas, Carl Alving, and Mangala Rao. Characterizing HIV-1 Variable Loop Peptide and Virion Interactions with α4β7 Integrin.

Mangala Rao, Sayali Onkar, Kristina Peachman, Victor Padilla-Sanchez, Ousman Jobe, Gary Matyas, Susan Zolla-Pazner, Timothy Cardozo, Abraham Pinter, Jerome Kim, Venigalla Rao, and Carl Alving. Potent V2-Specific Antibodies Induced in Humans Using Liposome-Encapsulated HIV-1 gp120 Recognize a Well-exposed V2 Epitope on Envelope Trimer.

Daniel Adams, Sodsai Tovanabutra, Anjali Kunz, Panita Pathipvanich, Kriengkrai Srithanaviboonchai, Abraham Pinter, Nelson Michael, Jerome Kim, Mangala Rao, and Merlin Robb. The Role of HIV-1 V2-specific Antibodies in Mother to Child Transmission.

C. **Oral presentations**

1. Courso Avancado de Patogeneses do HIV, Sao Paolo, Brazil, 04/2014

Hendrik Streeck, “T cell responses in HIV infection”,
2. CFAR HIV Elite Controllers Mini Symposium, Miami, USA, 04/2014

Hendrik Streeck, “Clues from Acute HIV Infection for T Cell Mediated Control”,

3. Infection& Immunology, Graduiertenkolleg, Mülheim an der Ruhr, Germany, 06/2014

Hendrik Streeck, “Multitasking of CD4 helper cells in HIV infection”,

4. University Hamburg-Eppendorf, Germany, 06/2014

Hendrik Streeck, “CD4 T cells in HIV infection: Targets, Helpers, Killers?”

5. Deutscher STI Kongress, Berlin, Germany, 06/2014

Hendrik Streeck, “Immunpathogenese der akuten HIV Erkrankung”,

6. Keystone Symposia HIV Vaccine, Banff, Canada, 03/2014

Jerome Kim, “RV144 and HIV Acquisition: Insights and New Questions,” Plenary Session

Susan Johnson, “Cooperativity of HIV-specific cytolytic CD4 and CD8 T cell responses

Rao, M., Onkar, S. Peachman, K., Padilla-Sanchez, P., Yamini, G., Jobe, O., Matyas, G., Zolla-Pazner, S., Cardozo, T., Pinter, A., Kim, J., Rao, V., Alving, C. Potent V2-Specific Antibodies Induced in Humans Using Liposome-Encapsulated HIV-1 gp120 Recognize a Well-exposed V2 Epitope on Envelope Trimer. Keystone Symposia, HIV Vaccines: Adaptive Immunity and Beyond, 9-14 March 2014, Fairmont Banff Springs, Banff, Alberta, Canada.

Monica Vaccari, Shari N. Gordon, Brandon F. Keele, Luca Schifanella, Xiaoying Shen, Georgia Tomaras, Erik billings, Mangala Rao, Diego Vargas-Inchaustegui, Namal Liynage, Melvin Doster, Poonam Pegu, David C. Montefiori, Kathryn Foulds, David S. Quinn, Mitzi Donaldson, Mario Roederer, Zhong-min Ma, Christopher Miller, Guido Ferrari, David Venzon, Don Stablien, Marjorie Robert Guroff, Silvia Ratto-Kim, Jerome H. Kim, Nelson L. Michael, Sanjay Phogat, Susan W. Barnett, James Tartaglia, Genoveffa Franchini. Modulation of the complex pathways as a biomarker of protection against HIV and as a means to improve vaccine efficacy. HIV Vaccines: Adaptive Immunity and Beyond. Keystone Symposia, Banff, Alberta, Canada March 9-14, 2014.

7. International Liposome Society, London, UK, 14-17 December 2013

Induction of V2-specific antibodies in humans vaccinated with liposome-encapsulated recombinant HIV-1 envelope protein and lipid A.

8. AIDS 2014, Melbourne, Australia, July 20-15, 2014

Jintanat Ananworanich, HIV Cure Research in resource limited Settings

Jintanat Ananworanich, HIV Persistence in Pediatric HIV Cure: Where do we go after the Mississippi baby?

9. ID Week 2014, Philadelphia, PA, October 8-12, 2013

Trevor Crowell, MD, Acute Retroviral Syndrome is Associated with Gut Mucosal CD4 Depletion, Inflammation and High Viral and Proviral Burden in Systemic and Tissue Compartments. October 10, 2014: 10:30 AM

D. **Poster Sessions**

1. Conference of Retroviral and Opportunisitic Infections (CROI 2014):

Sebastien M. Maloveste, Susan Johnson, Alexander Oster, Richard Lu, Franco Pissani, Mary Marovich, Diane L. Bolton, Hendrik Streeck, “Distinct Functional Properties of HIV-Specific Cytolytic CD4 T Cells Compared to Th1 or CD8 T Cells”

Franco Pissani, Sebastien Maloveste, Bruce Schultz, Michael Eller, Silvia Ratto-Kim, Mary Marovich, Merlin Robb, Jerome Kim, Nelson Michael, Hendrik Streeck, “Individual HIV-specific CD8 T cell responses mounted during acute HIV infection drive long-term control”

Streeck H, Routy JP, Little S, Jessen HK, Kelleher AD, Hecht FM, Sekaly RP, Rosenberg ES, Allen TM, Carrington M and Altfeld M, “Divergent HIV-specific CD4 T cell Response Profiles in HIV vaccine trials”

Mark M. Manak, Sheila Peel, Jennifer Malia, Ashley Shutt, Siriwat Akapirat, Tippawan Pankam, James Fletcher, Merlin Robb, Jerome Kim, Jintanat Ananworanich, Loss of HIV Serological Markers Following Early Treatment of Acute HIV Infection

Mark M. Manak, Holly Hack, Tracy Trsic, Sangeetha Nair, Andrew Worlock, Sheila A. Peel, Jennifer Malia, Linda Jagodzinski, Evaluation of the Hologic Aptima HIV-1 Quant Dx assay with HIV-1 subtypes

Leigh Anne Eller Evaluation of the Proposed US CDC Algorithm for Detection of Acute HIV infection in Serial Samples, CROI 2013, Poster

Netanya Sandler Inflammation in Acute HIV Infection Correlates with Blood and Gut CD4 T-Cell Loss and Viral Burden, CROI Poster

Michael Peluso, Immediate Antiretroviral Therapy Mitigates the Development of Neuronal Injury in Acute HIV, CROI 2013 Poster

Christina Polyak, CTX Prophylaxis Discontinuation Among ART-treated Adults: a Randomized Non-Inferiority Trial, CROI 2013, Poster

Alexandra Schuetz, Early ART Initiation Prevents Disruption of the Mucosal Barrier and subsequent T Cell Activation
CROI 2013, Poster

Franco Pissani, Divergent HIV-specific CD4 T Cell Response Profiles in HIV Vaccine Trials, CROI Poster

Siriwat Akapirat, Antibody Responses in Anogenital Secretions of RV305, a Late Boost Vaccination of RV144 Volunteers, CROI 2013 Poster

Lishomwa Ndhlovu, Early Monocyte Inflammation among Treatment-Naïve Acute HIV- infected Thai Subjects, CROI 2013, Poster

Victor Valcour, CNS Outcomes of cART vs. cART plus Maraviroc and Raltegravir Intensifcation During Acute HIV, CROI 2013, Poster

Susan Johnson, Distinct Functional Properties of HIV-Specific Cytolytic CD4 T Cells Compared to Th1 or CD8 T Cells, CROI 2013, Poster

Bhatt Nilesh, Concentrations of Nevirapine or Efavirenz on and off Anti-Tuberculosis Therapy, CROI 2013 Poster.

2. Keystone Symposium “HIV Vaccines”, Banff, Canada, March 9-14, 2014

Franco Pissani, Sebastien Maloveste, Bruce Schultz, Michael Eller, Silvia Ratto-Kim, Mary Marovich, Merlin Robb, Jerome Kim, Nelson Michael, Hendrik Streeck, “Divergent HIV-specific CD4 T cell Response Profiles in HIV vaccine trials”

Characterization of B- and T cells in the gut mucosa of humanized DRAG mice. Atef Allam, Kristina Peachman,
Jiae Kim, Sai Majji, Doris Thelian1, Sofia Casares and Mangala Rao. Keystone Meeting on HIV Vaccines: Adaptive Immunity and Beyond. March 9-14, 2014, Banff, Alberta, Canada.

Mangala Rao, Sayali Onkar1, Kristina Peachman, Victor Padilla-Sanchez, Goli Yamini, Ousman Jobe, Gary Matyas, Susan Zolla-Pazner, Timothy Cardozo, Abraham Pinter, Jerome Kim, Venigalla Rao, Carl Alving. Potent V2-Specific Antibodies Induced in Humans Using Liposome-Encapsulated HIV-1 gp120 Recognize a Well-exposed V2 Epitope on Envelope Trimer.

3. 2014 AIDS Conference, Melbourne, Australia

Allan Omalla, Keith Crawford, Prossy Naluyima, Michael Eller, Francis Kiweewa, Lily Yu, Fatim Cham, Leigh Anne Eller, Hannah Kibuuka and Julie Ake; “Cellular and Soluble Immune Activation Markers are Associated with HIV-1 Infection in Rural Uganda”, Poster presentation

Miruka, A. Aoki, R. Achieng, J. Mumbi, S. Kassim, J.Tarus, J. Maswai, F. Sawe, S. Sinei, K. Crawford, Successful follow up of HIV exposed infants (HEIs) in ten district hospitals (DH) in the rural Southern Rift Valley (SRV) region of Kenya

K Crawford (MHRP) Etravirine/Rilpivirine-Specific Mutations Selected by EFV and NVP in Kenyan Patients Failing ART, CROI 2013, Poster

A. Letizia1, J. Kim2, M. Robb2, L.A. Eller2, S. Nitayaphan2, F. Sawe2, A. Sekiziyivu2, L. Maganga2, RV-217 Study Group, Developing a scoring algorithm to stratify individuals at risk for acute HIV infection: analysis of RV 217 data a multi-site research study

Stakeholder engagement in HIV cure research: Lessons learned from other HIV interventions and the way forward

Jintanat Ananworanich, Plenary: State of the ART: HIV cure - where are we now and where are we going?

4. AIDS Vaccine 2013, Barcelona, Oct 6-8, 2013

Krebs Shelly Comparative Analysis of Binding Antibody Responses elicited by a Cross-Section of Human HIV-1 Vaccine Clinical Trials AIDS Vaccine 2013, Oral Abstract
Peachman Tina Peptide Binding to HIV-1 Variants and Interaction of HIV-1 with 47 Integrin Receptor AIDS Vaccine 2013, Poster

Thomas Rasmi HLA Class II Genes Interact with the Immune Correlates from the RV144 Vaccine Efficacy Trial and Impact HIV-1 Acquisition. AIDS Vaccine 2013, Poster

Rolland MEP, Gottardo R, et al. 2013. Genetic and immunological evidence for a role of Env-V3 antibodies in
the RV144 trial. Abstr. P03.73 LB. Proc. AIDS Vaccine 2013, Barcelona, Spain

Matyas, G.R., Rao, M., Tucker, Kalyanaraman, V., Whitney, S., VanCott, T., Michael1, N.L., Robb, M.L., Polonis, V., Alving, C.R Stability of an Acute HIV-1 Tanzanian Subtype C gp145 Envelope Protein for Clinical Development. AIDS Human Retroviruses (2013) 19(11) A29.

Mutengu Lillian, Engaging and Recruiting MSM in HIV Research: Experiences from the Early HIV Capture Cohort Study in Kampala, Uganda Makerere University Walter Reed Project, Uganda, AIDS Vaccine 2013, Poster

Seaton Kelly, Duke University. Human HIV-1 Vaccine Induced Antibody Durability and Env IgG3 Responses AIDS Vaccine 2013, Poster

Zolla-Pazner Susan, NYU School of Medicine A V2 Conformational Immunodominant Epitope Recognized by Human Monoclonal Antibodies* AIDS Vaccine 2013, Poster

Karnasuta Chitraporn, AFRIMS, Thailand. Antibody Responses to Recombinant gp120, gp70 V1V2 Proteins and Cyclic V2 Peptide in Thai Phase I/II Vaccine Trials using Different Vaccine Regimens. AIDS Vaccine 2013, Poster

Rutvisuttinunt Wiriya, AFRIMS Thailand Qualification of the Particle Diffusion Assay for Single Particle Tracking AIDS Vaccine 2013, Poster

Pollara Justin Duke University. Heterogeneity of anti-V2 ADCC Ab Responses and Implications for Vaccine Development AIDS Vaccine 2013, Poster

Chung Amy, Ragon Institute Distinct HIV-Specific Antibody Fc-Profiles in RV144 and VAX003 Vaccines, AIDS Vaccine 2013, Poster

Hu Haitao, MHRP Adenovirus 5 hexon-Specific CD4 T Cells are More Susceptible to HIV and Preferentially Depleted During Infection Compared to CMV-Specific CD4 T Cells, AIDS Vaccine 2013 Poster

Rao Mangala Siglec-1 on Macrophages is a Major Infectivity Receptor for HIV-1: Differential Effects of GM-CSF and M-CSF on HIV-1 Entry and Replication, AIDS Vaccine 2013 Poster

Eller Leigh Anne, MHRP Stability of an an Acute HIV-1 Tanzanian Subtype C gp145 Envelope Protein for Clinical Development, AIDS Vaccine 2013 Poster

Kihak Gustavo, MHRP New Insight in HIV-1 Evolution during Acute Infection gained through Dense Sampling and Targeted Deep Sequencing (TDS), AIDS Vaccine 2013, Poster

Kibuuka, Hannah MHRP Recruitment and Retention of Urban Population in Vaccine Trials in Uganda, AIDS Vaccine 2013, Poster

Li SShuying SCHARP Host-genetic Polymorphism in FcγRIIC Associated with HIV-1 Vaccine Efficacy in RV144 Trial, AIDS Vaccine 2013, Poster

Herrera Carolina, Imperial College London. Preliminary Evaluation of Mucosal Immune Responses with Mucosal Tissue Explants in Humans Vaccinated with ALVAC/AIDSVAX B/E during the ongoing RV305 trial, AIDS Vaccine 2013, Poster

Schuetz Alexandra, AFRIMS Evaluation of Peripheral and Mucosal Cellular Immune Responses induced by Late Boost Strategies in HIV-negative Participants prior enrolled in RV144, AIDS Vaccine 2013, Poster

Karasavvas Nicos, AFRIMS Investigation of Antibody Responses Induced in RV305 a Late Boost Vaccination of HIV-1 Uninfected Volunteers that Participated in RV144, a Thai Trial, AIDS Vaccine 2013, Poster

Charuthamrong Patchara, AFRIMS, Implementation of Invasive Procedures in Clinical Trials, AIDS Vaccine 2013, Poster

Wieczorek, L., Krebs, S., Kalyanaraman, V., Whitney, S., Matyas, G.R., Rao, M., Alving, C.R., Tong, T., Molnar, S.,Wesberry, M., Laurence Chenine, A., Tovanabutra, S., Sanders-Buell, E., Slike, B., Alam, S., Liao, H., Haynes, B.F., Williams, C., Zolla-Pazner, S., Moscoso, C., Cheng, H., Hoelscher, M., Maboko, L., Michael, N., Robb, M.L., VanCott, T., Marovich, M., Polonis, V. Comparable Antigenicity and Immunogenicity of Multimeric Forms of a Novel, Acute HIV-1 Subtype C Gp145 Envelope for Clinical Development.

Cameron Mark, Vaccine and Gene Therapy Institute, Florida. Transcriptional profiling of RV144 Participants Reveals a Gene Expression Signature that C
Vaccine 2013, Poster.

O'Connell Robert, USAMC-AFRIMS Looking Back to Move Forward: Understanding ALVAC/AIDSVAX Immune Responses, AIDS Vaccine 2013. Plenary

Lindsey Wieczorek, Comparable antigenicity and immunogenicity of oligomeric forms of a novel, acute HIV-1 subtype C gp145 envelope for use in preclinical and clinical vaccine research

5. 16th S Annual International Meeting of the Institute of Human Virology. September 14-17, 2014. Baltimore, MD.

Kristina K. Peachman, Nicos Karasavvas, Carl Alving, and Mangala Rao. Competition and Characterization of HIV-1 Envelope Variable Loop V2 and V3 Binding to α4β7 Integrin Receptor.

6. St.Jude/Pediatric Infectious Diseases Society meeting, Feb 21-22, 2014, Memphis, TN.

Daniel Adams, Sodsai Tovanabutra, Anjali Kunz, Panita Pathipvanich, Kriengkrai Srithanaviboonchai, Abhram Pinter, Nelson Michael, Jerome Kim, Mangala Rao, and Merlin Robb. The Role of HIV-1 V2-specific Antibodies in Mother to Child Transmission.

7. 62nd American Society for Mass spectrometry Conference. Baltimore, MD, June 15 - 19, 2014.

Hung V. Trinh, Colquhoun, D., Graham, D.R., and Rao, M. Identification of viral phosphorylation in human immunodeficiency viruses.

E. **Patents**

Method on handheld diagnostic device for HIV viral load measurement (patent pending. Filing No: #HJF-358-13 (103783 0169))

Zoltan Beck (HJF) and Carl Alving (WRAIR). Title: Non-toxic Adjuvant Formulation Comprising Liposomes Containing MPLA and QS21; Application title: Compositions and Methods for Vaccine Delivery. /U.S. Provisional Application No. 61/970,118 filed 25 March 2014.

F. **Grants/Awards**

Award #: 1R21AI110214-01A1
Institute: NIAID
Impact score: 16;

Project title: SUSCEPTIBILITY OF ANTIGEN-SPECIFIC CD4 T CELLS TO HIV: IMPLICATIONS FOR HIV VACCINE RESPONSE

G. **Patents Pending**

Casares, S., Allam, A., and Rao, M. Characterization of B- and T Cells in the Gut Mucosa of Humanized DRAG Mice. US Provisional application No. 61/950,071 filed March 8, 2014.

Carl R. Alving, Mangala Rao, and Jerome Kim. Methods for Enhancing The Immunostimulation Potency of Aluminum Salt-Adsorbed Vaccines. US Provisional 61/969,905 filed 25 March 2014; PCT/US/14/45940 Filed 9 July 2014.

H. **Awards**

ILIR: A humanized mouse model to study the efficacy of HIV-1 vaccines: The importance of gut-associated lymphoid tissues (GALT) in HIV-1 infection. March 2014 Year 2. PI: (b) (6) .

I. **Other Awards**

The following are the awards received by CPT (b) (6) for his work on Mother-Child transmission studies done in (b) (6) lab, USMHRP.
Finalist, (b) (6) Award - "for the best paper by a uniformed services pediatrician on either basic research or applied research on the development, evaluation, or application of an emerging technology in pediatrics." - Given by the Uniformed Services Section of the American Academy of Pediatrics, Oct 12, 2014.
Winner, 29th Annual Navy wide Research Competition in the Category 1B for approved basic science research conducted by a Fellow/Staff Physician, May 22, 2014 for platform presentation on "The Role of HIV-1 V2-specific Antibodies in Mother to Child Transmission."
Winner (b) (6) Award in the Laboratory Category for Fellow/Staff Physician - Given by the WRNMMC Department of Research Programs, Mar 25, 2014 for platform presentation on "The Role of HIV-1 V2-specific Antibodies in Mother to Child Transmission."

Section 11

Fiscal Year 2014
Annual Historical Report

Combat Casualty Care Research Program

Mission Statement & Covenants

The MRMC Combat Casualty Care Research Program (CCCRP) strives to optimize survival, resiliency, and recovery in injured service members. Our people are our most valued and valuable resource. Ensuring that we have a professional, supportive, and collegial working environment is essential in enabling us to innovate on a consistent basis and deliver on our promises. We at the CCCRP agree to abide by these covenants, and when we fail to do so, we agree to address the issue in a direct and timely manner in order to resolve it constructively.

1. We agree to exercise the highest level of professional and ethical behavior at all times.
2. We agree to treat everyone with respect and trust at all times, regardless of position.
3. We agree to provide honest effort towards optimizing the survival and recovery of injured service members, including asking for -- and giving -- help freely and enthusiastically.
4. We agree to make every attempt to be flexible with both our time and knowledge while in the pursuit of getting to "yes".
5. We agree to communicate early, honestly, and completely with all who have a direct interest in the given subject, all while remaining open to other points of view.
6. We agree to be trustworthy: to follow through on commitments, admit mistakes, and discuss changes before acting.
7. We agree to never undermine colleagues either directly or indirectly: praise in public, criticize in private, and always do so in a constructive manner.
8. We agree to work jointly to resolve disagreements in good faith. If necessary, we agree to take disagreements to a higher authority together, then accept and support the solution.
9. We agree to support leadership and all accompanying decisions at all times.
10. We agree to promote the use of these covenants at all times

STAFF

The Combat Casualty Care Research Program was directed by COL (b) (6), USA, MC, and has been replaced by Col (b) (6), USAF, MC; (b) (6), PhD, was the Civilian Deputy Director and has been replaced by (b) (6) PhD, CPT (b) (6), MS, is the Military Deputy Director. Other staff members include: (b) (6), MD, Portfolio Manager, Neurotrauma; (b) (6), PhD, Portfolio Assistant, Neurotrauma; (b) (6), PhD, Portfolio Manager, Hemorrhage/Resuscitation (b) (6), Portfolio Manager, Treatments for Tissue Injury; (b) (6), PhD, Portfolio Manager for Forward Surgical - Intensive critical Care; (b) (6), PhD Defense Health Program (Enhanced) DHPe, Manager; (b) (6), PhD, Senior Scientist; (b) (6), PhD, Senior Research Analyst; (b) (6), Health Science Administrators; (b) (6), DHPe Action Coordinator; (b) (6), Information Specialist; (b) (6) Administrative Assistant. There are two military liaisons in the program: Lt Col (b) (6), Air Force also portfolio manager for en-route care; and CDR (b) (6), Navy. There is also one civilian liaison from the U.S. Army Medical Material Development Activity, (b) (6), PhD, Product Transition Specialist.

ACHIEVEMENTS

A. **Military Health System Research Symposium (MHSRS) 2014:**

1) - MHSRS is the DOD's premier scientific meeting that addresses critical advances in trauma medicine and the unique medical needs of the warfighter. It focuses on growing and changing operational issues and the technologies available today and in the future that can be used to meet these increasingly complex goals. Nearly all of DoD's combat casualty care scientists and biomedical researchers presented their latest research results.

B. **Conference Firsts:**
1) Initiated government owned-contractor operated website
2) Brought automation to every aspect of the symposium build
3) Central "go-to" for symposium information – website had over 65,000 hits since going live
4) Young Investigator Competition
5) Formal Annual Award Solicitation Process
6) CME expanded from 1 to 3 categories – Nurse, MD, Psychologist
7) Publication of Journal supplement(s) parallel to date of symposium

C. **Statistics:**
Scientific Content
1) Number of abstracts received doubled (1,135 in 2014 vs. 520 in 2013)
2) 2014 abstract acceptance was 55% compared to 95% in 2013
3) Number of posters presented in 2014 increased by 52% compared with 2013 (387 vs. 252, respectively)
4) Awards were given for the overall best posters, plaques for 1st, 2nd, 3rd - and certificates for best posters within research areas

D. **Registrants:**
1) Up 31% compared with 2013
2) 1,554 with 71 exhibitors vs. 1,175 in 2013 with 80 exhibitors
3) 55% were repeat attendees; 45% were first time attendees
4) DoD attendee breakdown exceeded quota (530) by 47
5) 376 U.S. Military Service attendees (Army: 167, AF: 136, Navy: 73)
6) 201 DoD attendees
7) 84 Foreign national attendees

TASK AREAS

A. **Forward Surgical and Intensive Critical Care Portfolio:** This portfolio address military relevant gaps across a broad range of research areas including pre/out-of hospital care, emergency care, surgical care, intensive care, nursing care, advanced monitoring, and battlefield medical equipment. The objective of this portfolio is to Decrease mortality and morbidity across all echelons of care in the battlefield by conducting research and fostering development in order to expand knowledge and develop new algorithms, devices, and procedures that advance the decision-making capabilities of medical personnel and promote earlier intervention in pre-hospital (decrease the 25% potentially preventable Death), emergency room, and intensive care combat casualty management.

Progress to date:
1) The endovascular hemostatic started clinical study for FDA clearance
2) Initiated several research projects to study next generation of life saving resuscitative procedure using resuscitative endovascular balloon occlusion of the aorta
3) Initiated the CAMIT (Close Area Medical Integration
4) Technology) system which will allow point of injury data collection and reachback capability.
5) Developed a field anesthesia working group to help developing a close loop anesthesia system
6) Developed an ECLS (extra corporeal lung support) working group to help developing a close loop ECLS system.
7) Oversaw integrated product team for the transport telemedicine system to allow communication across the continuum of care.
8) Oversaw integrated product team for the intra-thoracic pressure therapy for enhancement of central perfusion.

B. **The Hemorrhage and Resuscitation Portfolio:** includes DoD efforts in the general areas of blood products, damage control resuscitation, coagulopathy of trauma, immune/inflammatory modulation, metabolic and tissue stabilization, hemostatics and pathophysiologic responses to traumatic hemorrhage, with a view ranging from basic and discovery research through clinical and advanced development

Progress to date:

1) Reprioritizing portfolio based on the need for prolonged evacuation for up to 72hrs before surgery
2) FDA approval of X-Stat, trade name for expanding sponge pellets, dressing for a deep wound tract
3) Solvent Detergent/Spray Dried Plasma, Platelet Derived Hemostatic Agent (PDHA), Valproate, EE-3-SO4 (Surviving Blood Loss Program) and Wound Stasis System, are transitioned to advanced development
4) Pragmatic, Randomized Optimal Platelet and Plasma Ratio (PROPPR) trial was completed
5) Expandable hemostatic pellets for junctional bleeding (510k expected)
6) Joint Transition Planning Process is up and running and includes, amongst others, Service advanced developers, S&T, DGSO.
7) Interagency cooperative programs are being integrated successfully
8) National Heart Lung & Blood Institute (NHLBI)/DoD TACTIC Program
9) Health & Human Services (HHS) Biomedical Advanced Research & Development Authority (BARDA) Spray Dried Plasma
10) HHS BARDA Platelet Derived Hemostatic Agent Programs
11) -Planning underway for development of National Interagency Strategic Action Plan for Blood Products for Emergency Preparedness (DoD, BARDA, NHLBI, FDA) – will include leveraging funding

C. **Treatments for Tissue Injury Portfolio:** This portfolio seeks to advance functional recovery of traumatic tissue injuries; applying novel therapeutics and techniques to reduce complications and prevent repetitive procedures, ultimately leading to restoration of the wounded warfighter's quality of life. The Portfolio encompasses research conducted on the development of alternate methods, biologics, pharmaceuticals, and engineered technologies to address orthopaedic, burn, craniomaxillofacial and organ injuries, and includes basic bench-top through clinical evaluations.

Progress to date:

1) Established the Intracompartmental Pressure Relief Integrated Product Team with USAMMA and the USAISR.
2) Received the first programmed funding for the portfolio. Most funding was destined for studies that allowed us to understand the outcomes associated with injuries and interventions. Specifically, prophylactic fasciotomies and genitourinary injuries. Results of these studies will help guide clinical practice guidelines and potential interventions.

D. **Joint En Route Care Portfolio:** The purpose of this portfolio is to pursue research from basic science through advanced development that ultimately minimize negative effects of patient transport and improve outcomes during movement (evacuation) within the continuum of care without clinically compromising the patient's condition.

Progress to date:

1) Established a multi-service En Route Care Research Consortium to support intramural collaboration and complete a comprehensive state of the science report to inform clinical practice and guide future research priorities.

2) Initiated an En Route Care Module within the DOD Trauma Registry to capture clinically-relevant retrospective data to monitor and improve en route care.

3) Funded the development of a transport-worthy, non-invasive body-worn devices to measure and automatically record traditional and advanced vital signs.
4) Supported the continued development of two next-generation spinal immobilization systems to avoid patient complications caused by current devices, which are appropriate for use in the tactical en route care setting.
5) Oversaw two active working groups identifying research priorities and project funding for virtual critical care, cybersecurity, medical device interoperability to ensure safe and secure en route care in the future.

E. **Neurotrauma Research Portfolio:** To develop and recommend for execution a program of research and development aimed at identifying and filling military-relevant gaps of knowledge, training and protection, diagnosis, treatment and rehabilitation of Traumatic Brain Injury and associated CNS insults including but not limited to complex injury (TBI+Shock; TBI+SCI) pain and behavioral sequelae.

Understand
Epidemiologic/Natural Hx studies of blast and impact TBI in military and civilian settings still underway.
Animal models, especially for blast, are not standardized and do not scale well-often impossible to compare one project to another, much less to human condition. Working with Blast PCO and others to rectify this problem. Also relying on our Operation Brain Trauma Therapy Consortium.
Chronic Effects of Neurotrauma Consortium is another major effort here.
Prioritization? We need to understand mechanisms and natural history of the spectrum of injuries as well as sort out whether blast TBI really does have any unique aspects that would require management that differs from impact injuries.

Diagnose
Foundational Research to develop clinically useful means to characterize TBI. (Mild/Mod/Severe isn't cutting it)
Multi-modality objective diagnosis platforms for field assessment and monitoring of TBI casualties. (Includes efforts to determine whether we can correlate sensor data with injuries and outcomes.)
Advanced imaging tools such as High Definition Fiber Tractography, “Super Gradient” MRI and functional imaging to verify diagnosis, drive therapeutic interventions, inform development of PPE and follow for chronic effects.

Treat
Foundational Research to identify, validate and standardize therapeutic end-points. (a CT scan and Glasgow Outcome-Extended haven't worked for the 30+ failed clinical trials over the past 20 years. Some of these may not have failed in some populations. Trial planning and inclusion criteria must be tighter-cannot take “all comers” due to heterogeneity.)
TBI will require combination therapies which add levels of cost, complexity to animal and human research. Need to step back from classical reductionist approach where minimally invasive and otherwise safe interventions work. (eg cranial neuromodulation, cognitive rehab and transcranial optical/magnetic/electrical stimulation.) Cell/Regen Med approaches also show promise-yet we cannot describe how, exactly, these work in many cases other than “The cells improve the local milieu and thus halt secondary insults and provide environments that enable regeneration.” We have far more promising therapeutic candidates than we can possibly translate due to cost.

Describe major research and development projects
Priority
Understand Capability Area
Near Term: Analyze epi/nat hx studies as they end to inform characterization effort (multiple efforts)
Midterm: Complete and validate new TBI characterization system
Far Term: Act upon lessons learned in Chronic Effects Program (Genetic and epigenetic risk assessment, PPE and training refinements, therapies/mitigation of effects)
Diagnose Capability Area
Near Term: Move existing modalities and sensors into pivotal validation and then combination efforts (will require down-select as performance data is accrued for each modality)

Mid Term: Complete HDFT, Super Gradient and other imaging efforts. Complete TBI Characterization development and validation.
Far Term: Refine diagnostic modalities to enhance/drive therapies longitudinally (of down-selected modalities above)
Treat Capability Area
Near Term: Complete Phase II trials of existing therapies as fiscally feasible. (see next slide-multiple efforts that will require down-select)
Mid Term: Complete initial set of end points
Far Term: Phase III Trials (Excepting minimally invasive approaches that meet FDA requirements)
Combination Therapies

DHP Transition Projects-Neurotrauma
In the Neurotrauma Portfolio, we have executed numerous TTAs with advanced Development at MRMC to include:
Laboratory Analysis of TBI Biomarkers
Neuren Drug
"Generic" TBI assessment tools (due to need for down select and fact that more than one assessment tool will be required to deal w/ heterogeneity of injury.
"Generic" Drug TTA (again because we must down-select)
"Generic" cell therapy
Next generation TBI/SCI litter (now in En Route Care Portfolio and Adv Dev)

History
The vast scope of TBI research, combined with the heterogeneity of injuries (see fig 1 from Saatman, et al in Journal of Neurotrauma, July 2008, p719-28. This shows the several very different types of "severe"TBI and the same heterogeneity applies at all severities) and the fact that our FY2007 funded programs are just now beginning to yield tangible results makes the measurement of performance and effectiveness difficult. Currently, within the clinical and research neurotrauma and neuropsychology communities, there are ongoing efforts to identify and validate improved research models and outcome metrics. Until Congress began to fund TBI and PH so significantly in 2007 much research and development was done in relative isolation and there was only one major source of funding-the NIH. Additionally, with few clinical guidelines combined with significant differences in capabilities between medical facilities even within the US, standardized assessment and treatment of neurotrauma has been limited to large healthcare systems and a small number of research networks. Prior to 2007 neurotrauma research was considered a backwater compared to topics such as cancer and even Alzheimer's disease and depression.

Given this historical backdrop, we have made significant progress through the following:
1. The DoD, through the Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury (DCoE), has partnered with the National Institute of Neurological Disorders and Stroke (NINDS) to refine and expand the NINDS Common Data Elements (CDE) program (see http://www.commondataelements.ninds.nih.gov/). As noted therein, "The use of different measures to assess similar study variables and/or differing metrics to assess outcomes may limit important advances in PH and TBI research. Without a common set of data elements (which include variable definitions and recommended measures), comparison of findings across studies is challenging." The CDE program aims to rectify this.
2. Meanwhile, we are working with the Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury (DCoE), the Defense and Veterans Brain Injury Center (DVBIC), the National Intrepid Center of Excellence and NINDS to develop a comprehensive patient data repository that will be populated by ANY clinical trial group using the CDE standards.
3. With respect to basic, applied and clinical research funded by Congress in DoD, we have an established process for identifying research gaps, releasing program announcements to address those gaps, and then scientifically and programmatically reviewing submitted proposals. The Joint Program Committees (JPCs) are responsible for gap identification and programmatic review, while scientific review is done in a manner that is peer-based yet blinded to the JPCs. Upon funding, investigators are now required to submit quarterly and annual reports that are reviewed by military subject matter experts for scientific and technical acceptability. We are beginning to

perform in-process reviews so that DoD and other stakeholders can assess progress directly from the investigator and can then use that information to inform the revision of research gaps.

4. Working groups have been formed to help guide the translation of research findings to clinical use. Since July 2010 we have presented the TBI portfolio to the Director, Defense Medical Research and Development Program (Defense Health Program) where recommendations are made regarding continuing and emerging research areas. A final report has been made available for each year having been presented. With respect to translation, USAMRMC utilizes the "Decision Gate" process where a drug or device under development must pass through a series of intensive reviews and "go"/"no-go" decision points on their way towards military acquisition. While one keeps in mind that we have nearly 300 projects active or pending award, there are several areas where we are making significant progress. We have identified several technologies, to include smooth pursuit eye tracking, serum biomarkers and quantitative electroencephalography that we anticipate will enable us to develop a suite of tools for rapid, objective diagnosis of mild TBI (also called concussion). Currently this is one of our highest priority goals and our investigators have been up to the challenge. Our medical imaging research is showing early results that may allow us to answer whether primary blast injury causes unique injury patterns to the brain. Research on blast related TBI is demonstrating the important role of inflammation in TBI. Other work is leading to improved understanding of the molecular and cellular pathways involved with neuronal and glial injury and repair.

In general our knowledge base is growing and we have also learned more about what we do not know. For example, it has become clear, as discussed above, that the issue of both physical and biological scaling between animal models and humans is problematic. This has stimulated research into improved assessment methods in animals as well as into development of better standardized animal models and animal assessment procedures. While advances must be made in executing clinical trials, we do have one promising drug, Neuren Pharmaceutical's NNZ-2566 in phase II clinical trial. Unfortunately the Progesterone study, the San Antonio Military Medical Centers were participants in Emory University's Phase III trial of progesterone which seemed to be promising was Terminated for Futility (ONLY PHASE III we have been involved with). We have a number of drugs in preclinical and phase I (safety) trials as well. However, we keep in mind that given the complexity of TBI there is not likely to be one "silver bullet" drug that "cures" TBI. We are therefore moving to identify the best means by which to perform combination therapy research, where we believe success is achievable.

Expanding on areas of success:

Biomarker Assessment for Neurotrauma Diagnosis and Improved Triage System (BANDITS)

Diagnosing and treating brain injury resulting from trauma is one of the major knowledge gaps within our TBI program. Most notable has been the lack of a rapid, definitive and cost-effective blood-based diagnostic test for TBI, particularly mild and moderate TBI. USAMRMC has partnered with Banyan Biomarkers, Inc., for the discovery of novel biomarkers for TBI diagnosis and management. The overall goal of the program is to develop and deliver an FDA approved assay for the screening/diagnosis/management of TBI. The program goals span the breadth of military health care by designing assay systems that are suitable to fixed hospital facilities, Combat Support Hospitals and forward deployed field medics. The program has received $63M in funding since 2003 to include multiple awards since the increased congressional funding for TBI research. The result is that Banyan and their government partners at WRAIR are the preeminent experts in the identification and utilization of TBI biomarker technologies. Multiple scientific and media articles have resulted as have a number of patents. The most promising biomarkers are currently being tested in clinical trials for their utility in the diagnosis of severe, moderate and mild TBI. Banyan completed pivotal trial on schedule in April, enrolling 2010 subjects at 23 sites in 15 months (2014). IPT and contractor identified benchtop and POC devices for final testing and submission to the FDA (2014). Banyan is currently working on bridging study for POC devices prior to submission to FDA The data from the initial trial showed that the biomarkers diagnosed mild TBI more accurately than the Automated Neuropsychological Assessment Metrics (ANAM). In addition, the team is working on selecting point-of-care devices better suited for use in a CSH and hand-held devices suited for use by field medics.

Banyan is currently in the process of a 510k submission for Point of care (POC) device in progress.

EYE-TR AC: Non-invasive diagnosis of concussion and post-concussion syndrome

The Brain Trauma Research Foundation with support from the USAMRMC is developing the EYE-TRAC. The EYE-TRAC is a smooth pursuit eye-tracking device, an objective test for attention and traumatic brain injury (concussion). The device uses specialized software for analysis of eye-target synchronization. The difference between this system and other eye tracking systems is that it requires the patient to follow a target in a specific manner. Performing this test engages several discrete parts of the brain and thus provides a good assessment of overall "connectivity" of neurons. This has been demonstrated through the ability to correlate test abnormalities with abnormalities in specific regions of the brain. A clinical study to validate and refine the diagnostic device is currently underway. The EYE-TRAC has been proven to rapidly and accurately detect attention and memory deficiencies in civilians with mild TBI. Data obtained thus far suggests the system is capable of differentiating post-concussion syndrome from sleep deprivation and post-traumatic stress disorder. Studies have shown that this system can also differentiate post-concussion syndrome from attention deficit disorder and alcohol or drug intoxication. In its final embodiment, the EYE-TRAC will be a ruggedized, head-mounted device that will require less than a minute to perform a test.

Section 12

Fiscal Year 2014
Annual Historical Report

Military Operational Medicine Research Program

Overview and Mission

The mission of the Military Operational Medicine Research Program (MOMRP) is to develop effective medical countermeasures against operational stressors and to prevent physical and psychological injuries during training and operations in order to maximize the health, fitness and performance of Service Members. Its continuing mission is to protect the whole Service Member -- head-to-toe, inside and out, across the operational spectrum. *Science to Service Member* is our focus.

The MOMRP, US Army Medical Research and Materiel Command (USAMRMC), manages biomedical research to deliver products and solutions to Service Members and Families that address health, fitness and performance throughout the deployment cycle and Service Member lifecycle. The MOMRP is centered on cutting-edge scientific research and bringing *Science to Service Member* on the battlefield and at home in a relevant, timely manner.

The MOMRP depends on a phenomenal cadre of dedicated scientists and engineers who continuously and tirelessly work to protect the Nation's most valuable asset – the Service Member.

Organization

The USAMRMC Research Area Directorate 3 (RAD 3) located at Fort Detrick, MD, manages the MOMRP. RAD 3 performs planning, programming, and budgeting (PPB) for research performed at intramural laboratories: the US Army Research Institute of Environmental Medicine (USARIEM), Natick, MA; the US Army Aeromedical Research Laboratory (USAARL), Fort Rucker, AL; the Walter Reed Army Institute of Research (WRAIR), Silver Spring, MD; the US Army Center for Environmental Health Research (USACEHR) at Fort Detrick, MD; and the Naval Health Research Center (NHRC), San Diego, CA. RAD 3 manages an effective comprehensive network of collaborative research partners, including Department of Defense (DoD) organizations, industry, other federal agencies, and international military research organizations. RAD 3 also manages the Joint Program Committee (JPC-5) which performs oversight of Defense Health Program Enhancement (DHPe) activities.

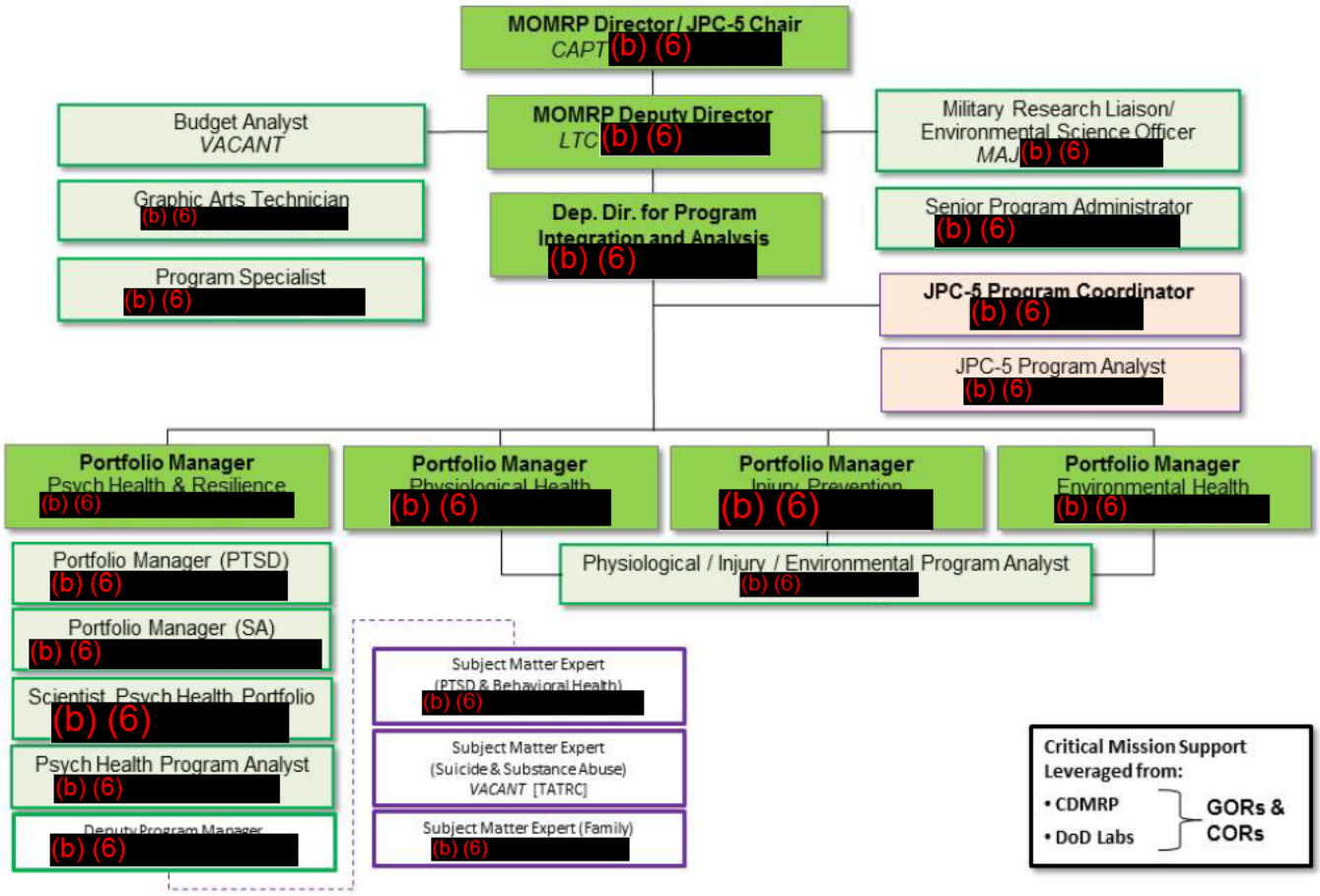
The MOMRP is divided into four research focus areas: Injury Prevention and Reduction, Psychological Health and Resilience, Physiological Health, and Environmental Health and Protection.

FIGURE 1: MOMRP Personnel

MIL – Military, GS – General Schedule/CIV, CTR – Contractor/Contract Support

Name	Position Classification and Title	Status
CAPT (b) (6)	MIL, Research Area Director	JAN - DEC 2014
LTC (b) (6)	MIL, Deputy Research Area Director	JAN - DEC 2014
MAJ (b) (6)	MIL, Military Research Liaison, Environmental Science Officer	JAN - DEC 2014
(b) (6)	GS, Deputy Director for Program Integration and Analysis	JAN - DEC 2014
	GS, Psychological Health Portfolio Manager	JAN - DEC 2014
	GS, Physiological Health Portfolio Manager	JAN - DEC 2014
	GS, JPC-5 Program Coordinator	NOV - DEC 2014
	CTR, Geneva Foundation, Injury Prevention Portfolio Manager	JAN - DEC 2014
	CTR, General Dynamics IT, Environmental Health Portfolio Mgr.	JAN - DEC 2014
	CTR, General Dynamics IT, PTSD Portfolio Manager	JAN - DEC 2014
	CTR, Capitol IT, Psychological Health Portfolio Scientist	SEP - DEC 2014
	CTR, Tunnell Govt. Services Inc., Substance Abuse Portfolio Mgr.	NOV - DEC 2014
	CTR, Capitol IT, JPC-5 Program Analyst	JAN - DEC 2014
	CTR, Capitol IT, Physiological / Injury / Environmental Program Analyst	JAN - DEC 2014
	CTR, Capitol IT, Psych. Health Program Analyst	JAN - DEC 2014
	CTR, General Dynamics IT, Senior Graphics Specialist	JAN - DEC 2014
	CTR, General Dynamics IT, Program Administrator	JAN - DEC 2014
	CTR, Capitol IT, Senior Program Administrator	DEC - DEC 2014
Previous MOMRP Employees		
(b) (6)	CTR, Capitol IT, Physiological / Injury / Environmental Program Assistant	JAN - JAN 2014
(b) (6)	IPA, DHP Program Coordinator	JAN - JUN 2014
CPT (b) (6)	MIL, Deputy Director for Advanced Development	JAN - AUG 2014
(b) (6)	CTR, Tunnell Govt. Services Inc., Psych. Health Senior Scientist	JAN - SEP 2014
(b) (6)	GS, Budget Analyst	JAN - OCT 2014
(b) (6)	CTR, Capitol IT, Senior Program Administrator	JAN - NOV 2014

FIGURE 2: Current Military Operational Medicine Research Program Organization



Statistical Data

A. Overall, MOMRP manages 402 active projects and $170M in research funding. In response to the USAMRMC Broad Agency Announcement (BAA) for Fiscal Year 2014 (FY14), the MOMRP received 107 pre-proposals, 52 full proposals, conducted 24 scientific reviews, turned down or transferred 99 proposals, and funded 10 proposals.

B. In 2014, the MOMRP completed a total of 284 formal Taskers from USAMRMC headquarters, and 75 informal Taskers received from various sources outside USAMRMC, including Congress and Defense Health Agency (DHA).

Healthcare Delivery

N/A

Veterinary Services

N/A

Training and Education

A. The MOMRP executed 100% of required training documented via the Army Training Management System (ATMS).

B. Several staff members completed the Science and Technology Acquisitions Level II Certification Training.

Research and Development

A. **MOMRP Psychological Health and Resilience (PH) Research Program.** This program area consists of Army funding as well as a significant amount of Defense Health Program (DHP) funding for psychological health research. In FY14, there was approximately $90M in new funds to support PH research, in addition to the almost $570M of active ongoing PH research. The goal of the program area is to develop and deliver evidence-based strategies to support and restore psychological health. The program area convened a series of scientific meetings, including Review and Analysis (R&A) and In-Progress Review (IPR) meetings focused on Post-Traumatic Stress Disorder (PTSD) (3), Suicide, Concussion/mild Traumatic Brain Injury (mTBI), Resilience, Family, Violence within the Military, and Alcohol/Other Drug Abuse research. The purpose and scope of these strategic planning workgroups and reviews was to inform recommendations for the MOMRP Director, who also serves as the Chair of the Joint Program Committee for Military Operational Medicine (JPC-5) for the DHP. Participants include internationally recognized leaders in their field of expertise, select military and DoD leadership, representatives from sister agencies such as Veterans Affairs (VA) and the National Institutes of Health (NIH) and other select stakeholders positioned to support and utilize the deliverables of Army and other Services' medical research.

1) New efforts in FY14 included MOMRP staff working with Booz Allen Hamilton (BAH) as part of the Survivability/Vulnerability Technology (SURVIAC) vehicle to construct capability roadmaps of the PH capabilities under development. These roadmaps will be used to assist in strategic portfolio planning. MOMRP began working with BAH and the Congressionally Directed Medical Research Program (CDMRP) to summarize and analyze findings from studies that have closed out to begin to reveal the return on research investment in PH research.

2) MOMRP staff worked with the Office of the Assistant Secretary for Defense for Health Affairs (OASD(HA)) to plan a longitudinal component of the Army Study to Assess Risk and Resilience in Service Members (Army STARRS).

3) The MOMRP worked with sister agencies to execute the National Research Action Plan (NRAP) which is a response to the White House Executive Order on Improving the Access to Mental Health (MH) Services for Veterans, Service Members, and Military Families released in August 2012. The NRAP supports a number of immediate, near, and far term action items related to posttraumatic stress disorder, suicide, and co-occurring disorders. A key aspect of the NRAP is to foster interagency initiatives and collaborations in order to effectively and rapidly improve access to MH services. MOMRP staff members participated in a variety of related working groups and monthly teleconferences as well as annual review and analyses and reports to the Office of Science Technology and Policy.

4) MOMRP staff also contributed to the National Action Alliance on Suicide Prevention Research Portfolio Analysis that was conducted by the National Institute on Mental Health during FY14.

5) Basic science research was conducted to better understand underlying neurobiological mechanisms of alcohol and substance abuse and addiction. The MOMRP staff worked with NIH program officers to release a joint funding opportunity focused on substance abuse prevention interventions. This first Joint DoD NIH announcement resulted in several rigorous prevention trials being awarded. These will be reviewed and tracked jointly with NIH. The MOMRP staff continues to serve on the Institute for

Translational Neuroscience Consortium (formerly the Molecular Neuroscience Consortium) steering committee that is focused on research to develop evidence-based substance abuse treatment interventions. As one intervention, a pilot study to treat substance abuse disorders comorbid with PTSD using N-acetylcysteine (NAC) in a Veteran population was conducted. This proof of concept clinical trial found that NAC was safe and effective in preventing relapse and reducing drug craving while also successfully treating PTSD symptoms.

6) A study to develop an algorithm to predict the likelihood of concussion (mTBI) based on defined blast and/or blunt force exposure(s). Biomechanical models of head motion, mathematical models of brain mechanisms at the tissue and cellular level, human exposure data and animal experiments will be used to produce an integrated model that links the external threat to the likelihood of concussion. The validated, integrated model will be translated into end user applications and packaged with Military-relevant sensors as part of a dosimeter that relates exposure to the likelihood of concussion.

7) Achievements from MOMRP managed research this year include:

   a. Enrolled over 10,000 spouses in the Millennium Cohort Family Cohort study linking to Millennium Cohort Service Members.

   b. Multiple research findings supports recently revised DoD/VA PTSD clinical practice guideline recommending Prazosin administered in conjunction with PTSD psychotherapy to reduce the frequency and intensity of nightmares.

   c. USAMRMC supported research also contributed to the new PTSD definition in the 5th edition of the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders (DSM-V).

   d. Mental Health Advisory Team (MHAT) data contributed significantly to development of policy and doctrine decisions. MHATs have led to numerous evidence-based recommendations that have impacted policy (e.g., dwell-time and deployment length), improved distribution of mental health resources and services throughout theater, impacted the number of mental health personnel in theater, and modified the doctrine of Combat and Operational Stress Control (COSC).

   e. An intensive telephone/webinar-based intervention to provide education, training in coping skills and support to the spouses of deployed Soldiers demonstrated improved resilience and coping behaviors, and decreased depression, anxiety and role strain. The research results led to wide-scale VA program implementation.

   f. Research evaluating a Supported Work Environment program for veterans within the VA system, compared to the usual work placement assistance program resulted in veterans maintaining job placement longer, with greater earnings, and high job satisfaction reports. A limited trial implementation at twelve VA sites followed this research finding.

   g. The Systems Biology Enterprise at USACEHR, USAMRMC, has recently filed a patent disclosure for the diagnosis and screening of PTSD and co-morbid illnesses. Next research steps building upon identifiable markers have initiated and include identification of early markers associated with disease onset and trajectory, classification of PTSD into subtypes based upon biological markers and detailed phenotypic data, documenting treatment response through biomarker changes, and development of patient-treatment matching techniques for improved treatment adherence and outcomes.

   g. An extramural researcher recently completed a PTSD treatment study and found that successive administration of propranolol over the course of six brief treatment sessions effectively reduced

PTSD symptoms. While there is a need for validation, this finding represents a potentially new avenue of combined medication and psychotherapy treatment for PTSD.

h. The VA DoD Suicide Data Repository was the result of extramural research that was funded by DHP to compile data to answer the question about whether suicide is directly tied to deployment. The research team developed a database in collaboration with other federal agencies to provide population-based estimates of the rates of suicide among service members with and without a history of deployment to Operation Iraqi Freedom (OIF) / Operation Enduring Freedom (OEF), and non-deployed veterans from the beginning of OIF/OEF forward.

i. Massachusetts Institute of Technology work and methods are being implemented into the DoD Military Health System transformation and the Army's behavioral health system of care.

j. An extramural researcher's Collaborative Assessment and Management of Suicidality approach is in implementation at the Walter Reed National Military Medical Center.

k. The establishment and continuation of interagency collaborations including the Consortium to Alleviate PTSD (CAP), the Military Suicide Research Consortium, and the Army Study to Assess Risk and Resilience in Among Service Members. At present, the CAP has selected and initiated four research projects.

l. Updated Army Spouse/Couples Resilience Training (pre and post-deployment) through Comprehensive Soldier and Family Fitness (CSF2).

B. **MOMRP Physiological Health Research Program.** This program area convened a series of scientific meetings and reviews focusing on support for basic and applied prevention and treatment research that address Warfighter cognitive and physical resilience, performance and readiness. Lines of effort include research to address the physical and cognitive demands in training and operational environments that produce physiological strain and fatigue, compromising Warrior resilience, health, functional capabilities and operational effectiveness. The outcome of nutrition research, real-time physiological monitoring and sleep management research efforts will lead to decreased injury rates in sustained and/or repeated deployments, optimized healthy lifestyle, increased resilience to operational and environmental stressors, decreased deployment-associated health problems and improved physical fitness. The purpose and scope of strategic planning workgroups was to formulate recommendations for the MOMRP Director toward development of evidence-based strategies for the Army and DoD. Participants included internationally recognized leaders in their fields of expertise, select Army leadership, and other select military and civilian representatives positioned to support Army and other Services medical research.

1) The Alertness Management for Military Operations (AMMO) platform has transitioned to Advanced Development and can be used by Commanders and Warfighters to manage work schedules and stimulant usage during times of chronic sleep restriction or total sleep deprivation.

2) Achievements from MOMRP managed research this year include:

a. Demonstrated role for higher protein diets in sparing lean body mass during energy deficit.

b. Completed data collection and began analysis for the omega-3 fatty acid containing foods dietary intervention study.

c. Developed, validated, patented, and transitioned core body temperature estimation algorithm using heart rate measurement.

d. Conducted human factors and technology assessments of military-specific, real-time thermal strain monitoring systems during operational training exercises.

e. Completed observational assessment of relationship between possible physiological biomarkers and resilience in US Army Survival, Evasion, Resistance, and Escape (SERE) training; developed relationship with elite US Army Special Forces unit.

f. Finalized resilience model construct to be used for research planning and to validate the physiological basis of resilience.

g. Utilized knowledge products from MOMRP sleep program to generate Sleep Guidance products for The Surgeon General (TSG) Army, Performance Triad Pilot.

h. Established standardized platforms for mTBI paradigms and outcome assessments.

C. **MOMRP Injury Prevention and Reduction Research Program.** This program area convened a series of scientific meetings, R&A and IPR meetings. The purpose of the meetings was to obtain current status of funded musculoskeletal, blast, acoustic and vision injury and neurosensory return to duty projects and to provide recommendations and guidance for future funded Army efforts to better fulfill Army and DoD goals and objectives. This support guides our program researchers and labs helping them to focus on prevention of physical injuries through the development of injury prediction models, equipment design specifications and guidelines, health hazard assessment criteria, and strategies to reduce musculoskeletal injuries. Current research areas within the program include Neurosensory Injury Protection, Injury Return-to-Duty (RTD) Standards and Strategies, and Physiological Mechanisms of Musculoskeletal Injury.

1) Achievements from MOMRP managed research this year include:

a. Completed validation of the Military Fitness Assessment Program at Ft. Campbell, Kentucky. This test would be one component of a battery of tests with optimal sensitivity, specificity, and clinical utility for RTD decisions after mild traumatic brain injury. Work by USAARL and Courage Kenny Research Center were published in the Journal of Head Trauma Rehabilitation, Military Medicine, Physical Therapy Journal and the American Journal of Occupational Therapy.

b. An extramural performer has developed a phenomenological muscle fatigue model that can predict fatigue during fast running applications. The next step for this model will be to adjust for muscle adaptation as fatigue increases and determine the effects on performance and injury mechanisms. This work was published in the European Journal of Applied Physiology.

c. Assessed and disseminated protective capabilities of Authorized Protected Eyewear List (APEL) spectacles and goggles resulting from blast wave forces. Even though protective eyewear on the APEL were designed to defeat fragmentation eye injuries, most failed to provide protection against primary blast injuries. The next step is developing minimum objective criteria for protective eyewear and validated test methodology.

D. **MOMRP Environmental Health and Protection Research Program.** This program area convened a series of scientific meetings and reviews focusing on support of basic and applied diagnostics, prevention and protection research to address threats related to exposures to austere environmental extremes and hazardous materials. Current research areas within the research program include heat/cold products (mitigation and predictive models), altitude products (training guidelines, prediction of acute mountain sickness and management of work performance and altitude acclimatization), hydration monitoring product development which uses saliva biomarkers to assess hydration status, and selecting biomarkers to detect and monitor exposures to toxic chemicals and other environmental hazards.

1) The MOMRP has continued to support three products in the Decision Gate process including, the Hydration Status Monitor, the Environmental Sentinel Biomonitor, and the Coliform Analyzer. Several decision aids and commanders' management tools have also transitioned to Advanced Development. These tools include the Load Carriage Decision Aid (LCDA) and the Altitude Readiness Management System (ARMS).

2) Achievements from MOMRP managed research this year include:

   a. Conducted a review of the Study of Active Duty Military for Pulmonary Disease Related to Environmental Dust Exposure (STAMPEDE). STAMPEDE is a follow-up study of clinical diagnoses of degraded pulmonary function observed in Soldiers returning from deployments to Afghanistan, assessment of the histopathology cases of bronchiolar inflammation, assessment technologies including micro ribonucleic acids (RNAs) that are associated with some respiratory clinical conditions, and modelling of pulmonary airways following hazardous exposures.

   b. Conducted IPRs of progress on operational performance of physiological status monitoring systems and modeling for extreme environments (heat, undersea and altitude); basic and applied altitude physiology research on assay for Acute Mountain Sickness and genomic phenotyping of altitude responses at high altitudes, basic research on phenotypes for heat acclimation.

   c. Developed a new task area to assess operational exposure dosimetry and neurological and physical health outcomes of environmental exposures to hazardous materials unique to military operations. The research will focus on exposures to permethrin and exposures to naphthalene in military fuels and animal toxicology models for simulated exposures to burn pits effluence to estimate health outcomes.

International Efforts

A. MOMRP staff members participated in the following international activities:

   1) NATO meeting on Suicide Prevention, Ottawa, Canada (14-15 May)
   2) 7th World Congress of Biomechanics, Boston (6-11 July)
   3) US & UK Suicide Prevention Workshop (1-2 Oct)
   4) NATO RTG 203 Mental Health Training Meeting submitted a final report.
   5) Technical Cooperation Sub-Committee Medical Working Group meeting with Korean delegation.

B. MOMRP staff transferred the Technical Project Officer (TPO) on the International US-Sweden and US-United Kingdom International Agreements to the US Army Medical Research Unit-Europe. MOMRP staff continued to serve as the TPO for the US-India and US-France Information Exchange Agreements (IEAs). The objectives are to enhance the capability to protect and optimize Warfighter health, performance, and resilience across the full spectrum of operations through improved medical knowledge of prevention and treatment of behavioral health problems.

C. MOMRP staff members continued support of The Technical Cooperation Program [TTCP (TP-13)] on Psychological Support during Military Operations.

Internal Project Management

A. The MOMRP conducted or attended the following reviews and meetings as part of its internal project management efforts:

   1) R&A, USARIEM Task Areas: B, H, F, R, S, T9, T10, T15, P2, Q3 (13-16 Jan)

2) R&A, USAARL Task Areas: A, A1, A2, A6, P1, S (21-23 Jan)
3) DHP TBI, PTSD & Suicide R&A (5-6 Feb)
4) R&A, WRAIR Task Areas: C, Q5, W1, W1A, W2, W3, WX (10-11 Feb)
5) R&A, NHRC and L-3 Task Areas: TA M, K6 (18-20 Mar)
6) DHP TBI R&A (3 Apr)
7) DHP MOMRP & MIDRP Health Affairs R&A (16 May)
8) IPR, PTSD Biomarkers (25-26 Feb)
9) IPR, Family Research (25-26 Mar)
10) IPR, TBI Biomarkers (1-2 Apr)
11) IPR, Extreme Environments (8-9 Apr)
12) IPR, Injury Biomechanics Research (29-30 Apr)
13) IPR, Suicide Prevention Research (14-15 May)
14) IPR, Concussion Research (22-23 Jul)
15) IPR, PTSD Services Research & Exposure Therapy (5-6 Aug)
16) IPR, Resilience Research (26-27 Aug)
17) IPR, PTSD Treatment Research (9-10 Sep)
18) IPR, Substance Abuse Research (22-4 Sep)
19) IPR, Violence Prevention Research (11 Oct)
20) IPR, Pulmonary Health, USACEHR (4 Dec)
21) JPC-5 Business Meeting (3 Jun)
22) JPC-5 Quad Services Meeting (7-8 Jul)
23) Marine Corps Behavioral Health Research Summit (23 Jan)
24) Military Suicide Research Consortium (MSRC) Military External Advisory Board (MEAB) (14 May)
25) Suicide Consortium (5-6 Jun)
26) MSRC Annual Principal Investigator Meeting (12-14 Nov)

Professional Meetings and Conferences

A. MOMRP staff members attended the following military and/or scientific professional meetings and conferences:

1) Massachusetts Institute of Technology Site Visit, Cambridge, MA (16 Jan)
2) Air Force Psychological Portfolio Review, San Antonio, TX (29-31 Jan)
3) American Association of Suicidology Presentation, Los Angeles, CA (9-11 Apr)
4) Human Dimensions Workshop, Ft. McNair, Washington, DC (23-24 Apr)
5) 2014 Annual Society for Experimental Biology, San Diego, CA (26 Apr-1 May)
6) American College of Sports Medicine, Orlando, FL (27-31 May)
7) Society for Prevention Research Annual Presentation, Washington, DC (28-31 May)
8) American Legion TBI & PTSD Symposium, Washington, DC (24 Jun)
9) National Neurotrauma Symposium, San Francisco, CA (29 Jun-2 Jul)
10) MacDill AFB & SOCOM Research Meeting, Tampa, FL (6-7 Aug)
11) Military Health System Research Symposium (MHSRS) Conference, Ft. Lauderdale, FL (18-21 Aug)
12) 2014 International Congress on Soldiers Physical Performance (ICSPP) Conference, Boston, MA (18-21 Aug)
13) Army Research Office, Human Brain Mapping, Princeton, NJ (25-27 Aug)
14) Human Performance Training and Eduction (HPT&E) Warrior Resilience TIA Meeting, Arlington, VA (16 Sep)
15) Air Force Surgeon General Requested PTSD Portfolio Review, Columbia University, NYC (18 Sep)
16) Brain at War Meeting, San Francisco, CA (15-17 Oct)
17) 2014 International Society for Traumatic Stress Studies (ISTSS), Miami, FL (5-9 Nov)
18) Annual Diabetes Technology Meeting, Bethesda, MD (6-8 Nov)
19) Annual Neuroscience Conference, Washington, DC (15-19 Nov)
20) Military Suicide Research Consortium Annual Meeting, Tallahassee, FL (27-28 Nov)

21) Intimacy After Injury Conference, Washington, DC (11-12 Dec)
22) Special Operations Medical Association Annual Meeting, Tampa, FL (13-17 Dec)
23) Army Study To Assess Risk and Resilience in Service Members (STARRS) (Multiple meetings throughout 2014)
24) Systems Biology Enterprise Quarterly Meetings (NYC, VA San Francisco, UC-Santa Barbara)

B. MOMRP coordinated and executed an Integrating Integrated Product Team (IIPT) review of all MOMRP research programs, funding plans and unfunded research projects on 11-12 March 2014.

C. MOMRP held a JPC-5 Quad Services Meeting on 7-8 July 2014 the purpose of which was to share Military Operational Medicine research being conducted by the other services and to collaborate on complimentary Joint research efforts to eliminate redundancy as well as to address gaps, in accordance with the Program Integration Advisory Committee recommendations. It was the intention of the JPC-5 to facilitate better integration among the services into the DHP Program and processes for MOMRP, thus representing a tightening of research collaboration within the DoD branches of service.

D. MOMRP supported the International Congress on Soldiers' Physical Performance (ICSPP) Conference held 18-21 August 2014 in Boston, MA, by processing the conference support contract, facilitating the selection site, preparing the MEDCOM Approval Packet, and providing the introductory digital presentation and other graphics requests. This highly successfully conference was attended by close to 400 professionals from over 20 countries, with 200 abstracts submitted for presentation and information exchange. A Reference Supplemental publication is expected in 2015.

E. MOMRP continued to actively participate in the CSF2 program, including providing members to the WRAIR/CSF2 Research Steering Committee.

F. MOMRP continued building a Product Development Portfolio. Products developed from each of the four research areas have been identified and are in the process of being programmed into the Command Decision Gate program. Additionally, MOMRP is an active participant in the product IPTs involving medical products. Finally, MOMRP has spearheaded Command collaboration efforts with the Medical Combat Developer in an effort to accelerate the transition of non-medical products through the identification of appropriate Program Managers.

G. MOMRP continued to actively participate in the Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) programs.

Peer Reviews

A. A peer review of the Systems Biology Effort to date was conducted in April, 2014, to include an evaluation of the research objective, procedures, technological innovations, and preliminary findings. The outcome of the review was generally very positive, with reviewers agreeing that the collaborative effort was making excellent progress toward identification of objective, blood-based biomarkers signifying the presence of changes at the biological level consistent with those seen in PTSD patients but not in healthy controls. The review panel made several suggestions to the researchers, including the importance of distinguishing PTSD from mTBI and Major Depressive Disorder at the biological level, and extending the research to include females.

Defense Health Program Enhancement (DHPe)

A. With oversight performed by the Joint Program Committee (JPC-5) and chaired by MOMRP Director, achievements this year included:

1) MOMRP/JPC-5 continued its role in support of the DHPe program roles in planning, organizing and executing program support functions at the direction of the JPC-5 Committee and Chair.

2) JPC-5 Members held a JPC-5 Business Meeting on 3 June 2014. The JPC-5 committee consisted of over 30 subject matter experts from all services, OASD (HA), Defense Advanced Research Products Agency (DARPA), Uniformed Services University of the Health Sciences (USUHS), Defense Centers of Excellence (DCOE), VA, NIH and joint/combatant commands. During this meeting, the JPC-5 panel members reviewed and provided concurrence with the FY15-17 Near-Term Program Plan (NTPP).
3) The JPC-5 Director presented a DHA Program Review to Defense Health Headquarters on 29 October 2014, which included near-, mid-, and far-term research goals as well as capability roadmaps for each scientific research portfolio area.

4) The JPC-5 Director convened a meeting of JPC-5 Working Group Chairs on 20 August 2014 at the Military Health System Research Symposium, which was held 18-21 August 2014 in Ft. Lauderdale, FL.

5) MOMRP/JPC-5 began restructuring the configuration of the JPC-5 in December 2014, based on guidance from DHA as well as the revised JPC-5 charter (signed by RADM Bruce Doll on 4 December 2014). The new JPC-5 will act at a higher, more strategic level, while the execution management will become one of the key duties of the JPC-5 Working Groups.

Resource Management and Budget

A. MOMRPs FY14 budget for Medical Research, Development, Test & Evaluation was approximately $170M. This number represents a combination of Army, DHP GDF and DHP CSI funding.

B. DHP CSI funding for PH/TBI accounts for roughly $48M of the FY14 funding. The DHP CSI funding allows MOMRP to fund programs and projects in the area of Psychological Health and Traumatic Brain Injury that would ordinarily not be funded due to lack of funding.

C. Overall, MOMRP's budget has slowly increased over the past several years. A significant decrease in FY15 funding as a result of the Budget Control Act (BCA) was avoided by legislation which restored a large portion of the previously decremented funding. However, MOMRP will realize an 18% decrease in DHP GDF funding from FY15 to FY16 as a result of the BCA.

D. To date all FY15 Army funding has been received by MOMRP and the labs. However, MOMRP has received none of the FY15 DHP GDF or CSI funding. Late arrival of these funds negatively impacts the program, especially with regard to timeliness of awards and obligation and disbursement rates.

Information Management

N/A

Operations

A. MOMRP staff members participated in a variety of National Research Action Plan (NRAP) related working groups and monthly teleconferences as well as annual review and analyses and reports to the Office of Science Technology and Policy.

Modernization

N/A

Logistics

N/A

Construction

A. The MOMRP facilitated the installation of a badge access security system for Building 722.

Health and Environment

N/A

Other

N/A

Appendices

None.

Section 13

Fiscal Year 2014
Annual Historical Report

Clinical and Rehabilitative Medicine Research Program

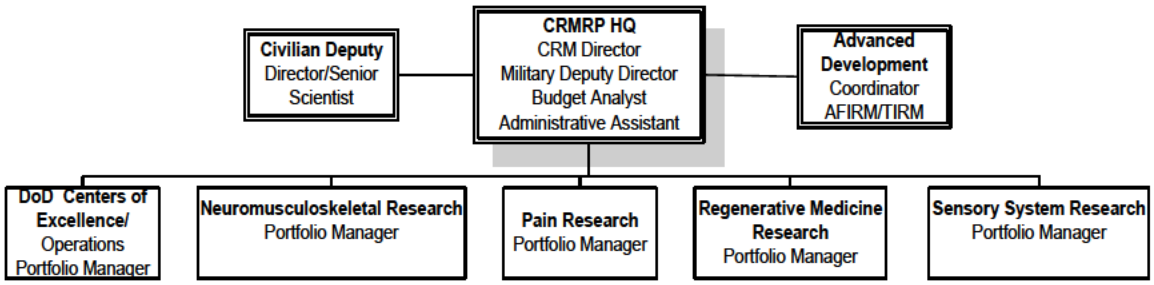
Mission

The Commanding General of United States Army Medical Research and Materiel Command (MRMC) directed the establishment of the Clinical and Rehabilitative Medicine (CRM) Research Area Directorate (RAD), effective 1 September 2008. The CRM RAD supports the Secretary of the Defense's imperatives to take care of and rehabilitate wounded Service Members. The overall mission of the CRM is to ethically plan, coordinate and oversee and responsibly implement long-term strategies to develop knowledge and materiel products to reconstruct, rehabilitate, and provide definitive care for injured Service members (SM). The ultimate goal is to return the SM to duty and restore their quality of life. Currently, key research focus areas include (1) rehabilitation of neuro-musculoskeletal injuries, (2) pain management, (3) regenerative medicine, (4) diagnosis, treatment, mitigation, restoration and rehabilitation of sensory system injury (vision and hearing), and (5) advanced prosthetics.

Organization and Personnel

A. Organization

Clinical and Rehabilitative Medicine Research Program Organization Chart



B. Personnel

COL (b) (6)	Director	Oct 2013 - July 2014
LTC (b) (6)	Deputy Director	Oct 2013 - Mar 2014
(b) (6)	Civilian Deputy Director	Oct 2013 - Sep 2014
MAJ (b) (6)	Deputy Director, Research Ops	Oct 2013 - Sep 2014
(b) (6)	Administrative Assistant , Azimuth	Oct 2013 - Sep 2014
(b) (6)	Contract support staff, Tunnel	Oct 2013 - Sep 2014
(b) (6)	Contract support staff, Tunnell	Oct 2013 - Sep 2014
(b) (6)	Contract support staff, GDIT	Oct 2013 - Sep 2014
(b) (6)	Contract support staff, GDIT	Oct 2013 - Sep 2014
(b) (6)	Contract support staff, Leidos	Oct 2013 - Sep 2014
LTC (b) (6)	Director	July 2014 - Sep 2014
MAJ (b) (6)	Deputy Director	July 2014 - Sep 2014
(b) (6)	Civilian, Sensory Systems Portfolio	Sep 2014 - Sep 2014

C. Key Personnel Functions

1. Plans, coordinates, and oversees the execution of core RDT&E funding for clinical and rehabilitative medicine.
2. Provides policy, process and execution oversight for all clinical and rehabilitative medicine-related congressional programs managed by TATRC and the CDMRP.
3. Assures that these congressional programs are aligned with appropriate core programs and that all RADs are informed of cross-cutting science opportunities.
4. Serves as Command lead for coordination and integration of appropriate core and Congressional programs with the clinical investigations community of the U.S. Army Medical Command, the Military Health System and the Department of Veterans Affairs.
5. Maintains technology watches for innovations in definitive and rehabilitative care required to reset wounded warriors relative to duty performance and quality of life.
6. Facilitates leveraging of external funding from other governmental and non-governmental organizations to advance core program goals.
7. Reports to the PA(R&T).

Training and Education

A. Training

1. October 1, 2013-Sep 2014, CRMRP Personnel completed various training session on the MRMC Electronic Document Management System (EDMS), Sexual Harassment and Assault, Army Substance Abuse Program, Master Resiliency Training, AT Level 1 Awareness Training, J3TA-US022 SERE 100.1 Level A Code of Conduct Training, Annual Ethics, Privacy Act and HIPAA Annual Refresher Training.
2. October 1, 2013 – Sep 2014, CRMRP Personnel completed training on the Department of Defense Travel System (DTS) and various Defense Acquisition and Project Management Professional (PMP) Training courses.
3. November 13, 2013, (b) (6), Administrative Support completed training on the Army Records Information Management System (ARIMS), which replaces the Modern Army Recordkeeping System (MARKS). Training helped the record keeper to understand the purpose of Army record keeping (manage information from creation through final disposition) and define the key design features in ARIMS. Training provided the user with a better understanding of how to navigate and operate the system and use the ARIMS Help Desk.

B. Education

August 2014 – present, (b) (6), CRMRP Budget Analyst enrolled in the Master of Business Administration program at Mount St. Mary's University. The program focuses on problem-solving, communication, critical analysis and ethical decision-making.

Research and Development

1. October 2013-September 2014, (b) (6) participated in Vision Setting and Programmatic Review meetings for the Peer Reviewed Orthopedic Research Program (PRORP), Spinal Cord Injury Research Program (SCIRP) and the FY14-15 Neuromusculoskeletal Injuries Research Award.
2. October 2013-September 2014, (b) (6) served as a reviewer for the Veteran's Administration (VA) Small Projects in Rehabilitation Research (SPiRE) program. SPiRE is an intramural funding

mechanism to support investigator-initiated research conducted by eligible VA Office of Research and Development (VA-ORD) investigators at VA medical centers or VA-approved sites. SPiRE Awards are a funding mechanism for small scope and duration basic, translational and clinical studies of disorders and diseases of importance to the rehabilitation of veterans.

3. October 2013-September 2014, (b) (6) served as an External Review Board Member for the Center for Rehabilitative Sciences Research (CRSR). Reviewed 5 year progress of CRSR and provided input to the future directions of the program.
4. January 13-15, 2014 (b) (6) attended the University of North Carolina (UNC) Rehabilitation Research workshop. The purpose of the meeting was to engage younger investigators in the field of rehabilitation research. The meeting was conducted in Raleigh, North Carolina.
5. January 31, 2014, (b) (6) participated as a reviewer for the Combat Casualty Care Research Program (CCCRP) Burn and Wound Healing programmatic review. The review was held at Ft. Detrick, Maryland.
6. February 7, 2014, (b) (6) presented an overview of the regenerative medicine portfolio for the AMEDD General Officer (GO) visit at Ft. Detrick, Maryland
7. Feb 11-12, (b) (6) attended the Extremity War Injury Symposium which provided research updates from the orthopedic surgery community.
8. March 14, 2014, (b) (6) attended the Combat Casualty Care Research Program Psychological Health and Traumatic Brain Injury (TBI) In Progress Review (IPR). The in-process review examined Defense Health Program funded research efforts from FY07 to current and focused on TBI Non-Invasive Diagnostics.
9. April 1, 2014, COL (b) (6) and (b) (6) presented a Regenerative Medicine Deep Dive to the Honorable Heidi Shyu, the Assistant Secretary of the Army (Acquisition, Logistics & Technology) and Army Acquisition Executive. The purpose of the presentation was to provide an overview of the Army regenerative medicine program. The presentation took place the Pentagon in Washington, DC.
10. February 19, 2014, COL (b) (6), (b) (6), and (b) (6) attended an informational exchange meeting with the Centers for Medicare and Medicaid Services (CMS). The meeting was designed to discuss possible CMS processes for DoD and VA stakeholders regarding innovative products such as prosthetics and vascularized composite allotransplantation technologies. The meeting was conducted in Baltimore, Maryland.
11. March 2014, As part of the MRMC Vision Grand Challenge, MRMC held the Ocular Therapies In-Progress (IPR) meeting on 21 March 2014. This IPR showcased MRMC funded efforts aimed at progressing the field of Ocular Therapies with presentations from researchers on progress to date, significant accomplishments, and future plans. This meeting was coordinated in response to the MDA's effort to expedite development of artificial vision capabilities for the Warfighter. At this meeting, the MDA announced the kickoff of the Horus Vision Restoration Project to develop visual prostheses technologies.
12. April 25, 2014, COL (b) (6) and (b) (6) attended an Air Force presentation on research projects aligning with JPC8. The meeting was held at Ft. Detrick, Maryland.
13. May 2014, (b) (6) attended the National Center for Medical Rehabilitation Research (NCMRR) Board Meeting. Received updates from NCMRR on research, research partners, upcoming announcements, and highlights of successful projects.
14. May 4-8, 2014, CRM (b) (6) Attended annual ARVO meeting in Orlando, FL. Met with researchers in the areas of vision restoration, ocular implants, and discuss the latest technologies in ocular injury treatments. The CRM team also engaged with the exhibitors and vendors to

market the MRMC Vision Grand Challenge and inform them of an upcoming opportunity to work with the DoD through a Public Private Partnership known as the Medical Technical Enterprise Consortium (MTEC).

15. May 4-7, 2014, COL (b) (6) and (b) (6) attended the Regenerative Medicine Foundation Conference. COL (b) (6) provided a presentation on the regenerative medicine program within the DoD. The purpose of the meeting was to provide participants with knowledge about product development advancements and the latest research discoveries in the regenerative medicine community in an **unbiased and open forum**. The meeting was conducted in San Francisco, California.

16. May 17-20 2014, (b) (6) attended the American Telemedicine Association Meeting, Baltimore, MD.

17. May 18-23, 2014, (b) (6) and COL (b) (6) attended NATO Regenerative Medicine Workshop. The focus of the meeting was to develop the foundation of an international network of experts in the field of Regenerative Medicine to bring forward new therapies to enhance the recovery of those wounded in action. COL (b) (6) served as the co-chairman for the workshop, and (b) (6) provided a presentation entitled "Bone loss and injury: What is the unique military need, and how best to impact a very crowded field?" The meeting was conducted in Berlin, Germany.

18. May 21, 2014, (b) (6) attended the Defense Advanced Research Projects Agency (DARPA) Demo Day at the Pentagon. DARPA provided updates on technology advances including the DEKA and John Hopkins University Applied Physics Laboratory prosthetic arms.

19. May 29, 2014, (b) (6) participated in the mission setting for the Care for Maxillofacial Injuries program within the combat casualty care research program. The meeting was held at Ft. Detrick, Maryland.

20. May 30, 2014, COL (b) (6) and (b) (6) participated in a programmatic review for the Regenerative Medicine Clinical Trial program announcement. The meeting was held at Ft. Detrick, Maryland.

21. June 2014, The CRM team (b) (6) was tasked to assemble a Working Group meeting to develop The Horus Vision Restoration Project with the primary goal of restoring vision to individuals with traumatic or functional enucleation. It is anticipated that this effort will include development of a brain-machine interface prototype technology ready for human testing within five years that provides (1) an individual with the ability to navigate, identify faces and objects critical to daily life, read large print, and is (2) an economically feasible option.

22. June – September 2014, (b) (6) attended State of the Science Symposia series hosted by the Center for Rehabilitative Sciences Research (CRSR). Topics included Regenerative Medicine for the wounded and Assistive Technologies.

23. July 8-10, 2014, (b) (6) attended the Federal Amputation Advanced Skills Training (FAAST) Symposium. The symposium was sponsored by the Veterans Health Administration (VHA) Employee Education System, the VHA Office of Rehabilitation and Prosthetic Services, and the Department of Defense and provided skills training and science updates on Amputee Care within the DoD and VA systems.

24. July 29, 2014, (b) (6) attended the Clinical Research Initiative (CRI) Intramural Research Award Programmatic Review. Intramural funding program announcement included a research topic for neuromusculoskeletal injuries.

25. August 18-21, 2014, LTC (b) (6), MAJ (b) (6) and (b) (6) attended the Military Health System Research Symposium (MHSRS). The primary theme of the conference was "Military medical research across the continuum of care". The meeting provides a forum for the military medical community to meet, present recent research findings, and discuss their impact. Sessions included plenary and breakouts covering topics ranging from pre-hospital care, surgery and resuscitation, and addressing related tissue injury. (b) (6)

(b) (6) served as the moderator for the breakout sessions on "Trauma Care – Craniofacial Trauma & Face Regenerative Research". The meeting was conducted in Fort Lauderdale, Florida.

26. August 19, 2014, LTC (b) (6) MAJ (b) (6) and (b) (6) attended the JPC8 meeting. The purpose of the meeting was to provide the JPC membership with an update on the portfolios, recent activities, and future plans. The meeting was conducted in Fort Lauderdale, Florida.
27. FY14 Restorative Transplantation Research (RTR) Program announcement was released.
28. $9.7 M was awarded in DHP 6.3/6.4 funds through the FY14 Regenerative Medicine Clinical Trial Award.
29. September 2014, Worked to finalize Materiel Development Decision brief for November 2014 PLRC review.
30. September 2014, Dr. Pamela Brown Baer published *Methods to Analyze Bone Regenerative Response to Different rhBMP-2 Doses in Rabbit Craniofacial Defects*, T.Guda, A. Darr, D.T. Silliman, M.H.R. Mango, J.C. Wenke, J. Kohn, and **P. R. Brown Baer**. Tissue Engineering: Part C, 20:9, September 2014, 749-760.
31. September 2014, Sensory System Portfolio Manager continued participation as a member of the IPT/Working Group for Advanced Development Efforts of the Corneal Bandage.

Resource Management and Budget

The Clinical and Rehabilitative Medicine Research Program managed the execution of $21 million of Army and $38 million of Defense Health Program RDT&E funding. Provided oversight for the execution of $100 million for Military relevant FY14 Congressional Special Interest programs which included Peer Reviewed Orthopedic Research, Peer Reviewed Spinal Cord Injury Research, Peer Reviewed Medical Research, Peer Reviewed Vision Research, Reconstructive Transplantation Research, Orthotics and Prosthetics Outcomes Research, Psychological Health/Traumatic Brain Injury and the DOD Joint Warfighter Medical Research Program.

Information Management

1. CRMRP Staff ((b) (6) and MAJ (b) (6)) continued to work improvements to the CRMRP website and provided a new format to MRMC Information Management. A final webpage is still in preparation.
2. CRM (MAJ (b) (6) and (b) (6)) worked with Information Management team to stand up a webpage for JPC-8 communication/meeting information for use by appointed JPC-8 membership.

Section 14

Fiscal Year 2014
Annual Historical Report

The Joint Program Committee Medical Simulation
and Information Sciences

Mission

The Joint Program Committee (JPC1) Medical Simulation and Information Sciences (MSIS) Research Program supports the Secretary of the Defense's imperatives to responsively and responsibly coordinate emerging military medical simulation and health information technologies/informatics research across all stakeholder communities and transfer research knowledge to meet Military Health System goals. The overall mission of the MSIS is to plan, coordinate, and oversee a world-class tri-service science and technology (S&T) program focused on improving military medical training through clinically relevant medical simulation, educational gaming, objective training metrics, and democratization of open source technology as well as improving health information sciences through increased interoperability, strategic planning and process development and medical applications. MSIS also has planning and programming responsibility for the Pacific Joint Information Technology Center (PJITC) mission.

The two key MSIS components and their respective research portfolio focus areas are as follows:

A. Medical Simulation and Training

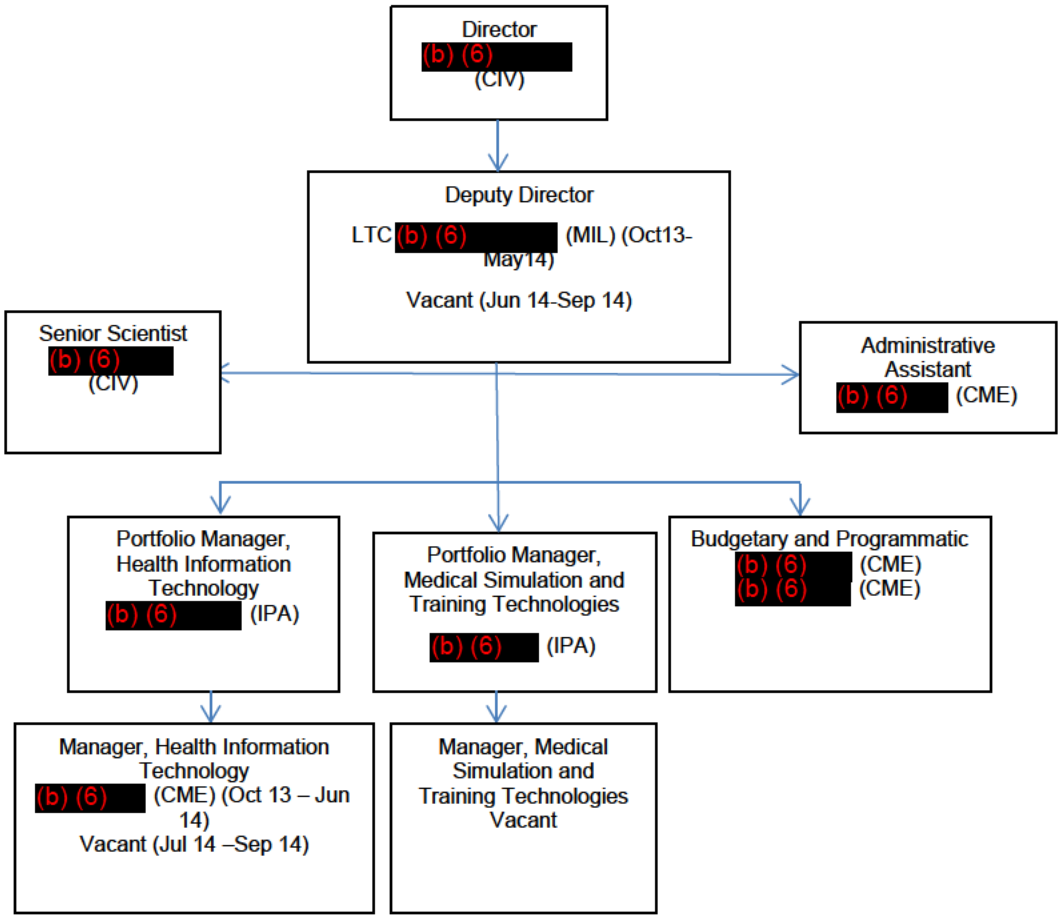
1) Combat Casualty Training Initiative: Advancing combat casualty training, R&D on ways to have tissue appropriate responses, develop High State of combat medical readiness tools, performance under stress training prior to deployment, and evaluate more efficient and effective ways to deliver team training.
2) Medical Readiness Initiative: Research and development of medical training systems & competency assessment for sustained military medical readiness. Methodologies, techniques, and tools that will allow for ethical, accurate, and appropriate pre-intervention rehearsal with input of potential authorized personalized medical info. Evidence-based efforts with measurable outcomes and reliable assessments.
3) Tools for Medical Education: Develop and test open source training platforms, toolkits, and models to shift the focus from developing basic medical training technology to generation of evidence-based training content in order to improve patient safety.
4) Health Focused Initiative: Seeks to develop and test self-care technologies patients will use, whenever and wherever they choose, to manage personal health and wellness. Advanced user interface and interactive technologies for healthy living, preventative-disease management, patient rehabilitation & re-engagement.

B. Health Information Sciences and Informatics

1) Theater/Operational Medicine: Research to capture, document, and transmission of bio-medical data. This area also explores transformational technologies for alternatives for enhanced core logistics systems to improve automatic identification technologies and medical material management.
2) Healthcare Services: Research to investigate the use of Health Information Technology (HIT) to improve user interface and decision support.
3) Medical Resourcing: Research possible uses of HIT as a mechanism to infuse improvements for the provision and management of military medical training.
4) Enterprise Infrastructure Management: Research to investigate and improve management and movement of data. This area also explores emerging technologies that improve the provision and management of healthcare outside the MTF walls or with a remote care provider.

Organization and Personnel:

Medical Simulation and Information Sciences Research Program Organizational Chart



One position (Manager, Medical Simulation and Training Technologies) remained vacant throughout 2014. Ms. Andrea Haught (Manager, Health Information Technology) left in early June 2014 and the position remained vacant from early June 2014 through September 2014. LTC (b) (6) (Deputy, Director) left in early May 2014 and the position was vacant from early May 2014 through September 2014.

NAME	POSITION	DATES
(b) (6)	Director	Oct 2013 – Sep 2014
LTC (b) (6)	Deputy Director	Oct 2013 – May 2014
Vacant	Deputy Director	May 2014 – Sep 2014
(b) (6)	Administrative Assistant	Oct 2013 – Sep 2014
(b) (6)	Senior Scientist	Oct 2013 – Sep 2014

(b) (6)	Support Staff, Univ. of MD, IPA	Oct 2013 – Sep 2014
	Support Staff, Univ. of AZ, IPA	Oct 2013 – Sep 5, 2014
	Contract Support Staff, IBA	Sep 6, 14 –Sep 30, 2014
	Contract Support Staff, IBA	Oct 2013 – Sep 2014
	Contract Support Staff, IBA	Oct 2013 – Sep 2014
	Contract Support Staff, IBA	Oct 2013 – Jun 2014
	Manager, Health Information technology	Jun 2014 – Sep 2014

Personnel Strength at beginning and end of FY14:

	October 1, 2013	September 30, 2014	
Military	1	0	
Civilian	2	2	
Contractor		4	3.5
IPA	2	1	
Total	9	6.5	

Statistical data:

A. Plan and Program Mid-term and Long-term Program Objectives
1) Lead 15 inter-agency committee meetings to prioritize capability gaps
2) Conducted 30 Interactions with functional proponents to identify capability gaps
3) Developed one Program Objective Memorandum (POM) package
4) Developed one mid-term Unfunded Requirement (UFR) list
5) Prepared and presented 8 decision briefs

B. Define Near- and Mid-Term Command Budget Estimate
1) Lead 15 inter-agency committee meetings
2) Created 6 program announcement topics
3) Reviewed 10+ SOO/SOW Documents for PJITC Projects
4) Developed one Command Budget Estimate (CBE) package
5) Developed one near-term UFR list
6) Revised Broad Agency Announcement (BAA) language
7) Created 1SBIR topic
8) Developed 6 near-term Program Announcements and Request for Proposals (RFP) to support the research program
9) Created 15+ funding distribution documents
10) Maintained one integrated spend plan for grants/contracts
11) Reviewed 125+ pre-proposals and 30+ full proposals
12) Revised 3 MedSim and HIT research roadmaps
13) Processed 26 Defense Business Information Technology Certification (DBITC) packages

C. Oversee and Report on Research Program
1) Evaluated 100+ new and ongoing project quad charts
2) Evaluated 45+ research projects
3) Responded to 28 taskings/congressional inquiries regarding research programs
4) Held/attended 10 In-Process Reviews (IPRs)
5) Conducted 17 Information Briefs

D. Distribute and Track Research Program Funds
1) Oversaw financial distributions of 63 new/ongoing awards
2) Determined continuation of 15 ongoing efforts

E. Management and Administration
1) Addressed 300+ Suspense Items/Taskers
2) Conducted 20+ Grant/contract management reviews
3) Participated in 72 USAMRMC management meetings

F. Technology Watch
1) Attended 4 Medical Simulation or Health Information Technology conferences

Part of the MSIS mission includes funding combat casualty simulation research to address decreasing the reliance on live animals for training purposes resulting in significant MSIS reporting requirements related to Congressional mandates and requests for information.

MSIS has responsibility for DBIT Certification of projects, programming for the Pacific Joint Information Technology Center (PJITC) mission, and new Military Health System (DHA) Governance requirements.

Healthcare Delivery:
N/A

Veterinary Services:
N/A

Training and Education:
N/A

Research and Development:
Both MSIS components have developed research portfolios and conducted programmatic reviews through participation of military and civilian end-users, who evaluated proposals and effectiveness of research plan developments. Major research project areas engaged are described below.

A. Health Information Technology Portfolio

1) Theater/Operational Medicine:
Research to promote, improve, conserve, or restore the mental or physical well-being of personnel through improved information management and technologies in Medical Command & Control, Medical Logistics and Humanitarian Assistance/Support Operations. Specific goals include:
   a. Conduct research on capabilities to enable commanders to efficiently and effectively manage medical information and medical work flows;
   b. Explore transformational technologies to improve core logistics systems: i.e. information systems, automatic identification technologies, medical material management to include blood, oxygen, or other materiel with specific environmental handling requirements;
   c. Conduct research on emerging technologies for providing assistance in response to natural or manmade disasters;
   d. Improve the capturing of physiologic data and care documentation from Role 1 through Role 3 and the transmission of that data to support patient care and evacuation.

2) Healthcare Services:
Research to enhance the efficiency of health care operations; ensure the delivery of high-quality healthcare services by improving information accessibility and by providing better decision support for clinicians. Specific goals include:

a. Improvements to systems or applications that will better assist health professionals in making clinical decisions;
b. Provide a user view of information that is a comprehensive of the patient record with the ability to exclude certain sensitive information for specific users when necessary i.e. mental health record information.

3) Health Operations Resourcing:
Research initiatives to improve the management of healthcare human and financial resources. Specific goals include:
a. Conduct research to improve the training by streamlining the access to and management of educational systems across the DHA;
b. Conduct research to explore the use of HIT in the provision of training.

4) Health Enterprise Infrastructure:
Research to improve the management of Information Technology (IT) and communications infrastructure, healthcare data management, and architecture. Specific goals include conduct of research:
a. Into system interfaces that will ensure that products or systems work efficiently with other products or systems, present or future, without any unintended restrictions;
b. To move toward a common data format capable of exchanging data seamlessly within the DHA and with external organizations;
c. To ensure the unique identification of each patient to support safe and efficient patient/ beneficiary care and management;
d. To provide real time access to data from sources in multiple, disparate physical locations and aggregation as necessary to facilitate crawling, indexing, security, identity, authentication, authorization and privacy.

B. Medical Simulation and Training Technologies Portfolio

1) Combat Casualty Training Initiative (CCTI):
This research focuses on advancing training in casualty care. This will examine the efficacy of modern simulation systems vs current training models with emphasis on multi-trauma and mass-casualty scenarios. Research to inform simulation development and acquisition on ways to reduce and refine the use of live tissue for training; to develop training assets for High State of combat medical readiness; provide resiliency training prior to deployment to better elicit higher performance under pressure when facing anticipated stressors; and evaluate more efficient and effective ways to deliver team (collective) training.
Specific goals include:
a. Continue to identify issues with current military models and curriculum to determine current strengths/weaknesses and address significant gaps between live tissue used for training vs. currently available medical simulation systems;
b. Researching material and/or virtual solutions as alternates to live tissue use for military training and education;
c. Emphasizing approaches toward “anytime readiness” in a near-future era of reduced deployment OPTEMPO;
d. Building psychological resilience towards stress inoculation into pre-deployment training.

2) Medical Readiness Initiative (MRI):
Research and development will lead to evidence-based clinical skills acquisition and sustainment techniques, along with management techniques to minimize recognizable psychomotor and cognitive skill degradation via technologies aimed to guide training throughout healthcare careers. Patient safety & improvement in Clinical Outcomes are the ultimate underlying themes of the MRI. R&D efforts will include, but are not limited to methodologies, techniques, and tools that will allow for ethical, accurate, and appropriate pre-intervention rehearsal with input of potential authorized personalized medical information as well as translation of educational outcomes to mimic real care-giving applications. Additionally, research efforts in this domain need be related to evidence with measurable outcomes.

Specific goals include:

a. Leveraging and creating training technology advances to keep U.S. military medicine on top;
b. Understanding proficiency and how to best facilitate it and when achieved how best to practice skills to minimize decay;
c. Pioneering automated adaptive learning to tailor training to health care providers' needs;
d. Leading the way to a sustainable medical education life cycle.

3) Health Focused Initiative (HFI):
This initiative seeks to develop and test self-care technologies patients use, whenever and wherever they choose, to manage personal health and wellness. Aimed at promoting patient engagement and resilience, this research will deliver technologies that improve the human-machine interface and bridge the gap between patients and clinicians. The focus is on advanced medical technologies research targeting the management of acute and chronic health challenges, and technologies that encourage health promoting behaviors at home and in theater.
Specific goals include:

a. Researching areas that capitalizes use of currently off-the-shelf technology and integrates educational applications relevant to the Wounded;
b. Research best motivational and behavioral changing adolescent and adult learning methodologies and package into user-friendly health promotional tools;
c. Investigating best methods to capture regional/sub-group population health issues and provide educational and training tools to assist non-health care providers when faced with community impactful emergency situations.

4) Tools for Medical Education:
Focus is to develop and test trans-disciplinary, open source training platforms, toolkits, and models. Research initiative intent is to shift the focus from developing basic medical training technology to generation of evidence-based training content in order to improve patient safety, maximize system and organization-level return on investment, increase available training opportunities, and minimize training burden. The initiative also includes resource sharing, leveraging collaborative research projects, and democratization of knowledge and products to the medical modeling, simulation, training, and education community at-large.
Specific goals include:

a. Ensuring that advanced medical simulation capabilities are ubiquitous;
b. Encouraging the highest level of innovation across all initiatives;
c. Democratizing access to advanced Medical Simulator technology so that it can be used by large and small innovators alike;
d. Saving money by eliminating wasteful and redundant research and development.

Resource Management and Budget:

The Medical Simulation and Information Sciences Research Program managed the execution of the Defense Health Program (DHP) research programs of $43.6M, inclusive of the Pacific Joint Information Technology Center (PJITC) funding. Military relevant programs include:

Health Information Technology	$26.7M
Medical Training and Simulation	$16.9M

HIT funds included PJITC executed projects (9) that came to a total of $21.4M
Due to the Budget Control Act (BCA), the JPC-1 FY14 budget was reduced by 29%.

Information Management:

MSIS continued to use of the MRMC Review Website in 2014 to collect, manage, and maintain programmatic input. This website is a robust tool that allows analysis of reviews for a myriad of pre and full proposals.

Operations:

A. JPC-1 Re-charter
JPC-1 was re-chartered in June of 2014. At this time the name of JPC-1 was changed to Medical Simulation and Information Sciences (MSIS) Research Program. The medical modeling research portfolio is now named Medical Modeling, Simulation and Training (MMS&T).

B. Steering Committee (Working Group) Members
Portfolio-based Steering Committee meetings were conducted to perform programmatic review, identify capability gaps, prioritize research proposals and build funding recommendations. Each member of the work group was responsible for supporting the processes that lead to refinement of research gaps; translation of these gaps into solicitations for research that leads to countermeasures/solutions; and balancing the portfolio of investment to maximize rapid development of critical solution to the Warfighter.

The JPC's mission is to support the DoD mission by planning and overseeing RDT&E activities that support discovery and development of materiel, knowledge, and training solutions that reduce medical capability gaps relevant to medical training and health information sciences; and advise on opportunities to enhance medical capabilities in this area. The JPC-1 advises and supports the JPC Chair in the development of planning, programming, and budgeting recommendations to the Office of the Assistance Secretary of Defense for Health Affairs (OASD(HA) for the DHP RDT&E appropriation. Committee members were invited from appropriate organizations to represent the equities and interests of their parent organizations and to share information on their respective programs. As part of this responsibility, members inform the JPC Chair of relevant RDT&E efforts that are independently sponsored by the Services and components they represent. Members ensure the program and its final products meet the following:

1) Align to validated capability gaps;
2) Are feasible and can be integrated into and implemented by the DHA and the military Services and components;
3) Effectively leverage and are not duplicative of other related RDT&E efforts within the DoD and/or other federal programs; and
4) Provide a balanced overall RDT&E program, including balance between technology push and requirements pull.

On 6 January 2014, the JPC-1 Committee met to discuss the FY15-17 near-term plan. The purpose of the meeting was for committee members to understand the Defense Medical Research and Development Program (DMRDP) and understand the responsibilities of JPC committee members. The medical simulation and training and health information sciences strategic plans and research roadmaps were discussed. The FY15-17 near-term research plans were discussed with concurrence from JPC members.

C. Briefings to Senior Leaders

January 25-29, 2014, (b) (6) attended the International Meeting for Simulation in Healthcare (IMSH). (b) (6) was able to provide an overview of the DHP medical simulation RDT&E concepts. (b) (6) was informed and educated on current information about medical training trends nationally, as well as peer-reviewed academic presentations on topics of relevance to military healthcare training. He was also exposed to the most recent advances in simulation-based devices and/or systems of training, as well as methods to assess training effectiveness.

February 7, 2014, Combat Casualty Training Consortia (CCTC) presented In-Progress Review findings to Dr. Woodson and others at ASD/HA. Biannual Videoconference with Dr. Woodson and others at ASD/HA provided the opportunity for the three Principal Investigators of the Combat Casualty Training Consortium (CCTC) to present updates on their research. (b) (6) all provided status updates, preliminary results, and research next-steps.

February 6, 2014, (b) (6) provided an update of the Combat Casualty Training Consortia (CCTC) progress to the FHP&R and AT&L co-chairs and committee.

February 12, 2014, (b) (6) briefed the JPC-1 FY 16-21 POM and Near-Term Plan to Drs. Glenn, Bertram, and Vesely.

Feb 18, 2014, (b) (6) attended the Institute for Creative Technology In Progress Review sponsored by RDECOM-STTC. Projects reviewed were funded through different military funding such Army (ARL), Navy (ONR), and DHP (JPC-1). Very successful review of the portfolio

Feb 19-21, 2014, (b) (6) attended the Medicine Meets Virtual Reality (MMVR) conference. Presented JPC-1 medical simulation & training RDT&E concepts. Additionally, Univ. of Minnesota presented an interim report to the public on their CCTC research.

February 25, 2014, (b) (6) attended a meeting between ASD (RE) and HASC Professional Staff Members to provide an update on JPC-1's Live Tissue Training Research.

March 5, 2014, (b) (6) briefed the Program Integration Advisory Committee (PIAC) for the Defense Health Agency (DHA) Research, Development and Acquisition Directorate about the JPC-1 FY16-20 POM Plan.
March 6, 2014, (b) (6) provided MG Caravalho a PJITC Overview and information briefing. (b) (6) attended with Lt Gen Robb, (b) (6), and CDR (b) (6).

March 10, 2014, (b) (6) assisted in the VIP demonstration and tour of the MRMC Innovation Center (Bldg 1078). He demonstrated a mannequin that had higher fidelity material properties that were more representative than most mannequins. Project funded through SBIR and DHP (JPC-1) funding.

April 3, 2014, (b) (6) briefed a Swedish military delegation on the HIT research program.

April 11, 2014, (b) (6) briefed (b) (6), Dr. Rauch, and CAPT Biggerstaff during their VIP visit to the Air Force Medical Evacuation Support Activity (AFMESA). Updates were provided on tissue material properties that could be used for Medical Simulation.

April 15, 2014, LTC (b) (6) held an Industry Day to discuss the concept for the Joint Evacuation Training System.

May 17-20, 2014, (b) (6) attended the American Telemedicine Association (ATA) 2014 Conference. The conference fulfilled JPC-1 expectations and provided tangible deliverables for DHP-funded attendees. JPC-1 participants also networked with colleagues in the field of telemedicine to learn what is known and unknown in this field in order to augment DoD knowledge and technology gap analysis and build an international base for ongoing research.

June 23, 2014, (b) (6) briefed RADM Doll on the JPC-1 FY15-17 Near-Term Plan.

June 17, 2014 (b) (6) briefed Brigadier General Bricknell & Brigadier General Nadin from the UK on the medical simulation and training portfolio Conducted Combat Casualty Training Initiative In-

Progress Review, which included many near-end research results from the three Combat Casualty Training Consortia.

June 24- 26, 2014, Medical Simulation & Training conducted an In Progress Review on the Combat Casualty Training Initiative projects and all three (3) PIs representing the CCTC were present and provided their updates to the (b) (6) and the committee.

July 15, 2014, (b) (6) participated in a meeting and presentation about Bio-Mathematical Modeling of Tissue for Virtual Reality to (b) (6). This was in response to the mandate to reduce and refine the use of live tissue for training but also to inform consequences of the current lack of PE 6.1/6.2 funding within JPC-1. The presentation discussed the concept of increasing research of measuring more, diverse range, and aggregated tissue properties; and analyzing the data and researching more elegant bio-mathematical models than are currently available. This knowledge was used to inform plans for more intense/robust virtual reality models in the future. In attendance were (b) (6), LTC (b) (6) (OASD-RDT&E), (b) (6) DoD Human Performance, Training, and Bio Systems), and (b) (6)

July 16, 2014, (b) (6) accompanied (b) (6) (HASC PSM), (b) (6) (HASC Fellow), and (b) (6) (HASC Staff) in their visit of the medical simulator facilities at the University of Maryland Medical Center in Baltimore, MD and a company (Operative Experience) in North East, MD that manufactures medical simulators. The purpose of the visit was to view advances in medical simulation as the PSMs are interested in how the DoD can use the simulators to decrease the use of animals in medical testing and training.

July 17, 2014, (b) (6) participated in a meeting convened by (b) (6) DASD (FHP&R) to discuss the abstracts accepted for presentation at the MHSRS by the Combat Casualty Training Consortium. Also in attendance were RADM Doll, Dr. Rauch, CAPT Sean Biggerstaff, (b) (6), LTC (b) (6), and (b) (6).

June 16 – 17, 2014, (b) (6) attended the Navy Central Simulation Meeting in Portsmouth, VA and provided updates of some of the DHP – JPC-1 funded projects plus provided a brief on some of the future roadmap concepts to the attendees.

July 21, 2014, (b) (6) participated in a briefing and discussion with the HASC and SASC regarding Simulation Use for Medical Education and Training in the DoD. (b) (6), LTC (b) (6) (DASD(FHP&R)), Dr. Terry Rauch, Dr. Frazier Glenn, (b) (6), Maj (b) (6), and SGM (b) (6) were in attendance.

July 23, 2014, (b) (6) attended the DHP Near Term PIAC meeting.

July 28-31, 2014, (b) (6) attended the Defense Health IT Symposium sponsored by the DHA Chief Information Office's (CIO).

August 17-21, 2014, MSIS attended the Military Health System Research Symposium (MHSRS) which is the Department of Defense's (DoD) premier scientific meeting. This Joint symposium provides a collaborative environment for military medical care providers with deployment experience, DoD scientists, academia, and industry to exchange information on research and health care advancements within the areas of Combat Casualty Care, Military Operational Medicine, Clinical and Rehabilitative Medicine, and Military Infectious Disease Research Programs. JPC-1 had three (3) breakout sessions: Training and Skills Sustainment; Combat Casualty Simulation and Training, Bioinformatics Training and Skills Sustainment; and, Military Medical Skills Acquisition and Sustainment.

September 30, 2014, (b) (6) provided a brief to (b) (6), Program Executive Officer (PEO) for the DoD Healthcare Management System (DHMS) on the JPC-1 processes. Also in attendance were (b) (6) (PEO DHMS), CAPT Sean Biggerstaff (DHA RDA), and (b) (6) (USAMRMC). The following items were discussed: DHA RDA organizational structure; JPC governance structure, roles and responsibilities, and program processes; Defense Business Information Technology (DBIT) certification; health information task areas and capability gaps; and the JPC-1 committee and Health Information Technology (HIT) workgroup memberships. (b) (6) was surprised that research efforts required DBIT certification.

D. Defense Business Investment Technology (DBIT) Certification
The Defense Business Information Technology Certification (DBITC) process requires that funds expended on Information Technology (IT), including those for research projects focused on IT, must be certified prior to execution. This process requires close coordination with, and the provision of a number of reports and other artifacts to the Defense Health Agency Chief Information Officer (DHA CIO) staff. JPC-1 develops and/or coordinates with the execution agents to develop and submit the required documents.

E. OMB Reporting
MSIS submits required data to DHA on the research program through the DHA CIO office to comply with Office of Management and Budget (OMB) requirements. The OMB 300A report is updated annually with program information, while the OMB 300B form is updated monthly with project activity details and risks.

F. Annual Performance Plan Reporting
The MSIS submits quarterly status reports on research projects to the DHA CIO for inclusion in the DHA CIO Annual Performance Plan to track progress against established milestones for the research projects.

G. Health Information Technology Portfolio

The HIT workgroup chair was transitioned from JPC-1 to the DHA CIO's office in August 2014.

MSIS participated in weekly Interagency Clinical Informatics Board (ICIB) teleconferences. The ICIB is a joint DoD/VA meeting of SMEs who represent the DHA and VA to define the requirements and clinical processes of the two organizations.

MSIS participated in weekly Clinical Portfolio Management Board (CPMB) teleconferences. The CPMB manages and reviews development and implementation of clinical information management/information technology (IM/IT) practices and systems throughout the DHA Strategic Plan with Health Affairs (HA), Defense Health Agency (DHA), and DASD (C&PP) guidance.

MSIS participated in the Theater Functional Work Group (TFWG) teleconferences. The TFWG serves as the senior-level board, under the auspices of the Force Health Protection Integrating Council (FHPIC), responsible for ensuring electronic healthcare information systems and technologies for use in theater/contingency/humanitarian assistance/disaster response operations meet functional business practice needs and validated user requirements. The teleconferences were held on October 2, 2013 and March 5, 2014.

MSIS participated in the DHA Chief Information Officer (CIO) – Management Board teleconferences.

February 23-27, 2014, MSIS attended the Health Information Management Systems Society (HIMSS) Conference. HIMSS is a not-for-profit organization dedicated to improving healthcare quality, safety, cost-effectiveness, and access, through the best use of information technology and management

systems. Medical Device Interoperability, Medical Device Simulators, and RESTful Exchange projects were exhibited.

June 4, 2014, MSIS attended the Command, Control, Communications, Computers, Intelligence, Surveillance, and Reconnaissance (C4ISR) demonstration sponsored by the Telemedicine and Advanced Technology Research Center (TATRC).

September 20-25, 2014, MSIS attended the Nevada Telemedicine Conference. The goal of the conference was to examine the state of the art in rural and mobile telemedicine, establish federal, state and industry partnerships and finally, begin the development of Nevada as a Telemedicine Center of Excellence in a template that can be applied universally. Telemedicine capacity, gaps and opportunities to improve enroute care were discussed and demonstrated.

The MSIS established a Health Information Technology Workgroup comprised of representatives from the Services, the Joint Staff and DHA to develop strategies, set priorities and review research proposals. The workgroup conducted regular meetings on October 10, 2013, October 17, 2013, November 14, 2013, December 20, 2013, January 9, 2014, April 10, 2014, April 15, 2014, July 14, 2014, August 4, 2014, and September 12, 2014. Minutes of those meetings are on file.

H. Pacific Joint Information Technology Center (PJITC)

In its role as the execution oversight manager of the research projects under its purview, the JPC-1 staff participated in IPRs conducted by the Pacific Joint Information Technology Center (PJITC) one of several execution organizations responsible for executing the JPC-1 research projects. Those reviews were held on the following dates: November 18-21, 2013, February 3-6, 2014, June 2-4, 2014, and August 18-22, 2014.

I. Medical Simulation and Training Technologies Portfolio

December 10, 2013, MSIS held a Joint Medical Simulation and Training Technologies and Health Information Technology Meeting with programmatic review of Medial Modeling and Simulation Joint Program Management Office Concept of Operations (JPMO CONOPS), Medical Simulation and Training Strategic Plan, Health Information Sciences Strategic Plan, Prioritization and Refinement of JPC-1 task areas and gaps, Overview of DHA Research Construct, and Overview of FY12 – FY 14 JPC-1 Budget Cuts.

December 2-6, 2013, MSIS attended the Inter-service/Industry Training, Simulation and Education Conference (I/ITSEC). I/ITSEC promotes cooperation among the Armed Services, Industry, Academia and various Government agencies in pursuit of improved training and education programs, identification of common training issues and development of multiservice programs.

December 13-17, 2013, MSIS attended the Special Operations Medical Association (SOMA) conference in Tampa, FL. Received recent information from Special Operations Forces (SOF) community regarding types of injuries, some changes in their training, and potential research gap opportunities.

January 25-29, 2014, MSIS attended the International Meeting for Simulation in Healthcare (IMSH) Conference. (b) (6) presented the JPC-1 Medical Simulation Strategic Road Map to the medical education community.

February 19-22, 2014, MSIS attended the Medicine Meets Virtual Reality (MMVR) Conference. MMVR explores data-enabled technology for clinical care and medical education. Primary topics were simulation, modeling, imaging, visualization, robotics, haptics, sensors, informatics, and data

networking. Participants were computer scientists and engineers, physicians, biomedical professionals, medical educators, and students, military medicine specialists, medical device and IT industry, and healthcare futurists.
August 11-14, 2014, MSIS held a Medical Simulation and Training Technologies Steering Committee Meeting in Orlando, FL with In-Progress Reviews of the eleven (11) medical simulation and training projects within the Medical Practice Initiative – Tools for Medical Education (MPI-TME) Initiatives. JPC-1 members visited several Orlando, FL organizations that have significant involvement in medical simulation and training to further understand the respective capabilities of each organization as well as see product updates applicable to combat medic training. Organizations visited included the Program Executive Office for Simulation, Training, and Instrumentation (PEOSTRI); the Research, Development, and Engineering Command- Simulation and Training Technology Center (RDECOM-STTC); and the Naval Air Warfare Center Training Systems Division (NAWCTSD).

September 3, 2014, MSIS attended and presented Physiology Engine and Virtual Tissue Advancement concepts at the National Institute of Health (NIH) sponsored Interagency Modeling and Analysis Group.

September 3-4, 2014, MSIS participated in Medical Simulation (MedSim) and Training Systems Development meeting with members from Federal Medical Simulation and Training Consortium (FMSTC) to discuss Cost Benefit Analysis (CBA) Framework for MedSim.

September 22, 2014, MSIS along with Joint Program Committee-Six (JPC-6), the United States Army Medical Materiel Agency (USAMMA), and the Congressionally Directed Medical Research Program (CDMRP) office, conducted an In-Progress-Review the Intracranial Hematoma/Burr Hole and Trauma Flap Simulator project.

The MSIS Medical Simulation workgroup is comprised of representatives from the Services, PEOSTRI, USUHS, METC, and DCDD. The members develop strategies, set priorities, review research proposals, and make funding recommendations. They also help the workgroup chair, (b) (6) [redacted], with completion of the Near Term Plan and the POM. The workgroup conducted regular meetings on January 6, 2014, February 4, 2014, March 21, 2014, April 21, 2014, May 15, 2014, June 24-26, 2014, July 14, 2014, August 11-14, 2014, and September 10, 2014. Minutes of those meetings are on file.

Modernization:
N/A

Logistics:
N/A

Construction:
N/A

Health and Environment:
N/A

Other:
N/A

Appendices:

Section 15

Fiscal Year 2014
Annual Historical Report

Joint Trauma Analysis and Prevention of Injury in Combat

Mission:

The mission of the Joint Trauma Analysis and Prevention of Injury in Combat Program is to facilitate the collection, integration and analysis of injury outcome, materiel performance, and operational intelligence data to improve the understanding of our vulnerabilities to threats and to enable the development of improved protective equipment; vehicular equipment; and tactics, techniques and procedures that will prevent and/or mitigate combat injuries.

1) The JTAPIC Program was established at USAMRMC, Fort Detrick, in July 2006 to assist in fulfilling portions of the Secretary of the Army's EA responsibilities under DoDD 6025.21E ("Medical Research for Prevention, Mitigation and Treatment of Blast Injuries").

2) Prior to establishment of the JTAPIC Program, military organizations focused on improving warfighter survivability individually rather than collaboratively. The medical community focused on battlefield medicine and increasing warfighter survivability by using the best medical and treatment modalities available. Protective equipment developers focused on performance specifications and the development of process improvements under testing conditions because few articles were returned from killed in action (KIA) or wounded in action (WIA) events for analysis. When an article was returned, the analysis was performed without the benefit of full knowledge of the operational context or the injuries sustained by the warfighter. Operational context means understanding what happened to the warfighter and what he or she was doing at the time of injury. When vehicle improvements were fielded in Operation Iraqi Freedom (OIF), there was no formal process to provide vehicle developers with relevant contextualized medical information on combat injuries that could allow them to understand how well vehicles protected their occupants. Conversely, for the medical community, no formal process existed for providing medical injury data associated with combat operations to nonmedical users, such as combatant commanders, materiel developers, and requirement developers.

3) To streamline and enhance joint Service information sharing and collaboration for the analysis and prevention of injuries in combat, the JTAPIC Program was established as a joint "matrix" partnership in fall 2006 and formalized in 2012. The medical, materiel, operations, and intelligence subject matter experts (SMEs) stay embedded in their parent organization while their support and service to the JTAPIC mission is managed and coordinated by the JTAPIC PMO. The integrated analysis that occurs within the JTAPIC partnership strives to provide actionable decision support to inform prevention or mitigation solutions across the doctrine, organization, training, materiel, leader development, personnel, facility, and policy (DOTMLPF-P) domains that will prevent or mitigate traumatic injuries relative to all military operations and ultimately in combat.

FIGURE 1: JTAPIC Partner Organizations and Associated Charter Responsibilities

Partner Organization	Partner Organization Unique Responsibilities
Army Aeromedical Research Laboratory	Collect aviation and accident related incident data; provide subject matter expertise and analysis
Dismounted Incident Analysis Team (Army)	Collect dismounted operations and intelligence incident data; provide subject matter expertise and analysis
Current Operations Analysis Support Team (Marine Corps)	Provide Marine Corps related operations research analysis and subject matter expertise
National Ground Intelligence Center (Army)	Collect mounted operations and intelligence incident data; provide forensic vehicle analysis, information management support and services, subject matter expertise, and analysis
Marine Corps Intelligence Agency	Provide Marine Corps related intelligence analysis and subject matter expertise
Armed Forces Medical Examiner System	Collect Killed In Action (KIA) injury data; provide KIA injury coding, subject matter expertise, and analysis
Naval Health Research Center	Collect Wounded In Action (WIA) injury data; provide WIA injury coding, subject matter expertise, and analysis

Joint Trauma System	Provide Wounded In Action traumatic injury subject matter expertise and analysis
Army Research Laboratory	Provide forensic evidence (ballistics, fragments, other metals, etc) analysis, experimentation support and services, comparative analysis between life-fire tests and operational events, survivability and lethality modeling and simulation support and services, information management support and services, subject matter expertise, and analysis
Project Manager, Soldier Protective Individual Equipment (Army)	Collect damaged personal protective equipment (PPE); provide PPE analysis and subject matter expertise
Product Manager, Infantry Combat Equipment (Marine Corps)	Collect damaged Marine personal protective equipment (PPE); provide PPE analysis and subject matter expertise

Organization and Personnel

A. **The Program Management Office (PMO) went through a few major changes in 2014.**

1) In early 2014 the JTAPIC PMO restructured its positions from four (4) Project Managers to three (3) Project Managers and one (1) Decision Support Product Manager. The new position and function of the Product Manager would be to coordinate all final products across the program to include: Requests for Information (RFI) products and deliverables in support of the JTAPIC PMO project areas Incident Analysis Project Area, Sensors and mTBI, and Information management. The Product Manager assists in project area planning and execution, development of policies and procedures, and serves as the focal point for project level deliverables. Since the establishment of the new structure, the JTAPIC program has seen an increase in RFI products and deliverables completed and delivered on time achieving 90% goal of on-time deliverables. The change in structure has also changed and improved the RFI process. The RFI process is more efficient and streamlined which has increased JTAPIC customer satisfaction.
2) In March 2014 the Operations Manager, (b) (6) , transitioned of off of the program and was replaced by the new Operations Manager, (b) (6) , in May 2014.
3) In May 2014 the Program Manager (PM), COL (b) (6) , performed a permanent change of station (PCS) move. The Deputy PM (DPM), (b) (6) , was the acting PM until the arrival in June 2014 of the new PM, COL (b) (6) .
4) In December 2014 the DPM, (b) (6) , resigned and accepted a different position with the U.S. Army Medical Materiel Development Activity (USAMMDA).

FIGURE 2: Program Management Office Structure

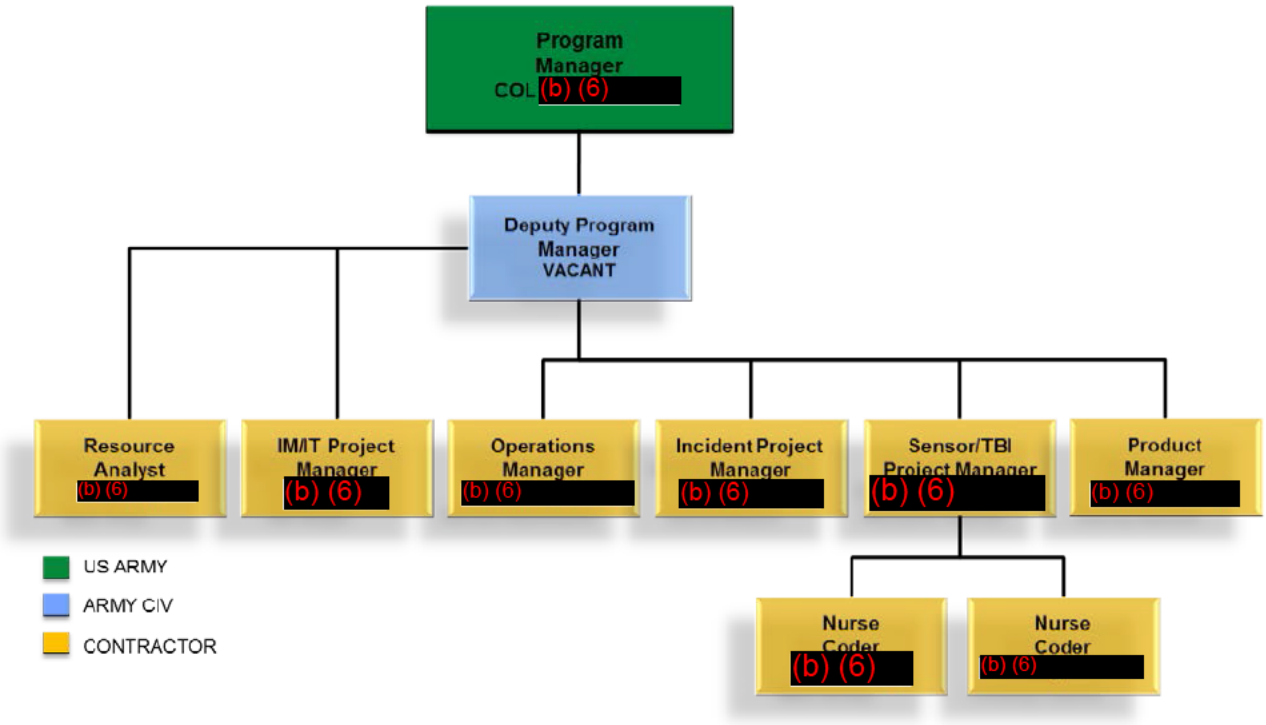


Table 1: Program Management Office Personnel

Name	Position	Dates
COL (b) (6)	Program Manager	Jan 14 – May 14
COL (b) (6)	Program Manager	Jun 14 – Dec 14
(b) (6)	Deputy Program Manager	Jan 14 – Dec 14
(b) (6)	Resource Analyst – Trideum	Jan 14 – Dec 14
(b) (6)	Project Manager – Universal Consulting Systems	Jan 14 – Dec 14
(b) (6)	Operations Manager - SAIC	Jan 14 – Mar 14
(b) (6)	Operations Manager – Booz Allen Hamilton	Apr 14 – Dec 14
(b) (6)	Project Manager – Booz Allen Hamilton	Jan 14 – Dec 14

(b) (6)	Project Manager – Trideum	Jan 14 – Dec 14
(b) (6)	Product Manager – Trideum	Jan 14 – Dec 14
(b) (6)	Program Analyst – Trideum	Jan 14 – Dec 14
(b) (6)	Program Analyst – Trideum	Jan 14 – Dec 14
(b) (6)	Program Analyst - Contractor support borrowed from the NHRC	Jan 14 – Dec 14
(b) (6)	Program Analyst – Contractor support borrowed from the NHRC (0.2 FTE)	Jan 14 – Dec 14

Statistical data:

A. In 2014, JTAPIC provided analysis products for 50 Requests for Information (RFI's) that provided actionable analysis and decision support. These analyses affect the materiel, doctrine, training, and policy domains.
B. In December 2013 established a requirement for PM-SPE to field an additional 13 thousand helmet sensors and 18 thousand blast gauges to designated deploying forces in support of Operation Enduring Freedom (OEF) in 2014. This effort resulted in an increase in sensor data analysis by JTAPIC.

Resource Management and Budget:

A. JTAPIC Total FY14 Budget: $24,529,000
   1) Operations and Maintenance [Army] (OMA) Base - $10,029,000
   2) OMA Other Contingency Operations (OCO) - $10,000,000
   3) JTAPIC Research Management - $4,500,000 Defense Health Program (DHP) Research, Development, Test and Evaluation (RDTE) funding.
B. Changes to budget from proceeding years (FY13)
   1) OMA Base – Increase of $6,645,000
   2) OMA OCO – Decrease of $5,871,000
   3) JTAPIC Research Management – Decrease of $1,600,000
C. Projections for future budget years (FY15)
   1) OMA Base - $8,356,000.
   2) OMA OCO - $3,000,000
   3) DHP Operations and Maintenance (O&M) - $870,000 for entry of legacy data into the JTAPIC database.
   4) JTAPIC Research Management - $5,300,000 DHP RDTE funding.
D. Beginning in FY13, JTAPIC underwent a shift in the primary source of program funding from Army OCO funds to OMA Base funds. Additionally, in response to decreased contingency operations, JTAPIC partnership OMA Base and OMA OCO FY15 funding is projected to decrease 43% from FY14 funding levels.
E. In 2012, in order to increase the availability of its analysis products, JTAPIC requested the conversion of its PMO staff from civilian contractors to Department of the Army Civilians (DACs). This request was approved these insourcing activities are expected to occur in FY15.

Information Management:

A. JTAPIC Database

JTAPIC has been in the planning and development process for a database focusing on the core data elements to provide support in meeting its mission through creation of products from Requests for

Information (RFI) from customers. Through the JTAPIC's Information Management Working Group (IMWG) providing oversight and recommendations to the PM the database reached the following milestones in this past year.

1) Development of the core data elements for the Initial Operational Capability (IOC) of the database.
2) Completion of critical data integration process maps in support of database business rules
3) Implementation Plan and Functional Requirements Document completed
4) IOC planned for September 2015

B. JTAPIC Distributed Incident Collaborative Environment (DICE)
The JTAPIC DICE system is consists of a number of components supporting the JTAPIC PMO and Partnership in their ongoing mission. These modules are:

1) Product Library – Provides searchable access to past JTAPIC Products.
    a. Enhanced searching capability
    b. Changes to allow faster approval to access products
    c. Began adding RFIs developed before the existence of the library
2) RFI Management System – Provides a project management system for RFI processing.
    a. Enhancements to streamline the RFI process
3) Data Management Tool – Provides a shared file storage location for the partnership
    a. Major user interface change to provide more features and ease of use

C. JTAPIC Web site
JTAPIC's web presence previously has existed as pages within the BLAST web site. With a move to separate JTAPIC from BLAST it was determined that a standalone web site was needed. The following work was completed:

1) Gathered JTAPIC partner information for inclusion on the web site.
2) Completed design and layout of the web site
3) Began development and initial functionality with planned rollout in 2015

D. JTAPIC SharePoint
JTAPIC began evaluating and then testing migration of the PMO's daily functions to the SharePoint environment. Working with MRMC developers the PMO began learning the capabilities of SharePoint and determining what will provide positive return on investment. Initial focus is in three areas:

1) Migration of content from the current shared P drive.
2) Development of dashboards to support decision making
3) Develop a taxonomy allowing for readily finding documents

Meetings and Engagements:

A. During calendar year 2014, the JTAPIC conducted meetings at six different partner sites. This rotation afforded partners to showcase capabilities at their sites that would enhance JTAPIC mission effectiveness.
B. COL (b) (6), JTAPIC Program Manager presented an environmental sensor update to (b) (6) Deputy Assistant Secretary of Defense (DASD) for Forces Health Protection and Readiness (FHP&R) (DASD(FHP&R)), 13 May 2014. The PM answered all of (b) (6) questions regarding sensor utilization, medical documentation, and the science behind the sensors. (b) (6) had additional questions about the difference environmental sensors are making which could not be answered in the time allotted for the visit. Accordingly, JTAPIC scheduled subsequent updates to (b) (6) to respond his questions and concerns.

C. COL (b) (6), JTAPIC PM, and staff had an office call with (b) (6) (SES), Director, Joint Operations Support, Office, Under Secretary of Defense (USD), Acquisition, Technology, and Logistics (AT&L) on 21 May 2014 at the Pentagon. The PM discussed JTAPIC's support to USD(AT&L) and DoDD 6025.21, Medical Research for Prevention, Mitigation and Treatment of Blast Injuries. (b) (6), from Assistant Secretary of Defense, Research and Engineering and staff attended. (b) (6) provided great recommendations to further develop additional relationships with the National Guard Bureau and US Northern Command staff in order to establish communication for Public Safety related events. The discussion was informational and (b) (6) emphasized his willingness to assist JTAPIC in completion of its mission in the future. Accordingly, JTAPIC continues to coordinate with USD(AT&L) to further enhance the joint mission.

D. COL (b) (6) had an office call with the (b) (6), Joint Improvised Explosive Device Defeat Organization (JIEDDO) Division Chief, J-9 Operations Research and Systems Analysis (ORSA) on 21 July 2014. The office call will be at (b) (6) office in Reston, Virginia. The purpose of the office call was an initial visit by COL (b) (6) and to continue communications between JIEDDO and JTAPIC.

E. COL (b) (6), JTAPIC PM, along with COL (b) (6) of PEO Soldier briefed the office of REP Louise Slaughter (D-NY) concerning ongoing helmet sensor and blast gauge efforts on 16 September 2014. The JTAPIC discussion focused on: providing an awareness of our analytical process as well as the correlation of sensor data with medical documentation.

F. COL (b) (6) had an office call with (b) (6), Deputy to the Commanding General Maneuver Center of Excellence (MCoE), Capabilities Development and Integration Directorate (CDID), Soldier Division in Fort Benning Georgia. The office call was in conjunction with one of the JTAPIC Partner Meeting with our Dismounted Incident Analysis Team (DIAT). JTAPIC's purpose of the office call was: an initial visit by COL (b) (6) and to continue communications between MCoE and JTAPIC. (b) (6) expressed his strong support for the JTAPIC program and its contributions to MCoE activities.

G. COL (b) (6), JTAPIC PM, and (b) (6), JTAPIC Operations Manager, conducted an office call with (SES) Dr. Tanenbaum, Director of the Survivability/Lethality Analysis Directorate of the US Army Research Laboratory (SLAD/ARL), followed by briefings and tours of test ranges on 21 October 2014. Specific topics included vehicle and aircraft survivability, ballistic wound modelling, helmet blunt trauma modeling. From 22-23 October 2014 conducted a JTAPIC Partner meeting at ARL. This meeting achieved synergy by linking items from previous day's tour to JTAPIC partners, specifically - using free-field blast testing sites to calibrate recently fielded blast gauges against measured standards in multiple distances and positions (ARL + PEO-Soldier/PM ICE) -correlating the predicted computer modelled injuries from the Operational Requirement-based Casualty Assessment (ORCA) program to actual combat injuries (ARL + JTS/ISR + AFMES). Other synergies achieved: -correlating unsolved WIA/KIA cases with medical/medical examiner results [National Ground Intelligence Agency (NGIC) + Naval Health Research Center (NHRC) + Joint Trauma System (JTS)] -group solution to completing an JTAPIC product in a 45-minute session, instead of weeks by email (all partners) - consensus improvements in the system used to request, monitor, and store JTAPIC products (all partners). Looking forward: assigned group to work expansion of JTAPIC's range beyond CENTCOM; recommended "Megacities" as reading for context for future planning.

H. On 23 October 2014, COL (b) (6), JTAPIC PM, and (b) (6), JTAPIC DPM conducted an office call with COL (b) (6), Armed Forces Medical Examiner System (AFMES), and received tour of AFMES facility.

I. On 18 November 2014 COL (b) (6) met with (b) (6), Senior Mission Advisor to the Commander, National Ground Intelligence Center (NGIC). (b) (6) expressed great satisfaction with the successes of JTAPIC and NGIC's relationship with it, to the benefit of both organizations, and looked forward to future accomplishments. COL (b) (6) also met with COL (b) (6) of NGIC, who briefed upcoming testing programs.

J. COL (b) (6) visited the office and facilities of L-3 Technologies, Inc., in San Diego, CA on 2 December 2014. L-3 is the contractor providing technical and software support for three separate TBI sensor programs tracked by JTAPIC. COL (b) (6) received briefings on the state of L-3's sensor work, followed by a tour of the company's blast testing facilities.

K. COL (b) (6) visited one of our partner organizations, Naval Health Research Center (NHRC), at Point Loma Base in San Diego on 3 December 2014. Meetings, briefings, and discussions took place with CAPT Rychnovsky (Commanding Officer), CAPT (b) (6) (Executive Officer) and pertinent staff, to include extensive discussion and demonstration of JTAPIC-specific activities and NHRC programs of interest. Thoughtful, energetic, and collegial discussion occurred at all meetings, including widening availability of JTAPIC services to U. S. Navy (USN) and US Pacific Command (PACOM) activities.

L. COL (b) (6), JTAPIC PM, visited the Army Research Laboratory (ARL) Warrior Injury Assessment Mannequin (WIAMan) Program on 9 December 2014. COL (b) (6) visited the leadership of the WIA-Man Program at ARL, Aberdeen Proving Grounds (APG), MD and received briefings from (b) (6), Program Manager, (b) (6) and (b) (6) on the purpose and progress of the Program. The current WIAMan will replace the presently used live-fire test mannequins which were designed to detect horizontal-force vehicle impacts. The next generation, expected to be in production in 2016, are designed to detect under-belly blast attacks, and likelihood of skeletal fractures from such attacks. A detailed discussion of mannequin technology and development was included, followed by a visit to a mannequin testing site. JTAPIC has collaborated in program development with information on the frequency and severity of skeletal injuries from underbelly blasts in theater, which will assist WIAMan in prioritizing the placement of sensor technology in their mannequin prototype. COL (b) (6) pointed out the need for validation of prototype testing data against theater medical results. Following the office call 10-11 December 2014, JTAPIC conducted a Partner Meeting at ARL. This meeting achieved synergy by linking items from previous day's tour to JTAPIC partners. COL (b) (6) emphasized the importance to continue expansion of JTAPIC's range beyond US Central Command (CENTCOM), further defining processes through standard operating procedure (SOP) development and continued open dialogue among partner organizations.

M. On 12 December 2014 (b) (6), JTAPIC DPM, transferred to U.S. Army Medical Materiel Development Activity (USAMMDA), Tissue Injury & Regenerative Medicine Program Management Office (PMO).

N. COL (b) (6) presented a JTAPIC sensor data analysis update to in Fort Benning, Georgia COL (b) (6), Chief, Maneuver, Aviation and Soldier Division, Army Capabilities Integration Center (ARCIC), Headquarters (HQ), US Army Training and Doctrine Command (TRADOC) on 18 December 2014. The update was in support of the ARCIC TRADOC holistic review of the Army's present and future blast effect sensors and TBI mitigation requirements. JTAPIC's input was to review the sensitivity and specificity analysis data for the Helmet-Mounted Sensor System. COL (b) (6) specifically noted that both the sensitivity and negative predictive values of the GEN II Helmet-Mounted Sensor were far too low for it to serve as a field-level referral decision-making tool. Also, the helmet-mounted sensor carries a significant flaw: it only works when the helmet is worn. Given the large proportion of "empty helmet" readings in Service Members who were later diagnosed with concussion, this is a serious flaw that can't be mitigated. Energetic and collegial discussion followed. In attendance at the update were stakeholders from the ARCIC (TRADOC) PEO-Soldier Maneuver Center of Excellence (MCoE) Program Manager Technology Enabled Capabilities (b) (6), G-3/5/7 CIC, Force Application Branch Chief COL (b) (6), HQDA DCS G-3-5-7 HQDA OTSG Research Institute of Environmental Medicine (USARIEM).

Section 16

Fiscal Year 2014
Annual Historical Report

DoD Blast Injury Research Program Coordinating Office

Mission

The mission of the DoD Blast Injury Research Program Coordinating Office (PCO) is to support the Department of Defense (DoD) Executive Agent (EA) by coordinating DoD-sponsored biomedical research programs aimed at preventing, mitigating, and treating blast-related injuries. The Blast Injury Research PCO identifies knowledge gaps, shapes research programs to fill knowledge gaps, and promotes information sharing among the operational, intelligence, medical, and materiel development communities. The PCO facilitates collaborative research among DoD laboratories and the laboratories of other federal agencies, academia, and industry to leverage resources and take full advantage of the body of knowledge that resides both within and outside of the DoD to accelerate the fielding of blast injury prevention and treatment strategies.

Organization and Personnel

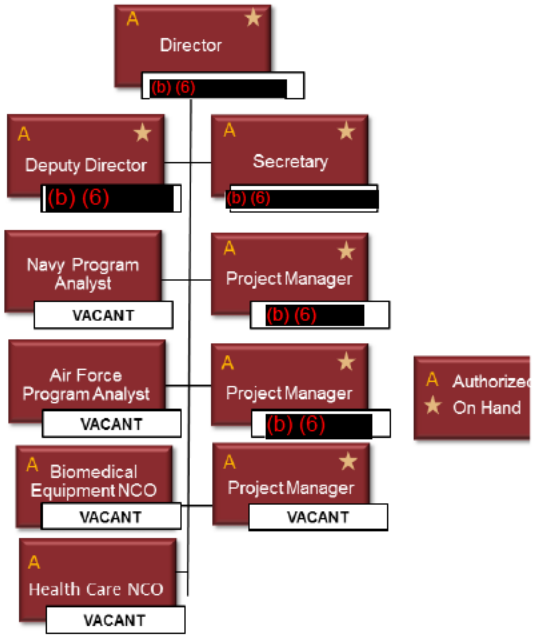
In April 2014, the PCO underwent significant personnel changes with a 100 percent turnover of contract support personnel coupled with the unanticipated, short-notice permanent change of station of the Air Force staff officer who departed the PCO for a new assignment on 18 April 2014. A new contract support team is currently providing support to the PCO. The PCO Director is coordinating with the USAMRMC leadership and the Office of the Air Force Surgeon General to fill the vacant Air Force staff officer position. The PCO organizational structure is represented in Figures 1 and 2.

A. Personnel strength in FY 2014

Figure 1: Table of Personnel, FY14

Name	Position	Dates
(b) (6)	Director	Oct 2013 – Sept 2014
(b) (6)	Deputy Director	Oct 2013 – Sept 2014
(b) (6)	Secretary	Oct 2013 – Sept 2014
LtCol (b) (6)	Air Force Program Analyst	Oct 2013 – April 2014
(b) (6)	Budget Analyst	Oct 2013 – March 2014
(b) (6)	Senior Program Analyst	Oct 2013 – March 2014
(b) (6)	Project Manager Advanced Technology	March 2014 – June 2014
(b) (6)	Project Manager	April 2014 – Sept 2014
(b) (6)	Program Manager	May 2014 – Sept 2014
(b) (6)	Project Manager Advanced Technology	June 2014 – Sept 2014
(b) (6)	Project Manager	Sept 2014

Figure 2: DoD Blast Injury Research PCO, 30 September 2014



Position	1 Oct. 2013	30 Sept. 2014
Military	1	0
Civilian	3	3
Contractor	2	3
Total	**6**	**6**

B. Staffing shortfall

Uniformed staff officers bring critically important operational and Service-unique perspectives to the PCO. The 0111 Table of Distribution and Allowances documented requirements for Army, Navy, and Air Force staff officers. The Air Force Staff Officer was filled from November 2009 until April 2014. At the end of FY14, the Air Force, Army, and Navy Staff Officer positions were vacant. The mitigation strategy has been to hire two Intergovernmental Personnel Agreement staff to backfill for the uniformed staff officers. A summary of the Table of Distribution and Allowances (TDA) is shown in Figure 3, which reflects personnel as of 30 September 2014.

Figure 3: Summary of TDA, 30 September 2014

PCO	Required	Authorized	On Hand
Military	2	0	0
Civilian	3	2	3
Contractor	3	2	3
Total	**8**	**4**	**6**

Statistical Data

Summarize data that illustrates the organization's activities and workload over the previous FY. Cite any recurring reports from which the data is drawn. Not Applicable (N/A).

Healthcare Delivery

Discuss notable trends, significant issues, or innovations that have been noted in your organization over the course of the FY. Include sections for all inpatient and outpatient healthcare related areas as appropriate (e.g., surgery, internal medicine, nursing, dental care, nutrition, rehabilitation). N/A.

Veterinary Services

Discuss notable trends, significant issues, or innovations that have been noted in your organization over the course of the FY. N/A.

Training and Education

Discuss significant training events, objectives, training programs, and results. If sufficient training is not available, discuss the causes of unavailability and effect on the organization. Organizations whose core mission is providing training and education will include information about significant changes in courses offered, capacity, and any other items of significance. N/A.

Research and Development

Program Coordinating Office Achievements

The PCO achievements can be categorized by the PCO's five key functions: disseminate blast injury research information; facilitate collaboration both within and outside the DoD; identify blast injury knowledge gaps; promote information sharing and partnerships; and shape research programs to fill knowledge gaps.

A. Disseminate Blast Injury Research Information

1) Reports to the Executive Agent

These reports provide organizations with the opportunity to highlight their most significant blast injury prevention, mitigation, and treatment accomplishments and to help ensure that blast injury research is shared as widely as possible throughout the DoD, in accordance with the EA responsibility mandated by DoD Directive (DoDD) 6025.21E. The reports to the EA are viewed by senior DoD leadership and made available to the broader research community on the PCO website.

a. In October 2013, the FY12 PCO Report to the EA was initially made available for download on the Blast Injury Research Program website (https://blastinjuryresearch.amedd.army.mil/). Subsequently the report was removed from the website, and the EA solicited comments in early August 2014 from across the DoD in order to revise the report. The updated FY12 EA Report was cleared by the Public Affairs Office, and was posted to the PCO website on 2 December 2014.

b. On 25 October 2013, the PCO staffed a request to solicit updates on blast injury research accomplishments for inclusion in the FY13 report to the EA. In early August 2014, the EA requested comments on the draft report from across the DoD. Comments were incorporated and the FY13 report to the EA was finalized, approved for distribution, and posted to the PCO website (2 December 2014).

2) Briefings

On 28 October 2013, (b) (6) Director, PCO, briefed (b) (6), Director, Human Performance, Training, and BioSystems Directorate, Office of the Director, Assistant Secretary of Defense for Research and Engineering (ASD(R&E)). The ASD(R&E) has oversight of the EA under DoDD 6025.21E. The purpose of this briefing was to update the ASD(R&E) on the PCO's accomplishments and initiatives in support of the DoD EA for blast injury research. (b) (6) was interested in the PCO's focus on multidisciplinary teamwork and collaboration across the Services, federal agencies, industry, academia, and nations. The PCO will provide periodic briefings to ASD(R&E) on EA activities, such as the State-of-the-Science (SoS) Meeting Series, the DoD Brain Injury Computational Modeling Expert Panel (EP), and the North Atlantic Treaty Organization (NATO) Human Factors and Medicine (HFM) technical activities.

B. Facilitate Collaboration Within and Outside the DoD

1) United States (US) Army Research Laboratory (ARL)

In October 2013, the Deputy Director, PCO, (b) (6), met with (b) (6), Director, Weapons and Materials Research Directorate (WMRD), and (b) (6), a Senior Research Scientist from the ARL to explore potential areas for enhanced collaboration. (b) (6) presented a synopsis of the mission of the WMRD, and (b) (6) discussed an overview of the DoD Brain Injury Computational Modeling EP.

C. Identify Blast Injury Knowledge Gaps

1) Military Health System (MHS) Blast Injury Prevention Standards Recommendation (BIPSR) Process

a. On 17 December 2013, the PCO hosted the second meeting of the BIPSR Process Focused Lower Extremity (LE) Stakeholder Committee to review the stakeholders' needs for specific LE blast injury prevention standards. Participants in this virtual meeting included 24 stakeholders representing the Army and Navy test and evaluation, materiel development, and medical communities. The committee identified several specific needs for both mounted and dismounted personnel.

b. The PCO coordinated with the US Army Medical Research Acquisition Activity (USAMRAA) to post a Request for Information (RFI) on Lower Extremities Blast Injury Prevention Standards on FedBizOpps.gov in support of the BIPSR LE Blast Injury Type Stakeholder Committee, effective 30 January 2014. The RFI solicited input related to existing or developing LE Blast Injury criteria, thresholds, and models, for consideration as potential DoD MHS Blast Injury Prevention Standards.

c. On 29 July 2014, the third meeting of the BIPSR Process LE Stakeholders was held at the Johns Hopkins University/Applied Physics Laboratory (JHU/APL). Sixteen DoD, Army, and Navy stakeholders from the medical, materiel development, operational, and test and evaluation communities participated in the virtual meeting. The purpose of this meeting was to advise the stakeholders on the findings of JHU/APL's extensive search for existing, candidate LE Blast Injury Prevention Standard (BIPS), and to solicit stakeholder feedback on the proposed next steps in this iteration of the BIPSR process. The JHU/APL's search revealed no suitable candidate LE BIPS. The search also identified several knowledge gaps associated with the LE injury criteria and testing methodologies currently used by the DoD. The stakeholders concurred with JHU/APL's proposal to convene an independent Subject Matter Expert (SME) panel to review and validate the findings. This meeting also featured a presentation by the Warrior Injury Assessment Manikin (WIAMan) Project Manager, which helped stakeholders understand to what extent the WIAMan project is addressing the needs for the LE BIPS.

2) Force Health Protection and Readiness (FHP&R)

a. In November 2013, the PCO participated in an interview sponsored by the Assistant Secretary of Defense for Health Affairs (ASD(HA)) in support of a Medical Research Capabilities Based Assessment (CBA) working meeting. The CBA assessed medical research and development (R&D) activities related to operational capabilities and gaps, and recommended suitable solutions to improve the joint force's ability to support the health and resilience of Service Members. The interview solicited the PCO's recommendations for potential solutions to the gaps identified in the CBA.

b. In January 2014, (b) (6) represented the EA in the "Solutions Working Meeting," sponsored by the Deputy Assistant Secretary of Defense for FHP&R. The primary focus of this CBA was on medical R&D needed to support casualty care from point of injury through role IV. The working meeting focused on the development of recommended approaches to closing gaps that had been identified in previous working meetings. Many of the identified gaps and proposed solutions are within the scope of the EA's blast injury research coordinating responsibilities. The product of this CBA will be the submission of an Initial Capabilities Document to the Joint Requirements Oversight Council for review and approval.

3) International State-of-the-Science (SoS) Meeting Series

a. In November 2013, the PCO cancelled the proposed SoS meeting on Limb Salvage originally scheduled to take place at Fort Detrick on 14-16 Jan 2014. The Planning Committee members and the Chair of the Joint Program Committee (JPC) on Clinical and Rehabilitative Medicine agreed that this topic would be adequately addressed in other venues, such as the American Academy of Orthopaedic Surgeons Extremity War Injuries Symposia and the congressionally mandated Peer Reviewed Orthopaedic Research Program.

b. In March 2014, the PCO began planning a SoS meeting for Fall 2014 that would focus on emerging trends regarding the causes of non-impact, blast-induced mild traumatic brain injury (mTBI) as well as a review of the algorithms and threshold values for translating sensor data into an understanding of blast injury mechanisms. The SoS meeting was scheduled for 4-6 November 2014 and officially announced in June 2014. Planning meetings were held in July and August 2014 with participation from multiple federal agencies as well as the National Football League and the National Collegiate Athletic Association. The meeting title selected by the Planning Committee was "The Biomedical Basis for mTBI Environmental Sensor Threshold Values," and the format was designed to include working group sessions focused on four key questions defined by the Planning Committee. In addition, recognized experts in the field were identified and selected by the Planning Committee to serve as members for the SoS meeting Expert Panel (EP). The EP will guide discussions, identify knowledge gaps, and provide recommendations for future research requirements relevant to mTBI environmental sensor threshold values. The SoS meeting proceedings will be documented in the FY15 Annual Historical Report.

4) US Army Research Laboratory (ARL)

On 7 January 2014, (b) (6) participated in a workshop organized by the ARL's WMRD and co-sponsored by the WIAMan Program Management Office and the Blast Protection for Platforms and Personnel Institute. The purpose of the workshop was to discuss the numerical analysis tools available to simulate human and human surrogate response to the accelerative loading that occurs when vehicle occupants are exposed to blasts, with an emphasis on under-body blast exposure. Workshop participants explored the scope of current research activities, documented the capabilities of existing tools, extracted knowledge and insights, and identified gaps and critical future needs. The workshop also provided a forum for presentation and discussion of the latest innovations in state-of-the-art technologies regarding numerical analytic techniques for anthropomorphic test devices (ATD), multi-scale modeling, simulating human tissue response to high-rate loading, methods to simulate blast loading conditions, and methods for analysis of ATD materials undergoing high-rate loading.

D. Promote Information Sharing and Partnerships

1) Allied Neurosensory Warrior Related Research (ANSW2R)

a. On 21 October 2013, the PCO, along with the Hearing Center of Excellence (HCE) and other organizations, took part in a strategic kick-off meeting to discuss the goals of ANSW2R, a consortium comprised of a diverse membership representing the interests of neurosensory research across the DoD and Department of Veterans Affairs (VA). ANSW2R was initiated to increase efficiency among the DoD Centers of Excellence (CoE), Federal Agencies, International Agencies, and particular academic institutions working on Neurosensory Polytrauma research. The consortium will analyze past, present, and future research efforts to identify knowledge gaps, overlap, and promising areas for collaboration. The consortium will work to develop a research framework that comprehensively examines the impact of concurrent injuries on all affected systems, as well as the effect of treatment and rehabilitation of one system on the others.

b. The PCO participated in the HCE's ANSW2R monthly stakeholder meeting in November 2013, December 2013, and January 2014. Activities occurring during these meetings included a presentation by (b) (6) from the University of California, San Francisco/VA Medical Center, San Francisco entitled, "Basal Ganglia Neuromodulation for Tinnitus Suppression," as well as review of the initial draft of the Business Case Analysis report.

2) Audiology and Speech Pathology Center (ASPC)

The PCO participated in the Audiology and Speech-Language Pathology meeting hosted by the ASPC at the Walter Reed National Military Medical Center on 8 November 2013. The objective of this meeting was to review cutting-edge clinical care and innovative clinical research on a broad range of audiology and speech-language pathology topics, including blast injury topics of interest to the EA. Topics included the physiology underlying difficulties some blast-exposed, normal hearing patients have with understanding speech in complex and noisy environments, and the assessment and treatment approaches for wounded warriors with cognitive-communication impairment as a result of traumatic brain injury (TBI).

3) Briefings

In August 2014, (b) (6) presented orientation briefings to the US Army Medical Research and Materiel Command's (USAMRMC) new Deputy Chief of Staff for Operations (DCSOPS) and the Secretary of the General Staff (SGS). These briefings provided background information on the PCO, including the program's congressional mandate, the designation of the EA, the establishment of the PCO as a permanent office at USAMRMC to support the EA, the scope of the PCO's EA support mission, and the PCO's current initiatives. Also discussed were key areas where DCSOPS and SGS support is vital to the PCO's mission success, including staff coordination, Operations Security reviews, and foreign travel clearances.

4) Invited Lecture

On 1 August 2014, (b) (6) presented an invited keynote lecture titled "Multiscale modeling of blast induced traumatic brain injury: From whole body responses to brain microdamage," at the 11th World Congress on Computational Mechanics. The lecture presented a novel multiscale, multiphysics simulation framework for modeling blast-induced brain injury. The conclusion arising from the lecture and discussion was that there was a need to link models of the primary blast event with the resulting brain tissue damage including the secondary mechanobiology of injury to the neurofunctional outcome. This will require a concerted collaborative effort between biophysicists, neurobiologists, mathematicians, and experimentalists to advance the current understanding of brain injury mechanisms, and help in neurodiagnostics, treatment, and protection.

5) Institute of Medicine (IOM)

(b) (6) represented the EA at a briefing of the IOM Report, "Long-Term Effects of Blast Exposures," (http://www.nap.edu/catalog.php?record_id=18253) at the VA on 13 January 2014. The

IOM prepared the report at the request of the VA. (b) (6), IOM Committee Chair, presented the committee's findings. The committee highlighted the significant weaknesses and limitations of the published literature, and found evidence to support only one causal relationship: blast exposure and penetrating eye injuries.

The VA working group tasked with preparing the VA response invited the DoD to provide a response to the IOM report. The PCO, on behalf of the EA, solicited input from medical and non-medical organizations across the DoD to ensure a fully coordinated and representative response. The PCO produced the DoD response to the IOM report incorporating input from 22 DoD organizations in June 2014. The final document was sent by the Commander, US Army Medical Command, as the EA, to the ASD(HA), who provided the DoD response to the Secretary of the VA.

6) NATO HFM-234 Research Task Group (RTG) on "Environmental Toxicology of Blast Exposures: Injury Metrics, Modeling, Methods, and Standards"

a. (b) (6), as Chair of the HFM-234 (RTG) Technical Team (TT), hosted regular monthly teleconferences throughout FY14 with members of the TT to: 1) develop agendas for upcoming HFM-234 (RTG) meetings; 2) determine the status of action items from completed meetings; and 3) review the ongoing development of the dictionary of blast injury research terms.

b. Meeting #2 of the HFM-234 (RTG) TT, "Blast Injury Epidemiological Study Data Collection Guidelines," was held on 11-12 December 2013. The meeting, hosted by the PCO and chaired by (b) (6), included nine team member participants representing Canada, France, Germany, Great Britain, Netherlands, Sweden and the US. The team developed an initial outline of a guideline for the types of data needed to conduct epidemiological studies of blast injury, and also reviewed the ongoing development of the blast injury dictionary of terms.

c. Meeting #3 of the HFM-234 (RTG) TT, "Reproducing Blast Exposures in the Laboratory," was held on 21-23 May 2014 and hosted by the Defence Research and Development Canada in Suffield, Alberta. (b) (6) chaired the meeting where the team heard presentations by blast physicists, engineers, and experimentalists, and then developed an initial outline of guidelines for reproducing military-relevant blast exposure conditions in the laboratory for use in blast injury research. The team was also provided with updates on the Blast Injury Epidemiological Study Data Collection Guidelines and progress on the development of the blast injury dictionary of terms.

7) Personal Armour Systems Symposium 2014 (PASS 2014)

(b) (6) served as co-chair of the session on blast injury prevention at the PASS 2014, held on 8-12 September 2014 at the University of Cambridge, Cambridge, United Kingdom. The International Personal Armour Committee sponsors the PASS meetings which take place every two years. PASS2014, the 12th meeting in this series, served as a venue for international collaboration and information sharing on the development of personal protection systems designed to protect against blast and ballistic injuries. (b) (6) session included presentations on the performance of combat helmets in preventing blast-related brain injuries, the behavior of soft tissues under blast strain rates, the prevention of LE injuries from under-body blast, and the proper use of shock tubes in blast injury research.

8) US-India Science and Technology Collaboration Effort

(b) (6) participated in the Indo-US Workshop on Cognitive Sciences/Autonomy from 8-10 September 2014 held at the Defence Institute of Physiology and Allied Sciences in New Delhi, India. The meeting was organized by the Under Secretary of Defense for Acquisition, Technology and Logistics (USD (AT&L)) and the Defence Research and Development Organization, Ministry of Defence. The goals of the workshop were to share research ideas and data, identify collaboration opportunities, as well as to understand more about each country's respective military organizations and culture. The US delegation was headed by (b) (6), Director, Human Performance,

Training and BioSystems Directorate, Office of the ASD(R&E). After extensive workshop discussions, a list of 34 potential topics for future collaborations was developed. A report of daily activities and progress was prepared and submitted to (b) (6), Principal Deputy, ASD(R&E). (b) (6) subsequently forwarded the report to (b) (6), USD (AT&L), who in turn submitted the report to the Secretary of Defense.

9) Telemedicine and Advanced Technology Research Center (TATRC)

On 28 October 2013, the PCO participated in a scientific meeting organized by TATRC that included presentations on recent work related to risk factors and sequelae of TBI. An overview of the Neurotoxin Exposure Treatment (Parkinson's) Research portfolio and presentations by members from the National Institute of Aging and academia covering ongoing research on topics related to Alzheimer's disease, Parkinson's disease, and Major Depressive Disorder were presented.

10) VA's Office of Research and Development

On 27 May 2014, the PCO participated in a DoD/VA-sponsored meeting on "Extremity and Traumatic Brain Injury Tracking using DoD and VA Databases," at the VA's Office of Research and Development. The purpose of the meeting was to explore opportunities for linking relevant injury, treatment, and early clinical information from the DoD Trauma Registry to Veterans' current and long-term health issues, and to discuss current research initiatives on the assessment and long-term effects of TBI. (b) (6) gave a presentation on the efforts of the PCO-sponsored DoD Brain Injury Computational Modeling EP to develop a research roadmap to elucidate the underlying mechanisms of primary-blast-induced mTBI.

11) Force Health Protection and Readiness

On 25 September 2014, (b) (6) participated in the science and technology program review titled "Blast Load Assessment: Sense and Test (BLAST) for Navy Corpsman and Other Medical Providers," as part of the Force Health Protection Future Naval Capabilities Pillar organized by the Office of Naval Research. The focus of the program is to develop technologies to quantify the physiological effects of blast loads on personnel in the field environment in order to replace the arbitrary stand down times that compromise both operational and clinical goals. The enabling capabilities envisioned from this project include: 1) BLAST Sensor - a field-able, body-mounted sensor to record blast pressure, impulse and acceleration for detecting and quantifying blast loads, 2) Neuro-functional Assessment Tool - a forward deployable neurological deficit screening tool, and 3) BLAST Algorithm - an algorithm that incorporates physiological and neuro-functional data to provide a "Go/No Go" response to blast events. The BLAST program is developing all three products in parallel and plans to transition the products to Bureau of Medicine and Surgery by FY18.

12) Other

a. On 18 February 2014, the PCO hosted the Joint Non-Lethal Weapons Directorate/USAMRMC Injury Modeling Information Sharing Meeting. The meeting highlighted opportunities for both organizations to share injury and physiological modeling information and expertise. The meeting also highlighted opportunities to collaborate with the Biotechnology High Performance Computing Software Applications Institute to prevent unnecessary duplication of effort and to accelerate solutions for the Warfighter. This meeting supported the EA's responsibility to promote information sharing and partnerships.

b. On 26 September 2014, the Combat Casualty Care Research Program, Military Operational Medicine Research Program, and the PCO jointly hosted a presentation and discussion on "Ultrastructure damage model of blast-induced traumatic brain injury." (b) (6), Office of Research and Development of the VA, (b) (6), Department of Physics and Astronomy, University of Missouri, and (b) (6), Professor and Chair, Military and

Veterans' Clinical Rehabilitation Research, University of Alberta presented work on the mechanism of cellular damage due to shock wave passage through the brain. The presentation focused on the non-impact blast-induced mTBI/concussion Phonon mechanism including pathophysiology and modeling considerations.

E. Shape Research Programs to Fill Knowledge Gaps

1) Chronic Effects of Neurotrauma Consortium (CENC)

The PCO participated in the CoE Research Directors Monthly conference call on 1 August 2014, during which the CENC team presented the program overview and requested CoE support and input for on-going efforts, including scientific reviews and development of a research road map. The CENC provided information on the program mission and discussed the solicitation on "mTBI and Chronic Traumatic Encephalopathy." The participants also discussed the need for establishing a central repository of information of past and ongoing research efforts.

2) Defense Advanced Research Projects Agency (DARPA)

In November 2013, the PCO participated in a DARPA Systems Based Neurotechnology for Emerging Therapies proposer one day workshop. The objectives of the project are to deliver a platform technology for targeted therapy in humans living with neuropsychiatric and neurologic disease, including Veterans and active duty Service Members suffering from mental health issues. The program combines novel device development, complex computational modeling of human neural systems, clinical neurology, and animal research to advance the understanding and translation of safe, effective neuro-technological therapies. The project seeks to create new interventions based on insights gained from the intersection of neuroscience, neuro-technology, and clinical therapy.

3) JPC-2, Military Infectious Diseases Research Program

(b) (6) participated in the JPC-2 meeting at Fort Detrick on 27-28 Feb 2014. Briefings included an overview of the FY14 military infectious disease applied research award, clinical trial award mechanisms, and programmatic review process. The overview was followed by programmatic review of selected proposals culminating in an order of merit list. The JPC-2 business meeting focused on presentation and discussion regarding the bacteriophage effort and program goals, the rapid blood donor screen project, and the status of a nucleic acid-based detection device for human immunodeficiency virus 1/2, Hepatitis B virus, and Hepatitis C virus in the deployed environment.

4) JPC-5, Military Operational Medicine

In FY14, the PCO participated in several JPC-5 research planning and programmatic review activities as part of the PCO's role to shape research programs and ensure that high-priority blast injury research issues are addressed in future medical research investments. These meetings included the JPC-5 FY13 Basic and Applied Psychological Health Award Programmatic Review, the JPC-5 In-Progress Review of Injury Prevention Biomechanics and Hearing Research, and the JPC-5 business meeting.

5) JPC-6, Combat Casualty Care

(b) (6) participated in the JPC-6 meeting at Fort Detrick in February 2014. Briefings included a JPC-6 overview followed by presentation and discussion on various JPC-6 research portfolios. Presentation and discussion topics included: no drift in commitments to combat casualty care research, joint trauma system, forward surgical and intensive critical care, hemorrhage and resuscitation, joint en-route care, treatments for tissue injury, neurotrauma, and photomedicine.

6) Military Operational Medicine Research Program (MOMRP)

(b) (6) participated in the USAMRMC MOMRP Integrating Integrated Product Team (IIPT) meeting held at Fort Detrick on 11-12 March 2014. The purpose of this meeting was to review and recommend program priorities, FY15 program plan and resource distribution, FY15 project unfunded requirements (UFRs) and FY17-21 program objective memorandum UFRs.

7) Other Program Review Activities

a. On 6-7 November 2013, LtCol (b) (6) represented the PCO at the Defense Health Program (DHP), VA, JPC-6, and JPC-8 Clinical and Rehabilitative Medicine and Orthopedics Research Programs Portfolio Review & Analysis Meeting held at Fort Detrick. Presenters from the DoD, DHP, and the VA reviewed the current status of research programs in clinical and rehabilitative medicine and orthopedics. The meeting outcomes included formulating information on DHP and VA program sponsor objectives and research in clinical and rehabilitative medicine and orthopedics, a review and assessment of the status of clinical and rehabilitative medicine and orthopedics programs, and providing recommendations for next steps and program adjustments needs.

b. On 11 December 2014, LtCol (b) (6) participated in the JPC-8 Clinical and Rehabilitative Medicine Research Program and IIPT meeting at Fort Detrick. There were briefings on the current research portfolio status, followed by discussion on strategic planning for the research portfolio.

c. On 5-6 February 2014, the PCO represented the EA at the Review and Analysis of Traumatic Brain Injury, Posttraumatic Stress Disorder (PTSD) and Suicide Prevention Research Portfolios meeting at Fort Detrick, MD. The purpose of the meeting was to review the current status of agencies' research activities in the areas of TBI, PTSD and suicide prevention, identify potential research gaps, and identify activities meeting National Research Action Plan requirements.

8) Small Business Innovation Research (SBIR)

a. In February 2014, (b) (6) initiated the kick-off meeting to start the SBIR project titled "Human Body Model for Computational Assessment of Blast Injury and Protection." The objective of this SBIR Phase I project is to design a modeling framework integrating the anatomical data (e.g., skin, skeletal, major organs), geometric modeling tools for human body articulation (e.g., size, shape, posture), blast scene generation, and material property data needed for biodynamic and biomechanical simulations. This human body model and corresponding software tools have immense application in military and civilian medicine.

b. A project submitted in response to the SBIR Phase II topic titled "Antimicrobials Textiles," authored by (b) (6) was awarded by USAMRAA in September 2014 after successful demonstration of the synthesis and chemical coupling of a novel quaternary ammonium cationic antimicrobial dendrimer to the surface of cotton fabric in a Phase I research project. During Phase II, the catalytic antimicrobial system will be further characterized, optimized, and extended to functionalize multiple fabrics including cotton, polyester, and nylon and polyaramid textiles. In addition, a roll-to-roll process will be designed and developed to provide continuous antimicrobial chemistry coupling in a cost-effective versatile system. The ultimate goal of the project is to identify light-weight, durable, antimicrobial textile finishes that will prevent and/or control infections in military medical shelters and field hospitals, where blast injury infections have been frequently encountered in recent military operations.

Resource Management and Budget

A. FY14 Budget:

$4,555,665 Army and DHP Research, Development, Test, and Evaluation funding

B. Changes to Budget from FY13

1) PCO - $4,899,508 Army and DHP Research, Development, Test, and Evaluation (RDTE) funding

2) Joint Trauma Analysis and Prevention of Injury in Combat (JTAPIC) - $23,070,000 Operation and Maintenance, Army Overseas Contingency Operations Funding

3) JTAPIC Research Management - $6,350,000 DHP RDTE funding

C. Projection for FY15: $4,661,168

Information Management

Describe deployment of new information systems and strengths and shortcomings of existing information systems that were identified during the previous year. Identify significant internal changes to information policy implemented during the previous FY along with the reasons for those changes. If external information management policy affected the operational capability of the organization, identify the policy, impact, and solutions developed. N/A.

Operations

Describe major operations and exercises in which the organization was involved and include pertinent excerpts from after-action reports, command reports, or lessons learned documents. N/A.

Modernization

Describe major operations and exercises in which the organization was involved and include pertinent excerpts from after-action reports, command reports, or lessons learned documents. N/A.

Logistics

Describe major medical logistics programs that were initiated, ongoing, or completed during the preceding FY. Describe any shortcomings in availability of medical materiel and what solutions were employed. Note any significant or unusual supply or maintenance issues along with the methods employed to minimize their impact. N/A.

Construction

Describe significant new construction and status of ongoing significant construction projects. List any facility closures, with effective dates. N/A.

Health and Environment

Discuss significant factors affecting the health of the command or supported population such as incidence, epidemiology, and control of infectious diseases, environmental hygiene, occupational health, and nutrition. Describe unusual or important Army health nursing programs and activities. As appropriate, describe medical and health problems of the civilian or allied military population supported. N/A.

Other

Items of significance not covered in other categories such as impact of legislation/regulation on operations, support to combat/contingency operations. N/A.

Appendices

A. Acronyms

Figure 4: Table of Acronyms

Acronym	Description
ANSW2R	Allied NeuroSensory Warrior Related Research
ATD	Anthropomorphic Test Devices
ARL	Army Research Laboratory
ASD(R&E)	Assistant Secretary of Defense (Research and Engineering)
ASD(HA)	Assistant Secretary of Defense (Health Affairs)
ASPC	Audiology and Speech Pathology Center
BIPSR	Blast Injury Prevention Standards Recommendation
BIPS	Blast Injury Prevention Standards
BLAST	Blast Load Assessment: Sense and Test
CBA	Capabilities Based Assessment
CENC	Chronic Effects of Neurotrauma Consortium
CoE	Centers of Excellence
DARPA	Defense Advanced Research Projects Agency
DCSOPS	Deputy Chief of Staff for Operations
DHP	Defense Health Program
DoD	Department of Defense
DoDD	DoD Directive
EA	Executive Agent
EP	Expert Panel
FHP&R	Force Health Protection and Readiness
FY	Fiscal Year
HCE	Hearing Center of Excellence
HFM	Human Factors and Medicine
IIPT	Integrating Integrated Product Team
IOM	Institute of Medicine
JHU/APL	Johns Hopkins University/Applied Physics Laboratory
JPC	Joint Program Committee
JPC-2	Military Infectious Diseases Joint Program Committee

JPC-5	Military Operational Medicine Joint Program Committee
JPC-6	Combat Casualty Care Joint Program Committee
JTAPIC	Joint Trauma Analysis and Prevention of Injury in Combat
LE	Lower Extremity
MHS	Military Health System
MOMRP	Military Operational Medicine Research Program
mTBI	Mild Traumatic Brain Injury
N/A	Not Applicable
NATO	North Atlantic Treaty Organization
PASS	Personal Armour Systems Symposium
PCO	Program Coordinating Office
PTSD	Posttraumatic Stress Disorder
R&D	Research and Development
RDTE	Research, Development, Test, and Evaluation
RFI	Request for Information
RTG	Research Task Group
SBIR	Small Business Innovation Research
SGS	Secretary of the General Staff
SoS	State-of-the-Science
TATRC	Telemedicine and Advanced Technology Research Center
TBI	Traumatic Brain Injury
TT	Technical Team
UFR	Unfunded Requirement
US	United States
USAMRAA	US Army Medical Research Acquisition Activity
USAMRMC	US Army Medical Research and Materiel Command
USD (AT&L)	Under Secretary of Defense for Acquisition, Technology and Logistics
VA	Department of Veterans Affairs
WIAMan	Warrior Injury Assessment Manikin
WMRD	Weapons and Materials Research Directorate

Section 17

Fiscal Year 2014
Annual Historical Report

CBRN Defense Coordinating Office

Mission

The mission of the CBRN Defense Coordinating Office (formerly the Partnership Support Office) is to support and manage critical Command inter-and intra-agency partnerships, collaborations, and agreements, with emphasis on CBRN defense medical research and development activities. The office coordinates the planning and execution of research and development funding by the Department of Defense (DoD) Chemical Biological Defense Program (CBDP) at USAMRMC organizations, including:

a. Assist the Defense Threat Reduction Agency (DTRA) Joint Science and Technology Office for Chemical Biological Defense (JSTO-CBD) in the planning and execution of science and technology funding at USAMRMC laboratories, including funding for chemical and biological defense pretreatments and prophylaxes, therapeutics, diagnostics, basic research and supporting science and technologies, and infrastructure and core capabilities;

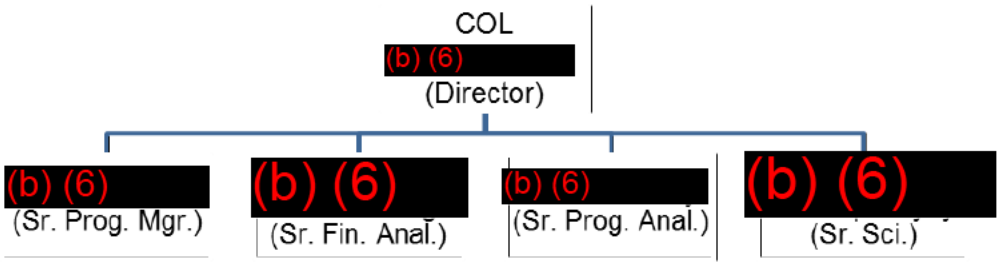
b. Assist the Joint Program Executive Office for Chemical Biological Defense (JPEO-CBD) in the planning and execution of collaborative research, development and acquisition activities and advanced development funding with USAMRMC and its laboratories;

c. Coordinate infrastructure support funding for USAMRMC laboratories in coordination with the Office of the Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs/Chemical and Biological Defense Programs (OASD(NCB/CB)), facilitate coordination and planning of military construction and initial outfitting, transition, and equipment (IOT&E) funding within the Defense Health Program (DHP), and facilitate coordination of operations and maintenance funding from the DHP and Army with the research program at USAMRMC laboratories;

d. Provide support for the Joint Program Committee – 7 (JPC-7) Chair of the DoD's Radiation and Nuclear Defense Research Program. Coordinate with the Armed Forces Radiobiology Research Institute (AFRRI) to plan, program, and budget an integrated research program within the DHP RDT&E appropriations. Conduct activities in coordination with the Assistant Secretary of Defense for Health Affairs (ASD(HA)); the President, Uniformed Services University of the Health Sciences (USUHS); the Armed Services Biomedical Research Evaluation Management (ASBREM) Committee and the Joint Technology Coordinating Group – 7, Medical Radiological Defense (JTCG-7).

Organization and Personnel:

A. **Organizational Diagram:**



B. **Personnel:** The current on-board strength of the CBRN Defense Coordinating Office as of 30 September 2014 was five (5) personnel: one (1) military officer and four (4) contractors. The key personnel positions are one (1) Veterinary Comparative Med as the Director, one (1) Senior Scientist, and three (3) Management Analysts, serving as the Senior Program Manager, Senior Financial Analyst and Senior Program Analyst:

COL (b) (6)	Director	AUG 2014 – SEP 2014
LTC (b) (6)	Director	OCT 2013 – AUG 2014
(b) (6)	Sr. Program Manager	OCT 2013 – SEP 2014
(b) (6)	Sr. Scientist	OCT 2013 – SEP 2014
(b) (6)	Sr. Financial Analyst	OCT 2013 – SEP 2014
(b) (6)	Sr. Program Analyst	OCT 2013 – SEP 2014

In addition to the above full-time personnel in FY14, the CBRN Defense Coordinating Office was directed by the USAMRMC's Principal Assistant for Research & Technology (PAR&T) in FY11 to fund a full-time permanent government civilian liaison officer to the OASD(NCB/CB). This position is currently filled by (b) (6) who was formerly of the Walter Reed Army Institute of Research (WRAIR), and reports to the Deputy PAR&T, (b) (6). Also in FY11, the CBRN Defense Coordinating Office was directed by the USAMRMC PAR&T to fund a half-time, permanent government civilian position to serve as Science Advisor to the JPC-7 Chair and appointed as the Army representative to the JTCG-7: Radiation Health Effects. This position is currently filled by (b) (6), who is assigned to the HQ USAMRMC Judge Advocate General (JAG) office. COL (b) (6) serves as the JPC-7 Chair.

Statistical data:
N/A

Healthcare Delivery:
N/A

Veterinary Services:
N/A

Training and Education:

No unusual or unique training activities to report for the CBRN Defense Coordinating Office. The CBRN Defense Coordinating Office Director met all standard and routine Army training requirements during 2014. The four Leidos (formerly SAIC) support contractors met all training requirements established by USAMRMC and applicable to contractors in addition to meeting training requirements established by Leidos for its employees during the reporting period.

Research and Development:

1) The USAMRMC CBRN Defense Coordinating Office does not directly engage in CBDP research and development activities. CBDP science and technology (S&T) programs are managed by the DTRA JSTO-CBD. The JSTO-CBD is designated as the Chemical and Biological Technologies Directorate of the DTRA and is responsible for the management, integration, and execution of medical chemical and biological defense S&T programs within the DoD. The CBRN Defense Coordinating Office coordinates the planning and execution of research and development funding by the DTRA JSTO-CBD at USAMRMC laboratories.

2) To accomplish the objectives and purposes of the defense-wide medical chemical and biological defense S&T program, USAMRMC supports DTRA JSTO-CBD's planning and program management of that portion of the CBDP assigned to the Army Medical Department, including research performed at the following key USAMRMC laboratories: U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), and U.S. Army Medical Research Institute of Chemical Defense (USAMRICD).

3) Support of USAMRMC laboratories engaged in medical CB S&T research funded by JSTO-CBD: The CBRN Defense Coordinating Office manages processes for extramural research and development contract and assistance agreement (i.e., grant and cooperative agreement) awards supporting efforts at USAMRMC laboratories that support the JSTO-CBD Medical CB S&T program (i.e., processing extramural proposals embedded in JSTO-funded intramural proposals from USAMRMC laboratories). The CBRN Defense Coordinating Office solicits funding recommendations and approvals from relevant USAMRMC laboratories and JSTO-CBD to provide essential information to initiate Purchase Requests (PRs) to fund and forward proposal documentation to the U.S. Army Medical Research Acquisition Activity (USAMRAA), the USAMRMC Office of Research Protections (ORP), and the USAMRMC Office of Surety, Safety and Environment for review and processing. Extramural organizations must submit proposals to the USAMRMC Broad Agency Announcement (BAA) via Grants.gov, which allows submission 24/7 throughout the year. The USAMRMC laboratory supervisor nominates, and USAMRAA appoints, a Contract/Grants Officer's Representative (COR/GOR)—the government's technical (scientific) representative who provides scientific and administrative monitoring of the award.

4) In 2014, the CBRN Defense Coordinating Office continued support of the JPC-7 Chair of the DoD's Radiation and Nuclear Defense Research Program and participated in meetings throughout the year to discuss medical radiation requirements and to develop the FY16-20 DHP Program Objectives Memorandum (POM). The JPC-7 supports the DoD's mission by planning and overseeing RDT&E activities that support discovery and development of materiel, knowledge, and training solutions that reduce medical capability gaps relevant to radiation health effects; and advise on opportunities to enhance medical capabilities in this area.

5) The JPC-7's areas of emphasis include: 1) Radiation Medical Technology, which is directed at basic and applied research in countermeasure(s) development for acute radiation exposure; using pharmacologic or biologic strategies, efforts include investigations leading toward identification of candidates for pre-exposure prophylaxis and post-exposure mitigation of radiation injury; 2) Radiation Biology Modeling, which emphasizes basic and applied research leveraging bioinformatics and computational modeling to analyze

molecular and cellular signaling pathways and complex physiologic data sets; and biodosimetry capability for assessing the severity of injury, triage, and medical decision making.

6) As part of the DHP POM development process, the CBRN Defense Coordinating Office supported the JPC-7 Chair by preparing a road map of studies needed to develop a radiation medical prophylaxis capability. Also in support of the JPC-7 Chair, the CBRN Defense Coordinating Office continued activities to draft and solicit comments from JPC-7 members on a Strategic Plan, which outlines a strategy for accomplishing the JPC-7 mission and will guide and measure progress toward prevention, mitigation, and treatment of radiation exposure health effects. The strategy describes a timeline coupled with intended goals for identifying and advancing potential solutions to address DoD capability gaps. The plan identifies approaches for research and development of medical countermeasures to prevent or treat the effects of Acute Radiation Syndrome (ARS) and includes a strategy composed of targeted research efforts supported by the approved budget combined with leveraging research conducted by other DoD and US government organizations. The plan notes that future research and development, to include clinical trials and pivotal animal studies, and transition of candidate drugs for eventual FDA approval will require a significant investment.

7) To facilitate the development of medical countermeasures to mitigate CBRN threats, the CBRN Defense Coordinating Office provided expert scientific and technical advice to effectively support USAMRMC's relationship with the CBRN stakeholders. In 2014, the office reviewed 12 invention disclosures from USAMRMC laboratories (USAMRIID and USAMRICD) and provided scientific and technical input during the monthly Invention Evaluation Committee (IEC) meetings with the USAMRMC JAG office, all the USAMRMC laboratories and stakeholders. In addition to invention disclosures, the CBRN Defense Coordinating Office reviewed 41 extramural pre-proposals and 14 full proposals and evaluated 30 statements of work (SOWs) for Cooperative Research and Development Agreements (CRADAs) between USAMRIID and several biotech companies, analytical consulting companies and academic institutions. The office has also reviewed over 50 DoD unclassified and classified acquisition requirements documents and CBRN Defense technical and national security policy documents from the Joint Requirements Office for CBRN Defense (JRO-CBRND), Office of The Surgeon General (OTSG) and Office of the Under Secretary of Defense for Policy (OUSD-P).

8) During 2014, the CBRN Defense Coordinating Office coordinated planning for the biennial international conference with the Israelis under the US-Israel Data Exchange Agreement (DEA) on Military Medicine. The DEA was signed in 1978 to share "research, development, test and evaluation data and defense information relevant to military medical operational forces." The biennial conferences, known as the Shoresh meetings, have been the cornerstone of the DEA on Military Medicine. On 19 November 2014, a teleconference was held between USAMRMC and Israeli Defense Force (IDF) personnel to discuss the preparations for the Shoresh meeting, which is scheduled to be held in Israel from 15 to 20 March 2015. The teleconference was led by the USAMRMC CG, MG Brian Lein, and the Surgeon General of the IDF, BG David Dagan, and attended by the Shoresh program officers and POCs for the Working Groups at both ends. In his opening remarks, BG Dagan mentioned the long tradition of data exchange and scientific collaboration between Israel and the United States military organizations. He emphasized that the extent, diversity and seniority of the US delegation were greatly appreciated and in his opinion, will significantly contribute to the success of the meeting. BG Dagan said that having all three Services on board at both ends is a wonderful opportunity to broaden and strengthen collaboration and stressed the importance that the new Air Force and Navy Working Groups integrate as much as possible with the six existing Working Groups [i.e., 1) Infectious Disease and Preventive Medicine, 2) Combat Casualty Care, 3) Physiological Stress, 4) Post-Traumatic Stress Disorder (PTSD) and Behavioral Sciences, 5) Chemical Biological Defense, and 6) Forensic Pathology/Identification of Victims of Mass Casualty Events].

9) MG Lein thanked BG Dagan for hosting the 16th Shoresh meeting in Israel. MG Lein mentioned that well over 70 US participants were currently lined up for the meeting with representation of all Working Groups and the three Services. He also confirmed that the Surgeons General of the US Army and US Air Force planned to attend the meeting in person. MG Lein reiterated the aggressive and comprehensive schedule

addressing timely scientific issues. He stated the importance of being flexible to address new priorities that may arise between now and the meeting in March 2015. The outline of the meeting was agreed to in the previous video teleconference (VTC) held in September 2014. The main scientific activities are planned to take place between 16 and 18 March 2015, and will include one plenary session each day and a total of 10 breakout sessions. The eight Working Groups each presented the main topics agreed for discussion and most Working Groups presented a complete or near-complete draft program. Most Working Groups also have site visits planned, mainly for 17 March 2015. Due to technical and logistical constraints and time differences, the meeting agenda will focus on presentations and discussions among those in attendance. Video and audio teleconference support may be provided on a limited basis to supplement specific topics and allow increased participation by those unable to travel to Israel. Both MG Lein and BG Dagan were pleased by the progress made by the Working Groups in preparation for Shoresh and are looking forward to a successful and fruitful meeting in March 2015.

Resource Management and Budget:

1) The CBRN Defense Coordinating Office budget has been stable over the past few years and, pending significant changes in the organization's mission, it is expected to remain so in future budget years. The following table provides the approved office budgets over a seven year period:

Budget Year	Amount
FY09	$1,365K
FY10	$1,520K
FY11	$250K*
FY12	$1,570K
FY13	$1,337K
FY14	$1,495K
FY15 (planned)	$1,440K

*Note: Due to Command-wide budget shortfall in FY11, the CBRN Defense Coordinating Office was able to shift FY11 contract costs into FY12 to return approximately $1,200K of FY11 funds to the HQ USAMRMC/RM office to support other Command activities in FY11.

2) At the conclusion of JSTO-CBD's FY2015 CB S&T program build, the CBRN Defense Coordinating Office developed the USAMRMC FY 2015 Command Budget Estimate (CBE) for Medical CB S&T research assigned to USAMRMC labs for execution by JSTO-CBD. The CBRN Defense Coordinating Office uses the CBE to track funding provided by JSTO-CBD to the USAMRMC Comptroller for distribution to USAMRMC labs that execute CB S&T research. In concert with the CBE, the CBRN Defense Coordinating Office maintains a detailed change control account of changes to JSTO-CBD funding awards at the proposal level throughout the execution year.

3) To ensure that USAMRMC meets reporting requirements established in the USAMRMC – DTRA Memorandum of Agreement (MOA), which was effective in July 2005, the CBRN Defense Coordinating Office collects monthly execution data from USAMRIID and USAMRICD business offices, incorporates this into monthly financial reports reflecting the level at which funding comes to USAMRMC from JSTO-CBD, and forwards the report through the HQ USAMRMC/RM office to the JSTO-CBD business office. Twelve (12) execution reports were processed and forwarded to JSTO-CBD during FY 2014.

4) Also in 2014, the DTRA JSTO-CBD informed USAMRMC of its intent to change from issuing CBDP funds via Funding Authorization Documents (FADs) to reimbursable Military Interdepartmental Purchase Requests (MIPRs), to improve obligations and prepare for an upcoming DoD audit of all CBDP funding transactions. In August 2014, USAMRMC and DTRA agreed to initiate a MIPR pilot test program for FY15, which includes USAMRIID's diagnostics capability area and USAMRICD's absorption, distribution, metabolism & excretion

(ADME) capability area. It's anticipated that the results of the pilot test program may be used to determine if DTRA should issue all CBDP funds via MIPR in FY16 & beyond.

Information Management:
N/A

Operations:
N/A

Modernization:
N/A

Logistics:
N/A

Construction:
N/A

Health and Environment:
N/A

Other:
N/A

Appendices:

1) DoD Directive (DoDD) 5160.05E, Subject: "Roles and Responsibilities Associated with the Chemical and Biological Defense (CBD) Program (CBDP)," dated October 9, 2008. This DoDD defines the roles and responsibilities of all departmental organizations and provided implementing procedures for management of the DoD CBDP IAW 50 USC 1522. The directive assigns management and integration of DoD Chemical Biological (CB) Science & Technology (S&T) efforts to DTRA.

2) MOA between USAMRMC and DTRA for Medical Chemical/ Biological (CB) Science & Technology (S&T) Program Management. In support of DoDD 5160.05E, the USAMRMC and DTRA jointly developed a MOA, which was effective on 30 July 2005, and documents a cooperative relationship between DTRA and USAMRMC for program management of the DoD Medical CB S&T program and provides the groundwork for establishing a cooperative working environment and the establishment of solid lines of communication to achieve the goals of the DoD Medical CB S&T program. The functions and responsibilities of the CBRN Defense Coordinating Office have evolved to that of principal coordinating office for USAMRMC on issues related to the DTRA – USAMRMC MOA and for addressing taskings, data calls, information requests, etc., generated by DTRA. The CBRN Defense Coordinating Office Director reports to the USAMRMC PAR&T.

3) MOA between USAMRMC and JPEO-CBD. This MOA, signed in January 2013, provides cooperative guidelines for all existing and future collaborative research, development and acquisition (RDA) projects and activities between JPEO CBD and the USAMRMC, including all subordinate components of these organizations. JPEO CBD and USAMRMC have the common goals of advancing the development of vaccines, therapeutics, and diagnostics against biological agents of high consequence and candidate pretreatment, prophylactic, and treatment compounds against chemical warfare agents, toxins, and toxic industrial chemicals, collectively referred to as medical countermeasures (MCM). JPEO CBD and

USAMRMC, through their complementary expertise and resources, can improve these collaborations and achieve greater synergy in CBD MCM advancement by cooperating under this agreement.

4) USUHS Acting President memorandum, Subject: "Membership for Joint Program Committee – 7 (JPC-7) for Radiation and Nuclear Defense," dated July 12, 2010. In this memorandum, the Acting President of USUHS recommended implementation of the January 2010 decision by the Board of Governors (BoG) for the Armed Forces Radiobiology Research Institute (AFRRI). Specifically, the decision directed that research at AFRRI would follow the guidance of JPC-7, Radiation and Nuclear Defense, and the JPC-7 would be chaired by a military officer selected in a similar manner to those that direct the other Joint Programs that fall under USAMRMC, and the support for the JPC-7 should fall under the Partnership Support Directorate of USAMRMC (now the CBRN Defense Coordinating Office).

5) Office of the ASD(HA) memorandum, Subject: "Membership for the Joint Program Committee – 7 for Radiation and Nuclear Defense," dated July 30, 2010. In this memorandum, the President, USUHS Performing the Duties of the ASD(HA) concurred with the Acting President, USUHS recommendation of July 12, 2010, but requested that USUHS coordinate implementation of the recommendation with the CG, USAMRMC.

6) DoD Instruction (DoDI) 5105.33, Subject: "Armed Forces Radiobiology Research Institute (AFRRI)," dated March 29, 2006. This DoDI clarifies the responsibilities and functions of the AFRRI and sets forth the organizational relationships and establishes the management and administrative procedures for the AFRRI, and provides for the establishment of a Board of Governors (BoG). The AFRRI mission is to conduct research in the field of radiobiology and related matters essential to the operational and medical support of the Department of Defense and the Military Services.

Department of Defense
DIRECTIVE

NUMBER 5160.05E
October 9, 2008

USD(AT&L)

SUBJECT: Roles and Responsibilities Associated with the Chemical and Biological Defense (CBD) Program (CBDP)

References: See Enclosure 1

1. PURPOSE. Pursuant to the authority vested in the Secretary of Defense by sections 113 and 125 of title 10, United States Code (Reference (a)), this Directive:

a. Reissues DoD Directive (DoDD) 5160.5 (Reference (b)) under a new subject to update policy, roles, and responsibilities for research, development, and acquisition (RDA) activities associated with the CBDP.

b. Updates and assigns responsibilities and functions associated with RDA of chemical, biological, and radiological (CBR) defense (CBRD) materiel (medical defense and physical (non-medical) defense) required to support combating weapons of mass destruction (WMD) missions as set forth in Secretary of Defense National Military Strategy and DoDD 2060.02 (References (c) and (d)). Specifically, the CBDP develops and acquires a family of integrated and interoperable CBRD capabilities that protect the force and enable military forces to operate successfully in CBR environments.

c. Designates and defines the role of the Secretary of the Army as the DoD Executive Agent for the CBDP pursuant to sections 1522 and 1523 of title 50, United States Code (U.S.C.), and Under Secretary of Defense for Acquisition, Technology, and Logistics (USD(AT&L)) Memorandum (References (e) and (f)), and in accordance with DoDD 5101.1 (Reference (g)).

2. APPLICABILITY

a. This Directive applies to OSD, the Military Departments, the Office of the Chairman of the Joint Chiefs of Staff and the Joint Staff, the Combatant Commands, the Office of the Inspector General of the Department of Defense, the Defense Agencies, the DoD Field Activities, and all other organizational entities within the Department of Defense (hereafter referred to collectively as the "DoD Components").

b. Implementation of this Directive shall comply with Reference (f). Changes to organizational assignments, structure, and processes defined by Reference (f) shall be approved by the USD(AT&L) prior to implementation.

3. DEFINITIONS. Terms used in this Directive are defined in Joint Publication 1-02 (Reference (h)).

4. POLICY. It is DoD policy that:

a. The Department of Defense shall be in full compliance with the provisions of the Biological and Toxin Weapons Convention and the Chemical Weapons Convention (References (i) and (j)), to which the United States is a party. Issues related to questions of compliance shall be addressed in accordance with DoDD 2060.1 (Reference (k)).

b. The Secretary of Defense shall carry out a coordinated U.S. CBDP to meet, within the constraints of resources available, the highest priority requirements of the Military Services in accordance with the provisions of Reference (e).

c. The DoD CBDP is a special interest program under Defense Acquisition Executive (DAE) oversight.

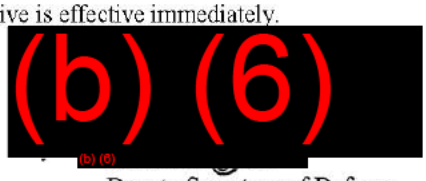
d. Funding requests for the CBDP shall be set forth in the DoD budget for each fiscal year as a separate account with a single program element for each of the categories of research, development, test, and evaluation (RDT&E); procurement; and military construction in accordance with Reference (e).

e. The Department of Defense shall fully comply with the requirements of parts 712-717 and 742.2 of title 15, Code of Federal Regulations (CFR); parts 120-130 of title 22, CFR; and DoDD 2040.2 (References (l), (m), and (n)).

5. RESPONSIBILITIES. See Enclosure 2.

6. RELEASABILITY. UNLIMITED. This Directive is approved for public release. Copies may be obtained through the Internet from the DoD Issuances Web Site at http://www.dtic.mil/whs/directives.

7. EFFECTIVE DATE. This Directive is effective immediately.



Deputy Secretary of Defense

Enclosures
1. References
2. Responsibilities

ENCLOSURE 1

REFERENCES

(a) Sections 113, 125, 133, 142, and 163 of title 10, United States Code
(b) DoDD 5160.5, "Responsibilities for Research, Development, and Acquisition of Chemical Weapons and Chemical and Biological Defense," May 1, 1985 (hereby canceled)
(c) Secretary of Defense National Military Strategy, "National Military Strategy to Combat Weapons of Mass Destruction," February 13, 2006[1]
(d) DoDD 2060.02, "Department of Defense (DoD) Combating Weapons of Mass Destruction (WMD) Policy," April 19, 2007
(e) Sections 1522 and 1523 of title 50, United States Code
(f) Under Secretary of Defense for Acquisition, Technology, and Logistics Memorandum, "Implementation Plan for the Management of the Chemical Biological Defense Program," as amended through October 1, 2007[2]
(g) DoDD 5101.1, "DoD Executive Agent," September 3, 2002
(h) Joint Publication 1-02, "DoD Dictionary of Military and Associated Terms," as amended
(i) Biological and Toxin Weapons Convention, "Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction," April 10, 1972[3]
(j) Chemical Weapons Convention, "Convention on the Prohibition of the Development, Production, Stockpiling, and Use of Chemical Weapons and on Their Destruction," January 13, 1993[4]
(k) DoDD 2060.1, "Implementation of, and Compliance with, Arms Control Agreements," January 9, 2001
(l) Parts 712-717 and 742.2 of title 15, C.F.R
(m) Parts 120-130 of title 22, C.F.R.
(n) DoDD 2040.2, "International Transfers of Technology, Goods, Services, and Munitions," January 17, 1984
(o) DoDD 5134.8, "Assistant to the Secretary of Defense for Nuclear and Chemical and Biological Defense Programs (ATSD(NCB))," June 8, 1994
(p) DoDD 5000.01, "The Defense Acquisition System," 12 May 2003
(q) DoDD 5105.62, "Defense Threat Reduction Agency (DTRA)," November 28, 2005
(r) DoDD 5143.01, "Under Secretary of Defense for Intelligence (USD(I))," November 23, 2005
(s) Joint Requirements Office for CBRN Defense Plan, "Joint Service Chemical, Biological, Radiological, and Nuclear (CBRN) Defense Modernization Plan," 2008[5]

[1] Available on the Internet at http://www.defenselink.mil/pdf/NMS-CWMD2006.pdf
[2] Available on the Internet at http://www.acq.osd.mil/cp/dodg.html
[3] Available on the Internet at http://www.opbw.org/convention/conv.html
[4] Available on the Internet at http://disarmament.un.org/WMD/cwc/index.html
[5] Available to authorized users at https://jro-cbrnd.cbiac.apgea.army.mil/Home.aspx

ENCLOSURE 2

RESPONSIBILITIES

1. USD(AT&L). The USD(AT&L) shall:

a. Serve as the Defense Acquisition Executive and be responsible for supervising the Defense Acquisition System pursuant to section 133 of Reference (a).

b. Oversee DoD RDA programs to ensure they support combating WMD policy efforts according to Reference (d).

c. Establish an OSD CBDP Overarching Integrated Process Team (OIPT) in accordance with the provisions of Reference (f) to serve as a single-tiered CBDP Defense Acquisition Board-like process to support DAE oversight and resolve cross-cutting program issues.

d. Oversee the activities of the DoD Executive Agent for the CBDP as required by Reference (g).

2. ASSISTANT TO THE SECRETARY OF DEFENSE FOR NUCLEAR AND CHEMICAL AND BIOLOGICAL DEFENSE PROGRAMS (ATSD(NCB)). The ATSD(NCB), under the authority, direction, and control of the USD(AT&L), shall:

a. Serve as the Principal Staff Assistant and advisor to the Secretary of Defense, the Deputy Secretary of Defense, and the USD(AT&L) for activities that combat current and emerging WMD threats, including all matters related to RDA of chemical, biological, radiological, and nuclear (CBRN) defense (CBRND) materiel pursuant to section 142 of Reference (a).

b. Oversee and integrate RDA of CBRND capabilities in nonproliferation, counterproliferation, and consequence management programs consistent with section 1522(b)(1) of Reference (e) and DoDDs 5134.8 and 5000.01 (References (o) and (p)). Responsibilities include CBRND in support of combating WMD missions consistent with Reference (d).

c. Through the Deputy Assistant to the Secretary of Defense for Chemical and Biological Defense, as the principal deputy to the ATSD(NCB) for CBDP matters, exercise overall coordination, oversight, and integration of the CBDP consistent with References (e) and (f).

(1) Execute CBDP oversight activities, related acquisition policy guidance, and interagency and international coordination.

(2) Provide oversight of Planning, Programming, Budgeting, and Execution processes and funds allocation for CBDP defense-wide accounts.

(3) Review, evaluate, integrate, prioritize, and provide guidance to DoD organizations to support CBDP investment planning.

(4) Ensure CBDP activities in support of combating WMD missions are aligned with national and DoD guidance.

(5) Develop policies and guidance in support of CBDP RDA activities.

(6) Chair the CBDP OIPT.

(7) Provide oversight, strategic guidance, and implementation of the CBD international program. Chair the CBD International Oversight Panel.

(8) Co-chair the Nonproliferation and Arms Control Technology Working Group.

d. Prepare, coordinate, approve, and sign non-policy DoD Instructions and DoD Manuals that are relevant and necessary to assigned responsibilities.

3. DIRECTOR, DEFENSE THREAT REDUCTION (DTRA). The Director, DTRA, under the authority, direction, and control of the ATSD(NCB), consistent with Reference (o) and DoDD 5105.62 (Reference (q)), and pursuant to Reference (f), shall:

a. Exercise funds management responsibility for the CBDP; designate an accountable official to perform the funds management functions for the CBDP under the oversight of the ATSD(NCB) and in compliance with applicable financial policy, standards, and principles.

b. Manage and integrate the CBD science and technology (S&T) programs.

(1) Establish a Joint Science and Technology Office for CBD to manage DoD CBDP S&T efforts in coordination with the Service laboratories, to include efforts with industry, academia, and other Government agencies and laboratories.

(2) Develop and maintain CBDP medical and physical sciences (non-medical) S&T plans.

(3) Develop, coordinate, and transition CBDP S&T medical and physical sciences technologies and associated CBDP test and evaluation (T&E) technology needs in response to validated and approved joint military capability needs.

(4) Preserve core scientific and technology capabilities within the Military Service laboratories that are necessary for conducting core CBDP RDT&E activities.

(5) Manage the CBDP Advanced Concept Technology Demonstration (ACTD)/Joint Capability Technology Demonstration (JCTD) process and individual ACTDs/JCTDs as assigned by the USD(AT&L).

4. UNDER SECRETARY OF DEFENSE FOR POLICY (USD(P)). The USD(P) shall:

a. Develop, coordinate, and oversee the implementation and integration of DoD combating WMD policy through the Assistant Secretary of Defense for Global Security Affairs and, as the policy pertains to homeland defense activities, through the supervision of the Assistant Secretary of Defense for Homeland Defense and the Americas' Security Affairs, as set forth in Reference (d).

b. Coordinate with the USD(AT&L) on issues associated with combating WMD related to CBRND policy and the CBDP.

5. UNDER SECRETARY OF DEFENSE FOR INTELLIGENCE (USD(I)). The USD(I) shall:

a. Serve as the Principal Staff Assistant and advisor to the Secretary of Defense for all matters relating to intelligence, counterintelligence, security, sensitive activities, and other intelligence-related matters.

b. Exercise authority, direction, and control over the Defense Agencies and DoD Field Activities that are Defense intelligence, counterintelligence, or security components.

c. Through the Director, Defense Intelligence Agency (DIA), and pursuant to DoDD 5143.01 (Reference (r)), provide all required intelligence support for the validation and prioritization of CBRN threats to DoD personnel in consultation with the Chairman of the Joint Chiefs of Staff (paragraph 8.b. of this enclosure).

6. SECRETARIES OF THE MILITARY DEPARTMENTS. The Secretaries of the Military Departments shall:

a. Organize, train, equip, and otherwise prepare their respective forces to combat WMD, means of delivery, and related materials.

b. Validate operational concepts and develop Military Service-sponsored CBRND capabilities documentation consistent with the Joint Capabilities Integration and Development System process and the Joint Staff/J-8 Joint Requirements Office for CBRN Defense (JRO-CBRND) Modernization Plan (Reference (s)).

c. Support development of Military Service annexes to joint CBRND capability documents as appropriate.

d. Be responsible for the CBRND training, readiness, and sustainment of their respective Services.

e. Budget for the operations and sustainment of CBRND equipment.

7. SECRETARY OF THE ARMY. The Secretary of the Army shall:

a. Pursuant to Reference (e), as the DoD Executive Agent for the CBDP:

(1) Coordinate and integrate RDT&E and acquisition requirements of the Military Departments for DoD chemical and biological warfare defense programs.

(2) Review all funding requirements for the CBDP.

b. Pursuant to Reference (f):

(1) Serve as Milestone Decision Authority for CBRND programs as delegated by the USD(AT&L).

(2) Establish a Joint Program Executive Officer for Chemical and Biological Defense (JPEO-CBD), reporting through the Army Acquisition Executive to the DAE, to serve as the Joint Service Materiel Developer and oversee total life-cycle acquisition management for assigned CBRND programs.

(3) Designate a CBDP T&E Executive to ensure adequacy of T&E programs and infrastructure.

(4) Establish a Joint Combat Developer for Experimentation for CBRND under the direction and supervision of the Director of the Joint Staff/J-8 JRO-CBRND.

(5) Provide support and operational direction to the Director, Joint CBRND Program Analysis and Integration Office (PAIO).

8. CHAIRMAN OF THE JOINT CHIEFS OF STAFF. The Chairman of the Joint Chiefs of Staff shall:

a. Advise the Secretary of Defense in identifying, assessing, and prioritizing joint CBRND military capability needs.

b. In consultation with the Commanders of the Combatant Commands, the Secretaries of the Military Departments, and the Director, DIA, validate and prioritize CBRN threats to DoD personnel, equipment, and weapon systems.

c. Through the Director of the JRO-CBRND, under the Joint Staff/J-8 Director for Force Structure, Resources, and Assessments, plan, coordinate, and approve joint CBRN defense operational requirements (medical and non-medical), joint operational concepts and architectures for passive defense, consequence management, force protection, and homeland security.

(1) Serve as the Chairman of the Joint Chiefs of Staff focal point for all CBRND issues associated with combating WMD missions.

(2) Pursuant to section 163 of Reference (a), support the Chairman of the Joint Chiefs of Staff in advising and making recommendations to the Secretary of Defense regarding Combatant Commander CBRND operational capabilities requirements.

(3) Collaborate with appropriate Joint Staff elements on CBRND operational readiness, risk assessment, logistics and sustainment, and policy issues.

(4) Coordinate and integrate requirements and capability needs for all DoD CBRND programs, ensuring that Military Service and Combatant Command capability needs are developed and approved in a prompt and efficient manner.

(5) Develop and maintain appropriate CBRND Joint Concepts and Architectures and a Joint CBRND Modernization Plan (Reference (s)) for fielding integrated DoD CBRND capabilities.

(6) Lead development of the CBDP Program Objective Memorandum (POM) strategy according to Reference (f).

(7) Support and facilitate the development of multi-Service and joint CBRND doctrine, tactics, techniques, and procedures; training and leader development and education; and exercises.

(8) Maintain visibility of RDA and demonstration activities associated with the CBRND activities of the Services, Combatant Commands, and relevant Defense Agencies.

9. DIRECTOR, JOINT CBRND PAIO. The Director, Joint CBRND PAIO, shall:

a. Provide independent analysis, review, and integration functions for the CBDP.

b. Determine the overall health of the CBDP against objectives and provide recommendations and evaluate alternatives to shape program policy and guidance.

c. Support JRO-CBRND-led development of the CBDP POM. Lead development of budget submissions and change proposals.

d. Develop and maintain the CBDP RDA plan that details mid- and far-term CBDP goals, objectives, and transition of materiel within each phase of the acquisition process consistent with the USD(AT&L) comprehensive RDA strategy for the eight areas to combat WMD set forth in Reference (c). Maintain the CBDP Future Years Defense Program.

e. Integrate Planning, Programming, Budgeting, and Execution functions across CBDP defense-wide program elements and organizations.

Agreement No. 04-044

MEMORANDUM OF AGREEMENT
BETWEEN
THE U.S. ARMY MEDICAL RESEARCH AND MATERIEL COMMAND
AND
THE DEFENSE THREAT REDUCTION AGENCY
FOR
MEDICAL CHEMICAL/BIOLOGICAL SCIENCE AND TECHNOLOGY
PROGRAM MANAGEMENT

1. PURPOSE: This memorandum of agreement (MOA) documents the relationship between the U.S. Army Medical Research and Materiel Command (USAMRMC) and the Defense Threat Reduction Agency (DTRA) (hereinafter referred to as "the Parties") in support of DTRA program management of the Department of Defense (DoD) Medical Chemical/Biological Science and Technology (CB S&T) Program, and provides the groundwork for establishing a working relationship and the establishment of solid lines of communication between the Parties to achieve the goals of the DoD Medical CB S&T Program (hereinafter referred to as the Medical CB S&T Program). USAMRMC is the provider in this relationship and DTRA is the receiver.

2. AUTHORITY: This MOA is authorized and was developed under the provisions of:

a. Section 1535, Title 31, United States Code, Agency Agreements (The Economy Act)

b. DoD Directive 5105.62, "Defense Threat Reduction Agency," September 30, 1998

c. DoD Instruction 4000.19, "Interservice and Intragovernmental Support," August 9, 1995

d. Office of the Secretary of Defense Memorandum, "Implementation Plan for the Management of the Chemical and Biological Defense Program," April 22, 2003

e. DoD Program Budget Decision 250, "Medical RDT&E, Chemical/Biological Defense and Air Force Other Support," November 17, 1994

f. DoD FY00-05 Program Decision Memorandum I, "Biological Warfare Defense," August 18, 1998

3. SCOPE: This MOA is applicable to all levels of USAMRMC and DTRA that will be directly or indirectly involved in providing or receiving support.

4. BACKGROUND:

a. USAMRMC is responsible for maintaining infrastructure capability for conducting research, development, and acquisition resulting in medical solutions to protect the warfighter.

b. DTRA is responsible for program and project management and integration of all medical CB S&T efforts pursuant to the approval of the "Implementation Plan for the Management of the DoD Chemical/Biological Defense Program" by the Under Secretary of Defense (Acquisition, Technology, and Logistics) on April 22, 2003. The Joint Science and Technology Office (JSTO) for Chemical and Biological Defense (CBD), which oversees the Medical S&T Division (CBM) of DTRA's Chemical and Biological Defense Directorate and a DoD entity, is responsible for this program. The JSTO CBD is hereinafter referred to as "the JSTO-CB."

5. POLICY:

a. Neither of the Parties, nor any of their respective employees, will be construed to be the agent, employer, or representative of the other, nor will they have an expressed or implied right of authority to assume or create any obligation or responsibility on behalf of or in the name of the other Party.

b. In the event of mobilization or other emergency, this MOA will remain in force and the agreed upon services and support will continue to be provided within the Parties' contingency capabilities.

c. Any changes to the agreed type, level and quality of support must be brought to the attention of the Headquarters (HQ), USAMRMC Deputy for Resource Management, and the DTRA Plans and Agreements Branch Chief.

d. All references to DTRA and JSTO-CB in this MOA are to be considered synonymous.

6. PLANNING ASSUMPTIONS:

a. The requirement for the Medical CB S&T Program will continue and associated funding will be appropriated.

b. Both USAMRMC and DTRA will continue to receive and retain personnel, facilities, and other resources and assets required to provide agreed program management support specified in this MOA.

7. MUTUAL AGREEMENTS AND INDIVIDUAL PARTNER RESPONSIBILITIES:

a. Mutual agreements:

(1) To accomplish the objectives and purposes of the defense-wide Medical CB S&T Program, USAMRMC will support DTRA's planning and program management of that portion of the program assigned to the Army Medical Department as documented by this MOA.

(2) Designated USAMRMC and DTRA principals will accomplish required communications, directions, consultations, and advisements. The principal for HQ, USAMRMC, will be the Deputy for Research and Development. The principal for DTRA will be the Chief, Medical S&T Division, JSTO-CB.

(3) Either Party, as mutually agreed during the research and development process, will collect programmatic and management information under the auspices of this MOA. USAMRMC will collect and analyze data as may be required by DTRA. DTRA will have access to all such data and analyses. All scientific data deriving from research, development, test, and evaluation funds provided by DTRA to USAMRMC will be transferable to DTRA.

b. USAMRMC will

(1) provide program support as identified in Annex A to this MOA;

(2) establish or maintain program management responsibilities and processes needed to manage the work effort as assigned by DTRA;

(3) establish a communication mechanism to keep DTRA informed of all issues concerning the Medical CB S&T Program and a separate mechanism to allow access to the program performers, as required for effective program responsiveness.

c. DTRA will

(1) establish Medical CB S&T Program objectives and provide management and guidance of the program;

(2) establish an effective research prioritization and review process to determine investment strategy for future program year execution and to review current program year cost, schedule, and performance;

(3) establish and publish fiscal guidance and the timetable for program and budget development, resource tracking, and program evaluation;

(4) establish working groups as necessary to produce an effective management structure in accordance with integrated product and process development procedures to ensure that the program goals and objectives as established in the Chemical Biological Defense Program Objective Memorandum (POM) are achieved;

(5) represent USAMRMC's interests in matters related to the Medical CB S&T Program when interfacing with the Joint Requirements Office and the Joint Program Executive Office;

(6) support initiatives listed in Annex B to this MOA.

8. FUNDING AND REIMBURSEMENT:

a. USAMRMC will

(1) allocate expenses for providing support to the various components of the management support services;

(2) charge DTRA management fees commensurate with fees charged to other DoD organizations;

(3) establish and/or maintain a mechanism to receive and track funds for Medical CB S&T Program execution. The official United States Army Standard Finance System (STANFINS) tracks funds control, obligations, and disbursements to the Program Element (i.e., 6.1, 6.2, 6.3) and project level (i.e., TB1, TB2, TB3, TC1, TC2, TC3).

(4) notify DTRA during the mid-year review of any unobligated, available funds that USAMRMC will not execute by end-of-year;

(5) notify DTRA of any anticipated inability to execute all or part of the current FY funded program within 14 days of discovery.

b. DTRA will

(1) provide funding to USAMRMC for the execution of assigned Medical CB S&T Program and associated support services, including agreed upon administrative fees as determined by the HQ, USAMRMC Deputy for Resource Management, and negotiated between the Parties;

(2) reimburse USAMRMC for all negotiated fair and reasonable termination expenses related to project termination, including, but not limited to those incurred and payable under the applicable provisions of affected contracts and agreements for each project under the Medical CB S&T Program being executed by or

planned for execution by USAMRMC pursuant to DTRA-provided program guidance as set forth in this MOA and subsequently terminated by DTRA;

(3) provide USAMRMC funding information for the year of execution and over the Program and Budget Estimate Submission programming period for the management support and execution of the Medical CB S&T Program conducted by USAMRMC medical research laboratories and associated extramural research performers. For FY06, funding information required to build Command Budget Estimates and extramural execution plans will be provided to USAMRMC by the end of the third quarter of FY05. The eventual goal is to provide this data by the end of the second quarter. The target for achieving this goal is FY08.

(4) provide fiscal guidance over the Future Years Defense Program period to USAMRMC prior to the start of each POM planning cycle for use in planning and programming resource requirements beyond the coming year of execution.

c. Funding requirements will be reviewed annually as part of the budget review and development process.

9. ADMINISTRATION: Compliance with the provisions of this MOA is the responsibility of the Commander, USAMRMC, and the Director, DTRA. Each may appoint points of contact (POC) for routine administration and management of this MOA and a POC for implementation of this agreement.

a. The Deputy for Resource Management will administer this MOA for USAMRMC. The Deputy for Research and Development will address operational/technical matters.

b. The Plans and Agreements Branch, Facilities, Logistics and Mission Support Division, Business Directorate, will administer this MOA for DTRA. The Chief, Medical S&T Division, JSTO-CB, will address operational/technical issues.

10. CONFLICT RESOLUTION: Nothing in this MOA is intended to conflict with any applicable law or regulation. If a term of this MOA is inconsistent with such law or regulation, the term shall be invalid to the extent of such inconsistency, but the remaining terms and conditions of this MOA shall remain in full force and effect. The Office of the Under Secretary of Defense (Acquisition, Technology and Logistics) will mediate issues that are not resolvable by other means.

11. DATA AND INTELLECTUAL PROPERTY: Both Parties will act to preserve the value of intellectual property for use by the U.S. Government. DTRA will participate on the USAMRMC Invention Evaluation Committee to ensure that any inventions emerging from DTRA funded programs under the auspices of this MOA receive equal attention

to other inventions emerging from within the USAMRMC laboratory structure. DTRA will fund its share of patent prosecution following negotiation with USAMRMC regarding costs. DTRA inventions will be given the same consideration as any other invention coming from the laboratories selected for patent prosecution. USAMRMC will coordinate related marketing activities with DTRA.

12. INFORMATION RELEASE:

a. The information in this MOA is jointly owned by the Parties to this agreement; therefore, requests for release of information from or concerning this MOA, the relationship documented in this MOA, or any provisions of this MOA submitted under the provisions of the Freedom of Information Act (FOIA) must be coordinated through the FOIA officer of each Party.

b. Routine requests from the public or media for information regarding this MOA must be coordinated through the public affairs office of each Party.

c. Each Party shall provide a copy of any proposed press release related to this MOA to the other Party for review and comment at least 10 business days in advance of the proposed publication date.

13. CHANGES, REVIEWS, AND REVISIONS:

a. This MOA, and all annexes, may be reviewed at the request of either Party, whenever changing conditions require substantial alterations, or the development of a new agreement. All revisions to this MOA must be approved in writing by both Parties prior to implementation, and will require administration by the Parties identified in this MOA. Annexes may not amend or alter the provisions of this MOA.

b. This MOA must be thoroughly reviewed at intervals not to exceed 5 years.

14. EFFECTIVE DATE AND TERMINATION:

a. This MOA is effective upon the date of the last signature and will remain in effect until terminated by mutual agreement of the Parties or by unilateral termination by one of the Parties.

b. This MOA may be terminated unilaterally by either Party by providing 180 days prior written notice by the terminating Party to the other Party or otherwise by the mutual written consent of both Parties. All reimbursements and support required by the terms of this MOA will continue during the 180-day notice period, unless otherwise agreed by the Parties. Termination costs will need to be paid for all obligated transactions through closeout of each appropriation. No Party will make new

commitments or obligations related to this MOA after notice of termination and must, to the extent feasible, effect disposition on all outstanding commitments and contracts by the termination date.

(b) (6)

Director
Defense Threat Reduction Agency

30 July 05
Date

(b) (6)

Colonel, MS
Acting Commander, USAMRMC

22 June 2005
Date

ANNEX A

U.S. Army Medical Research and Materiel Command Support

U.S. Army Medical Research and Materiel Command (USAMRMC) program management support includes the following:

1. Provide program planning assistance to include appropriate internal USAMRMC coordination to facilitate Defense Threat Reduction Agency (DTRA) program management support requirements and preparation of the Medical Chemical/ Biological (CB) Defense Research Program build and Command Budget Estimates (CBE) for that portion of the program assigned to USAMRMC.

2. Manage interactive, Web-based resources developed by USAMRMC for solicitation and review of research proposals for the entire Medical Chemical/Biological (CB) Science and Technology (S&T) Program.

3. Facilitate and coordinate management of congressionally-directed medical CB S&T adds identified by DTRA or Congress for USAMRMC and not specifically identified for other DoD entities (e.g., Navy, Air Force, or Marine Corps).

4. Establish a mutually agreed timeline for the annual development of DTRA's entire medical CB S&T program.

5. Support the DTRA directed Broad Agency Announcement. At a minimum, this activity will be held once a year to coincide with the intramural program build and subject to the availability of funds.

6. Facilitate and coordinate management of the USAMRMC CBE.

(a) Develop an annual CBE listing all estimated costs for Joint Science and Technology Office for Chemical and Biological Defense (JSTO-CB) approved intramural and extramural medical CB S&T projects.

(b) As the single POC for the U.S. Army executing DTRA funds at USAMRMC's subordinate organizations, the Headquarters (HQ), USAMRMC Director of Resource Management ensures reporting out of costs (to the capability area, thrust and subthrust areas), schedule, and performance.

(c) Furnish financial obligation and disbursement execution reports and other associated data to DTRA at the Program Element level by the 10th of each month, and further breakdown at the project/thrust level by the 15th of each month.

7. Provide a list of Cooperative Research and Development Agreements (CRADAs) at USAMRMC's laboratories that have gone through appropriate legal review, and that support the USAMRMC portion of the Medical CB S&T Program by capability area.

8. Provide assistance in preparation and submission of key program documents for that portion of the Medical CB S&T Program assigned to USAMRMC by DTRA to include

(a) Annual Congressional budget exhibits (R-2 process)

(b) "DoD Chemical Biological Radiological Nuclear Defense Program Annual Report to Congress"

(c) "Counter Proliferation Program Review Committee Annual Report to Congress"

(d) Chemical Biological Defense Technology Area Review and Assessment briefings

(e) "Joint Warfighting S&T Plan"

(f) "Defense Technology Area Plan"

(g) "Joint Service Research, Development, and Acquisition Plan"

9. Maintain regulatory and quality assurance and safety oversight for the portion of the Medical CB S&T Program assigned to USAMRMC by DTRA. This includes ensuring compliance of research activities by USAMRMC assets and their subcontractors with all Federal regulatory requirements in the development of medical products; review and oversight of the use of human subjects and animals in research.

10. Provide acquisition support to include preparation and execution of contracts and other transactions for the procurement of research, development, test and evaluation and other services, grants, and cooperative agreements for assistance, broad agency announcement preparation, appropriate public announcements, source selection administration, peer-review process assistance, final award, administration, and close-out as required by the Federal Acquisition Regulation, and relevant supplements.

11. Provide resource management support to include fund acceptance and distribution by the United States Army Program, Budget, and Accounting System as recorded by the Department of the Army accounting classification codes established for recording DTRA allotments in the United States Army Standard Finance System

(STANFINS), project-level and organization-level funds tracking systems and procedures for Medical CB S&T Program expenditures to include headquarters management and matrix support functions, account balancing between the Commitment Accounting System and STANFINS Monthly Status of Approved Resources from STANFINS after completion by the Defense Finance and Accounting Service, and other reasonable financial reports, as requested. Accomplish data entry into the Joint Service Chemical Biological Information System for current fiscal year obligations and disbursements through the second year of execution.

12. Provide legal services for that portion of the Medical CB S&T Program pertaining to USAMRMC and assigned by DTRA to include patent prosecution and licensing, technology transfer, in addition to normal legal services including procurement and administrative law, ethics, litigation support, and legal assistance to include CRADA and materiel transfer agreements.

13. Provide public affairs support to DTRA as may be required for media requests pertinent to USAMRMC associated activities for the Medical CB S&T Program.

14. Oversee surety, safety, and environmental compliance for that portion of the Medical CB S&T Program assigned to USAMRMC by DTRA to include review and approval of Facility Safety Plans and related environmental documentation; CB programmatic environmental document preparation; laboratory safety inspections (initial and annual); and biosurety/chemical surety oversight, review, and inspection per U.S. Army regulatory guidance.

15. Provide support for Freedom of Information Act requests as related to that portion of the Medical CB S&T Program assigned to USAMRMC by DTRA.

16. Provide technical watch communications as may be collected/identified by USAMRMC laboratories that could be relevant to the further advancement of the Medical CB S&T Program.

17. Furnish annual progress reports in agreed upon standardized formats for all intramural and contract-derived research for that portion of the Medical CB S&T Program assigned to USAMRMC by DTRA.

18. Provide written reviews for all extramural proposed work associated with the Medical CB S&T Program as assigned to USAMRMC by DTRA.

ANNEX B

Defense Threat Reduction Agency Support

The Defense Threat Reduction Agency (DTRA) will actively support the following program management initiatives:

1. Identify a single DTRA point of contact (POC) for major transactions that occur between the U.S. Army Medical Research and Materiel Command (USAMRMC) and DTRA under this agreement (e.g., fiscal year research program development process; data calls and reporting on the progress of Joint Science and Technology Office for Chemical and Biological Defense (JSTO-CB) funded research projects; coordinating defense-wide research, technology, development, and evaluation funded congressionally directed research programs; etc.).

2. Assist USAMRMC in investigating the availability or usefulness of existing databases to gain visibility of annual and quarterly progress reports required by JSTO-CB.

3. Establish mechanisms and processes to enable DTRA to provide timely responses to USAMRMC requirements through a single USAMRMC appointed POC.

4. Coordinate with USAMRMC to develop improvements and refinements to processes to support the actions of both Parties to comply with this agreement.

Memorandum of Agreement

Between the

Joint Program Executive Office for Chemical and Biological Defense

and the

United States Army Medical Research and Materiel Command

1.0 INTRODUCTION:

The purpose of this Memorandum of Agreement (MOA) is to provide over-arching guidelines under which future collaborative research, development and acquisition (RDA) activities between the Joint Program Executive Office for Chemical and Biological Defense (JPEO CBD) and the United States Army Medical Research and Materiel Command (USAMRMC), U.S. Department of Defense (DoD) (collectively "the agencies") may be implemented. JPEO CBD and USAMRMC have the common goals of advancing the development of vaccines, therapeutics, and diagnostics against biological agents of high consequence and candidate pretreatment, prophylactic, and treatment compounds against chemical warfare agents, toxins, and toxic industrial chemicals, collectively referred to here as medical countermeasures (MCM). These collaborations will achieve efficiencies and synergies for medical countermeasure development through JPEO CBD's program integration with the CBD S&T manager, Defense Threat Reduction Agency Joint Science and Technology Office (DTRA JSTO), enterprise –wide acquisition and portfolio management excellence, and JPEO CBD's experience with determining efficacy under the FDA "animal rule", combined with USAMRMC's wide range of core capabilities including medical research, specialized military medical expertise, medical materiel development, development of new technologies to improve military health care, research materials, and facilities.

2.0 AUTHORITY:

This MOA provides for all cooperative technical interactions between the JPEO CBD and USAMRMC, as well as all subordinate components of these organizations (specific Work Plans to support collaborative RDA projects will be documented as subordinate annexes to this MOA). This MOA is entered into under the inherent and specific authorities of each agency to execute their legal missions in support of the Chemical and Biological Defense Program (CBDP). The

agencies believe that this will advance effective mission accomplishment, and is consonant with the recommendations by, and provided to, Congress and the Secretary of Defense for improved interagency effort on this subject. To the extent, under this agreement, that the agencies provide services, or provide supplies and facilities to each other, it will be accomplished in accordance with the Economy Act, 31 U.S.C. Section 1535, and DoD Instruction 4000.19.

3.0 BACKGROUND:

The mission of the DOD Joint Program Executive Office for Chemical and Biological Defense (JPEO-CBD) is the research, development, acquisition, and life cycle support of chemical, biological, radiological, and nuclear defense equipment, medical countermeasures, and installation and force protection supporting the National Military Strategy. JPEO CBD provides centralized program management and joint service CBDP acquisition program integration for all assigned joint CBDP non-medical and medical programs. Within the JPEO-CBD, Joint Project Managers (JPM) lead, manage and direct the acquisition and fielding of medical devices, drugs and vaccines, chemical and biological detection and reconnaissance systems, individual and collective protection systems, decontamination systems, information management systems, and installation and force protection systems. Currently, three JPMs directly support the JPEO-CBD's medical mission: Joint Project Manager for Chemical and Biological Medical Systems (JPM CBMS), Joint Project Manager for Transformational Medical Technologies (JPM TMT), and Joint Project Manager for Medical Countermeasures (JPM MCM).

The mission of the USAMRMC is to protect and sustain healthy armed forces of the United States. This mission is accomplished through a wide range of core capabilities, including programs in medical research, medical materiel development, medical logistics medical information systems, and development of new technologies to improve military health care. USAMRMC is engaged in a broad spectrum of medical research activities, from basic laboratory research through product acquisition. USAMRMC is the lead agency for medical product research, development through FDA approval and full life cycle management, endemic infectious disease research and the lead executing agency for the tech-base development of MCM against selected chemical and biological (CB) warfare agents for the DoD.

Scientific and technical expertise for a biological medical response currently resides at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) and for a chemical medical response at the U.S. Army Medical Research Institute of Chemical Defense (USAMRICD). This expertise includes extensive scientific knowledge and expertise for the development of rapid diagnostic assays and MCM against biological and chemical agents. USAMRIID's and USAMRICD's capabilities and expertise represent critical resources that are essential for development of candidate products of interest to the DoD. Scientific expertise for general infectious disease research, within USAMRMC, resides at the Walter Reed Army Institute of Research (WRAIR) and its subordinate detachments spread globally, which conduct biomedical research on HIV/AIDS, malaria, leishmaniasis and other infectious diseases. The United States Army Medical Material Development Activity (USAMMDA) and the US. Army Medical Materiel Agency (USAMMA) are the Army's advanced medical materiel development activities for products designed to protect and preserve the lives of Service members. The

product managers at USAMMDA/USAMMA guide promising new concepts and technologies developed in the USAMRMC laboratories through advanced development and the regulatory process to obtain U.S. FDA licensure. The Office of the Surgeon General (OTSG) Regulatory Sponsor Office which supports compliance with FDA requirements also resides at USAMMDA.

4.0 PURPOSE:

This MOA provides cooperative guidelines for all existing and future collaborative RDA projects and activities between JPEO CBD and the USAMRMC, including all subordinate components of these organizations. It continues and preserves longstanding, extensive, and successful collaborations between JPEO CBD and USAMRMC, and leverages the distinct capabilities of each organization. Both JPEO CBD and USAMRMC, through their complementary expertise and resources, can improve these collaborations and achieve greater synergy in CBD MCM advancement by cooperating under this agreement.

Specific Work Plans to support collaborative RDA projects covered under this agreement will be described in subordinate annexes to this MOA. New annexes should be named the same as the existing agreement with an annex number before the date, and a unique number shall be assigned to the end of each annex to delineate it from others, e.g., 01-02-03, etc., and designate the nature of the research activity, e.g. B01 (biodefense project 01), R01 (regulatory project 01), F01 (Surety Infrastructure Projects to include BSL4 GLP MCM infrastructure sustainment 01), C01 (chemical defense project 01). All new and amended annexes to this MOA shall be signed by the authorized USAMRMC unit/laboratory Commander and the authorized JPEO CBD signatory. USAMRMC unit/laboratory Commanders will ensure that final documents are sent to HQ USAMRMC using existing electronic staffing procedures prior to signature. All new annexes shall be executed in accordance with the provisions of this MOA.

5.0 SCOPE AND PROVISIONS OF AGREEMENT:

A. This joint program will support collaborative RDA activities on potential CB agents, including but not limited to the following:
    1) Exchange of information and technical procedures,
    2) Exchange of laboratory specimens between the organizational units/laboratories and local, state, or regional public health laboratories,
    3) Exchange of resources as defined in Section 6,
    4) Expansion of training opportunities,
    5) Use of facilities and enhancement of capacities,
    6) Conduct of applied research, and MCM T&E.

B. Annexes shall be developed (or renewed) by the agencies for each specific Work Plan to support a collaborative RDA project or activity covered by this MOA. Each annex shall:

1) Describe in detail the scope of work (SOW) for the collaborative RDA project or activity.
2) Delineate the contributions, roles and responsibilities of JPEO CBD and USAMRMC.
3) Address notification timelines for starting and terminating projects and activities and the execution of reports.
4) Address legal authorities; services, supplies, equipment and costs thereof; and financing and method of transfer of funds.
5) Provide a listing of the technical and administrative Points of Contact (POC) for each activity, to include addresses, phone numbers, fax numbers, and email addresses.
6) Discuss and delineate as appropriate the following terms:
    a. Timeline, schedules, resource requirements
    b. Project management
    c. Use, storage and disposition of RDA materials; inventories
    d. Access to data, specimens, biological and/or chemical materials
    e. Security classification
    f. Confidentiality
    g. Publications and press releases
    h. Reporting requirements
    i. Intellectual property, proprietary information, and potential patent rights
    j. Data management issues to address include; data rights, data definition and description, data transfer and/or transmissions and protections, data storage/retention/destruction and protections, data de-identification, physical storage, system interface description, and training/vetting requirements for personnel handling or having access to the data (as appropriate for the work plan).
    k. And other provisions necessitated by the specific collaborative effort addressed in the annex, such as third party interaction, training.
7) Identify the appropriate staffing process (MRMC Decision Gate or JPEO MDA) for acquisition decisions.

C. GOVERNANCE

On an annual basis, all collaborative RDA activities encompassed by this MOA shall be reviewed at a meeting convened by the USAMRMC/JPEO CBD leadership. The respective project officers for each activity shall review the collaborative activities, including status of the activity, accomplishments, future plans, and obstacles encountered. In addition, any projected future collaborative activities that will need

additional subordinate annexes shall be brought to the attention of the USAMRMC/ JPEO CBD leadership at the MDA level or the level that the MDA delegates to.

Identified project officers for each joint activity shall monitor the progress of the activity and resolve any problems that arise. Unresolved issues will be referred through each organization's chain of command, as appropriate, for resolution.

6.0 RESOURCES:

Each subordinate annex shall address items A. through H. in greater detail as appropriate:

A. Funding: Funding to support collaborative RDA activities will be provided in each Work Plan/annex as mutually authorized between JPEO CBD and USAMRMC. Such mechanisms through which resources are exchanged will constitute an Economy Act Order (31 U.S.C. 1535) or other authority as applicable. USAMRMC will establish spend plans for any funding received from the JPEO CBD and execute those funds at a rate to meet or exceed annual OSD Comptroller Obligation and Expenditure goals. USAMRMC will utilize the General Fund Enterprise Business System (GFEBS) and an appropriate activity-based costing, or an equivalent costing methodology system, to substantiate all activities and associated transactions to allow both parties to develop more accurate cost projections for appropriate resource planning in the out years. Any study plans requested by JPEO-CBD will be submitted to the proposed executing laboratory one year in advance, if appropriate, of the planned start time for the project.

B. Materials: Laboratory specimens or other materials transferred under this MOA will be provided in accordance with, as applicable, the Public Health Service Act and the Federal Technology Transfer Act of 1986, as amended, and as applicable, may be transferred under a Materials Transfer Agreement (MTA). In addition, any research activity requiring the transfer of select agents will be in accordance with 42 CFR Part 73, 7 CFR Part 331 and AR 50-1; other applicable biosafety and chemical safety requirements apply as appropriate.

C. Inventions: Rights in Subject Inventions made with federal assistance will be governed by 35 U.S.C. Sections 201 et seq. and all implementing regulations.

D. Travel: Travel under this MOA will be subject to allowances authorized in accordance with the Joint Travel Regulations, Joint Federal Travel Regulations and/or Foreign Service Regulations as applicable for USAMRMC personnel. Travel under this MOA for other personnel will be subject to the established procedures of their employer.

E. Equipment: Equipment purchases for work under any annex to this MOA will be made consistent with the administrative regulations and procedures governing the party that is making the purchases, as provided in the annex.

F. Facilities: Facilities used in carrying out work under this MOA will be under the control of the party or collaborator which owns the facilities. Each annex will describe process and protocol for facility access to include Personnel Security requirements (clearances or visits requests), scheduling, appropriate funds transfer, and other facility issues as needed.

G. Animals: When animals are used in research under the terms of an annex, unless otherwise specified, the animals are owned by the owner of the facility in which the research takes place. The Institutional Animal Care and Use Committee (IACUC) of record will be the IACUC overseeing the work in the facility where the research occurs.

7.0 CONTACTS:

USAMRMC:
Strategic Partnerships Office
USAMRMC
MCMR-SP
504 Scott Street
Fort Detrick, MD 21702-5012
(b) (6)

Technical POC:
CBRN Defense Coordinating Office
USAMRMC
MRMC-RTM
504 Scott Street
Fort Detrick, MD 21702-5012
(b) (6)

JPEO CBD:
(b) (6)
Deputy Chief of Staff for Medical Acquisition
Joint Program Executive Office for Chemical and Biological Defense (JPEO-CBD)
5183 Blackhawk Road, Building #E5101
Aberdeen Proving Ground, MD 21010-5424
(b) (6)

8.0 IMPLEMENTATION AND ADMINISTRATION:

A. Effective Date: This MOA will be implemented and become effective on the date of the last signature.

B. This agreement shall be reviewed approximately one year from its effective date to determine whether any changes are needed, and subsequently at two-year intervals.

C. Duration: This agreement shall remain in effect until September 30, 2017, unless extended by mutual agreement during any scheduled review or terminated in accordance with provisions in the following paragraph.

D. Modification and Termination: This MOA may be modified by mutual agreement of the agencies and may be terminated either by mutual agreement or unilaterally by the agencies. Unilateral termination requires that the agency terminating this MOA provide written notification to the other agency at least 180 days prior to termination.

E. Modification and Termination of Subordinate Annexes: The termination and modification of subordinate annexes will be specified in those annexes.

USAMRMC

Signature valid
(b) (6)

Brigadier General (P), Medical Corps
Commanding General

JPEO CBD

(b) (6)

Joint Program Executive Office
for Chemical and Biological
Defense

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UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES
4301 JONES BRIDGE ROAD
BETHESDA, MARYLAND 20814-4799
www.usuhs.mil

July 12, 2010

OFFICE OF THE
PRESIDENT

MEMORANDUM FOR (b) (6)
PERFORMING THE DUTIES OF THE ASSISTANT SECRETARY
OF DEFENSE FOR HEALTH AFFAIRS

SUBJECT: Membership for Joint Program Committee – 7 (JPC-7) for Radiation and Nuclear Defense

At the January 2010 Board of Governors (BOG) meeting for the Armed Forces Radiobiology Research Institute (AFRRI), it was determined that AFRRI should continue to use the Joint Program Committee for Radiation and Nuclear Defense to provide oversight and guidance for the science being conducted at AFRRI. However, the BOG recommended that the JPC-7 be reconstituted with membership that paralleled the structures of the other Joint Program Committees that fall under the United States Army Medical Research and Materiel Command.

To meet this recommendation by the AFRRI BOG, we suggest the following membership be considered to constitute the new JPC-7:

U.S. Army Surgeon General Representative – Radiation Health Specialist
U.S. Navy Surgeon General Representative – Radiation Health Specialist
U.S. Air Force Surgeon General Representative – Radiation Health Specialist
U.S. Marines Representative
Uniformed Services University for the Health Sciences Representative
Armed Forces Radiation Research Institute Representative
J-4 Surgeons Office Representative
J-8 Joint Requirements Office Representative
Health Affairs Representative
Special Forces Medical Specialist Representative
Defense Threat Reduction Agency Representative
Department of Energy Representative
National Institutes of Health Representative

The AFRRI BOG recommended that the JPC-7 be chaired by a military officer selected in a similar manner to those that direct the other Joint Programs that fall under MRMC. It was recommended that the Director of AFRRI no longer Chair this committee. The support for the JPC-7 should fall under the Partnership Support Directorate of MRMC.

(b) (6)
Brigadier General, U.S. Army (Ret.)
Acting President

Learning to Care for Those in Harm's Way

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, DC 20301-1200

JUL 30 2010

HEALTH AFFAIRS

MEMORANDUM FOR (b) (6) ACTING PRESIDENT, UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES

SUBJECT: Membership for Joint Program Committee-7 for Radiation and Nuclear Defense

This is in reference to your memorandum, dated July 12, 2010, subject: "Membership for Joint Program Committee-7 (JPC-7) for Radiation and Nuclear Defense." We concur with the recommendations made in your memorandum, but we request that you coordinate implementation of the recommendation with the Commanding General, U.S. Army Medical Research and Materiel Command. The point of contact for this matter is (b) (6) who can be reached at (b) (6) or (b) (6)

(b) (6)

President, Uniformed Services University of the Health Sciences
Performing the Duties of the Assistant Secretary of Defense (Health Affairs)

Department of Defense

INSTRUCTION

NUMBER 5105.33
March 29, 2006

USD(P&R)

SUBJECT: Armed Forces Radiobiology Research Institute (AFRRI)

References: (a) DoD Directive 5105.33, "Armed Forces Radiobiology Research Institute," November 25, 1987 (hereby canceled)
(b) Deputy Secretary of Defense Memorandum, "DoD Directives Review – Phase II," July 13, 2005
(c) DoD Directive 5105.45, "Uniformed Services University of the Health Sciences (USUHS)," March 9, 2000
(d) DoD Directive 5136.1, "Assistant Secretary of Defense for Health Affairs (ASD(HA))," May 27, 1994
(e) DoD Directive 5105.18, "DoD Committee Management Program," February 8, 1999
(f) DoD Directive 8910.1, "Management and Control of Information Requirements," June 11, 1993

1. REISSUANCE AND PURPOSE

This Instruction:

1.1. Reissues Reference (a) as a DoD Instruction according to the guidance in Reference (b) to update and clarify the responsibilities and functions of the Armed Forces Radiobiology Research Institute (AFRRI).

1.2. Sets forth the organizational relationships and establishes the management and administrative procedures for the AFRRI, and provides for the establishment of a Board of Governors (BoG).

2. APPLICABILITY

This Instruction applies to the Office of the Secretary of Defense, the Military Departments, the Chairman of the Joint Chiefs of Staff, the Combatant Commands, the Office of the Inspector General of the Department of Defense, the Defense Agencies, the DoD Field Activities, and all other organizational entities in the Department of Defense (hereafter referred to collectively as the "DoD Components").

3. MISSION

The mission of the AFRRI shall be to conduct research in the field of radiobiology and related matters essential to the operational and medical support of the Department of Defense and the Military Services. The AFRRI may provide services and perform cooperative research with other Federal and civilian agencies and institutions with the approval of the Assistant Secretary of Defense for Health Affairs (ASD(HA)).

4. ORGANIZATION AND MANAGEMENT

The AFRRI, according to DoD Directive 5105.45, "Uniformed Services University of the Health Sciences (USUHS)," and DoD Directive 5136.1, "Assistant Secretary of Defense for Health Affairs (ASD(HA))" (References (c) and (d)), is established as a joint entity of the Military Departments, subject to the authority, direction, and control of the President of USUHS, under the ASD(HA) and the Under Secretary of Defense for Personnel and Readiness (USD(P&R)). The ASD(HA) shall appoint:

4.1. A BoG, consistent with DoD Directive 5105.18, "DoD Committee Management Program" (Reference (e)), to advise the ASD(HA) on programs and policies and facilitate broad DoD participation in supporting accomplishment of the AFRRI mission. At a minimum, the BoG shall meet annually. The BoG membership shall consist of:

4.1.1. The Principal Deputy ASD(HA), who shall be the Chairman;

4.1.2. The Surgeons General of the Army, Navy, and Air Force;

4.1.3. The Deputy Chiefs of Staff for Operations of the Army, Navy, and Air Force;

4.1.4. The Joint Staff Surgeon;

4.1.5. The President of USUHS;

4.1.6. A representative of the Assistant to the Secretary of Defense for Nuclear, Chemical and Biological Defense Programs;

4.1.7. The Director of AFRRI, who shall serve as Executive Secretary;

4.1.8. Any additional representatives of DoD Components or other Federal agencies as the ASD(HA) determines appropriate in achieving the purpose of the BoG.

4.2. A Director of AFRRI who shall be a military officer (in grade O-6), and who holds an earned academic doctoral degree in one of the life sciences. The candidates for Director position shall be nominated by the Surgeons General of the Army, the Navy, and the Air Force. Each Service shall nominate one individual with the proper professional qualifications and demonstrated management ability. The BoG shall review the Service nominees and provide a prioritized list of candidates to the ASD(HA). This appointment shall be for a 4-year term.

5. RESPONSIBILITIES AND FUNCTIONS

5.1. The AFRRI shall:

5.1.1. Operate research facilities for the study of radiobiology and ionizing radiation bioeffects and for the development of medical countermeasures against ionizing radiation, and the results shall be disseminated.

5.1.1.1. The scope of this research shall reflect requirements identified by the DoD Components for support of military operational planning and employment (current and future), and shall put special emphasis on individual and organizational performances under nuclear and radiological combat conditions in realistic operational and force protection scenarios.

5.1.1.2. The AFRRI program shall consider present and projected threats, Service and joint operational concepts and weapons, and defense systems developments.

5.1.2. Provide analysis, study, and consultation on the impact of the biological effects of ionizing radiation on the organizational efficiency of the Military Services and their members.

5.1.3. Conduct cooperative research with the Military Medical Departments in those aspects of military operational and medical support considerations related to nuclear weapons effects and the radiobiological hazards of space operations.

5.1.4. Conduct advanced training in the field of radiobiology and the biological effects of nuclear and radiological weapons to meet the internal requirements of the AFRRI, the Military Services, and other DoD Components and organizations.

5.1.5. Participate in cooperative research and other enterprises, consistent with the AFRRI mission and applicable authorities, with other Federal agencies involved in homeland security and emergency medical preparedness.

5.1.6. Perform such other functions as may be assigned by the ASD(HA).

5.2. The President of USUHS, consistent with Reference (c), shall:

5.2.1. Exercise authority, direction, and control over the AFRRI.

5.2.2. Ensure that the Director of AFRRI executes those responsibilities and functions pertaining to the day-to-day operations of the AFRRI.

5.3. The ASD(HA), under the USD(P&R), shall:

5.3.1. Exercise authority, direction, and control over the programs, funding, and associated resources in the Department of Defense as they relate to the AFRRI according to Reference (d).

5.3.2. Develop policies and issue policy guidance to ensure the effective administration and efficient operation of the AFRRI. This includes, but is not limited to, the development of DoD Directives, the issuance of DoD Instructions, and OSD-level participation in the Planning, Programming, Budgeting, and Execution process.

5.3.3. Ensure that the advice of the BoG is considered in operational and programmatic direction of the AFRRI.

5.4. The Secretaries of the Military Departments shall provide authorized resources to support the activities of the AFRRI.

6. RELATIONSHIPS

6.1. The Director of AFRRI shall:

6.1.1. Ensure that the DoD Components are kept fully informed of AFRRI activities with which they have collateral or related functions.

6.1.2. Use established facilities and services of the Department of Defense and other Federal Agencies, whenever practicable, to avoid duplication and to achieve an appropriate balance of modernization, efficiency, and economy of operations.

6.1.3. Maintain appropriate liaison, consultation, and coordination with other Governmental and non-Governmental Agencies, as required, to exchange information and advice on programs in the fields of assigned responsibility.

6.2. The Heads of the DoD Components shall coordinate with the Director of AFRRI, as appropriate, on matters relating to AFRRI operations, functions, and responsibilities.

7. AUTHORITIES

The Director of AFRRI is specifically delegated authority to:

7.1. Obtain information, advice, and assistance necessary to carry out AFRRI programs and activities from other DoD Components, which is consistent with the policies and criteria of DoD Directive 8910.1 (Reference (f)).

7.2. Communicate directly with appropriate representatives of the DoD Components, other Executive Departments and Agencies, and members of the public, as appropriate, on matters related to AFRRI programs and activities. Communications to the Commanders of the Combatant Commands shall be relayed through the Chairman of the Joint Chiefs of Staff.

8. ADMINISTRATION

8.1. Funding for the AFRRI shall be the responsibility of the ASD(HA) and shall be programmed and budgeted within the Defense Health Program (DHP), Operation and Maintenance, and Research, Development, Testing and Evaluation appropriations.

8.2. The Military Departments shall be responsible for providing authorized military manpower to the AFRRI. AFFRI military manpower should be DHP-resourced in the Program Objective Memorandum with Military Personnel appropriation resources transferring from the DHP to the Military Departments in the Budget Estimate Submission/President's Budget submissions.

9. EFFECTIVE DATE

This Instruction is effective immediately.

(b) (6)

Under Secretary of Defense for
Personnel and Readiness

Section 18

Fiscal Year 2014
Annual Historical Report

Congressionally Directed Medical Research Programs

Mission

The mission of the Congressionally Directed Medical Research Programs (CDMRP) of the U.S. Army Medical Research and Materiel Command (USAMRMC), Fort Detrick, Maryland, is to provide hope by promoting innovative research, recognizing untapped opportunities, creating partnerships, and guarding the public trust.

The function of the CDMRP is to manage Congressional Special Interest (CSI) appropriations for research targeted on breast, prostate, ovarian, lung, and other cancers; neurofibromatosis; autism; bone marrow failure; multiple sclerosis; Duchenne muscular dystrophy; military health; orthopaedics; spinal cord injury; tuberous sclerosis complex; psychological health and traumatic brain injury; amyotrophic lateral sclerosis; Gulf War Illness; deployment-related health research; and other health concerns. Historical Congressional appropriations for these targeted diseases, injuries, and conditions total approximately $8.223 billion through fiscal year (FY) 2014. The CDMRP uses a flexible 7-year management cycle that follows a proven, established path:

A. Congressional appropriation and receipt of funds
B. Inaugural stakeholders meeting for new research programs
C. Vision setting
D. Writing and release of program announcements
E. Receipt of applications
F. Scientific peer review
G. Programmatic review
H. Funding approval
I. Award negotiations and management
J. Program evaluation
K. Award close-out

In addition, the CDMRP assists with the execution of non-CSI funding for the extramural program funded by the Guidance for the Developing Force appropriations for the Defense Medical Research and Development Program office within the Office of the Deputy Assistant Secretary of Defense for Force Health Protection and Readiness.

Organization

A. The CDMRP organizational chart dated 30 September 2014 (Attachment 1) is appended to this report.
B. The CDMRP continued operating within the following divisions:
    1) CDMRP Leadership
    2) Research Programs Division
    3) Grants Management Division
    4) Administrative Division
    5) Research Program Contractors
        a. Peer Review Division
        b. Programmatic Review Division

C. The following organizational meetings were held among the CDMRP staff and support contractors:

1) *Team Leader Meetings* were held biweekly to facilitate coordination among the various teams within the CDMRP. The Director, Deputy Director, Chief of Staff, Deputy Director for Grants Management, and CDMRP team leaders attended.

2) *Program Management Meetings* were held weekly to facilitate program management and coordination among the Program Managers.

3) *Science Officer Meetings* were held weekly to facilitate grants management and coordination among the Deputy Director for Grants Management and the Science Officers.

4) *Business Meetings* were held monthly to facilitate the administrative and management tasks of the organization and provide coordination among the Chief of Staff and administrative personnel.

5) *Integrated Program Team Meetings* were held weekly for individual research programs to facilitate program coordination among the Program Manager, Science Officers, and technical contract support staff.

6) *Director's Meetings* were held quarterly to address specific topics and issues such as milestones, program updates, safety, information security, etc. The CDMRP staff and technical contract support staff attended these meetings.

7) *Contractor Performance Evaluation Meetings* were held quarterly for each support contract to provide feedback on contract performance and address any outstanding issues. The CDMRP Director, Deputy Director, Chief of Staff, Contract Manager, Contracting Officer (U.S. Army Medical Research Acquisition Activity), Contract Specialist, and relevant contract support staff attended these meetings.

   a. The *EGS/eBRAP Coordination Meetings* were held as needed to facilitate coordination among the CDMRP EGS (Electronic Grants System), Electronic Biomedical Research Application Portal (eBRAP), and Grants.gov systems. Attendees included system developers and project managers for EGS and eBRAP. Topics involved data transfers, improvements, and troubleshooting issues.

   b. The *Public Affairs* team met every 2 weeks to keep abreast of speaking engagements, news stories, and press releases in development and hear presentations by leadership and staff.

   c. CDMRP Leadership met weekly with Telemedicine and Advanced Technology Research Center (TATRC) Leadership to develop plans for transition of all execution management functions to CDMRP.

   d. Program Area Liaisons began meeting regularly to coordinate CDMRP's process for supporting each Joint Program Committee (JPC).

   e. The new CDMRP Meeting and Travel Team began meeting every 2 weeks to develop a process and roles for supporting all meeting planning and travel.

D. Several standing committees are maintained to develop and analyze standard operating procedures for program execution, evaluation, and management:

1) The *Inquiry Review Panel* met monthly to address inquiries submitted by Principal Investigators (PIs) or third parties with regard to submitted applications to ensure that a fair review process occurred.

2) The *Program Evaluation Steering Committee (PESC)* met monthly to evaluate the strengths and weaknesses of the CDMRP's processes and research programs, with the ultimate goal of improving the quality of the programs and the diversity of each research portfolio.

3) The *Professional Development Working Group* (PDWG), initiated in early 2013, offers CDMRP staff monthly on-site opportunities to increase their professional repertoire. Events span research management, scientific/medical topics, and training to enhance professional skills, with invited speakers from USAMRMC, Government, and academia. The events were well attended, had meaningful impact, and enhanced the performance of CDMRP staff.

4) The (b) (6) Working Group ((b) (6)) was established in 2013 to execute legacy activities to honor (b) (6) , who died after a brief illness on 23 January 2013. She was a dedicated colleague who served as a CDMRP Program Manager from 1998 to 2013. In the subsequent year, the (b) (6) invited two distinguished investigators for (b) (6) Legacy Lecture. The inaugural lecture was given in December 2013 by (b) (6) to discuss her Department of Defense (DoD)-funded research in prostate cancer health disparities. In May 2014, (b) (6) was invited to present her scientific findings on bridging the human-machine interface through body wearable sensors. The (b) (6) also organized a successful back-to-school supply drive with donations going to the United Way of Frederick Maryland for the Frederick County Public Schools. Other activities included the expansion of the memorial garden with the mount of a plaque and a framed photo of (b) (6) with inscription inside building 1076.

Personnel

A. Col (b) (6) , M.D., U.S. Air Force, Director

B. COL (b) (6) , D.D.S., Deputy Director

C. CDR (b) (6) , Ph.D., U.S. Public Health Service, Deputy Director for Grants Management

D. (b) (6) , MBA, Chief of Staff

E. Program Managers

1) (b) (6) , Ph.D. (Became a civilian on 8 September 2014.)
2) (b) (6) , Ph.D. (Departed CDMRP in May 2014.)
3) (b) (6) , Ph.D.
4) (b) (6) , Ph.D.
5) (b) (6) , Ph.D. (Became a civilian on 11 August 2014.)
6) (b) (6) , Ph.D. (Became a civilian on 25 August 2014.)
7) (b) (6) , Ph.D.
8) (b) (6) , Ph.D., RN (Departed CDMRP in March 2014.)
9) (b) (6) , Ph.D. (Became a civilian on 24 August 2014.)
10) (b) (6) , Ph.D.
11) (b) (6) Ph.D. (Became a civilian on 11 August 2014.)
12) (b) (6) , M.A. (Transitioned from TATRC to CDMRP in July 2014.)
13) CAPT (b) (6) , Ph.D., R.N., U.S. Public Health Service
14) (b) (6) , Ph.D.
15) (b) (6) , Ph.D.
16) (b) (6) Ph.D.
17) (b) (6) , Ph.D.
18) (b) (6) Ph.D. (Transferred from TATRC to CDMRP in July 2014.)
19) (b) (6) ., MBA (Transferred from TATRC to CDMRP in July 2014.)
20) Col (b) (6) , MD, U.S. Air Force (Joined CDMRP on 8 July 2014.)
21) (b) (6) , M.S.H.A. (Transferred from TATRC to CDMRP in July 2014.)

22) (b) (6), Ph.D. (Became a civilian on 8 September 2014.)
23) (b) (6), MBA (Transferred from TATRC to CDMRP in July 2014.)
24) (b) (6), Ph.D.
25) (b) (6) Ph.D. (Became a civilian on 8 September 2014.)

F. Science Officers

1) (b) (6), Ph.D. (Became a civilian on 8 September 2014.)
2) (b) (6) MD (Transferred from TATRC to CDMRP in July 2014.)
3) (b) (6), Ph.D. (Transferred from TATRC to CDMRP in July 2014.)
4) (b) (6), M.S. (Transferred from TATRC to CDMRP in July 2014.)
5) (b) (6), Ph.D. (Terminated Intergovernmental Personnel Agreement [IPA] in December 2013.)
6) (b) (6) (Transferred from TATRC to CDMRP in July 2014.)
7) (b) (6), MS(c) (Transferred from TATRC to CDMRP in July 2014. Became a civilian on 11 August 2014.)
8) (b) (6), Ph.D. (Became a civilian on 22 September 2014.)
9) (b) (6), Ph.D. (Transferred from TATRC to CDMRP in July 2014.)
10) (b) (6), Ph.D. (Transferred from TATRC to CDMRP in July 2014.)
11) (b) (6), Ph.D. (Transferred from TATRC to CDMRP in July 2014.)
12) (b) (6), Ph.D. (Transferred from TATRC to CDMRP in July 2014.)
13) (b) (6), Ph.D. (Departed CDMRP in April 2014.)
14) (b) (6), Ph.D.
15) (b) (6), Ph.D.
16) CDR (b) (6), M.P.H., U.S. Public Health Service
17) (b) (6), Ph.D.
18) CAPT (b) (6), D.V.M., M.P.H., U.S. Public Health Service
19) (b) (6), Ph.D. (Became a civilian on 11 August 2014.)

G. Administration

1) (b) (6), M.S., MBA, Finance Manager (Terminated IPA Agreement in June 2014.)
2) (b) (6), Logistics Engineer
3) (b) (6), Financial Management Analyst
4) (b) (6), MBA, Chief of Acquisition Management

Training

A. All CDMRP military, civilian, IPA, and contract support staff are required to complete annual training courses depending on their position within the organization. The following training courses were completed in FY 2014:

1) DoD Information Assurance Awareness
2) Level I Anti-Terrorism
3) Environmental Awareness
4) Health Insurance Portability and Accountability Act
5) Ethics
6) Army Substance Abuse Program
7) Threat Awareness and Reporting Program
8) Sexual Harassment/Assault Response and Prevention
9) Act, Care, Escort Suicide Prevention
10) Operations Security
11) Combat Trafficking in Persons
12) No Fear Act
13) Composite Risk Management
14) Constitution Day
15) Personnel Recovery
16) Local Hazards Training
17) Emergency Preparedness Response Course
18) Risk Recognition in the Workplace

B. In June 2014, the CDMRP held their annual team building event to fortify strong working relationships within the organization. The event took place at Nallin Pond, Fort Detrick on 12 June 2014 and more than 90 CDMRP military, civilian, IPA, and contract support staff participated.

C. The CDMRP program staff were provided an opportunity to participate in numerous Government-sponsored training classes:

1) Acquisition 101 and 201
2) Defense Acquisition University's Contracting Officer's Representative Course
3) U.S. Army Medical Research Acquisition Activity's Contracting Officer's Representative Course
4) Introduction to Grants and Cooperative Agreements
5) Army Leadership Education and Development
6) Management and Leadership Skills
7) Time and Stress Management
8) Intermediate Medical Acquisitions Course
9) Retirement Planning Course
10) Equal Employment Opportunity Course

D. Due to restrictions in travel in FY 2014, the scientific staff was limited in the number of scientific meetings they were able to attend. Scientific staff attended the following scientific conferences, meetings, and workshops related to their research programs: Amyotrophic Lateral Sclerosis Association National Conference; National Institutes of Health (NIH) 2014 Lung Cancer SPORE Workshop; NIH Multiple Dystrophy Conference Committee; NIH NCI 10th Early Detection Research Network Scientific Workshop; Military Health Systems Research Symposium; Multi-Team Award Semi-Annual Meeting at the City of Hope Beckman Research Institute; ASIA Conference; DoD Military Health Research Foundation and Neurotrama Meeting; Meeting of the Research Advisory Committee on Gulf War Veterans' Illnesses; Department of Veterans Affairs (VA), Washington, D.C.; 2014 Ovarian National Alliance Conference; 2014 Neurofibromatosis Conference; National Breast Cancer Coalition 2014 Advocate Leadership Summit; Meeting of the Advisory Committee on Breast Cancer in Young Women Centers for Disease Control and Prevention (participated via teleconference); American Association for Cancer Research Annual Meeting; Prostate Cancer Foundation Retreat; 2014 Tuberous Sclerosis Conference.

E. For professional development, the CDMRP staff was provided an opportunity to attend lectures and seminars given by investigators funded by the CDMRP at the Frederick National Laboratory for Cancer Research facilities at Fort Detrick. The PDWG organized seminars with the following speakers: (b) (6) ; Supervisory Consumer Safety Officer, Food and Drug Administration (FDA); (b) (6) CDMRP; (b) (6) , Chief, Section on Functional Imaging Methods Laboratory of Brain and Cognition, National Institute of Mental Health, NIH; (b) (6) , Director, Office of Extramural Programs (OEP), NIH; (b) (6) Director, Preclinical Medication Efficacy Testing Program, National Institute on Alcohol Abuse and Alcoholism; Chair, Program Leadership Committee, OEP, NIH; (b) (6) , Director, Reproductive Neuroendocrinology, Fertility Preservation, and Reproductive Scientist Development Programs, National Institute of Child Health and Human Development; (b) (6) , Senior Scientific Advisor for Extramural Research, NIH; (b) (6) , Special Assistant to the Director, Office of Policy for Extramural Research Administration, NIH; (b) (6) Decision Gate Office; (b) (6) , Austere Environment Consortium for Enhanced Sepsis Outcomes Director, Naval Medical Research Center; (b) (6) , Entrepreneur-in-Residence, University of Virginia; (b) (6) Professor of Tumor Biology, Massachusetts General Hospital.

Research and Development

A total of 77 award mechanisms in three different categories – Clinical/Innovative Research, Resource, and Training/Recruitment – were offered in FY 2014. These mechanisms were created to fund innovative, high-risk/high-reward research efforts for the benefit of Warfighters, their families, and the American public. Among the previously offered award mechanisms, 18 were new to the individual program.

FIGURE 1: Synopsis of FY 2013/2014 Award Mechanisms by Category

Programs Managed by CDMRP[1]	Clinical or Innovative Research	Resource	Training/Recruitment
Amyotrophic Lateral Sclerosis (ALSRP)	Therapeutic Development Therapeutic Idea		
Autism (ARP)	Idea Development Clinical Trial		
Bone Marrow Failure (BMFRP)	Idea Development		

[1] CDMRP executed and managed the full appropriation.

Programs Managed by CDMRP[1]	Clinical or Innovative Research	Resource	Training/Recruitment
Breast Cancer (BCRP)	Breakthrough Levels 1 & 2 Breakthrough Levels 3 & 4 Era of Hope Scholar Innovator		
Duchenne Muscular Dystrophy (DMDRP)	Investigator-Initiated Research Therapeutic Idea		
Gulf War Illness (GWIRP)	Clinical Trial Investigator-Initiated Research Innovative Treatment Evaluation		New Investigator
Lung Cancer (LCRP)	Clinical Exploration Concept Idea Development		Career Development
Multiple Sclerosis (MSRP)	Investigator-Initiated Partnership		
Neurofibromatosis (NFRP)	Clinical Trial Exploration – Hypothesis Development Investigator-Initiated Research		New Investigator
Ovarian Cancer (OCRP)	Clinical Translational Leverage Pilot Ovarian Cancer Academy Collaborative Award Investigator-Initiated Research Award		Ovarian Cancer Academy – Early-Career Investigator Ovarian Cancer Academy Dean and Assistant Dean (Leadership) Award
Peer Reviewed Alzheimer's (PRARP)	Convergence Science Research Award Quality of Life Research Award Military Risk Factors Research Award		
Peer Reviewed Cancer (PRCRP)	Idea Award with Special Focus		Career Development

Programs Managed by CDMRP[1]	Clinical or Innovative Research	Resource	Training/Recruitment
Peer Reviewed Medical (PRMRP)	Clinical Trial Discovery Focused Program Award Investigator-Initiated Research Technology/Therapeutic Development		
Peer Reviewed Orthopaedic (PRORP)	Clinical Trial Clinical Trial Development Expansion Award Idea Development Outcomes Research Translational Research		
Prostate Cancer (PCRP)	Biomarker Development Clinical Exploration Award Exploration – Hypothesis Development Health Disparity Research Idea Development Laboratory – Clinical Transition Population Science Impact Transformative Impact Synergistic Idea Development	Prostate Cancer Biospecimen Resource Site Award	Collaborative Undergraduate Historically Black Colleges and Universities (HBCU) Student Summer Training Program Physician Research Training Postdoctoral Training
Spinal Cord Injury (SCIRP)	Clinical Trial Investigator-Initiated Research Qualitative Research Translational Research Award		
Tuberous Sclerosis Complex (TSCRP)	Exploration – Hypothesis Development Idea Development Pilot Clinical Trial		

FIGURE 2: Synopsis of FY 2013/2014 Award Mechanisms by Category

Programs Managed on Behalf of Others[2]	Clinical or Innovative Research	Resource	Training/Recruitment
Defense Medical Research and Development (DMRDP)	Clinical Research Initiative (CRI) Intramural Research Award – Military Training Injuries Neurosensory Research Neuromusculoskeletal Injuries Research Reconstructive Transplantation Research Regenerative Medicine Clinical Trial Vision Research Program Hypothesis Development Vision Research Program Translational Research		
Psychological Health/ Traumatic Brain Injury (PH/TBIRP)	Community Partners in Mental Health Research Investigational Treatments for TBI and PTSD Clinical Trials Psychological Health Research TBI Endpoints Development		

A. New Clinical or Innovative Research Awards

1) The *New Investigator Award* was offered by the GWIRP to support investigators new to the field of GWI research at different stages of career development. This award enables such investigators to compete for funding separately from investigators with established programs of GWI research.

2) The *Investigator-Initiated Partnership Award* offered by the MSRP supports the development of translational research collaborations among no more than three independent investigators who synergistically combine efforts to address a central problem or question in MS.

3) The *Ovarian Cancer Academy Collaborative Award* offered by the OCRP provides an opportunity for Early-Career Investigator award recipients to form meaningful and productive collaborative efforts both within the Ovarian Cancer Academy and in the ovarian cancer research community.

4) The *Investigator-Initiated Research Award* offered by the OCRP is intended to support studies that will significantly impact ovarian cancer research and/or patient care. Research projects may focus on any phase of research from basic laboratory research through translational research. The rationale for a research idea may be derived from a laboratory discovery, population-based studies, a clinician's first-hand knowledge of patients, or anecdotal data.

5) The *Focused Program Award* offered by the PRMRP intends to optimize research and accelerate the solution for a critical question related to a designated FY 2014 PRMRP Focused Program Award Topic Area through a synergistic, multidisciplinary research program.

[2]CDMRP assisted with execution of the specified portion of a larger appropriation(s).

6) The *Expansion Award* was designed to provide support for the continued investigation and further development of highly impactful research projects that were previously funded through the FY 2009 PRORP Hypothesis Development, Idea Development, Technology Development, and Translational Research Partnership Awards.

7) The *Outcomes Research Award* offered by the PRORP is intended to support research that evaluates the effectiveness and functional outcomes of health care practices and interventions for traumatic military or Veteran amputee and/or limb salvage patients with the potential to impact the standard of care and contribute to evidence-based policy or guidelines for patient evaluation and care.

8) The *Prostate Cancer Biospecimen Resource Site Award* offered by the PCRP intends to expand the Prostate Cancer Biorepository Network by adding Resource Sites that will enhance the biorepository's utility to prostate cancer researchers through the provision of biospecimens that are unique and/or in limited supply.

9) The *Clinical Research Initiative Intramural Research Award – Military Training Injuries Award* offered by the DMRDP is intended to foster intramural clinical research aimed at protecting, supporting, and advancing the health and welfare of military personnel, families, and communities while supporting the development of military researchers and the Military Health System research culture.

10) The *Neurosensory Research Award* offered by the DMRDP is intended to support both applied (preclinical) research and clinical trials addressing traumatic brain injury (TBI) within specific Focus Areas of pain management, hearing loss/dysfunction, balance disorders, tinnitus, vision, or physical rehabilitation.

11) The *Neuromusculoskeletal Injuries Research Award* offered by the DMRDP is intended to support both applied (preclinical) research and clinical trials within specific Focus Areas of pain management, hearing loss/dysfunction, balance disorders, and/or tinnitus.

12) The *Regenerative Medicine Clinical Trial Award* offered by the DMRDP was intended to support Phase I or II clinical trials focused on extremity regeneration, craniomaxillofacial regeneration, vascularized composite allografts, and/or genitourinary/lower abdomen reconstruction. All clinical trials must be responsive to the health care needs of military Service Members and Veterans, and all applications must specifically and clearly address the military relevance of the proposed research.

13) The *Vision Research Program Hypothesis Development Award* offered by the DMRDP supports conceptually innovative, high-risk/high-reward research that could ultimately lead to critical discoveries or major advancements that will drive the field of vision research forward. Research projects should include a testable hypothesis based on a strong scientific rationale.

14) The *Vision Research Program Translational Research Award* offered by the DMRDP supports translational research that will accelerate the movement of promising ideas in vision research into clinical applications. Observations that drive a research idea may be derived from a laboratory discovery, population-based studies, or a clinician's first-hand knowledge of patients and anecdotal data.

15) The *Community Partners in Mental Health Research Award* offered by the PH/TBIRP supports research on the causes, development, and innovative treatment of mental health, substance use disorders, TBI, and suicide prevention in members of the National Guard and Reserves, their family members, and their caregivers.

16) The Investigational Treatments for TBI and PTSD Clinical Trials Award offered by the PH/TBIRP focuses on focus on new clinical trials or leverage existing studies. Investigational treatments considered under this award mechanism may include a device, drug, biologic, surgical procedure, rehabilitative modality, behavioral intervention, or other relevant intervention. All studies must clearly describe how they would incorporate the requirements and meet the intent of this award mechanism.

17) The Psychological Health Research Award offered by the PH/TBIRP is intended to support both applied (preclinical) research and clinical trials within specific Topic Areas addressing the prevention and treatment of military-relevant psychological health issues.

18) The TBI Endpoints Development Award offered by the PH/TBIRP supports the establishment of a collaborative, multidisciplinary research team to advance endpoints for use in trials involving diagnosis and treatment of mild to moderate TBI.

B. Existing Award Mechanisms

The remaining 59 award mechanisms offered by the FY 2014 programs were established in previous fiscal years by the individual programs. These mechanisms have been highly successful and are still critical in the appropriate fields of research. The mechanisms spanned clinical/innovative research, resource, and training/recruitment awards. Some of these cutting-edge award mechanisms developed by the CDMRP have been emulated by other funding agencies.

C. The CDMRP participated in the Small Business Innovation Research (SBIR)/Small Business Technology Transfer (STTR) program during FY 2014.

1) Three Phase II applications were submitted to the SBIR topic *Therapeutic Development to Restore Lymphatic Function in Secondary Lymphedema*, originally released in the 2011.3 SBIR solicitation. Following review, one Phase II contract was awarded.

2) Three Phase I contracts were awarded under the topic *Drug Delivery System for Topical Treatment of Peripheral Neuropathy,* released in the 2012.2 SBIR solicitation. Subsequent to the Phase I performance period, three Phase II applications were received and reviewed, and one Phase II contract was awarded.

D. Research highlights describing progress and success of CDMRP-funded projects were posted to the CDMRP website (http://cdmrp.army.mil/highlights/default.shtml) on a regular basis. In FY 2014, 64 text research highlights were posted:

1) ***ALSRP***

a. (b) (6), Ph.D., Baylor University, Waco, Texas: "Designing Pharmacological Agents that Inhibit the Aggregation of SOD1 by Increasing the Net Negative Charge of the Protein" (20 May 2014)
http://cdmrp.army.mil/alsrp/research_highlights/14(b) (6)_highlight.shtml

2) ***ARP***

a. (b) (6) M.D., Johns Hopkins University, Baltimore, Maryland; (b) (6), M.D., Children's Hospital, Boston, MA: "Discordant Monozygotic Twins as a Model for Genetic-Environmental Interaction in Autism" (22 April 2014)
http://cdmrp.army.mil/arp/research_highlights/14(b) (6) highlight.shtml (b) (6), Ph.D., Columbia University, New York, New York: "Systematic Characterization of the Immune Response to Gluten and Casein in Autism Spectrum Disorder" (18 April 2014)
http://cdmrp.army.mil/arp/research_highlights/14(b) (6)_highlight.shtml

b. (b) (6), M.D., Dr.PH, (b) (6), Sc.D., (b) (6), Sc.D., Ph.D., Harvard University, Boston, Massachusetts: "Maternal Risk Factors for Autism Spectrum Disorders in Children of the Nurses' Health Study II" (21 October 2013)
http://cdmrp.army.mil/arp/research_highlights/13(b) (6)_sant_weis_highlight.shtml

3) ***BMFRP***

a. (b) (6), Ph.D., University of Michigan, Ann Arbor, Michigan: "Modulation of Memory T Cells to Control Acquired Bone Marrow Failure" (19 December 2013)
http://cdmrpweb-ua.srahosting.com/bmfrp/research_highlights/13(b) (6)_highlight.shtml

4) ***BCRP***

a. Produced by the Staff of the BCRP and OCRP: "DoD BCRP and OCRP Contributions to Advancements in BRCA. (7 August 2014) http://cdmrp.army.mil/brca_timeline/default.shtml

b. (b) (6), Ph.D., Johns Hopkins University, Baltimore, Maryland: "Novel Methylated Biomarkers and a Robust Assay to Detect Circulating Tumor DNA in Metastatic Breast Cancer" (2 July 2014) http://cdmrp.army.mil/bcrp/research_highlights/14(b) (6)_highlight.shtml

c. (b) (6), M.D., Ph.D., University of Texas MD Anderson Cancer Center, Houston, Texas and (b) (6), M.D., COL, U.S. Army, Brooke Army Medical Center, San Antonio, Texas: "HER-2/neu (E75) Vaccine to Prevent Breast Cancer Recurrence in High-Risk Patients" (1 May 2014) http://cdmrp.army.mil/bcrp/research_highlights/14(b) (6)_highlight.shtml

d. (b) (6), M.D., Stanford University, Stanford, California: "Stimulation of Natural Killer Cells Enhances Trastuzumab Efficacy in Breast Cancer" (27 March 2014) http://cdmrp.army.mil/bcrp/research_highlights/14(b) (6)_highlight.shtml

e. (b) (6), Ph.D., Duke University Medical Center, Durham, North Carolina: "Mechanisms Behind Hypercholesterolemia-Associated Breast Cancer Risk and Progression" (31 January 2014) http://cdmrp.army.mil/bcrp/research_highlights/14(b) (6)_highlight.shtml

f. (b) (6), Ph.D., The University of Akron, Akron, Ohio: "Engineering an Intraoperative Imaging System to Improve Breast Cancer Surgery" (18 November 2013) http://cdmrp.army.mil/bcrp/research_highlights/13(b) (6)_highlight.shtml

g. (b) (6), Ph.D. and (b) (6), Ph.D., University of Washington, Seattle, Washington: "Genome-Wide Discovery of Inherited Structural Mutations in Breast Cancer Families" (31 October 2013) http://cdmrp.army.mil/bcrp/research_highlights/13(b) (6)_highlight.shtml

h. (b) (6) Ph.D., Georgetown University, Washington, D.C.: Targeting Cadherin-11 in Basal-Like, Hormone-Refractory Breast Cancer" (24 October 2013) http://cdmrp.army.mil/bcrp/research_highlights/13(b) (6)_highlight.shtml

i. (b) (6), M.D., Ph.D., Sanford-Burnham Medical Research Institute, La Jolla, California; (b) (6), Ph.D., Massachusetts Institute of Technology, Cambridge, Massachusetts; (b) (6), Ph.D., University of California, San Diego, San Diego, California: "Hybrid Nanotechnologies for Synergistic Therapies for Breast Cancer" (22 October 2013) http://cdmrp.army.mil/bcrp/research_highlights/13(b) (6)_highlight.shtml

j. (b) (6), Ph.D., and (b) (6), M.D., University of Colorado Cancer Center, Aurora, Colorado: "Targeting Androgen Receptor in Breast Cancer: Enzalutamide as a Novel Breast Cancer Therapeutic" (17 October 2013) http://cdmrp.army.mil/bcrp/research_highlights/13(b) (6)_highlight.shtml

k. (b) (6), Ph.D., Sunnybrook Health Science Centre, Toronto, Ontario, Canada: "Enhancing Radiation Therapy with Ultrasound-Stimulated Microbubbles" (10 October 2013) http://cdmrp.army.mil/bcrp/research_highlights/13(b) (6)_highlight.shtml

5) ***GWIRP***

a. (b) (6) Ph.D. and (b) (6), M.D., Nova Southeastern University, Fort Lauderdale, Florida: "Theory-Driven Models for Correcting 'Fight or Flight' Imbalance in Gulf War Illness" (21 August 2014) http://cdmrp.army.mil/gwirp/research_highlights/14(b) (6)_highlight.shtml

b. (b) (6), M.D., Ph.D., University of California, San Diego, San Diego, California: "Novel Diagnosis of Gulf War Illness by Measuring Mitochondrial Function" (17 June 2014) http://cdmrp.army.mil/gwirp/research_highlights/14(b) (6)_highlight.shtml

6) ***LCRP***

a. (b) (6), M.D., Ph.D., Dana-Farber Cancer Institute, Boston, Massachusetts: "Functional Analysis of Somatic Mutations in Lung Cancer to Identify Novel Therapeutic Targets" (25 November 2013) http://cdmrp.army.mil/lcrp/research_highlights/13(b) (6)_highlight.shtml

b. (b) (6) Ph.D. and (b) (6) M.D., Ph.D., Stanford University, Stanford, California: "Improving the Diagnostic Specificity of CT for Early Detection of Lung Cancer" (12 November 2013) http://cdmrp.army.mil/lcrp/research_highlights/13(b) (6)_highlight.shtml

7) ***MSRP***

a. (b) (6), Ph.D., University of Illinois, Chicago, Chicago, Illinois: "Determination of the Role of Sulfatides in Remyelination and Disease Progression of Multiple Sclerosis" (15 July 2014) http://cdmrp.army.mil/msrp/research_highlights/14(b) (6)_highlight.shtml

b. (b) (6), Ph.D., Oregon Health & Science University, Beaverton, Oregon and (b) (6) Ph.D., Oklahoma Health Sciences Center, Oklahoma City, Oklahoma: "Inhibition of PH20 Hyaluronidase May Effectively Promote Remyelination in Multiple Sclerosis Lesions" (9 January 2014) http://cdmrp.army.mil/msrp/research_highlights/14(b) (6)_highlight.shtml

8) ***NFRP***

a. (b) (6), Ph.D., Massachusetts General Hospital, Boston, Massachusetts: "Oncolytic Herpes Simplex Virus Vectors Expressing Therapeutic Transgenes for the Treatment of NF1 Tumors" (26 August 2014) http://cdmrp.army.mil/nfrp/research_highlights/14(b) (6)_highlight.shtml

b. (b) (6) M.D., Ph.D., University of Texas Southwestern Medical Cancer at Dallas, Dallas, Texas: "Cell of Origin and Microenvironment Contribution in NF1-Associated Peripheral Nerve Sheath Tumor Development" (3 June 2014) http://cdmrp.army.mil/nfrp/research_highlights/14(b)_highlight.shtml

c. (b) (6) M.D., Ph.D., Indiana University, Indianapolis, Indiana: "Preclinical Murine Model for Fracture Healing in NF1" (10 April 2014) http://cdmrp.army.mil/nfrp/research_highlights/14(b) (6)_highlight.shtml

d. (b) (6), M.D., Indiana University, Indianapolis, Indiana: "Characterization of an NF2 Model that Develops Intracranial Vestibular Schwannomas and Meningiomas Associated with Hearing Loss" (17 December 2014). http://cdmrp.army.mil/nfrp/research_highlights/13(b) (6)_highlight.shtml

9) ***OCRP***

a. (b) (6), Ph.D., University of Alabama at Birmingham, Birmingham, Alabama, "Role of Receptor Sialylation in the Ovarian Tumor Cell Phenotype" (30 September 2014) http://cdmrp.army.mil/ocrp/research_highlights/14(b) (6)_highlight.shtml

b. (b) (6) Ph.D., University of Washington, Seattle, Washington: "Whole Genome Sequencing to Identify Novel Ovarian Cancer Genes" (18 September 2014) http://cdmrp.army.mil/ocrp/research_highlights/14(b) (6)_highlight.shtml

c. (b) (6), M.D., University of Texas MD Anderson Cancer Center, Houston, Texas: "Rethinking the Spread of Ovarian Cancer" (11 September 2014) http://cdmrp.army.mil/ocrp/research_highlights/14(b) (6)_highlight.shtml

d. Produced by the staff of the OCRP and BCRP: "DoD BCRP & OCRP Contributions to Advancements in BRCA" (17 August 2014) http://cdmrp.army.mil/brca_timeline/default.shtml

e. (b) (6), Ph.D., University of Chicago, Chicago, Illinois: "The Role of Omental Microenvironment in Ovarian Cancer Metastatic Colonization" (11 August 2014) http://cdmrp.army.mil/ocrp/research_highlights/14(b) (6)_highlight.shtml

f. [redacted], Ph.D., Vanderbilt University Medical Center, Nashville, Tennessee: "Nuclear Factor-Kappa B Activity in the Host-Tumor Microenvironment of Ovarian Cancer" (24 July 2014)
http://cdmrp.army.mil/ocrp/research_highlights/14[redacted]_highlight.shtml

g. [redacted], M.D., Ph.D., Dana-Farber Cancer Institute, Boston, Massachusetts: "Seeking to Improve Ovarian Tumor Response to Chemotherapy" (18 February 2014)
http://cdmrp.army.mil/ocrp/research_highlights/14[redacted]_highlight.shtml

10) ***PRCRP***

a. [redacted], M.D., Ph.D., [redacted], Ph.D., [redacted], M.D., Ph.D., St. Jude's Children's Research Hospital, Memphis, Tennessee, and [redacted], M.D., The Hospital for Sick Children, Toronto, Ontario, Canada: "Molecular-Targeted Therapies of Childhood Choroid Plexus Carcinoma" (12 December 2013)
http://cdmrp.army.mil/prcrp/research_highlights/13[redacted]_highlight.shtml

11) ***PRMRP***

a. [redacted], Ph.D., Dartmouth College, Hanover, New Hampshire: "Targeted DNA Methylation to Treat Testicular Cancer" (29 July 2014)
http://cdmrp.army.mil/prmrp/research_highlights/14[redacted]_highlight.shtml

b. [redacted], M.D., Georgetown University, Washington, D.C.: "Discovery of Drugs to Fight Osteosarcoma Metastasis" (17 July, 2014)
http://cdmrp.army.mil/prmrp/research_highlights/14[redacted]_highlight.shtml

c. [redacted], Ph.D., Cleveland Clinic Foundation, Cleveland, Ohio: "Characterization of the Role of Adenosine in the Acceleration of Hepatic Fibrosis by Alcohol" (28 May 2014)
http://cdmrp.army.mil/prmrp/research_highlights/14[redacted]_highlight.shtml

12) ***PCRP***

a. [redacted], M.D., Cleveland Clinic Foundation, Cleveland, Ohio: "Discovery of a Single Genetic Mutation in Castration-Resistant Prostate Cancer Could Lead to New Biomarkers and Targeted Therapies" (2 September 2014)
http://cdmrp.army.mil/pcrp/research_highlights/14[redacted]_highlight.shtml

b. [redacted], Ph.D., University of California at San Francisco, [redacted], Ph.D., University of California at San Francisco, and [redacted], Ph.D., Stanford University, California: "Novel Hyperpolarized Molecular Imaging Biomarkers for Prostate Cancer" (19 August 2014)
http://cdmrp.army.mil/pcrp/research_highlights/14[redacted]_highlight.shtml

c. [redacted] Ph.D., University of Southern California, Los Angeles, California: "Reprogramming Prostate Cancer Cells to Normal Prostate Cells" (31 July 2014)
http://cdmrp.army.mil/pcrp/research_highlights/14[redacted]_highlight.shtml

d. [redacted], Ph.D., Ohio State University, Columbus, Ohio: "Tumor-Selective Targeting of Androgen Receptor Expression by Small Molecule Agents" (13 May 2014)
http://cdmrp.army.mil/pcrp/research_highlights/14[redacted]_highlight.shtml

e. [redacted], Ph.D., City University of New York, New York: "Nowhere to Hide: Better Non-Invasive Detection of Prostate Cancer Using Improved Imaging" (15 April 2014)
http://cdmrp.army.mil/pcrp/research_highlights/14[redacted]_highlight.shtml

f. [redacted], M.D., Attending Surgeon in Urologic Oncology and Associate Professor of Cancer Biology, Fox Chase Cancer Center of Temple University, Philadelphia, Pennsylvania *with collaborator* [redacted]*, M.D., Ph.D., Fox Chase Cancer Center:* "Reduction of Zinc Levels as a Novel Mechanism for Prostate Cancer Therapy" (25 March 2014)
http://cdmrp.army.mil/pcrp/research_highlights/14[redacted]_highlight.shtml

g. (b) (6), Ph.D., Fairfield University, Fairfield, Connecticut: "Optical Sensing of Microscopic Structures May Be Used to Grade Prostate Cancer and Predict Patient Outcome" (11 March 2014) http://cdmrp.army.mil/pcrp/research_highlights/14(b) (6)_highlight.shtml

h. (b) (6), Ph.D., Emory University, Atlanta, Georgia: "Predicting Prostate Cancer Recurrence – Using Biomarkers to Guide Treatment Decision Making" (11 March 2014) http://cdmrp.army.mil/pcrp/research_highlights/14(b) (6)_highlight.shtml

i. (b) (6), Ph.D., Professor of Pharmacology and (b) (6) M.D., Ph.D., Assistant Instructor in Urology, University of Texas Southwestern Medical Center, Dallas, Texas: "A Newly Developed Therapeutic Antibody that Induces Immunity to Prostate Cancer" (27 February 2014) http://cdmrp.army.mil/pcrp/research_highlights/14(b) (6)_highlight.shtml

j. (b) (6) Ph.D., The Hormel Institute, University of Minnesota, Minneapolis, Minnesota: "Polycomb Gene BMI1 as a Promising Target in Prostate Cancer Chemoresistance" (13 February 2014) http://cdmrp.army.mil/pcrp/research_highlights/14(b) (6)_highlight.shtml

k. (b) (6), M.D., Ph.D., University of Kansas, Medical Center Research Institute, Kansas City, Kansas: "Improving Therapy for Advanced Prostate Cancer Using Nanoparticle-Driven Drug Delivery" (21 February 2014) http://cdmrp.army.mil/pcrp/research_highlights/13(b)_highlight.shtml

l. (b) (6), M.D., Memorial Sloan Kettering Cancer Center, New York, New York: "Circulating Tumor Cells as Better Predictors of Response to Prostate Cancer Treatment" (28 January 2014) http://cdmrp.army.mil/pcrp/research_highlights/14(b) (6)_highlight.shtml

m. (b) (6) Ph.D., Creighton University, Omaha, Nebraska: "Attacking Androgen-Insensitive Prostate Cancer from a New Angle" (16 January 2014) http://cdmrp.army.mil/pcrp/research_highlights/14(b) (6)_highlight.shtml

n. (b) (6), Ph.D., University of Tennessee Health Science Center in Memphis, Tennessee: "PSMA Targeted Nano-Radioimmunotherapy Using Curcumin for Advanced Prostate Cancer" (30 December 2013) http://cdmrp.army.mil/pcrp/research_highlights/13(b) (6)_highlight.shtml

o. (b) (6), Ph.D., Johns Hopkins University, Baltimore, Maryland: "The Prognostic Potential of microRNA in Prostate Cancer" (5 December 2013) http://cdmrp.army.mil/pcrp/research_highlights/13(b) (6)_highlight.shtml

p. (b) (6), M.D., Ph.D., Sunnybrook Health Science Centre, Toronto, Ontario, California: "Enhancing Radiation Therapy with Ultrasound-Stimulated Microbubbles" (16 October 2014) http://cdmrp.army.mil/pcrp/research_highlights/13(b) (6)a_highlight.shtml

13) ***SCIRP***

a. Produced by the SCIRP team, numerous researchers and their projects are featured in the overview article: "Spinal Cord Injury Research Program: The First Five Years" (28 August 2014) http://cdmrp.army.mil/scirp/research_highlights/14(b) (6)_highlight.shtml

b. (b) (6), M.D., Ph.D., Mount Sinai School of Medicine, New York, New York and (b) (6) Veterans Affairs Medical Center, Bronx, New York: "Preventing Bone Loss Following Spinal Cord Injury" (14 August 2014) http://cdmrp.army.mil/scirp/research_highlights/14(b) (6)_highlight.shtml

c. (b) (6), M.D., University of Pennsylvania, Philadelphia, Pennsylvania: "Repairing the Injured Spinal Cord with Engineered Nervous Tissue" (10 June 2014) http://cdmrp.army.mil/scirp/research_highlights/14(b) (6)_highlight.shtml

d. (b) (6), Ph.D., University of Maryland, Baltimore, Maryland: "An Interview with (b) (6) How Motor Cortex Stimulation Ameliorates Pain Following Spinal Cord Injury" (17 April 2014) http://cdmrp.army.mil/scirp/research_highlights/14(b) (6)_highlight.shtml

e. (b) (6), Ph.D., University of Louisville, Louisville, Kentucky: "Retaining Bladder Function after Spinal Cord Injury" (13 November 2014)
http://cdmrp.army.mil/scirp/research_highlights/13(b) (6)_highlight.shtml

14) ***TSCRP***

a. (b) (6) M.D., Brigham and Women's Hospital, Boston, Massachusetts: "Dysregulation of Cellular Metabolism: Novel Therapeutic Opportunities for TSC" (26 June 2014)
http://cdmrp.army.mil/tscrp/research_highlights/13(b) (6)_highlight.shtml

b. (b) (6) III, Ph.D., Boston Children's Hospital, Boston, Massachusetts: "Defining Early Markers of Autism in Infants with TSC" (24 April 2014)
http://cdmrp.army.mil/tscrp/research_highlights/14(b) (6)_highlight.shtml

c. (b) (6) Ph.D., Brigham and Women's Hospital, Boston, Massachusetts: "Targeting Estrogen-Induced COX-2 Activity in Lymphangioleiomyomatosis (LAM)" (18 March 2014)
http://cdmrp.army.mil/tscrp/research_highlights/14(b) (6)_highlight.shtml

d. (b) (6), M.D., Ph.D., University of Rochester, Rochester, New York: "A Mouse Model for Lymphangioleiomyomatosis (LAM)**" (13 March, 2014)**
http://cdmrp.army.mil/tscrp/research_highlights/14(b) (6)_highlight.shtml

e. (b) (6), Ph.D., Yale University, New Haven, Connecticut: "Understanding the Etiology of Tuberous Sclerosis Complex" (14 January 2014)
http://cdmrp.army.mil/tscrp/research_highlights/14(b) (6)_highlight.shtml

f. Produced by the TSCRP staff: "The TSCRP Recognizes November as Epilepsy Awareness Month" with brief summaries of four funded researchers contributing to this medical issue: (b) (6) Sanford-Burnham Medical Research Institute, La Jolla, California, (b) (6), Columbia University, New York, New York; (b) (6), Washington University of St. Louis, St. Louis, Missouri; (b) (6), Massachusetts Institute of Technology, Boston, Massachusetts (14 November 2013)
http://cdmrp.army.mil/tscrp/research_highlights/13(b) (6)_highlight.shtml

E. Several programs funded the development of research consortia either in previous fiscal years or in this fiscal year. These multi-institutional organizations serve the scientific community by combining and sharing their resources and research results. The consortia with which the CDMRP worked in FY 2014 are as follows:

1) The PTSD Multidisciplinary Research Consortium, *South Texas Research Organizational Network Guiding Studies on Trauma and Resilience,* or *STRONG STAR*, is dedicated to the development and evaluation of the most effective interventions for the detection, prevention, and treatment for combat-related post-traumatic stress disorder (PTSD). The STRONG STAR team of approximately 100 military, civilian, and VA investigators and clinicians is led by (b) (6) at the University of Texas Health Science Center at San Antonio (UTHSCSA). This location is ideal as Texas includes the largest military medical complex in the DoD, the nation's largest concentration of Operation Iraqi Freedom/Operation Enduring Freedom Veterans, and is home to Fort Hood with more than 50,000 active duty personnel. The STRONG STAR Administrative Core coordinates recruitment of human subjects at nearby Fort Hood and other military and Veteran locations for collaborating investigators from across the country, including (b) (6) Jeff Cigrang (Wright Patterson Air Force Base), (b) (6) (University of Pennsylvania), (b) (6) (Boston VA), (b) (6) (Ryerson University, Canada), (b) (6) (University of Texas, Arlington), (b) (6) (UTHSCSA), Col (R) (b) (6) (San Antonio Military Medical Center), COL (R) (b) (6) (UTHSCSA), (b) (6) (UTHSCSA), (b) (6) (Boston VA), (b) (6) (UTHSCSA), and (b) (6) (UTHSCSA). The ultimate goal of the STRONG STAR Consortium is to reduce or eliminate combat-related PTSD in active duty military and recently discharged Veterans, thereby contributing to the resilience and long-term health of our fighting forces. The STRONG STAR

Consortium is conducting 13 projects including one animal study, retrospective data analyses, epidemiological studies, a data repository, a biorepository, and 10 clinical studies that are being conducted at 7 sites.

2) The *INjury and TRaumatic STress Consortium (INTRuST)* was established to combine the research efforts of the nation's leading experts on PTSD and TBI in order to develop innovative treatments or interventions for those who suffer from PTSD and/or TBI. The INTRuST Consortium is comprised of the Coordinating Center located at the University of California, San Diego, 10 competitively selected clinical sites, a biorepository core, a neuroimaging core, a biostatistics core, an informatics core, and 19 additional military treatment and Veterans' facilities – all conducting clinical trials or collecting samples for clinical trials in PTSD and/or TBI. The 10 clinical sites and their PIs are (b) (6) (University of Maryland), COL (b) (6) (Uniformed Services University of the Health Sciences), (b) (6) (Spaulding Rehabilitation Hospital), (b) (6) (Dartmouth College), (b) (6) (University of Washington), (b) (6) (University of Cincinnati), (b) (6) (Duke University), (b) (6) (University of California, San Diego), (b) (6) (South Carolina Research Authority/Medical University of South Carolina), and (b) (6) (National Center for Telehealth & Technology [T2]). Entering its seventh year, the INTRuST Consortium has completed enrollment of subjects in seven core trials (typically Phase II) and an additional three pilot clinical trials, with enrollment still open in two other pilot trials. The portfolio of clinical trials spans psychotherapy to pharmacotherapy to telephone-delivered psychotherapy to device therapy (e.g., transcranial magnetic stimulation of the prefrontal cortex). All trials are designed to decrease the impact of military-relevant PTSD and TBI for the benefit of Service Members and their families and caregivers, and the American public.

3) *The Mission Connect Consortium*, recipient of the TBI Multidisciplinary Research Consortium Award, is composed of experienced TBI investigators from seven academic institutions and four Level I trauma facilities in Texas and Virginia. The goal of the Consortium is to reduce disabilities caused by mild TBI (mTBI) by focusing on improving the diagnosis and treatment of mTBI. Specifically, the Consortium focuses on standardization of animal models of mTBI using clinically relevant neurobehavioral endpoints, improvement of the diagnosis of acute and chronic mTBI, and development of new and innovative treatment strategies for mTBI. A Phase II clinical trial is in progress to evaluate the safety and effectiveness of atorvastatin given during the acute phase of mTBI. These innovative studies have the potential to lead to improvements in the diagnosis and treatment of mTBI. The TBI Consortium is led by (b) (6) (University of Texas Health Science Center at Houston) and (b) (6) (Baylor College of Medicine). The Partnering Investigators are (b) (6), (b) (6) (University of Texas Health Science Center at Houston); (b) (6) (Baylor College of Medicine); (b) (6) (Rice University); (b) (6) (University of Texas Medical Branch, Galveston); (b) (6) (Virginia Tech Carilion Research Institute); and (b) (6) (University of Tennessee Health Science Center).

4) The Consortium to Alleviate Post-Traumatic Stress Disorder (CAP) is dedicated to improving the health and well-being of Service Members and Veterans with the most effective diagnostics, prognostics, novel treatments, and rehabilitative strategies to treat acute PTSD and to prevent chronic PTSD. The CAP award is a joint effort supported by funding from both the DoD and the VA and involves the collaboration of many academic, VA, and DoD investigators. (b) (6) is the Director of the CAP at the University of Texas Health Science Center, San Antonio, where he will leverage the existing PTSD Multidisciplinary Research Consortium, *South Texas Research Organizational Network Guiding Studies on Trauma and Resilience*, or STRONG STAR, and build upon it with the new consortium called STRONG STAR CAP. (b) (6) of the Boston VA Healthcare System will serve as the STRONG STAR CAP co-director and lead VA representative. The STRONG STAR CAP will conduct studies approved by a Government Steering Committee comprised of DoD, VA, and NIH representatives. Studies are to focus on two main objectives: (1) advancing treatment strategies for

PTSD including interventions for early, chronic, and latent onset cases and (2) identifying and confirming clinically relevant biomarkers as diagnostic and prognostic indicators of PTSD and co-occurring disorders. The STRONG STAR CAP award began in September 2013.

5) The Chronic Effects of Neurotrauma Consortium (CENC) is a joint DoD and VA consortium award dedicated to establishing a comprehensive understanding of the chronic sequelae associated with neurotrauma, primarily focused on mTBI/concussion as defined by the DoD/VA. This includes establishing the association, causality, diagnosis, and treatment/rehabilitation of mTBI to neurodegeneration. In addition, the consortium efforts address the common comorbidities associated with chronic mTBI such as neurosensory system involvement (vision, balance, hearing, pain) and psychological dysfunction. The consortium coordinating center is located at Virginia Commonwealth University and is led by the (b) (6) . Also leading the consortium are (b) (6) (Uniformed Services University of the Health Sciences) and (b) (6) (RTI International). As of May 2104, the CENC leverages collaborations among 18 participating institutions across academia, industry, the DoD, and the VA. Current efforts include a controlled longitudinal study to identify and characterize conditions associated with chronic mTBI and to identify potential risk factors and pathways of neurodegeneration among Service Members and Veterans. A second study focuses on tau protein, which is associated with chronic traumatic encephalopathy and conformational changes that lead to neurodegeneration following TBI. Other studies executed by the consortium include efforts in the area of epidemiology, neurosensory comorbidities, neuroimaging standardization, and follow-up from studies initiated in-theater. The CENC leverages current and past funding efforts across numerous Government agencies in order to effectively target studies to meet current and evolving research priorities in the field.

6) The Prostate Cancer Clinical Trials Consortium (PCCTC) has received support from the PCRP since 2005, and in February 2014 filed paperwork to become a limited liability company (Prostate Cancer Clinical Trials Consortium, LLC). Led by Memorial Sloan Kettering Cancer Center, the PCCTC has completed 106 clinical trials, and an additional 42 trials are still active or pending activation. Over 4,380 patients have been enrolled in these trials, with 13 percent representing patients from minority populations. Since biomarkers are increasingly being recognized as essential in the evaluation of treatment response, as well as for risk assessment, early detection, prediction of aggressiveness, and/or progression of prostate cancer, biomarker studies are being strongly pursued and validated across institutions. In 2008, PCCTC investigators led a collaborative initiative to issue recommendations on the design and end points for prostate cancer clinical trials, Prostate Cancer Working Group (PCWG2), which have had a profound impact on the clinical research community and how clinical trials are designed; the consortium is currently working on releasing an update to this effort. The PCCTC's extensive clinical trial experience and collaborative efforts have helped bring numerous potential new therapeutics into Phase III clinical trials, with two agents having now received approval by the FDA: abiraterone acetate, which blocks formation of testosterone by inhibiting CYP17A1, and enzalutamide, which binds to the ligand binding domain of the androgen receptor (AR), prevents nuclear translocation, and blocks AR interaction with coactivator proteins preventing transcription of AR-regulated genes. Other promising agents advanced to Phase III testing include ARN-509, another androgen antagonist showing even greater efficacy than enzalutamide; dasatinib, a tyrosine kinase inhibitor; the CYP17A1 inhibitor orteronel; two immunotherapies, namely, cixutumumab, which targets insulin-like growth factor-1 receptor, and ipilimumab, an antibody that binds to the T-cell-specific molecule CTLA4; and tasquinimod, an angiogenic inhibitor that prevents cancer cell growth by inhibiting the growth of new blood vessels.

7) Since 2005, with funding from the NFRP, the *Neurofibromatosis Clinical Trials Consortium (NFCTC)* has been developing clinical trials investigating treatments for neurofibromatosis (NF) and its complications, including plexiform neurofibromas, cognitive disorders, low-grade gliomas, vestibular schwannomas, and malignant peripheral nerve sheath tumors (MPNSTs). The NFCTC, led by (b) (6) at the University of Alabama, Birmingham, now includes 13 member sites, as well as 5 additional collaborating sites, to improve geographical coverage and inclusion of adults and children with neurofibromatosis type 1 (NF1) and type 2 (NF2), and schwannomatosis. The following four

studies, funded by the FY 2006 Consortium Award, are nearing completion: (1) "STOPN," a Phase II clinical trial of the mTOR inhibitor sirolimus for treatment of plexiform neurofibromas; (2) "STARS," a double-blind placebo-controlled, double-blind Phase II clinical trial of lovastatin for the treatment of learning disabilities in children with NF1; (3) "RAD001," a single-arm Phase II study of the mTOR inhibitor RAD001 (or everolimus) for the treatment of chemotherapy-refractory progressive low-grade gliomas; and (4) "MPNST," a Phase II study of bevacizumab combined with irinotecan-based chemotherapy for children with NF1 and recurrent/refractory MPNST, conducted in collaboration with the SARC (Sarcoma Alliance for Research through Collaboration) Consortium.

Additional funding for the NFCTC through the FY 2011 Consortium Award is currently supporting the following three trials, which are in various stages: (1) An open-label Phase II study of bevacizumab in children and young adults with NF2 and progressive vestibular schwannomas that are poor candidates for standard treatment with surgery or radiation (currently enrolling: NCT01767792); (2) a Phase II trial of the MEK inhibitor PD-0325901 in adolescents and adults with NF1-associated morbid plexiform neurofibromas; and (3) a Phase II study of cabozantinib (XL184) for plexiform neurofibromas in subjects with NF1 aged 16-65 years. A fourth trial is in the planning stage.

In addition to performing clinical trials, the NFCTC provides standalone CDMRP-funded clinical trials with access to NF clinical sites. The NFCTC is also leveraging information from the NF Preclinical Consortium funded by the Children's Tumor Foundation to help develop a pipeline of drug trials that will be tested in the NFCTC.

8) The *Bridging Advanced Developments for Exceptional Rehabilitation (BADER) Consortium* will improve the quality of life for Warfighters who suffer significant limb injuries in combat through orthopaedic rehabilitation research conducted at several military and civilian research institutions across the country. (b) (6) at the University of Delaware leads the collaborative team of scientist and clinician researchers from C-Motion, Inc. (Germantown, Maryland); Christiana Care Health System (Newark, Delaware); (b) (6) VA Medical Center (Richmond, Virginia); (b) (6) Veterans' Hospital (Tampa, Florida); Mayo Clinic (Rochester, Minnesota); Minneapolis VA Health Care System (Minneapolis, Minnesota); Naval Medical Center (Portsmouth, Virginia); Naval Medical Center (San Diego); New York University; Providence VA Medical Center (Rhode Island); San Antonio Military Medical Center; Spaulding Rehabilitation Hospital (Boston); University of Colorado Boulder; University of Michigan; University of Texas at Austin; VA Eastern Colorado Healthcare System; and Walter Reed National Military Medical Center (Bethesda, Maryland). Clinical trials addressing lower-extremity trauma are currently aimed at improving step-to-step control during walking, improving limb loading on the prosthetic and the intact limb via gait training, analyzing the benefits of powered ankle prostheses for amputees with differing levels of mobility, and maximizing outpatient rehabilitation effectiveness. Consortium projects focused on prosthetic devices strive to determine the optimal height and stiffness of a running-specific leg prosthesis, as well as characterize the response of prosthetic feet to applied loads and impacts representative of military tasks and the effects of such loads upon gait. A clinical study to examine functional outcome measures for individuals with upper-extremity trauma is also included.

9) In FY 2009, one *Dean* and seven *Early-Career Investigator* awards marked the realization of the OCRP's vision of a unique, virtual *Ovarian Cancer Academy* that supports the development of career ovarian cancer researchers. This Academy brings together a group of talented and highly committed Early-Career Investigators (ECIs) with their mentors and an Academy Dean. The OCRP envisions the synergy produced from sharing information, ideas, and research findings, as well as the substantial research funding provided to the ECIs, will create opportunities to establish them as the next generation of successful and highly respected ovarian cancer researchers. The Academy has expanded to currently include 11 ECI-Mentor pairs, and the ECIs have demonstrated remarkable progress including over 160 publications and over 100 abstracts focused on ovarian cancer, to date. Their growth as independent, committed ovarian cancer researchers is evident in the 49 funded grants obtained (including NIH R01s), as well as their service on the boards of well-established journals and women's cancer foundations. Additionally, in the span of 4 years, the ECIs have advanced well along the tenure

track, mentored increasing number of personnel, and collaborated within the Academy on publications, grant applications, and technical ventures. The annual Ovarian Cancer Academy in-person workshop in Seattle, Washington in September 2014 promoted further collaborations and fostered cross-mentoring within the group of ECIs. It preceded the (b) (6) Ovarian Cancer Research Symposium, wherein several Academy members were invited speakers and all had poster presentations.

10) The *Detection of Early Lung Cancer among Military Personnel (DECAMP) Consortium* is designed to develop and improve the early detection of lung cancer among military personnel, military family members, and Veterans believed to be at high risk. The DECAMP Consortium is a multidisciplinary and translational research program that includes seven VA hospitals, four military treatment facilities (MTF), and two academic hospitals as clinical study sites, several molecular biomarker laboratories, along with biostatics, bioinformatics, pathology, and biorepository cores. (b) (6) of Boston University is the PI and Consortium Director, overseeing all aspects of the consortium and leading the Bioinformatics/Molecular Database Core, Administrative Core, and Biorepository Core. (b) (6) from the University of Pennsylvania, Department of Radiology and the Chair of the American College of Radiology Imaging Network (ACRIN) is the co-PI. The ACRIN Biostatistics and Data Management Center will manage clinical trial infrastructure, protocol development, clinical trial data management, quality assurance, regulatory compliance, imaging analysis, and site management. Other participants include co-investigators (b) (6) of the Naval Medical Center Portsmouth; CAPT (b) (6) of the Naval Medical Center San Diego; (b) (6) of the San Antonio Military Medical Center, and CDR (b) (6) of the Walter Reed National Military Medical Center. Two clinical studies have been initiated at all sites. The first is focused on validating a number of airway and blood-based molecular biomarkers that can distinguish benign vs. malignant lung diseases among smokers with indeterminate pulmonary nodules found on chest CT (computed tomography). The second study is looking at identifying molecular biomarkers of preclinical disease and disease risk in minimally invasive and non-invasive biospecimens to improve lung cancer surveillance in high-risk individuals.

11) Early ovarian cancer usually has no obvious symptoms, and currently there is no sufficiently accurate screening test for the early detection of ovarian cancer in average-risk women. The majority of cases (61 percent) are diagnosed at late stages, for which the 5-year survival rate is 27 percent (United States, 2014). A multi-institutional team headed by (b) (6) research team at the Johns Hopkins University along with collaborators at the gynecologic oncology powerhouses of Memorial Sloan Kettering Cancer Center, University of Toronto, and Yale University, successfully competed for the first *Ovarian Cancer Consortium Award (OCCA)* awarded in 2010. Their objective is to develop a prevention strategy to reduce the burden of ovarian cancer, and toward this end they are focused on definitively identifying and characterizing early changes associated with the disease. To accomplish this, the OCCA is testing the hypothesis that an early lesion in the fallopian tube called a serous tubal intraepithelial carcinoma (STIC) is the precursor of ovarian high-grade serous carcinomas (HGSCs), which account for a majority of ovarian cancers and ovarian cancer-related mortalities. The consortium's research plan has four preclinical projects focused on the molecular and morphological characterization of the precursor lesions/STICs and a fifth epidemiological study designed to evaluate whether these STIC characteristics are modifiable by oral contraceptives or anti-inflammatory agents.

    Several major accomplishments of the consortium are:

    a. Verified several new identifying markers in STICs.

    b. Identified a putative premalignant precursor to STICs, known as STILs or serous tubal intraepithelial lesions, and are examining the gain or loss of markers in STILs, STICs, and HGSCs.

    c. Made progress in evaluating whether the presence of a STIC is associated with different clinical manifestations and/or outcomes, as compared to patients in whom STICs were not identified.

d. Identified molecular changes preceding STICs in high-risk women using in vitro and in vivo models. The researchers presented some of their latest discoveries at the 5th Annual Ovarian Cancer Symposium on the Prevention and Early Detection of Ovarian Cancer, held in September 2014 at the Princess Margaret Cancer Center in Toronto.

12) The *Gulf War Illness Consortium* brings together established Gulf War Illness (GWI) researchers to investigate the pathobiological mechanisms responsible for GWI symptoms as they relate to brain-immune interactions. Neurological and immune measures have rarely been assessed in the same Veterans, barring understanding of whether such alterations are part of an overall pathobiological picture or represent discrete findings in different GWI cohorts. This consortium was designed to more fully elucidate the underlying pathobiology of GWI in one integrated model that, once validated, can lead to focused treatment trials that can be quickly implemented. Consortium research will be carried out through a series of preclinical and clinical studies with the overall goal to identify whether chronic neuroinflammation, and the resultant release of proinflammatory cytokines, are associated with GWI symptoms such as cognitive dysfunction, fatigue, and pain. Boston University will serve as the coordinating center for the consortium, which will be led by (b) (6) . Participating in the consortium along with (b) (6) at Boston University are (b) (6) , Ph.D., (b) (6) Ph.D., (b) (6) , Ph.D., and (b) (6) , Ph.D. Other participating institutions and investigators include (b) (6) , Ph.D., Baylor University; (b) (6) , M.D., Miami VA Medical Center/Nova University; and (b) (6) , Ph.D. and (b) (6) , Ph.D., University of Adelaide (Australia). Preclinical research sites include the U.S. Centers for Disease Control and Prevention/National Institute of Occupational Safety and Health, with (b) (6) , Ph.D.; (b) (6) , Ph.D., at the National Institute of Neurological and Communicative Diseases and Stroke; (b) (6) , Ph.D., Drexel University; (b) (6) , Ph.D., and (b) (6) , Ph.D., University of Colorado; and (b) (6) Ph.D., Temple University.

13) *Understanding Gulf War Illness: An Integrative Modeling Approach* establishes a consortium aimed at developing translational models of GWI that integrate basic and clinical research through computational modeling. Evidence has suggested that GWI is caused by a disruption in normal cell signaling, in not just one, but within multiple organ systems, resulting in disabling symptoms. Given this complexity, it is unlikely that any single hypothesis or narrow approach will be effective in bringing effective therapies to patients with GWI. Instead, a broad-based, yet integrated, multisystem approach is needed to clarify GWI pathobiology. The work of this consortium centers on five studies, starting with the characterization of autonomic neural/adrenal dysfunction and cellular and molecular phenotypes in mouse models of GWI. Next, animal and human studies will be integrated, using computational biology, to identify mediators of deregulated balance. The resulting translational model will then be used to predict and test effective therapeutic interventions. The consortium is led by (b) (6) , Ph.D., at Nova Southeastern University, whose extensive background in GWI research includes contributions to the underlying chronic effects of sarin exposures in mouse models of GWI. (b) (6) will also oversee the Basic Science Core with (b) (6) , Ph.D., at the U.S. Centers for Disease Control and Prevention. The Clinical Core will be headed by (b) (6) , M.D., at the Miami VA Medical Center. The Computational Science Core will be headed by (b) (6) , Ph.D., at Nova Southeastern University, and the Therapeutic Science Core will include Southwest Research Institute and Baylor University, and will be led by (b) (6) Ph.D. and (b) (6) , Ph.D., respectively.

Resource Management and Budget

A. Because of the 7-year management cycle for medical research funding, the CDMRP continues to manage many awards made by the programs in previous years. The following table provides the historical data for those years:

FIGURE 3: Overview of Appropriations, Applications Received and Awards Made for FY 1992 to FY 2013

Programs Managed by CDMRP [3]	FY	Appropriations Received (in millions)	Applications Received	Applications Funded
Amyotrophic Lateral Sclerosis	2007, 2009-2013	$39.40	302	30
Autism	2007-2013	$47.40	1,081	114
Bone Marrow Failure	2008-2013	$20.15	337	46
Breast Cancer	1992-2013	$2,924.50	49,180	6,421
Chronic Myelogenous Leukemia	2002-2006	$22.05	252	61
Defense Women's Health	1995	$40.00	559	69
Deployment Related Medical	2008	$101.90	1,094	51
DoD/VA	1999-2000	$6.79	88	9
Programs Managed by CDMRP [4]	**FY**	**Appropriations Received (in millions)**	**Applications Received**	**Applications Funded**
Duchenne Muscular Dystrophy	2011-2013	$10.40	53	11
Genetic Studies of Food Allergies	2009-2010	$4.38	60	9
Gulf War Illness	2006, 2008-2013	$69.00	264	73
Institutionally Based Programs	1995-2010	$486.31	306	267
Lung Cancer	2009-2013	$68.50	1,599	110
Multiple Sclerosis	2009-2013	$23.10	525	57
Myeloproliferative Disorders	2004	$4.25	18	9
National Prion	2002	$42.50	136	38
Neurofibromatosis	1996-2013	$257.85	1,306	313
Osteoporosis	1995	$5.00	105	5
Ovarian Cancer	1997-2013	$216.45	2,910	313
Peer-Reviewed Cancer	2009-2013	$74.80	2,086	166
Peer-Reviewed Medical	1999-2006, 2008-2013	$644.50	6,559	543

[3] CDMRP executed and managed the full appropriation.
[4] CDMRP executed and managed the full appropriation.

Peer-Reviewed Orthopaedic	2009-2013	$218.50	734	187
Prostate Cancer	1997-2013	$1,290.00	15,441	2,765
Spinal Cord Injury	2009-2013	$97.85	593	124
Tuberous Sclerosis	2002-2006, 2008-2013	$47.00	500	107
Programs Managed on Behalf of Others[5]	**FY**	**Appropriations Received (in millions)**	**Applications Received**	**Applications Funded**
Army Rapid Innovation Fund	2011-2013	$28.84	Not applicable (N/A)	12
Chiropractic Clinical Trials	2010	$8.10	5	1
Programs Managed on Behalf of Others[6]	**FY**	**Appropriations Received (in millions)**	**Applications Received**	**Applications Funded**
Clinical Research Intramural Initiative	2013	$2.23	4	3
Defense Medical (DHPe)	2010-2013	$223.99	718	128
Joint Warfighter Medical	2012-2013	$3.95	2	2
Psychological Health/ Traumatic Brain Injury	2007, 2009-2013	$651.50	3,122	367
Vision	2013	$8.92	142	12
Total		**$7,690.11**	**90,081**	**12,423**

B. In FY 2014, the CDMRP completed the execution of the FY 2013 appropriations across 22 programs, including 6 programs executed on the behalf of others. As shown in the FY 2013 Funding Execution table below, the CDMRP executed a total of $557.65M with $471,913,008.00 used to fund 621 new research awards and $41,832,190.00 in management costs, which equates to approximately 8.1 percent of the funding the CDMRP received after withholds.

[5] CDMRP assisted with the execution of the specified portion of a larger appropriation(s).
[6] CDMRP assisted with the execution of the specified portion of a larger appropriation(s).

FIGURE 4: FY 2013 Funding Execution for Congressional Appropriations Managed by CDMRP[7]

Program	Congressional Appropriation (millions)	Withholds	Management Costs	Research
ALSRP	$7,500,000.00	$804,274.00	$576,132.00	$6,119,594.00
ARP	$6,000,000.00	$649,452.00	$456,868.00	$4,893,680.00
BMFRP	$3,200,000.00	$346,257.00	$242,625.00	$2,611,118.00
BCRP	$120,601,567.00	$12,031,571.00	$8,509,500.00	$100,060,496.00
DMDRP	$3,200,000.00	$346,155.00	$302,291.00	$2,551,554.00
GWIRP	$20,000,000.00	$2,121,531.00	$1,666,282.00	$16,212,187.00
LCRP	$10,500,000.00	$1,137,557.00	$760,977.00	$8,601,466.00
MSRP	$5,000,000.00	$419,073.00	$512,522.00	$4,068,405.00
NFRP	$15,000,000.00	$1,502,000.00	$1,133,397.00	$12,364,603.00
OCRP	$20,000,000.00	$2,128,456.00	$1,635,709.00	$16,235,835.00
PRCRP	$15,000,000.00	$1,568,662.00	$1,000,232.00	$12,431,106.00
PRMRP	$50,000,000.00	$5,378,181.00	$3,827,140.00	$40,794,679.00
PRORP	$30,000,000.00	$3,089,746.00	$2,318,590.00	$24,591,664.00
PCRP	$80,000,000.00	$8,445,875.00	$6,386,281.00	$65,167,844.00
SCIRP	$30,000,000.00	$3,240,851.00	$1,981,037.00	$24,778,112.00
TSCRP	$6,000,000.00	$640,289.00	$1,025,750.00	$4,333,961.00
FY 2013 CDMRP Executed Funds and Management Costs for Programs Managed on Behalf of Others[8]				
ARIF	$9,375,625.00	N/A	$428,857.00	$8,946,768.00
CRII	$2,226,889.00	N/A	$130,889.00	$2,096,000.00
DMRDP	$33,806,201.00	N/A	$4,068,472.00	$29,737,729.00
JWMRP	$3,953,081.00	N/A	$813,327.00	$3,139,754.00
PH/TBIRP	$77,376,229.00	N/A	$3,830,452.00	$73,545,777.00
Total	**$548,739,592.00**	**$43,849,930.00**	**$41,607,330.00**	**$463,282,332.00**

D. In FY 2014, CDMRP initiated management of funds across 23 programs equaling $646.72M as well as execution of another 5 programs on the behalf of others. The programs and amounts are listed below.

[7] CDMRP executed and managed the full appropriation.
[8] CDMRP assisted with the execution of the specified portion of a larger appropriation(s).

FIGURE 5: FY 2014 Funding Execution for Congressional Appropriations Managed by CDMRP

Programs Managed by CDMRP[9]	Funds Received (in millions)
Alcohol and Substance Abuse Disorders	$4.00
Amyotrophic Lateral Sclerosis	$7.50
Autism	$6.00
Bone Marrow Failure	$3.20
Breast Cancer/Breast Cancer Research Semipostal	$120.49
Duchenne Muscular Dystrophy	$3.20
Gulf War Illness	$20.00
Lung Cancer	$10.50
Military Burn	$8.00
Multiple Sclerosis	$5.00
Neurofibromatosis	$15.00
Neurotoxin Exposure Treatment Parkinson's	$16.00
Orthotics and Prosthetics Outcomes	$10.00
Ovarian Cancer	$20.00
Peer Reviewed Alzheimer's	$12.00
Peer Reviewed Cancer	$25.00
Peer Reviewed Medical	$200.00
Peer Reviewed Orthopaedic	$30.00
Prostate Cancer	$80.00
Spinal Cord Injury	$30.00
Trauma Clinical Research Repository	$5.00
Tuberous Sclerosis	$6.00
Vision	$10.00
Programs Executed on Behalf of Others[10]	**Funds Received (in millions)**
Army Rapid Innovation Fund	To be determined
Clinical Research Intramural Initiative	~$5.00
Defense Medical R&D	~$190.00
Joint Warfighter Medical Research	$100.00
Psychological Health/Traumatic Brain Injury	~$80.00
Total	**$1,021.89**

[9] CDMRP executed and managed the full appropriation.
[10] CDMRP assisted with the execution of the specified portion of a larger appropriation(s).

Information Management

A. Existing Information Systems

1) The CDMRP website (http://cdmrp.army.mil) remains a central mode of communication to the public. The dynamic website features facts and news about the CDMRP, individual research programs, funding opportunities, and consumer involvement. The CDMRP provides transparency through a searchable database providing details on CDMRP funded awards. The CDMRP has accomplished 393 task orders to provide new content, frequent updates, news worthy over the year. The media center has been a popular feature of the website, offering visitors a unique experience with broad access to various media about CDMRP programs and research. During FY 2014, visitors to our website could access new postings for 75 new funding opportunities, 8 new videos, 22 press releases, 30 consumer stories, and over 400 research news items in research highlights, program booklets, and the annual reports.

2) Through FY 2013, the CDMRP's eReceipt website (https://cdmrp.org) accommodated electronic submission of all pre-applications including Letters of Intent, preproposals, and application nominations. Application information, including research focus of the proposed study, animal use and human use, and contact information for the PI and institutional Business Officials, is also submitted and maintained through this website. eReceipt's GAP (Grants Application Processor) retrieves and processes full applications from Grants.gov. Furthermore, funding status and associated summary statements informing investigators of the strengths and weaknesses of their applications are provided through this website. Information and documents required from the PI for award negotiations and regulatory approvals are submitted via eReceipt.

3) The CDMRP continued using Grants.gov to receive applications submitted to its research programs. Grants.gov implements the requirement in the Federal Financial Assistance Management Improvement Act, Public Law 106-107, to develop a simple, unified source to electronically find, apply, and manage grant opportunities. Grants.gov is the Federal Government's single-entry portal for posting program announcements, which the CDMRP has used since 2006. Grants.gov has a FIND functionality that enables PIs to find open solicitations for research funding and an APPLY functionality that enables organizations to submit Grants.gov application packages for that research funding.

4) The CDMRP continued to utilize its Electronic Grants System (EGS) in FY 2014. EGS is an electronic business system developed by CDMRP for processing and management of its biomedical research grants. The system integrates data, files, and processes from application receipt, peer review, programmatic review, negotiations, and management of awards. It enables electronic workflow between all contractors and agencies in support of the CDMRP. EGS also captures scientific research outcomes and findings from all funded awards, which are then categorized and analyzed for program evaluation efforts and reporting to stakeholders. EGS interacts with several internal and external systems ensuring that relevant data are made available for various administrative grants management functions. The system allows for rapid retrieval of information for data requests and reporting. EGS enables electronic processing, increases efficiency, and ensures quality and security of data management.

5) The CDMRP and the Fort Detrick Network Enterprise Center (NEC) have completed the migration of the virtualized EGS application and public website to the NEC's new "Virtualized Hosting Service" running on NEC-provided hardware. This Virtualized Hosting Service will provide CDMRP with increased system scalability, performance, and reliability while reducing support cost throughout the application product life cycle.

6) In FY 2014, the CDMRP continued using social media as a means to expand its information dissemination strategies. The CDMRP implemented the use of YouTube in February 2013. By the end of FY 2014, CDMRP had received over 8,000 YouTube views to improve and encourage the public's ability to access videos about its publically funded research programs and investigators. The public is encouraged to visit the CDMRP on YouTube at http://www.youtube.com/CDMRP, where viewers can find more than 40 brief interviews with researchers describing their CDMRP-funded research (videos

are continually being added). The CDMRP website also has a video library dating back to 2006, with 186 videos available. Making further strides in the use of social media, the CDMRP started using Twitter in April 2013 to exchange information about current news and happenings within the organization. Twitter users can subscribe or follow CDMRP tweets at https://twitter.com/CDMRP. At the end of FY 2014, CDMRP had over 2,500 Tweets offering links to new website information. Our number of Twitter Followers rose from 220 to 475 during FY 2014.

B. New Information Systems/Solutions

1) The CDMRP completed testing, detailed preparation, and migration to the Defense Enterprise Email system. This Cloud-based DoD-wide email solution reduces support cost while providing end users with increased email storage capacity and the ability to find email addresses and contacts across the entire DoD.

2) The electronic Biomedical Research Application Portal (eBRAP) is Defense Business Certified (DBC) and replaced eReceipt in FY 2014 for submissions of research applications from extramural organizations. eBRAP enables not only the CDMRP, but also all of USAMRMC and the Department of Health Affairs, to streamline operational efficiency and effectiveness in retrieving and processing research applications through increased automation and greater data integrity. eBRAP automates many of the business processes associated with receipt, compliance, and processing of applications, and it provides capabilities not available in Grants.gov or eReceipt. This multifunctional system allows PIs to submit their pre-applications electronically over the Internet through a secure connection, to view and edit the content of their pre-applications and full applications, to receive communications from the Program Office, and to submit documentation during award negotiations and performance. A key feature of eBRAP is the ability of an organization's representatives and PIs to view and modify the Grants.gov application submissions associated with them.

Operations

A. Vision Setting meetings were held for the following programs:

1) FY 2014 PRORP (14 November 2013)
2) FY 2014 NFRP (4 December 2013)
3) FY 2014 TSCRP (6 December 2013)
4) FY 2014 OCRP (13 December 2013)
5) FY 2014 MSRP (16 December 2013)
6) FY 2014 BMFRP (9 January 2014)
7) FY 2014 LCRP (31 January 2014)
8) FY 2014 ALSRP (10 February 2014)
9) FY 2014 PRCRP (14 February 2014)
10) FY 2014 PRMRP (14 February 2014)
11) FY 2014 BCRP (25 February2014
12) FY 2014 ARP (26 February 2014)
13) FY 2014 DMDRP (3 March 2014)
14) FY 2014 SCIRP (5 March 2014)
15) FY 2014 GWIRP (27 March 2014)

B. Corresponding to the funding mechanisms, 77 program announcements were released on Grants.gov.

C. Pre-applications for the following FY 2013/2014 programs were received and reviewed:

FIGURE 6: Pre-Applications Received for FY 2013/2014 Programs

Programs Managed by CDMRP[11]	# Received/Reviewed
Amyotrophic Lateral Sclerosis	139
Autism	231
Bone Marrow Failure	120
Breast Cancer/Breast Cancer Research Semipostal	3,769
Duchenne Muscular Dystrophy	74
Gulf War Illness	47
Lung Cancer	407
Multiple Sclerosis	194
Ovarian Cancer	536
Peer Reviewed Cancer	757
Peer Reviewed Medical	1,551
Peer Reviewed Orthopaedic	275
Prostate Cancer	1,205
Spinal Cord Injury	249
Programs Executed on Behalf of Others[12]	**# Received/Reviewed**
Clinical Research Intramural Initiative	24
Defense Medical R&D	700
Psychological Health/Traumatic Brain Injury	191
Total	**10,469**

D. Peer review was executed for FY 2013/2014 research programs.

[11] CDMRP executed and managed the full appropriation.
[12] CDMRP assisted with the execution of the specified portion of a larger appropriation(s).

FIGURE 7: Peer Review Conducted for FY 2013/2014 Programs

Programs Managed by CDMRP[13]	Number of Submissions Peer Reviewed
Amyotrophic Lateral Sclerosis	57
Autism	93
Bone Marrow Failure	37
Breast Cancer/Breast Cancer Research Semipostal	2,275
Duchenne Muscular Dystrophy	11
Gulf War Illness	36
Lung Cancer	455
Multiple Sclerosis	39
Neurofibromatosis	66
Ovarian Cancer	158
Peer Reviewed Cancer	403
Peer Reviewed Medical	750
Peer Reviewed Orthopaedic	0
Prostate Cancer	1479
Spinal Cord Injury	83
Tuberous Sclerosis Complex	44
Programs Executed on Behalf of Others[14]	**Number of Submissions Peer Reviewed**
Clinical Research Intramural Initiative	4
Defense Medical R&D	211
Joint Warfighter Medical	1
Psychological Health/Traumatic Brain Injury	10
Total	**6,212**

[13] CDMRP executed and managed the full appropriation.
[14] CDMRP assisted with the execution of the specified portion of a larger appropriation(s).

E. Programmatic Review was performed for the following FY 2013/2014 research programs:

FIGURE 8: Programmatic Review Conducted for FY 2013/2014 Programs

Programs Managed by CDMRP[15]	Number of Applications Recommended for Funding	Value of Applications Recommended for Funding (in millions)
Amyotrophic Lateral Sclerosis	6	$5.40
Autism	17	$4.42
Bone Marrow Failure	5	$2.57
Breast Cancer/Breast Cancer Research Semipostal	158	$149.39
Duchenne Muscular Dystrophy	3	$2.57
Gulf War Illness	16	$12.34
Lung Cancer	23	$7.42
Multiple Sclerosis	6	$3.73
Neurofibromatosis	18	$10.17
Ovarian Cancer	25	$14.78
Peer Reviewed Cancer	26	$12.11
Peer Reviewed Medical	58	$46.70
Peer Reviewed Orthopaedic	23	$21.95
Prostate Cancer	127	$58.37
Spinal Cord Injury	21	$21.31
Tuberous Sclerosis	10	$4.25
Programs Executed on Behalf of Others[16]	**Number of Applications Recommended for Funding**	**Value of Applications Recommended for Funding (in millions)**
Defense Medical R&D	63	$97.45
Psychological Health/Traumatic Brain Injury	5	$27.77
Total	**610**	**$502.70**

F. A total of 621 applications were negotiated and awarded for the following FY 2013 research programs.

[15] CDMRP executed and managed the full appropriation.
[16] CDMRP assisted with the execution of the specified portion of a larger appropriation(s).

FIGURE 9: Applications Negotiated for FY 2013 Programs

Programs Managed by CDMRP[17]	Applications Funded
Amyotrophic Lateral Sclerosis	7
Autism	17
Bone Marrow Failure	5
Breast Cancer/Breast Cancer Research Semipostal	107
Duchenne Muscular Dystrophy	3
Gulf War Illness	16
Lung Cancer	29
Multiple Sclerosis	6
Neurofibromatosis	19
Ovarian Cancer	29
Peer Reviewed Cancer	27
Peer Reviewed Medical	50
Peer Reviewed Orthopaedic	28
Prostate Cancer	161
Spinal Cord Injury	26
Tuberous Sclerosis	10
Programs Executed on Behalf of Others[18]	**Applications Funded**
Army Rapid Innovation Fund	4
Clinical Research Intramural Initiative	3
Defense Medical R&D	15
Joint Warfighter Medical Research	2
Psychological Health/Traumatic Brain Injury	45
Vision	12
Total	**621**

G. The BCRP received $601,567 in FY 2013 as a result of the Stamp Out Breast Cancer Act. The Act allocates a portion of revenues from the sale of Breast Cancer Awareness stamps to the CDMRP to support breast cancer research.

1) With FY 2013 stamp monies, the BCRP fully funded the following Breakthrough Award:

a. (b) (6), Ph.D., University of California, Santa Cruz: "Inhibition of Retinoblastoma Protein Inactivation."

[17] CDMRP executed and managed the full appropriation.
[18] CDMRP assisted with the execution of the specified portion of a larger appropriation(s).

2) The BCRP partially funded the following Breakthrough Award with FY 2013 stamp monies:

   a. (b) (6) Ph.D., University of Texas, at Austin: "Noninvasive Label-Free Detection of Micrometastases in the Lymphatics with Ultrasound-Guided Photoacoustic Imaging."

3) As of October 2014, the BCRP has received $315,690 in FY 2014 Breast Cancer Research Semipostal funds. The BCRP anticipates awarding up to two FY 2014 BCRP awards with FY 2014 stamp monies.

H. The CDMRP disseminated information regarding its research programs and the availability of funding opportunities.

1) The CDMRP prepared and published the FY 2013 CDMRP Annual Report in December 2013. The Annual Report includes information on Congressional directives, program execution, and accomplishments for each of the research programs managed by the CDMRP. All of the CDMRP Annual Reports are available on the CDMRP website: http://cdmrp.army.mil/pubs/annreports/annual_reports.shtml.

2) News releases were posted on the CDMRP website announcing funding opportunities for each of the CDMRP's research programs, providing news and research summaries: http://cdmrp.army.mil/pubs/press/press.shtml.

3) Informational materials have been developed and are used to describe the CDMRP and/or its research programs including:

   a. Brochures: In FY 2014 a trend toward utilizing promotional materials on the CDMRP website and sending communications with emailed links to materials resulted in lower costs.

   b. The CDMRP brochure was updated and made available electronically on the website: http://cdmrp.army.mil/pubs/pips/CDMRP_overview.pdf.

   c. The consumer brochure describes the role of consumer peer reviewers and how to apply and is available on the website (updated to include email addresses): http://cdmrp.army.mil/cwg/docs/Consumer_Brochure.pdf.

   d. The funding opportunities brochure was designed to provide new applicants with details including specific information on the application process in a question-and-answer format. This brochure has been distributed to Department of the Army Congressional liaisons and is available on the website: http://cdmrp.army.mil/funding/default.shtml.

4) Displays ´

   a. The CDMRP Display is an 8´-x-8´' pop-up display for exhibition at national conferences and meetings. The display provides information on the FY 2013 research programs and their respective appropriations and is designed to draw meeting participants toward the exhibit space to interact with the CDMRP support staff.

   b. The CDMRP Military Display, also an 8´-x-8´pop-up display for exhibition at national conferences, was designed and used at the Military Health System Research Symposium. It features the military-relevant programs and innovative research for Warfighters, Veterans, and their families.

   c. Banner Displays summarize the mission and vision of the CDMRP or the specific research program being featured. Programs have been encouraged to use designs that focus on the goals and achievements and utilize banners for multiple years.

5) Several programs produced Program Booklets – glossy, multi-page publications that highlight a program's vision, goals, funding history, and specific highlights of recent years. Program Booklets were developed or updated for the following programs in FY 2014:

   a. ALSRP

   b. BCRP

c. Breast Cancer Research Semipostal Stamp Program

d. GWIRP

e. NFRP

f. OCRP

g. SCIRP

h. TSCRP

6) Several programs produced videos in FY 2014. These investigator highlights are brief (4- to 6-minute) videos based on interviews of researchers describing their CDMRP-funded research or consumers describing their experiences as reviewers in the CDMRP two-tiered process of application review. In FY 2014, eight videos were released for viewing on the CDMRP website and on the CDMRP YouTube channel.

7) The Public Affairs Office uses an annual schedule to provide coverage of each of the various programs' research achievements and notable research. As advocacy efforts have successfully designated particular months to promote awareness of specific diseases or health topics, CDMRP joins with the national emphasis of specific advocacy communities and highlights its related programs on the CDMRP website, (e.g., BCRP, PCRP, OCRP, and others). Programs not affiliated with "awareness months" are assigned a month so that those program teams can focus on delivering research highlights, consumer stories, and videos during specifically designated weeks during the year. At the end of a program's awareness month, advocates for that program are emailed links to those features of interest posted on the CDMRP website.

8) The CDMRP employs email to notify the scientific/research community when research funding opportunities become available. During FY 2014, the new eBRAP system implemented a subscription service that would allow subscribers to receive all CDMRP email notifications or to select among the many CDMRP programs. The eBRAP subscription service has invigorated our subscribers who now number over 84,000. Interested parties can subscribe by going to: https://ebrap.org/eBRAP/programSubscription/Subscribe.htm.

9) In FY 2014, the CDMRP continued using social media as a means to expand its information dissemination strategies. The CDMRP implemented the use of YouTube in February 2013. By the end of FY 2014, CDMRP had received over 8,000 YouTube views to improve and encourage the public's ability to access videos about its publically funded research programs and investigators. The public is encouraged to visit the CDMRP on YouTube at http://www.youtube.com/CDMRP, where viewers can find more than 40 brief interviews with researchers describing their CDMRP-funded research (videos are continually being added). The CDMRP website also has a video library going back to 2006, with 186 videos available.

10) Making further strides in the use of social media, the CDMRP started using Twitter in April 2013 to exchange news items among scientific, advocacy, and military research organizations. Twitter users can subscribe on https://twitter.com/CDMRP and become a "Follower" of CDMRP to receive CDMRP tweets. During FY 2014, our number of Twitter Followers rose from 220 to 475. By the end of FY 2014, the CDMRP Twitter account had provided over 2,500 tweets offering links to website information.

I. CDMRP staff presented program information to several audiences in FY 2014. Among the presentations were:

1) (b) (6) speaking at the National Association of Veterans' Research and Education Foundations 2014 Conference on medical research collaborations and funding opportunities available through the CDMRP (15 September 2014)

2) COL (b) (6) speaking to the NIH, Veterans Affairs Committee on Traumatic Brain Injury providing information on DoD CDMRP overview (22 September 2014)

3) (b) (6) speaking at the Early Detection Research Network Scientific Workshop on new research findings in prostate cancer (19 August 2014)

4) (b) (6) speaking at the North Eastern American Urological Association ZERO Summit to End Prostate Cancer on new research findings in prostate cancer (22 August 2014)

5) (b) (6) speaking to the 2014 Lung Cancer SPORE Workshop (25 July 2014)

6) (b) (6) speaking at the American Urological Annual Meeting on research funding opportunities in prostate cancer from the CDMRP (29 May 2014)

7) (b) (6) speaking at the National Breast Cancer Coalition Advocacy Leadership Meeting on research skills building (5 May2014)

8) (b) (6) speaking in a Webinar Presentation providing an overview of CDMRP at the University of Texas at Dallas (10 April 2014)

9) (b) (6) at the NIH, National Cancer Institute, Center for Cancer Research Fellows and Young Investigators (23 March 2014)

10) (b) (6) speaking at the NIH, Members of the Muscular Dystrophies Conference Committee (7 February 2014)

11) (b) (6), speaking at the VA-DoD Gulf War Illness Meeting at the VA Office of Research and Development (28 October 2013)

J. The CDMRP maintained the PESC to evaluate its programs and processes. Monthly meetings of the PESC are held to design and monitor progress on evaluation projects that assess research relevance, productivity, and accomplishments. Subcommittees are formed to pursue specific program evaluation projects. Periodic updates are provided to the PESC, along with final reports once a project has reached completion. Ongoing initiatives within the Program Evaluation Division include the following:

1) International Cancer Research Partnership (ICRP): The CDMRP is a founding member of the ICRP, along with the NCI in the United States and the National Cancer Research Institute of the United Kingdom.

   a. The mission of the ICRP is to enhance the impact of research to benefit all individuals affected by cancer through global collaboration and strategic coordination of research. The Partnership aims to improve access to information about cancer research being conducted and enable cancer research organizations to maximize the impact of their efforts for the benefit of researchers and cancer patients worldwide.

   b. The ICRP currently includes 80 cancer-funding partner organizations from across the United States, Canada, the United Kingdom, France, the Netherlands, Australia, and Japan. Potential Partnership organizations are other funders located in the United States, Australia, and countries within the European Union.

   c. ICRP Partners contribute funding data coded in a shared classification format (known as the Common Scientific Outline, or CSO) to facilitate pooling of information and the ability to analyze these data across organizations. The CSO has been translated into French and is currently being translated into Japanese to facilitate use among the Partners as well as other individuals and organizations.

   d. The Partnership's searchable database, which is open to the public via the Internet at https://www.icrpartnership.org/, contains the combined portfolios of all ICRP members, capturing and displaying over $13.6 billion, or approximately 65 percent of global cancer research funding. Investigators can search the ICRP database to avoid duplication of research effort and to further their work by identifying national and international collaborators. Partnership organizations can similarly mine the database to make investment decisions from a global perspective.

e. The ICRP launched its first international analysis of cancer research in 2012, based on data from over 80 current members about their individual organization's portfolios of projects and programs, each classified using the CSO and displayed by various measures such as type of cancer and type of research. Future analyses are expected to build on this initial report as the Partnership expands and more data become available. Other reports completed by the Partnership in 2012 include an analysis of chemoprevention research in breast cancer and an overview of pancreatic cancer research. Evaluation projects initiated by the Partners include one focused on obesity and cancer incidence, as well as one targeting environmental influences on cancer.

2) Tracking Outcomes of CDMRP-Funded Research: Investigators funded by the CDMRP are required to submit annual and final progress reports that summarize their research efforts as well as the accomplishments of the project. All progress reports are technically and contractually reviewed by the CDMRP staff and contract support staff.

a. Award Outcomes: The CDMRP reporting guidelines require investigators funded by the CDMRP to report on specific outcomes of their award(s) such as publications, patents, patent applications, additional funding applied for and/or obtained, presentations, and career advancement. These "award outcomes" are entered into EGS (see Information Management A.4), where they are associated with the appropriate grant file and tracked for the life of the award.

b. Research Result: During the process of reviewing annual and final progress reports, a taxonomy system developed by the PESC is used to identify, catalog, and track the outcomes of the CDMRP-funded research on an ongoing basis. These "research results" are entered into EGS, where they are associated with the grant file and are tracked throughout the life of the award.

c. Research Result Management: Since the CDMRP research programs typically fund basic or early-phase translational/clinical research, the end result of this research is not usually realized during the life of a CDMRP award.

i) The goal of Research Result Management is to monitor progress on the CDMRP-funded research outcomes of scientific and/or clinical interest after the period of performance for funding has expired and the CDMRP is no longer receiving annual progress reports.

ii) The ultimate purpose is to identify tangible products, drugs, devices, treatments, interventions, changes to standard-of-care, and/or major advancements in the relevant field(s) of research that were funded, at least in part, by the CDMRP.

Other Significant Developments/Issues

A. The CDMRP continued to emphasize increased coordination and collaboration with other medical research funding agencies in FY 2014. In addition to the ICRP, which includes 80 funding organizations from around the world, the CDMRP increased its coordination with the NIH, NCI, Centers for Disease Control and Prevention, VA, and other medical research offices within the DoD. The CDMRP staff serves and participates on multiple Federal and non-Federal committees to compare research portfolios, identify gaps in research funding, and improve existing research efforts. In addition, the CDMRP encourages reciprocity by engaging individuals from Federal and non-Federal committees to participate in the peer and programmatic review of applications, as well as serve on review boards to monitor and oversee the progress of awards. These interagency collaborations strive toward synergy with other agencies, diversification of research portfolios funded, and underscoring the importance of research coordination efforts. Finally, in FY 2014, the CDMRP continued its efforts to support Government transparency by participating in the STAR METRICS Federal RePORTER initiative, which is consolidating award data from several agencies including the Department of Health and Human Services, National Science Foundation, NASA, and VA. The CDMRP has made its recent award data available on this new site.

B. As part of a USAMRMC Headquarters multi-year reengineering effort, in January 2014 the CDMRP was assigned the lead to consolidate all execution management for the USAMRMC. The CDMRP immediately

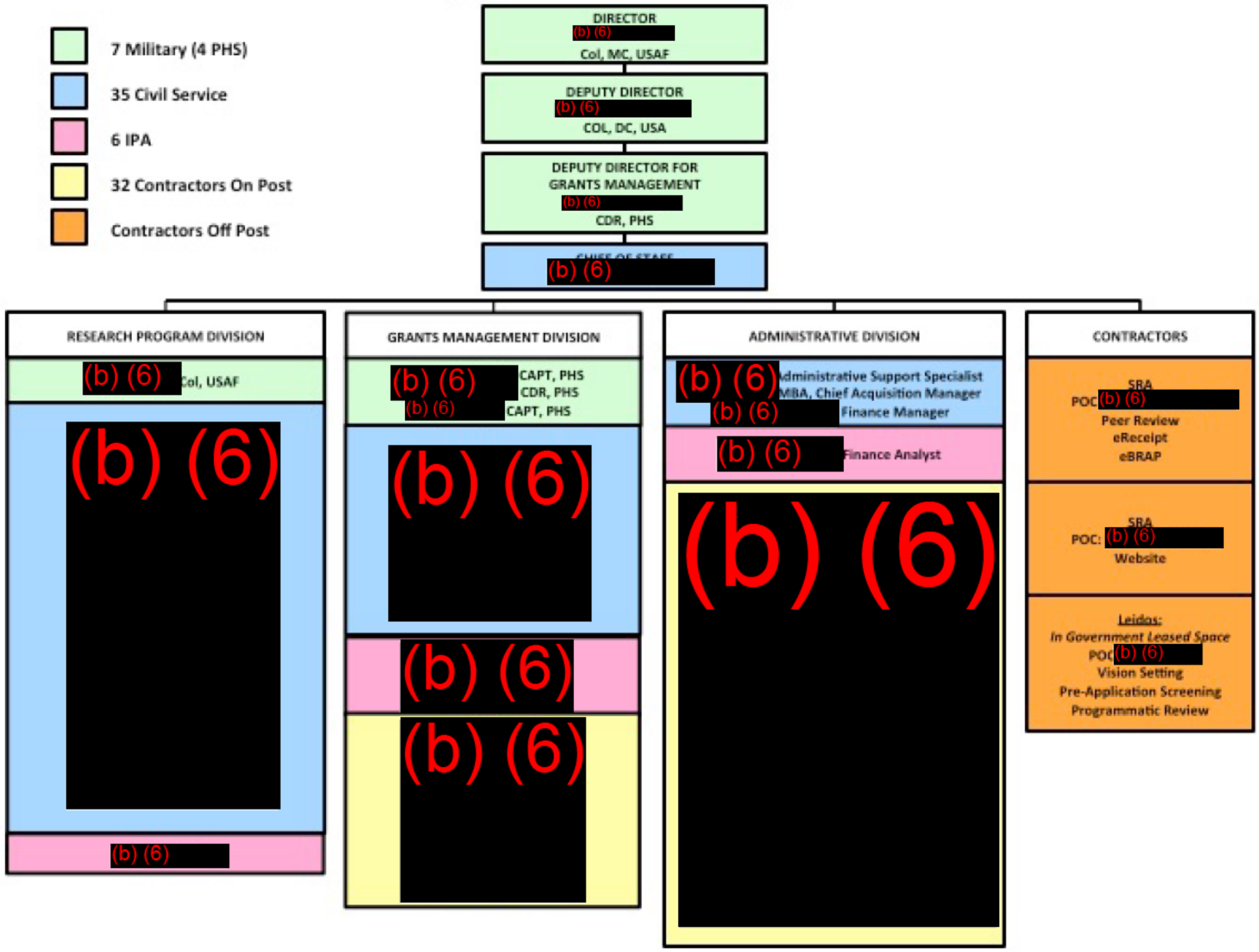
began working with TATRC staff to transition its staff, portfolios, and space to CDMRP. The CDMRP gained ~40 staff members and ~600 awards across many research areas. The CDMRP also acquired the responsibility to support Defense Health Agency Research, Development, and Acquisition meetings and all JPC meetings. The CDMRP is working on a structure, training, and new processes to better support its expanded mission.

Attachments

Supplemental Information

1) CDMRP 2014 Annual Report http://cdmrp.army.mil/pubs/annreports/2014annrep/2014annreport.pdf

CDMRP Organization Chart – 30 September 2014



Section 19

Fiscal Year 2014
Annual Historical Report

Telemedicine and Advanced Technology Research Center

Mission and Vision

In the two years leading up to 2014, the Telemedicine & Advanced Technology Research Center (TATRC) operated as the execution management agency (EMA) in support of the Joint Program Committees (JPCs). It was decided in March 2014, to re-shift those responsibilities to the Congressionally Directed Medical Research Progam (CDMRP) and they assumed the role of EMA in July 2014. Prior to 1 July 2014, TATRC provided telehealth solutions and executive medical research management support that enhanced and supported military healthcare and promoted innovative medical technologies. TATRC served as the primary execution manager for Defense Health Programs research while exploring science and engineering technologies that leveraged other programs to maximize benefits to military health care.

On 1 July 2014, at the direction of MRMC-HQ, TATRC was re-missioned to operate as a lab and assumed their new role, mission and responsibilities. Currently, TATRC fosters research on health informatics, telemedicine/m-Health, medical training systems and computational biology to address gaps in DoD medical research programs and military healthcare.

TATRC is an office of the Headquarters of the U.S. Army Medical Research and Materiel Command (USAMRMC), located at Fort Detrick, Maryland. TATRC conducts and supports research through its six key laboratories and programs which include: Computational Biology, Health I.T., Mobile Health, Medical Modeling & Simulation, Operational Telemedicine and the AAMTI Program. With an extensive network of partners, TATRC expertise is focused on the entire research spectrum, from early stage innovative research to technology demonstrations and implementation to benefit the Warfighter. TATRC Labs actively collaborate with commercial entities and academic institutions to address the requirements of our medical research programs through special funding and partnership opportunities.

With the strategic application of funding from small business innovation research/small business technology transfer, Army Medical Department (AMEDD) Advanced Medical Technology Initiatives (AAMTI), and other sources, TATRC accelerates the implementation of novel science and engineering technology applications through validation studies, translational research, and demonstration projects. As a result, TATRC is a network of experts and capabilities positioned to rapidly address urgent Department of Defense (DoD) needs. Since 1994 TATRC has been the center of gravity for telemedicine initiatives and is the leader for eHealth and mHealth research programs. Health Information Technology, Medical Training Simulation, and Computational Biology are major research components with laboratory capabilities.

Our Mission is to exploit technical innovations for the benefit of military medicine by developing, demonstrating and integrating across a variety of technology portfolios including teleHealth, medical simulation and training, health IT, medical robotics, command and control, and mobile solutions. TATRC sponsors bottom-up innovation through limited technology demonstrations focused on readiness, access to care, and healthcare delivery.

Our Vision is to be the model of transformational medical research for our Armed Forces and the Nation.

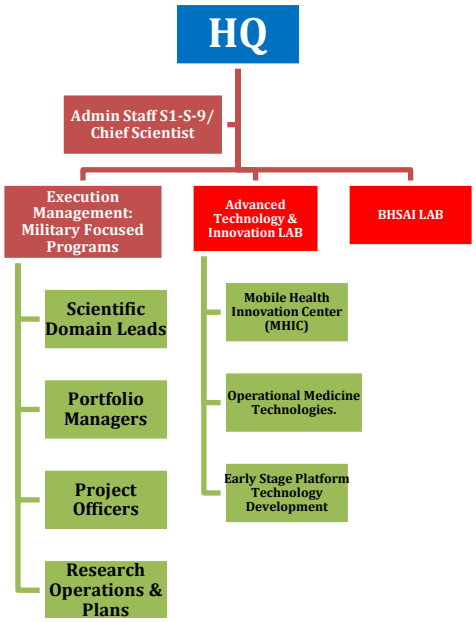
Organization

TATRC is located at Ft. Detrick, MD part of the US Army Medical Research and Materiel Command. TATRC is comprised of external offices including assets in Frederick, Maryland that include approximately 45 persons at The Biotechnology High Performance Computing Software Applications Institute (BHSAI). More distant assets are located at Fort Gordon. Prior to 1 July 2014, when TATRC was operating as the EMA on behalf of the JPC's, there were 9 separate scientific domains that compromised Bioengineering, Medical Simulation, Innovative Information, Health and Wellness, Rehabilitation and Human Performance, Pain and Brain, Remote Solutions, Biocomputational High Performance Computing, and Blood, Deployed Biologics and Medical Logistics.

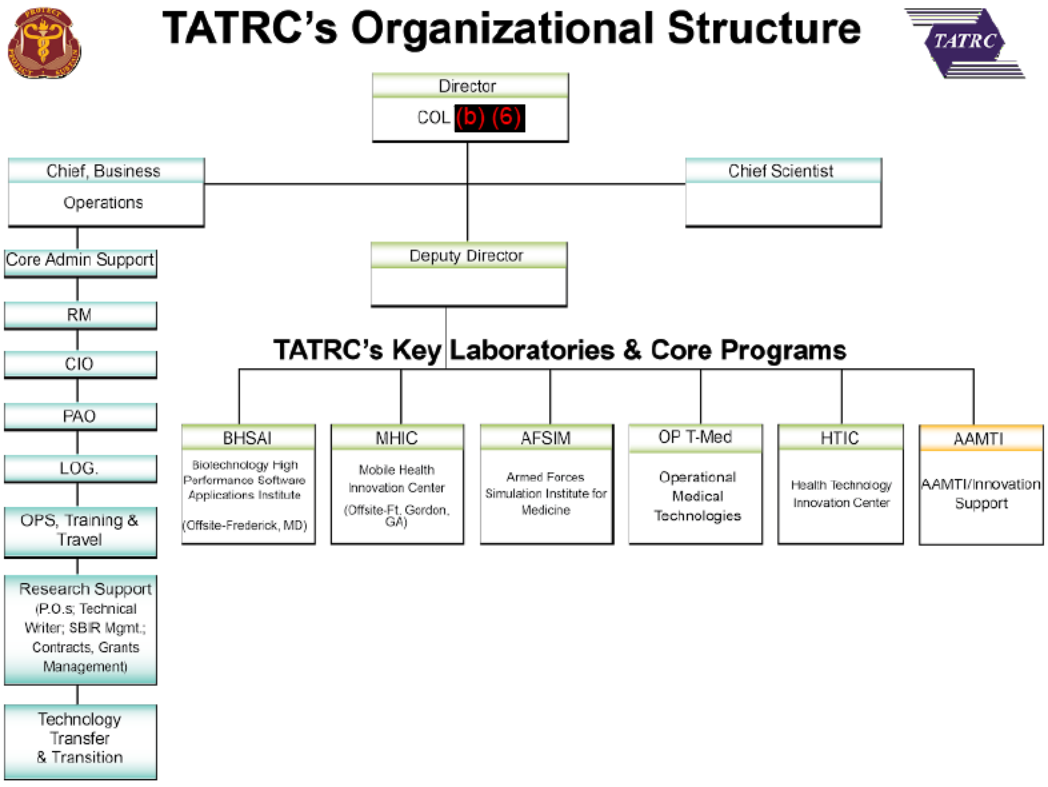
Currently, under its new Lab structure, TATRC has five labs and one key program to include, the AMEDD Advanced Medical Technology Initiative (AAMTI), The Armed Forces Simulation Institute for Medicine (AFSIM),

Biocomputational HPC Software Applications Institute (BHSAI), Health Technology Innovation Center (HTIC), Mobile Health Innovation Center (mHIC), and Operational Telemedicine. These efforts are supported by a research support division charged with project management and coordination, TATRC provides medical research expertise in the areas of: teleHealth, health information technology, medical simulation and training, intelligent medical systems, medical humanitarian assistance/disaster relief communications support, and medical technology innovation programs. TATRC continues to partner with numerous universities, commercial enterprises and other federal agencies supporting a multitude of projects. TATRC's vision, as an important extension of its legacy, encompasses the creation of opportunities for technology transfer to the public sector as well as the battlefield.

Organizational Structure through 30 June 2014



Organizational Structure as of 1 July 2014



Major Initiatives

On 1 July, 2014, the MRMC-HQ directed reengineering effort to separate out execution management functions from intramural lab functions was completed and TATRC assumed its new organizational structure, mission, and vision.

Personnel

Until 30 June 2014, TATRC consisted of research and development (R&D) groups which managed research projects in the following key scientific domains: Blood, Deployed & Medical Logistics, Health & Wellness, Innovative Information Technology (SD-IIT), Medical Simulation, Pain and Brain (PBSD), Protective and Restorative Bioengineering, Rehabilitation and Human Performance, Remote Solutions & Robotics, and Computational Biology. TATRC personnel also managed projects in seven special interest areas: Military Burn Research, Neurotoxin Exposure Treatment (Parkinson's) Research Relevant, Peer Reviewed Alzheimer's Disease Program, Joint Warfighters Research Program, Vision Research and Substance and Alcohol Abuse. An Administrative Support Group included the Resource Management; Information Technology; Communications and External Affairs; Logistics; Security, Plans Operations and Training; and Research Support. Satellite Activities included TATRC Mobile Health Innovation Center (TATRC-mHIC) and The Biotechnology High Performance Computing Software Applications Institute. TATRC staff had 141 personnel which included: 2 Military Officers; 18 GS Civilians (including 1 ST); 13 IPAs (6 part-time); and 108 Contractors until 30 June 2014.

On 1 July 2014 TATRC transferred employees to CDMRP and realigned their mission to a scientific lab structure per the Command's guidance and as of 30 September 2014, TATRC staff has 95 personnel which includes: 2 Military Officers; 10 GS Civilians (including 1 ST); 4 IPAs; and 79 Contractors.

Statistical Data
N/A

Healthcare Delivery
N/A

Veterinary Services
N/A

Training

All TATRC personnel completed required training in 2014, in accordance with assigned duties and personnel category types, including those assigned as Contracting Officer's Representatives (CORs), and Grants Officer's Representatives (GORs). Additionally, in support of the consolidation of execution management functions under one USAMRMC agency (EMA), TATRC transferred the comprehensive training records for all transitioning personnel.

Research and Development

TATRC conducts research in telehealth solutions, health information technology and medical training and simulation and manages research projects that comprise a diverse portfolio that spans all the scientific labs executed by USAMRMC. TATRC serves as the corporate visionary and manager for the AMEDD Advanced Medical Technology Initiative (AAMTI). TATRC also has two laboratories that are wholly, or in part, supported by outside competitive funding which includes:the Biotechnology High Performance Computing Software Applications Institute and the Innovation Laboratory. TATRC fosters research on health informatics, telemedicine/m-Health, medical training simulation systems, and computational biology, and promotes science and engineering within a flexible lab construct that now has five key areas of endeavor which include:

The AMEDD Advanced Medical Technology Initiative (AAMTI)

Purpose

The AMEDD Advanced Medical Technology Initiative (AAMTI) is focused on identifying, exploring, and demonstrating key technologies and enabling biomedical principles required to overcome technological barriers that are medically and militarily unique. The fundamental goals of the AMEDD Advanced Medical Technology Initiative (AAMTI) are: to demonstrate advanced medical technologies and their impact on cost, access, quality, and safety of care and medical readiness; to provide senior AMEDD leadership with medical tech-watch capabilities; and to encourage medical technology entrepreneurship by funding MEDCOM technology innovators through a bottom-up (provider/MTF level) approach.

Program Description

The Army Surgeon General, through the Telemedicine and Advanced Technology Research Center (TATRC) at the U.S. Army Medical Research and Materiel Command (USAMRMC) funds MEDCOM technology demonstrations leveraging the AMEDD Advanced Medical Technology Initiative (AAMTI).

The scope of the AAMTI includes the identification, exploration, and demonstration of key technologies and enabling biomedical principles required to overcome technological barriers that are medically and militarily unique. The fundamental goals of the AAMTI are: to demonstrate advanced medical technologies and their impact on cost, access, quality, and safety of care and medical readiness; to provide senior AMEDD leadership with medical tech-watch capabilities; and to encourage medical technology entrepreneurship by funding MEDCOM technology innovators through a bottom-up (provider/MTF level) approach. The results of AAMTI demonstration projects are expected to either directly result in, or support, efforts to:

A. Provide technologies needed to enhance full spectrum force health protection and readiness;

B. Reduce the cost of delivering care;

C. Reduce the time it takes to access care and critical specialty intervention;

D. Improve the skills and efficiency of care providers; and

E. Improve the quality and safety of care throughout the TRICARE healthcare continuum.

AAMTI-funded projects leverage and/or demonstrate primarily Commercial-off-the-Shelf (COTS) and emerging technologies and systems, some of which evolved from projects funded through Congressional Special Interest, Small Business Innovative Research, Defense Health Program, core medical research programs, and other DoD and Government sources. AAMTI projects inform technology transfer efforts by providing data and information to enable smarter acquisition decisions that positively affect the enterprise.

FY14 AAMTI Projects

A. In silico proof-of-concept analysis of freeze dried plasma for early trauma resuscitation in combat casualties with hemorrhagic shock

B. Utility of Portable Video Technologies to Discriminate Alterations in Postural Control

C. Using Structural Health Monitoring to Improve Diagnosis and Treatment of Low Back Injury in U.S. Service Members- Phase 2

D. Using In Shoe Real Time Biofeedback to Alter Running Biomechanics

E. Feasibility Study: Addressing Documented Gaps in Internal CSH Communication and Recall with a Garrison Optimized COTS Solution leveraging Wi-Fi and Vocera Mobile Health Technologies

F. Evaluation of the efficacy of a novel soft-tissue clamp for hasty compressible hemorrhage control versus tourniquet application during "Care under Fire"

G. ENDO-CAST: The Endocrinology Screencast Educational Series

H. Occlusion Training in the Rehabilitation Patient

I. Army Critical Care Flight Paramedic Program - MEDEVAC Medical Direction and Quality Management Program Demonstration

J. The Relevance of Work Stress Awareness when Helping DoD Employees Suffering from Chronic Stress and Pain

K. Integration of Continua Approved Biosensor Devices with the Mobile Health Care Environment/mCare Application for Home Health Monitoring

L. Evaluation of the Defense and Veterans Pain Rating Scale (DVPRS) in an Inpatient Setting Through a Bi-Directional Secure Mobile Messaging System

M. Development of a Collaborative Learning Site to Improve Assessment and Management of Developmental Behavioral Pediatrics Conditions

N. Tele Spine and Neurosurgery (Virtual Spine Consult) A Model for Access to Care across the European Regional Medical Command (and AFRICOM, CENTCOM/Southwest Asia)

O. mHealth Convergence Feasibility Study: Integration of mCare/MHCE-R and the T2 Mood Tracker Mobile Application

P. Cognitive behavioral Treatment for insomnia (CBT-I) in the primary care setting: an efficacy and feasibility study

Q. LED treatment to promote recovery in Veterans and DOD personnel with blast TBI

R. Validation of real-time Dosimeter Technology for Personal Naphthalene Exposure to Improve Army Occupational Health

S. Assessment of the Iron Bow Tele-health System in Remote Clinical Evaluations

T. Tele Dermatology– Developing Methods to Provide Virtual Theater, Far Forward Medical Care and Provide Soft Power Projection Through Medical Partnering

U. Expansion of a Multi-Disciplinary, Joint-Service Advanced Telemedicine Service for Military Medical Care in Deployed Regions

V. Automated Urine Flow Rate and Volume Measurement for Hospital Care

W. Extend the PCMH (Patient Centered Medical Home) Dashboard To capture the complete PHR from non-military sources

Major Milestones

AAMTI Outreach: In FY14 AAMTI received 65 proposals and made 23 awards across all Regional Medical Commands from clinics to MEDCENs as well as USAMRMC Labs. AAMTI funded demonstrations covered a robust spectrum of technologies, from LED for blast to mHealth, addressing varied clinical/healthcare issues from low back injury and pain to the Patient Centered Medical Home (PCMH). Close to 40% of FY14 AAMTI recipients were first-time submitters. FY14 AAMTI recipient's ranged in rank from Major to Senior Colonel and Government Civilians and included Army Surgeon General Consultants. In August 2014 the TATRC Director, COL (b) (6) and the AAMTI Program Manager, (b) (6), briefed LTG Horoho's Consultants meeting, generating significant interest in the program. In FY14 there were 37 active AAMTI projects across multiple fiscal years.

AAMTI Processes: In FY14 a series of process improvements were initiated covering all aspects of the AAMTI from proposal submission and evaluation to program timelines, reporting requirements, and contracting. The initiatives begun in FY14 will continue in FY15 and beyond.

Notable Results: In FY14 a number of previous fiscal year funded AAMTI projects were concluded with the submission of final reports and publications/presentations. AAMTI project results were submitted to a wide-range of publications from the Journal of Military Medicine to the American Academy of Pediatrics. In addition, an AAMTI recipient, COL (b) (6), TAMC, was awarded the 2014 General Maxwell R. Thurman Award for his AAMTI-funded work on tele-Auscultation and the Pacific Asynchronous Tele-Health (PATH) system.

The Armed Forces Simulation Institute for Medicine (AFSIM)

Purpose

The Armed Forces Simulation Institute for Medicine (AFSIM)'s purpose is to improve patient safety and quality of care by identifying and advancing simulation-based technologies that increase the training effectiveness of healthcare providers, from the foxhole to the operating room and even beyond.

Lab Description

AFSIM is an innovative nexus of collaboration, discovery and expertise in medical simulation and training. AFSIM seeks high value opportunities such as enabling technologies, visionary concepts, and resources. AFSIM serves as a home to simulation developer resources such as the BioGears® physiology engine and other open source tools. AFSIM expertise is in high demand with the lab currently funded to assist in medical simulator transition efforts. Our laboratory research focuses on experimental concepts and novel applications. We collaborate with forward thinking research groups to realize this vision.

AFSIM is enhancing its team in preparation for expanded science and technology contributions to the Military Healthcare System (MHS) and beyond. The Defense Health Agency has identified AFSIM to provide clinical, scientific, and technology services to the Provisional Joint Project Office for Medical Modeling and Simulation, a mission assigned to the Program Executive Office Simulation Training and Instrumentation (PEOSTRI), especially regarding maturity of technologies with potential for transition into the MHS. The NATO Science and Technology (S&T) organization is extending its influence into medical science and technology areas. NATO's influence on modeling and simulation for training is significantly increasing, to ensure greater interoperability across the NATO alliance, and AFSIM actively participates as an official US delegate.

TATRC's AFSIM is comprised of (b) (6) (Director), (b) (6), MD, Chief Scientist (USC Institute for Creative Technologies), and (b) (6), Research Scientist (Naval Postgraduate School).

Projects Within AFSIM

A. BioGears® Physiology Engine

Major Milestones

A. BioGears®. The purpose of BioGears® (HYPERLINK: "http://www.biogearsengine.com") is to develop an open-source, publicly available physiology engine allowing for distributed collaboration and consistent simulation across the entire medical training community. The scope is to model human response to trauma and treatment and will include physiologically accurate models for multiple systems, including cardiovascular, respiratory, renal and endocrine. The project began in September 2013.
    1) The main goals are to:
        a. Create a comprehensive, extensible human physiology engine that will drive medical training technologies;
        b. Create a publicly available physiology research platform that enables accurate and consistent simulation physiology across training applications;
        c. Lower the barrier to create medical training content;
        d. Engage the community to develop and extend physiology models;
        e. Meet the training needs of the military;
        f. Expand the body of knowledge about the use of simulated physiology for medical education.
    2) Timeline of Major Project Milestones
        a. January 2014 – Upon invitation from the DOD, ARA presented BioGears at the International Meeting on Simulation in Healthcare (IMSH) conference.
        b. February 2015 – Upon invitation from the DOD, ARA presented BioGears at the Medicine Meets Virtual Reality (MMVR) conference.
        c. March 2014 - ARA delivered a fully functional BioGears software build for use the Combat Medic Immersive training game, to act as a test case for engine integrators.

d. October 2014 – ARA announced the formal release of the "Open Source BioGears Mini Build," through the Apache 2.0 license. Provided freely via an Apache 2.0 license, BioGears is now available for both proprietary and open source research and development purposes. BioGears source code is housed on source Forge and may be downloaded via the BioGears website (https://www.biogearsengine.com/download)

3) As of the close of calendar year 2014, BioGears includes cardiovascular and respiratory models and examples of multiple engine interfaces. New physiology system and software functionality is in progress. The Mini Build is meant to elicit feedback from the community, to enhance the Beta Build scheduled for the fall of 2015.

4) Medical simulation professionals can use BioGears as a stand-alone application or integrate it into their training and immersive learning technologies to simulate physiological response to trauma and treatment. The Mini Build delivered detailed documentation, a Software Development Kit (SDK) and a website that promotes community interaction. The SDK was developed by keeping in mind user groups, i.e., simulation content developers, biomedical modelers, MedSim technology integrators, and researchers / educators.

B. International Meeting for Simulation in Healthcare (IMSH). 25-29 January 2014, San Francisco, CA

1) The TATRC AFSIM team, in behalf of the DoD, spearheaded the formal request to the Assistant Secretary of the Army for approval for participation of eighteen Army attendees in this national conference of the Society for Simulation in Healthcare. This allowed representatives from TATRC, the Joint Program Office 1 (Medical Training and Health Information Sciences), the US Army Central Simulation Committee, RDECOM Simulation Training and Technology Center, the USA Special Operations Command, and the Program Executive Office for Simulation Training and Instrumentation (PEOSTRI) to participate in this national meeting.

2) (b) (6), with strong support and input from (b) (6) (JPC-1), developed a DoD academic program including ten relevant presentations addressing cutting-edge research in progress. (b) (6) facilitated a "DOD Research in Progress Demonstration" of twelve organizations conducting advanced technology research in "MedSim". These activities were extremely successful, both in delivering the message of DoD leadership in Medical Modeling and Simulation (MM&S) research and in facilitating understanding between DoD managers, principal investigators, and conference attendees from twenty-six nations.

C. Medicine Meets Virtual Reality (MMVR), 19-22 February 2014, Manhattan Beach, CA

1) The TATRC AFSIM team, in behalf of the DoD, developed and submitted the request for participation of eight Army representatives. The TATRC team developed an academic program featuring almost twenty presentations by either Army personnel or Army-funded researchers in government, academia, and industry. This accomplished the purpose of informing the community at large of specific research gaps for DoD's research to improve training effectiveness, to inform the community of policies and processes, and to hear progress reports directly from the Combat Casualty Training Consortia.

D. Military Health System Research Symposium (MHSRS), 18-21 August 2014, Ft. Lauderdale, FL

1) The MHSRS is the DoD's only scientific meeting completely focused on the unique medical needs of the warfighter. Over the years, the MHSRS has served to accelerate collaboration among military medical care providers with deployment experience, DoD scientists, academia, and industry in order to meet the life-saving needs of battlefield medicine. (b) (6) and (b) (6) (JPC-1) moderated two breakout sessions focused on Military Medical Skills Acquisition and Sustainment. (b) (6) University of Minnesota, presented a plenary presentation entitled "Comparing Live Animal & Simulator Alternatives for Training & Assessing Hemorrhage & Airway Procedures in a Tactical Field Situation."

Biotechnology High Performance Computing Software Applications Institute (BHSAI) Lab

Purpose

The purpose of the Biotechnology High Performance Computing Software Applications Institute (BHSAI) is to develop computational solutions to accelerate the research and development of militarily relevant medical products for Force Health Protection. The Institute collaborates with life scientists within and outside the Department of Defense (DoD) to develop and integrate computational biology and medical informatics applications into research programs focused on improving the medical protection and care of our military personnel. With the ability to model and simulate complex problems on computers, many potential solutions can be quickly evaluated, effectively reducing the dimensionality of the search space to focus on a few hypotheses that can be experimentally tested. The close computational-experimental interactions provide the foundation for the successful execution of our mission.

Lab Description

The BHSAI develops computational solutions to accelerate research in the broader DoD biotechnology and medical community. The Institute has a multidisciplinary staff with previous working experience in industry, government, and academia and expertise in bioinformatics, computer science, modeling and control, physical chemistry, physics, mathematics, biophysics, biomedical engineering, biochemistry, systems biology, cellular biology, physiology, and medicine. Our broad scientific expertise and biological problem-solving skills, coupled with the computational power of the DoD supercomputing assets, provide a unique environment for cutting-edge, computational-experimental interdisciplinary research.

Projects Within BHSAI

A. Biomathematical models for individualized prediction of cognitive performance impairment due to sleep deprivation

B. Prediction of human body core temperature via non-invasive measurements

C. Uncovering physiological markers linking sleep and PTSD

D. Risk stratification of stress fracture and prediction of return-to-duty

E. Decision-assist tools for assessing the need for life-saving interventions

F. Computational modeling of heterotypic epitope specificity for neutralizing antibodies in dengue virus

G. Antigenic escape in dengue

H. Body core-temperature prediction to prevent heat injury

I. Identification of drug targets to re-sensitize biofilms of wound pathogens to traditional antibiotics

J. Computational modeling of respiratory airflow for diagnosis of pulmonary disease

K. RNA virus evolution under host immune antibody response

L. Systems biology of blood coagulation and coagulopathy

M. Metabolic activity of *Plasmodium falciparum* during asexual reproduction in red blood cells

N. Development of an agent-based computational model to identify key determinants of immunopathogenesis and neutralization in dengue infection

O. Develop a data-driven computational approach for repurposing marketed drugs to improve Warfighters' physical and psychological health

P. Systems biology characterization of the molecular mechanisms of TBI-related neurodegenerative diseases
Q. A computational model for inflammatory response due to heat stress in rats
R. Computational investigation and modeling of flavivirus evolution, immunity, and pathogenesis
S. Metabolic adaptations of *Plasmodium falciparum* and *Acinetobacter baumannii* to drug treatments
T. Computational modeling of blast-induced TBI and stress-fracture injury
U. Integration of models of total/chronic sleep loss and caffeine effects into one single model
V. Computational network analysis of the inflammatory response to musculoskeletal injury
W. Establish toxicogenomic models of chemical exposure to predict organ-specific toxicity pathways and injury biomarkers
X. Transcriptional regulation by SMARCA3 in cholecystokinin-expressing neurons mediates the therapeutic effects of antidepressants
Y. Blast modeling on the eye
Z. Development of predictive models of ground troop performance at altitude

Major Milestones

We are developing a personalized fatigue management tool to improve Warfighter performance. We developed biomathematical models to predict, at an individual level, the effects of sleep loss on human cognitive performance and the performance-restoring effects of fatigue countermeasures, such as caffeine and naps. We integrated these real-time, individual-specific prediction models into a performance-testing and analysis software, the smartphone 2B-Alert app. This work was performed in collaboration with the Walter Reed Army Institute of Research.

We collaborated with the Massachusetts General Hospital Emergency Department and Boston MedFlight to develop, validate, and deploy our system, “Automated Processing of the Physiological Registry for Assessment of Injury Severity” (APPRAISE), to assess the effectiveness of novel vital-sign sensors for prehospital identification of hemorrhage in trauma patients in order to transition promising laboratory technology to the clinical arena.

We developed a mathematical method to identify new disease indications for existing U.S. Food and Drug Administration (FDA)-approved drugs. The methodology uses an innovative approach to suggest repurposing candidates with a high chance of success for the treatment of diseases for which there are very few drugs available. Detailed cross-validation studies using FDA-approved drugs for hypertension, human immunodeficiency virus, and malaria indicated that the method provides a robust repurposing tool.

Health Technology Innovation Center (HTIC) Lab

Purpose

The purpose of the Health Technology Innovation Center (HTIC) is to empower government, commercial, and academic partnerships to research and develop innovative information technologies that advance military healthcare. Our vision is to be the prominent organization to lead innovative health information technology research in support of the federal health sector.

Lab Description

The Health Technology Innovation Center delivers innovative solutions for military medicine by blending health information management and technologies. Health informatics experts conduct applied health IT research in

response to MHS capability gaps. This center has the knowledge required to manage the research and development of HIT emerging technologies and carry out product development in a state of the art development environment.

Clinical care, hospital management, research, information assurance, and engineering subject matter experts work collaboratively within the HTIC. They engage with government, academic, and industry partners to design and develop technology solutions that address key gaps in military medicine.

HTIC also maintains a state-of-the-art development environment to promote research of emerging HIT. This virtualized environment, called the Early Stage Platform (ESP) for R&D, provides access to multiple electronic record systems for use in designing and developing research projects in a safe environment while mitigating acquisition risk to the enterprise. In house developers with extensive knowledge of AHLTA, VLER, Health Information Exchanges, development standards, and current programming environments work on intramural projects and are available to collaborate with outside partners. The ESP supports test versions of Military Health System (MHS) applications such as: AHLTA, AHLTA Training System (ATS), CHCS, and various Web services such as the Patient Ancillary Web Service (PAWS). The ESP also contains a longitudinal and consistent computer generated synthetic data set that includes 1 million unique patient records.

Our major goals are to

A. Develop software to augment and support electronic health records and health information technologies;
B. Provide expertise to establish and maintain a research and development infrastructure environment that supports HIT projects;
C. Establish and maintain a R&D environment that contains electronic systems used by MHS as a “sand box” for research and testing;
D. Maintain synthetic data that is longitudinal and consistent to be used in research and testing that mitigates the need for PHI/PII and thus the need for institutional review board approval;
E. Investigate the integration of medical devices with the electronic health record and medical networks and the use of standards for this effort;
F. Use electronic health data to research analytics and clinical decision support systems to analyze individual and population health statistics;
G. Develop research projects that use HIT to address individual (chronic and acute care) and population health problems;
H. Provide subject matter expertise in clinical and scientific domains to support research initiatives related to, but not limited to, health data visualization, health language exchange, health data standards, and health and predictive analytics;
I. Conduct tech watch to identify emerging solutions in support of the electronic health record and health information technologies.

Projects Within HTIC

The Health Technology Innovation Center has a multidisciplinary staff with experience in industry, government, academia, and the military and expertise in medicine, hospital management, medical informatics, computer science, health technology research, and engineering. Our broad expertise coupled with the assets of our Early Stage Platform, provide a unique environment for undertaking cutting-edge interdisciplinary research. Our key projects include:

A. Early Stage Platform (ESP) for R&D

B. Synthetic Data

C. Restful Health Exchange (RHEx)

Major Milestones

Please write a narrative paragraph for each major milestone or accomplishment for your lab for the year. Include major research projects, outcomes, significant accomplishments, dates of accomplishments/milestones, key personnel, etc. Please create one paragraph for each accomplishment or milestone.

The Early Stage Platform (ESP) for Research and Development is a state-of-the art virtualized development, integration and testing lab accessible remotely to support 3rd party innovation. It provides researchers and developers access to AHLTA, the Composite Health Care System (CHCS), the Central Data Repository (CDR) and Essentris stacks, as well as web services such as Patient Ancillary Web Services (PAWS) and Submission Ancillary Web Services (SAWS). The ESP contains computer-generated synthetic patient data that is longitudinal and clinically valid. The ESP supports government, academic and commercial partners. An Interim Authority to Operate (IATO) was granted in Sep 2014 in preparation for the award of the Authority to Operate (ATO).
Our staff has continued to work with the vendor to customize a synthetic patient data set which contains realistic and longitudinally consistent patient data which contains no personal health information (PHI) or personally identifiable information (PII). This data has been made available to research partners for their projects, as well as the TATRC staff is working with the vendor to establish a joint CHCS/CDR/AHLTA environment to house the synthetic patient data. Thru a joint venture, TATRC has worked with the Defense Medical Information Exchange (DMIX) to further customize the data to meet the needs of the DMIX testers.

MITRE and the HTIC collaborated to develop a prototype to demonstrate secure health information exchange between MHS and VA systems using Web-based, RESTful Health Exchange (RHEx) technology. This endeavor also explored the idea of a Federal Health Information Exchange (HIE) to advance interoperability across federal sources using Fast Health Interoperability Resources (FHIR). The project was able to demonstrate the secure, automated exchange of patient data with a HIE, but also the ability to support queries of a federal HIE and third party providers.

Under a DOD award and execution management by TATRC, the Parsons Institute for Information Management identified areas of the User Experience (UX) and User Interface (UI) for the Emergency Department (ED) Essentris that needed improvement. Working closely with CDR Peter Park, Chief Medical Informatics Officer (CMIO) of Navy Medicine West and the members of the Content Advisory Group (CAG), they identified the most critical modules and UI components to evaluate for user experience. As a result, the team successfully evaluated and redesigned the ED Tracking Board and partially redesigned the Medical Records Note modules. Their redesigned modules were deployed at Naval Medical Center San Diego and are being evaluated for user satisfaction and improvement in ED tracking.

Collaborated in a new Army Advanced Medical Technology Initiative (AAMTI) project awarded to Madigan Army Medical Center, Tacoma, WA, and First Genesis, Inc., to improve the existing Primary Care Medical Home Dashboard to provide a complete view of the patient's medical care, including care received in the civilian sector. The application will provide Madigan's Medical Home personnel with situational awareness of military beneficiaries referred from Madigan Army Medical Center to Multicare Health System and Franciscan Healthcare System, or who otherwise receive civilian care in those private sector hospitals, under the provisions of the TRICARE managed care program. The application leverages First Genesis' secure Mobius Health Information Services Exchange (HISE) solution (http://www.firstgenesis.com/mobius-hise), which was certified to operate on the national Healtheway, Inc.'s eHealth Exchange (formerly NHIN-Connect). TATRC provided synthetic patient data for use in the project.

HTIC staff authored three new Small Business Innovative Research Topics which were accepted and announced for the Defense Health Program (DHP) FY 15 Solicitation. The topics were: (1) Virtual Medical Concierge Application, (2) Methodologies and Tools for Securing Medical Device Systems in Integrated Clinical Environments

(ICE), and (3) Methodologies and Techniques for Balancing Usability and Security for Medical Devices in an Integrated Clinical Environment.

HTIC staff provided subject matter expertise to the Joint Program Executive Office for Chemical and Biological Defense regarding a new Joint Health Risk Management (JHRM) capability and technical solution. This required attendance at multiple meetings and ongoing coordination of activities.

HTIC partnered with MITRE Corp to showcase a prototype solution at HIMSS 14 involving the use of RESTful Exchange technologies to share images between military and civilian clinicians. This venue was part of the the Office of the National Coordinator (ONC) Showcase at HIMSS. Numerous demonstrations were provided during this event.

Mobile Health Innovation Center (mHIC) Lab

Purpose

The purpose of the Telemedicine and Advance Technology Center (TATRC) Mobile Health Innovation Center (MHIC) Lab is to investigate, demonstrate and evaluate emerging mobile technologies to enhance the quality of life for our Soldiers, sailors, airmen, and marines. The MHIC serves as an innovation center of excellence for evaluating mobile health technologies and networks by providing subject matter expertise and a unique laboratory environment for intramural and extramural research activities in support of service members, beneficiaries, patients and Role 1 (first responders) through Role 4 (definitive health care facilities) of the military healthcare system (MHS) prior to enterprise wide deployment.

Lab Description

TATRC-MHIC is co-located with the Department of Clinical Investigation at Fort Gordon, GA. The staff of TATRC-MHIC is comprised of personnel from a diverse background and included expertise in Mobile Health, Telemedicine, Research, Program Management, Case Management, Clinical Information Systems, Operational Medicine, Network Design, Programming, and Information Assurance. TATRC-MHIC has established partnerships with OTSG, MEDCOM, Dwight David Eisenhower Army Medical Center (DDEAMC), the Regional Training Site Medical, the Cyber Center of Excellence Experimentation Division, Georgia Regents University, and Augusta Technical College.

Projects Within mHIC

In FY14, mHIC projects focused from battlefield hospitals to the medical centers and beyond to include reaching patients in between clinical encounters using mobile technologies:

A. Mobile Health Technologies in the Operational Environment.

1) In the spring of 2014, the mHIC team commenced a pilot project in partnership with the US Army Cyber Command and an Army Medical Reserve Training site. This project was entitled “Feasibility Study: Addressing Documented Gaps in Internal Combat Support Hospital’s (CSH) Communication and Recall with a Garrison Optimized COTS Solution leveraging WiFi and Vocera Mobile Health Technologies”. This project was funded by the Army Advanced Medical Technology Initiative (AAMTI). The focus of this effort was to establish and demonstrate the use of wireless networks and commercial, wireless communication badges in a CSH venue. These technologies are already used in fixed facilities, and the project was an initial exploration into how well the technologies would perform in a field hospital setting to provide internal communications and recall (paging) support to the clinical team members. In September of 2014, the technologies were embedded with the 75th CSH in a 44 bed slice of a CSH during the reserve unit’s annual training. A follow-on exercise of these technologies was conducted in FY15 at Fort A.P. Hill, Virginia. Preliminary results

have shown that the insertion of a wireless recall capability has the potential to ensure that the right clinical skill sets are informed and available when and where required to improve patient outcomes.

B. Mobile Health Technologies in the Patient's Home Environment. In FY14, the mHIC team focused on reaching patients in their 'lifespace' between clinical encounters was focused around a maturing system, known as the Mobile Health Care Environment (MHCE) system and its secure mobile application, known as mCare. There were a number of projects focused on specific aspects of the MHCE system, which are outlined below:

1) Ongoing Projects:

a. Mobile Secure Messaging Platform Versus Army Knowledge Online (AKO) Automated Comprehensive Transition Plan (aCTP) Web-Based Interface in Compliance with CTP Self-Assessment Among Wounded Warrior Groups. The purpose of this research project was to make the comprehensive transition plan (CTP) health information readily available to Soldiers and providers; and to allow for the secure transfer of information with the Mobile Health Care Environment (MHCE) system /mCare secure mobile application to optimize healthcare resources for our Soldiers. This project was funded by the Joint Program Committee (JPC-1) in FY13, and the work continued in FY14 as the protocols were awaiting Institutional Review Board (IRB) approvals. From a technological perspective, this project allowed the MHCE system and mCare secure mobile application to integrate the CTP recovery and reintegration process that is used by Wounded Warriors into the existing technology platform, extending the overall system capabilities to provide the patient's specific recovery and reintegration goals and milestones easy access by both case managers and patients.

b. Assessing Feasibility and Acceptance of Integrating a Pain Module into the mCare Secure Messaging Platform. The purpose of this ongoing research project is to integrate the graphical representation of the validated instrument, the Defense Veterans Pain Rating Scale (DVPRS) into the MHCE system and mCare secure mobile application. The DVPRS is a revised pain scale that ranges from 0-10 and utilizes colors, text and graphics to define levels of pain, as contrasted with the VAS instrument which is a text based means for patients to self-report their pain levels. This project was funding by the Joint Program Committee (JPC-1) in FY13, and the work continued in FY14 as the protocols were awaiting Institutional Review Board (IRB) approvals. From a technological perspective, this project allowed the MHCE system and mCare secure mobile application to integrate the new pain scale into the existing technology platform, extending the overall system capabilities for case managers and patients.

2) New Projects:

a. mHealth Convergence Feasibility Study. In FY14, the mHIC team partnered with the Defense Centers of Excellence (CoE) National Center for Telehealth and Technology (T2) office and successfully obtained funding from the AAMTI program. This research project involves the integration of MHCE system and the existing, native (standalone) Mood Tracker mobile app. This will expand this behavioral health functionality with a bi-directional; direct connection between the patient and their behavioral health team. The proposed study includes technical development, assessment of feasibility with both providers and potential patients, and an economic evaluation of potential cost savings due to time savings for both DoD providers and patients and is projected to be launched for use in FY15.

b. Integration of Continua Approved Biosensor Devices with the Mobile Health Care Environment/mCare Application for Home Health Monitoring Demonstration Project. In FY14, the mHIC team successfully obtained funding from the AAMTI project to explore the integration of home based biosensor technologies as an extended function of the MHCE system. The ability to take patient data, such as blood pressure and blood glucose readings directly from the patient's home device, transfer that data to the mCare app on the patient's personal phone, and then securely transmit this encrypted data back to the MHCE

system allows for more robust case management of patients who require case management oversight for high acuity clinical conditions while reducing the human error in manual entry of these readings. The project involved an evaluation of the technical and end user interface factors on a number of devices that met Continua alliance and/or FDA standards. The final report is scheduled to be completed in early FY15.

c. Enhancing mHealth technology in the PCMH environment to activate chronic care patients: a feasibility study. In FY14, the mHIC team successfully obtained funding from the JPC-1 research proposal to expand the current MHCE system to incorporate bi-directional data exchange with PHR functionality and receipt of data from biometric devices, and represents the first partnership between mHIC and the School of Public Health at Clemson University. To activate the self-management behaviors of patients with type-2 diabetes in the Patient Center Medical Home (PCMH) environment a multi-site phased feasibility study, will be conducted within the MHS, at the Mike O'Callaghan Federal Medical Center, Nellis AFB and Madigan Army Medical Center, and Joint Base Lewis: McChord, There are two phases to this research study, first a user-centered design phase will be launched in FY15, following by a clinically-based feasibility trial. This mobile health (mHealth) study is aligned with the Army Medicine's balanced scorecard and PCMH initiatives within the health system.

FY14 Major Milestones

A. February 2014 – mHIC was awarded 3 AAMTI funded research projects, two as a direct awards, and one in partnership with the DCoE T2 office.
B. March 2014 – mHIC was awarded a partnership research study with Clemson University through JPC-1 funding.
C. August 2014 – the MHCE system received a three year renewal to is Authority to Operate (ATO) to continue operations in its research environment.
D. August 2014 –an ISSA was established with DISA to host the MHCE-Enterprise System, setting the stage for use of the MHCE system outside of mHIC research activities in FY15.

Presentations at National Conferences

In FY14, members of the mHIC team presented at four national conferences:

A. mHealth Summit:
    1) The Impact of Mobile Messaging on Case Management Engagement, Holly Pavliscsak
B. American Telemedicine Association:
    1) mCARE: Results of a Large Scale Study on a Bi-directional Mobile Messaging System, (b) (6) , BS, MHSA, Project Manager. Mobile Health Innovation Center (MHIC), Telemedicine and Advanced Technology Research Center (TATRC), Fort Gordon, GA, USA
C. Military Health Service Research Symposium:
    1) The Impact of a Mobile Messaging System on Case Management Assessment, Contact Rate Requirements and Appointment Reminder Support. (b) (6)
    2) Assessment of Mobile Messaging Usability for Traumatic Brain Injury. (b) (6)
    3) Assessment of Mobile Messaging Support of Reintegration. (b) (6)
D. 3rd International Congress of Solder's Physical Performance:
    1) Mobile Messaging Promotion of the Performance Triad, (b) (6)

Peer Review Publications

In FY14, the mHIC team produced one peer review publication:

A. Poropatich RK, Pavliscsak HH, Tong JC, Little JR, and McVeigh FL. mCare: The Development, Implementation and Pilot Evaluation of a Mobile Phone Messaging Application for Case Management of Soldiers by the US Army Medical Department Telemedicine and e-Health. 3 June 2014, 20(6): 563-569. doi:10.1089/tmj.2013.0226.

Operational Telemedicine Lab

Purpose

The purpose of the Operational Telemedicine Lab is to research, prototype and evaluate technical solutions to meet operational gaps in theater health services support and force health protection at or near the tactical edge. The vision of the lab is to engineer the future of military operational medicine by leveraging and integrating emerging information, communications, robotics, and biomedical enabling technologies.

Lab Description

The Operational Telemedicine Laboratory is a robust group of research scientists and technologists from the fields of artificial Intelligence, engineering, computer science, telecommunications and robotics, as well as experienced research managers and field operators in combat health services support and force health protection.

The Operational Telemedicine Laboratory is focused on five primary areas of research:

A. Robotics & Knowledge Engineering focuses on integrating and prototyping robotic and unmanned technologies and medical intelligent systems in order to provide standoff and remotely operated capabilities for combat casualty care, operational medicine, and force health protection. This area also researches and prototypes robotic enablers for applications in other convergent scientific domains.

B. Tactical Edge Medical Information Exchange & Telemedicine focuses on prototyping lightweight ruggedized technologies for physiological monitoring, telemetry, medical imaging, voice, video and electronic data exchange; and integrating with SMART devices and tactical communications.

C. Biomonitoring, Diagnostic & Treatment Technologies focuses on technologies for improving health outcomes through the development of sensors, diagnostic tools and treatment technologies for use in deployed environments and remote locations away from medical facilities and/or trained medical providers.

D. Special Operations Medical Technology focuses on integrating and applying technologies from the other three research execution areas of this scientific domain to support the most extreme remote aspects and unique challenges of special operations missions.

E. Medical Command and Control (C2) Communications focuses on evaluating, demonstrating, and training communication capabilities intended for non-standard medical augmentation deployment scenarios in homeland defense, humanitarian relief, civil support, and foreign consequence management missions. Special focus areas include portable satellite-based communication platforms, mobile devices, and other systems which operate in a no or low-infrastructure environment and can be maintained by organic medical personnel with minimal training.

The overall goal of the Operational Telemedicine Lab is to identify, monitor, leverage, prototype, integrate, demonstrate and evaluate emerging technologies in diverse scientific domains such as artificial intelligence, robotics, mechanical engineering, linguistics, cognitive psychology, computer science, telecommunications, bio monitors, sensing and medical diagnosis and treatment in order to provide technical solutions to operational gaps in

health care and force health protection for military forces operating in remote locations, at the point of injury, during pre-hospital evacuation at Roles 1-3 Medical Treatment Facilities, and in hazardous or denied areas.

Specific Goals:

A. Become and continue to be the Command's center of expertise in enabling technologies for: medical intelligent systems; robotics & unmanned systems; tactical communications; secure wireless medical information exchange at the tactical edge; operational telehealth; special operations medicine; and medical command, control, and situational awareness.

B. Continually improve and expand collaborative relationships with relevant joint and individual service combat developers; maneuver, maneuver support, and service support Centers of Excellence (COE) and their battle labs; Combatant Commands and their operational component organizations; relevant Program Executive Offices (PEOs) and their Product Managers (PMs); and Research Development Test and Evaluation (RDT&E) laboratories from all four military services, The Office of the Secretary of Defense (OSD), other federal agencies, private industry, and academia.

C. Involve operational warfighter users from both the conventional and special operations forces in design, development, test and evaluation of prototype solutions to telemedicine, force health protection, and health services support operational gaps within the ground component forces from the points of injury through health services Role 3.

D. Develop relevant laboratory and operational prototypes up through Technical Readiness Level (TRL) 6, integrate as systems of systems, and evaluate in the field with Soldiers, Sailors, Marines and Airmen. Leverage all available funding sources from Small Business Innovative Research (SBIR), through OSD (Health Affairs) Joint Program Committee, to joint and separate service Rapid Fielding Initiative (RFI) funds.

E. Transition operational prototypes to relevant Programs of Record for further advanced development, acquisition, and fielding.

Projects Within Operational Telemedicine

A. Rugged Medic Smartphone

B. SMART Telemedicine Program

C. Ultraviolet Communication for Medical Applications

D. Battlefield Medical Situational Awareness Goggles (Human Computer Interface)

E. SWAC3: Secure Wireless Architecture for Combat Casualty Care

F. Application of a wireless Finger-,mounted Ultrasound Transducer and Imaging Platform

G. Enhanced-Mobile Integrated Diagnostic and Data Analysis System (E-MIDDAS)

H. Electronic Information Carrier Ultra Wide-Band (UWB) Integration w/ Joint Medical Distance Support and Evacuation (JMDSE) Joint Capability Technology Demonstration (JCTD)

I. Application of Finger-Mounted Ultrasound Array Probes

J. Electronic Information Carrier Ultra Wideband (UWB) Integration

K. Development of USB Capability to the Blacktoe Ultrasound Finger Probe and Integration with the Tempus IC Professional

L. Unmanned Ground and Air System for CBRNE Contaminated Personnel Recovery

M. Multi-Mission Medical and CASEVAC UAV/UGV (FY09) / Multi-Mission Medical and CASEVAC UAV/UGV

N. Improved Robot Actuator Motors for Medical Applications

O. Design of a Highly Articulated Mechanism for Surgical Applications

P. A Near Autonomous Combat Casualty Extraction Robotic System

Q. Mobility Optimization via Enhanced Robotic Sensing (MOVERS) (Robotic Research LLC) | Terrain-Dependent Driving Control for Medical Robots & Mobility Assist Devices

R. HCI and C2 for Autonomous Air Evacuation of Casualties

S. A New Generation of Actuators for Robotic Systems

T. Squad-Multipurpose Equipment Transport (SMET) Medical Module Payload for Casualty Extraction

Major Milestones

A. C4ISR E14 Exercise

1) The Operational Telemedicine Lab participated in the U.S. Army Communications-Electronics Research, Development and Engineering Center's (CERDEC) Command, Control, Communications, Computers, Intelligence, Surveillance and Reconnaissance (C4ISR) Ground Activity Event 2014 (E14) from 2 – 13 June 2014 at Range 1, Joint Base McGuire-Dix-Lakehurst (JBMDL), New Jersey. The purpose in participating in C4ISR E14 was to conduct research testing and evaluation of Point of Injury Telemedicine devices (physiological monitoring, hands-free voice to text electronic Tactical Combat Casualty Care (eTCCC) card, long and short range UWB transmission of eTCCC card to provide research and development guidance to the developers. Experienced operational Medics evaluated the system's capabilities in casualty scenarios on their ability to enhance a Medic's treatment, care and electronic record documentation of wounded personnel prior to evacuation and during casualty evacuation. The Operational Telemedicine Team coordinated with PM Nett Warrior, CERDEC, and Ground Activity to integrate the medical systems and applications on the Nett Warrior End User Devices (EUD) being deployed with dismounted Soldiers operating on a tactical radio network and in establishing a stable 4G LTE and Soldier Radio Waveform (SRW) tactical cellular/radio networks on Range 1 to other testing ranges in order to conduct medical system and application tests using medical casualty scenario exercise plans and telemedicine system to transmission medical data over the networks from a simulated point of injury to a simulated Battalion Aide Station.

B. C4ISR E14 Exercise VIP Week

1) The Operational Telemedicine Lab participated in the E14 VIP Week from 8 – 14 August 2014 at Range 1, JBMDL, NJ. The purpose in participating in C4ISR E14 VIP Week was to demonstrate in a field environment utilizing Infantrymen, Medics and simulated combat wounded patients several key Operational Telemedicine projects to: authorized foreign nationals, Pentagon SES staff, and high ranking military officers and non-commissioned officers with an interest in advanced Operational Telemedicine support. Specific projects demonstrated during VIP Week included: Voice-to-Text in support of the eTCCC card on a Medic's Nett Warrior EUD; the wireless UWB pulse oximeter transmitting to the open eTCCC card on the Medic's EUD while the record is open; demonstrating long range Ultra Wideband (UWB) communication transmitting the eTCCC from the ground Medic to the inbound flight Medic up to a kilometer away using a unmanned aerial vehicle (UAV) to simulate the helicopter; and the Tempus Pro pre-hospital monitor capturing and transmitting vital signs and providing tele-mentoring between the Medic and remote advanced provider.

C. Secure Telemedicine Exercise

1) In preparation for C4ISR Ground Activity Event 2015 (E15), the Operational Telemedicine Team traveled to Range 1, JBMDL, NJ from 16 – 21 November 2014 to conduct preliminary integration and testing of two possible Cross Domain Solution (CDS) capabilities for medical applications. The purpose of the pre-E15 testing was to conduct first time field testing of two CDS projects (Advatech Pacific's Tactical Cross Domain Solution (TACDS) and Tresys Technology's Multi- Domain Spaghetti Western VPN solution) and evaluate their capability to integrate with a tactical Soldier Radio Waveform (SRW) radio and the tactical 4G LTE Multi-Access Cellular Extension (MACE) networks. The objective of the test was to determine the technologies' ability to transmit unclassified medical data from a simulated point of injury to an unclassified MC4 laptop at a Battalion Aid Station over a classified network. The two CDS capabilities were integrated and tested on Range 1; both systems were able to successfully integrate and transmit unclassified eTCCC and Military Acute Concussion Evaluation (MACE) cards from a Nett Warrior EUD and Tresys Technologies EUD over the (closed-loop) classified 4G LTE and SRW networks through the Cross Domain Solution to be processed and received on an unclassified NIPRnet MC4 laptop running the AHLTA-T electronic health record (EHR) application. At the conclusion of the test; lessons learned were discussed on what did and did not work; plans and objectives were proposed to correct deficiencies prior to E15 in July 2015 where the technology will again be tested.

D. Special MEDCOM Response Capability - Medical Command and Control Communications Mission:

1) Beginning in 1998 TATRC was directed by the Army Surgeon General to develop and support telemedicine equipment sets for what is now called Specialized MEDCOM Response Capabilities Medical Command, Control, Communications and Telemedicine (SMRC-MC3T) in order to augment the other 21 SMRC teams when deployed in support of incident response. When tasked by MEDCOM for contingency missions, the SMRCs must have the communications assets in order to provide medical augmentation to local, state, federal and defense agencies or medical teams responding to either domestic or foreign disasters, civil military cooperative actions, humanitarian assistance, weapons of mass destruction incidents; chemical, biological, radiological, nuclear and high yield explosives (CBRNE) incidents and emergencies. These communications packages provide remote Telemedicine capabilities to small rapid deployment teams that would not have this capability without the SMRC-MC3T communications package. With this capability real time VTC, Tele-Consultation, Medical Imagery, store and forward, voice and e-mail are all available within minutes upon arrival of the deployment site worldwide. MEDCOM continues to provide yearly sustainment funds to perform maintenance and provide training for the 4 SMRC-MC3T communications packages that includes two at TATRC and one each pre-positioned in the European and Pacific Regional Medical Commands. From 7-11 July 2014 TATRC SMRC team members deployed to Hawaii and configured all SMRC-MC3T equipment to be used in RIMPAC Mass Casualty Event. Prior to the exercise all systems where tested with TAMC Telemedicine staff tested at the exercise location Ford Island, Pearl Harbor. The SMRC-MC3T mission and system capabilities where briefed to multiple groups first responders, U.S. and Chinese Navy's during the exercise. The TATRC SMRC team also traveled to Fort Sam Houston, Texas from 10-12 Dec 2014 to provide familiarization training on the SMRC-MC3T equipment set. Participants included representatives from BAMC SMRC teams and MEDCOM HQ MEDCOM Staff. An overview was presented to all SMRC teams present in addition to SMRC-MC3T communications systems and telemedicine use demonstrations. Current and future mission capabilities and training opportunity's was also discussed.

E. Operational Tele-Behavioral Health Mission:

1) Beginning in 2010 TATRC was directed by the Army Surgeon General to develop and support an in country Operational Tele-Behavioral Health system in support of CENTCOM in the combat theater resulting in what is now called Operational Tele-Behavioral Health (OTBH) Program. The TBH system provided approximately 20 % of the patient encounters during 2012 & 2013, while operating 87 remote sites throughout four regional commands. The Tele-BH system conducted on average, 2,000 visits

annually. Clinical over-sight of these patient encounters was provided in-country by the CENTCOM Mental Health Consultant for MED-A. Approximately 72% of this workload would not have occurred without the ability to conduct Provider /Patient encounters virtually. Telemedicine was able to over-come operational events and weather hazards that precluded patient travel for medical intervention. Tele-medicine was able to over-come these barriers to care delivery. The mission in MED-A was down-sized in 1Q15 to 10,000 supported. Right sizing of TBH is currently 12 active sites, centered at two regional Combat Support Hospitals and one Combat Operational Stress Command. The project is being positioned for transition, by CENTCON Surgeons office. The primary COA is to provide a long-term DHA-MITC supported, remotely managed system, operating over NIPR networks. TATRC continues to coordinate monthly coordination TCON and conduct liaison with DHA, MEDCOM, CENTCOM and MRMC, and medical units Afghanistan and Kuwait.

Resource Management and Budget

TATRC managed approximately $127M in funding in FY14. This included Army and DHP CSIs and funding to support four Centers of Excellence (COEs) in Breast Cancer, Gynecological Cancer, Integrative Cardiac Health and Pain Management. TATRC continued to receive funding for three core DHP O&M programs (AAMTI, Operational Telemedicine, and MHIC) as well as three TBI/PH programs (Access to Care, Transcranial Doppler, and mCare). TATRC provided execution management support for MRMC, principally the JPCs until 1 Jul 14. TATRC managed $13,621,000 in SBIR/STTR awards. The BHSAI received $7,245,000 in FY14 funding.

FY14 Funding

	Funding Amount Received FY14 (000)		Total Number of Funding Accounts
Army CSI	$	24,558	3
DHP CSI	$	50,136	8
AAMTI (P8)	$	4,800	1
Operational Telemedicine (P8)	$	1,400	1
TATRC MHIC (P8)	$	524	1
SBIR/STTR	$	13,620	1
TBI/PH	$	4,293	4
BHSAI/BIC	$	7,245	2
Execution Management	$	8,681	1
Reimbursables	$	624	3
GRAND TOTAL:	**$**	**115,881**	**25**

Information Management

Under the direction of the USAMRMC ODCSIM, (b) (6) [redacted], the ODCSIM team has completed a 100% tech refresh of TATRC user's laptops.

The ODCSIM team assisted the research and development labs in achieving a full Authority to Operate for Operational Telemedicine Laboratory (OP-TMED) and Mobile Health Care Environment - Research (MHCE-R), and an Interim Authority to Operate for Early Stage Platform (ESP).

Operations

TATRC supported no major operations, deployments, or exercises in 2014. TATRC Operations supported the consolidation of execution management functions to the new EMA by transferring DTS accounts and by providing estimated travel requirements for transitioning personnel.

Force Development

TATRC's force structure changed significantly on 1 July 2014 when 42 personnel transitioned to the new Execution Management Agency (EMA). This occurred as a result of USAMRMC's decision to consolidate execution management functions under one agency.

Modernization

N/A

Logistics and Construction

At the request, and under the guidance of the TATRC Command Staff, the Logistics Section undertook and completed a large scale realignment of the workforce between two organizations: TATRC and CDMRP. This realignment was comprised of Government Civilians and DOD Contractors with 40 individuals who were transitioned from TATRC to CDMRP. In a four phase relocation plan, personnel were transitioned between Bldgs. 1054, 1053, 1077, and 1078 respectively. In Bldg. 1054, 37 seats that included ten private offices and four semi-private offices, were made available to CDMRP on the second floor. Also, to the individuals who requested that their equipment be immediately set up and operational in their new areas, TATRC Command requested the DCSLOG grant a Lateral Transfer of certain items to the CDMRP Hand Receipt to ensure accurate accounting of property.

During this restructuring, TATRC also relinquished two primary conference rooms on the second floor of Bldg. 1054 to CDMRP, allowing them a seamless transition into the new space. With the loss of these conference rooms, TATRC requested, and was granted permission from the MRMC Space Utilization Committee to reconfigure several offices and small meeting areas on the first ground floor, into a larger, more accommodating, state-of-the-art, space at minimal cost to the government.

Bldg. 1078, which serves as TATRC's laboratory and prototyping facility, has been configured to its originally designed intent. The Operational Telemedicine Lab has been relocated from several smaller facilities within the PITLab, (Prototyping, Integration, and Testing Laboratory), into Bldg. 1078's Laboratory and vehicle storage area. This will allow the team more flexibility to evaluate deployable systems and incorporate TATRC's HMMWV into these capabilities in a climate controlled environment.

No new construction occurred during this reporting period.

Heath and Environment

N/A

Other

Conferences Participated in and/or Hosted

A. The Annual American Telemedicine Association (ATA) Conference & Exhibition:

1) The Annual American Telemedicine Association (ATA) Conference & Exhibition is the world's largest conference focusing exclusively on telemedicine & telehealth, held every spring in the April/May timeframe. In previous years, the U.S. Army TATRC office hosted a full one day session on ARMY Telemedicine Partnerships entitled: "Meeting Medical Challenges in a Changing World," and focused on a relevant new topic each year. Due to the new DoD directive on conference sponsorship and the current fiscal restraints, TATRC did not host or sponsor this annual telemedicine program. The last TATRC hosted program was in May of 2011.
2) The 19th Annual International Meeting of the American Telemedicine Association took place at the Baltimore Convention Center in Baltimore, Maryland, 17 - 20 May. ATA 2014 focused on outcomes and evidence for telemedicine and telehealth. The meeting featured roughly 350 peer-reviewed presentations, covering the full spectrum of telemedicine-related subject areas and specialties, within eight concurrent tracks. Presentations included oral concurrents, poster presentations, pre-meeting courses and general plenaries. TATRC served as the lead agent for DoD and coordinated a DoD Keynote panel which featured the Honorable Jonathan Woodson, the Assistant Secretary of Defense for Health Affairs, who gave a plenary talk on Tuesday, 20 May. ATA 2014 also included special Executive Roundtables, featuring top executives in the industry discussing the future of telemedicine from a corporate & DoD perspective. Six people from TATRC attended and participated at this event. ATA's website: http://www.americantelemed.org/ata-2014.

B. Military Health System Research Symposium (MHSRS) previously known as the Advanced Technology Applications for Combat Casualty Care (ATACCC):

1) Military Health System Research Symposium for Combat Casualty Care (MHSRS) is co-sponsored by the U.S. Army Medical Research & Materiel Command (USAMRMC) and managed by the Research Area Directorate (RAD) II for Combat Casualty Care. TATRC participates every year by sending selected staff from the Medical Modeling & Simulation and Training, HTIC, MHIC, and Operational Telemedicine Labs to attend sessions. Eight people from TATRC attended and actively participated at this event.
2) The MHSRS meeting is the DoD's premier scientific meeting that addresses critical advances in trauma medicine and the unique medical needs of the warfighter. It focused on growing and changing operational issues and the technologies available today and in the future that can be used to meet these increasingly complex goals. Nearly all of DOD's combat casualty care scientists present their latest research results.
3) The MHSRS Conference takes place every summer in August. MHSRS 2014 occurred 18-21 August 2014 at the Harbor Beach Marriott in Fort Lauderdale, Florida. The MHSRS conference 2015 is pending conference approval. The MHSRS website is: https://mhsrs.amedd.army.mil/SitePages/Home.aspx

C. The International Meeting on Simulation in Healthcare (IMSH) Conference:

1) The IMSH is the annual meeting of the SSiH, the professional simulation society for healthcare. Driven by a growing national mandate to improve patient safety, the IMSH reflects the emergence of Medical Modeling & Simulation (MM&S) as an entirely new professional field over the last two decades.

The IMSH conference is the main educational event for the SSiH members and non-member attendees. Attendance at this conference fosters DoD national leadership in research, development, implementation, and evaluation of medical simulation as a promising method of training healthcare personnel to remain current and competent in their respective fields as compared to traditional training methods. Additionally, participation in this national conference supports Dr. Jonathan Woodson's vision for the future of medical training. Dr. Woodson conveyed in an address to the Federal Medical Simulation Training Consortium in Feb 2012 his commitment to Medical Simulation ("MedSim") to advance medical teaching & training and his desire to make the MHS the "nation's model in simulation use." Three people from TATRC attended and actively participated.
2) The IMSH Conference took place 25-29 January at the Moscone Center in San Francisco, CA. The IMSH Website is: http://www.ssih.org/Events/IMSH-2014.

D. The Healthcare Information and Management Systems Society (HIMSS) 2014 Annual Conference and Exhibition:
    1) The HIMSS Annual Conference breaks new ground each year showcasing the value of Health Information Technology with leading-edge education, exhibition and critical knowledge sessions. This year the conference will also feature the Federal Health IT Solutions Pavilion which will have not only federal products and services on display, but also provide educational sessions from our federal partners. The HIMSS Annual Conference breaks new ground each year showcasing the value of Health Information Technology with leading-edge education, exhibition and critical knowledge sessions. This year the conference will also feature the Federal Health IT Solutions Pavilion which will have not only federal products and services on display, but also provide educational sessions from our federal partners. Four people from TATRC attended and actively participated.
    2) The HIMSS Conference took place 23-27 February 2014 in Orlando, FL. The HIMSS Website is: http://www.himss.org/Events/EventDetail.aspx?ItemNumber=22164.

Section 20

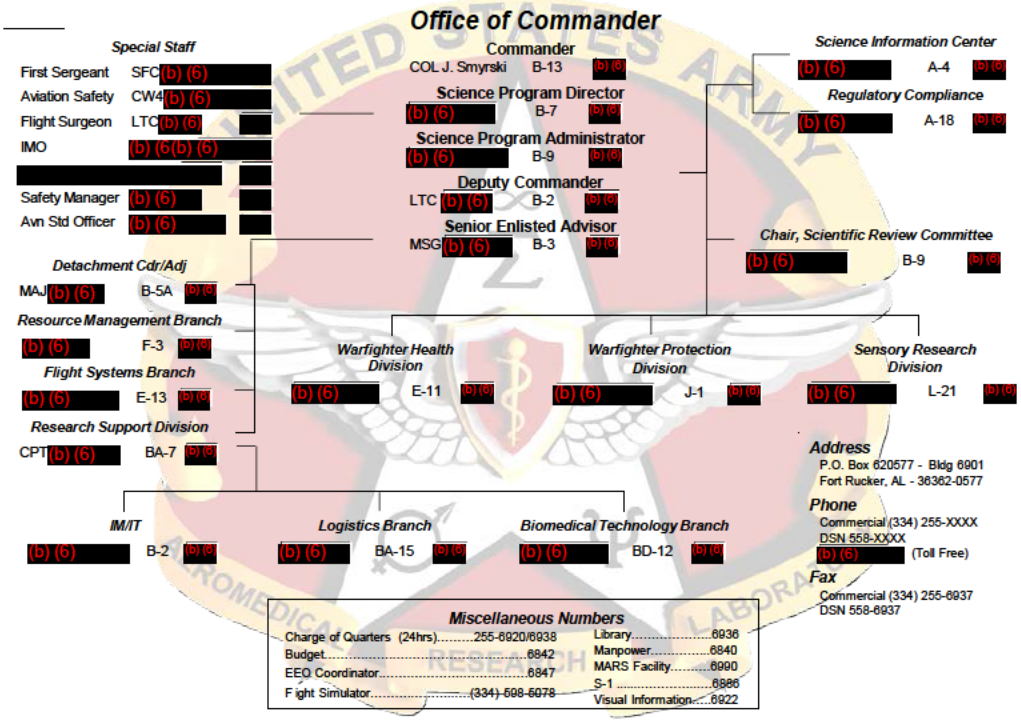
Fiscal Year 2014
Annual Historical Report

U.S. Army Aeromedical Research Laboratory

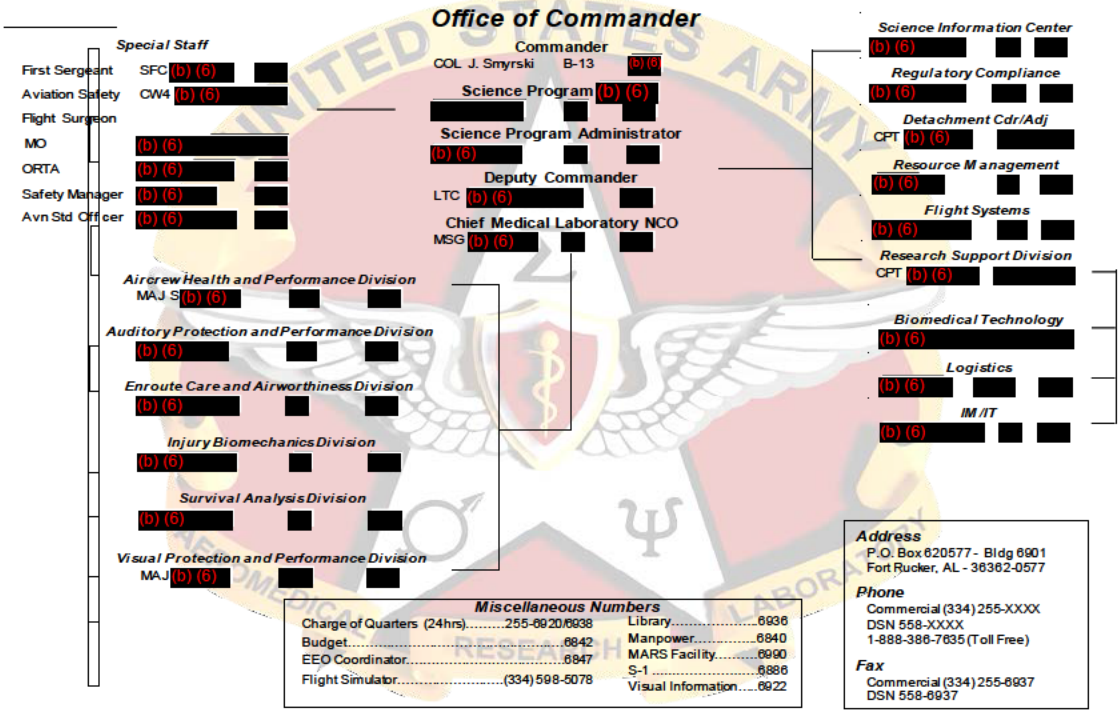
Mission

The U.S. Army Aeromedical Research Laboratory's (USAARL) mission is to conduct medical research, test, and evaluate performance solutions within the military environment to preserve the health, safety, and performance of the air and ground Warrior.

Organization and Personnel



Between October 2013 and July 2014, USAARL operated with three research divisions: the Warfighter Health Division, Warfighter Protection Division, and Sensory Research Division, each consisting of research branches (see above). However, in August 2014, the laboratory reorganized and formed six research divisions: Aircrew Health and Performance, Auditory Protection and Performance, Enroute Care and Airworthiness, Injury Biomechanics, Survival Analysis, and Vision Protection and Performance (see below). This report reflects the reorganization and changes in leadership.



Statistical Data
N/A

Healthcare Delivery
N/A

Veterinary Services
N/A

Training and Education
N/A

Research and Development

Aircrew Health and Performance Division

During FY14, the division's research objectives were to investigate issues of U.S. Army Warfighter health and performance, to include studies pertinent to psychological resilience, traumatic brain injury, post-traumatic stress disorder, back pain, and return-to-duty (RTD)/fitness-for-duty criteria, as well as to develop materiel countermeasures for military problems associated with endogenous (clinical or injury-related) and exogenous (environmental or operational) causes of vestibular disorientation and imbalance. The research accomplishments are as follows.

A. In collaboration with USAARL's Auditory Protection and Prevention Division, "3-dimensional auditory and tactile cueing for Soldiers with normal and impaired hearing wearing next generation hearing protection" is a study to improve the ability of pilots to localize targets using 3-dimensional (3D) auditory and tactile cueing, especially for pilots with hearing impairment. Preliminary data indicate that the errors in localization of 3D auditory cues in noisy environments can be overcome with tactile cueing. One medical researcher, a research coordinator, two psychologists, two research audiologists, and three technicians were assigned to the study. The study was funded by U.S. Army Medical Research and Materiel Command (USAMRMC) in the amount of approximately $405K.

B. "A simple field test for balance impairment" was a device-development project to produce a medical tool that screens for balance dysfunction associated with vestibular and organ damage. As a result of the study, a novel portable, head-mounted medical device capable of measuring the subjective visual vertical was developed and is currently being marketed in Europe while awaiting a partner for U.S. Food and Drug Association approval. Three companies are now in Phase I development of an expanded version of the SVV device developed in this project. One research doctor, a research psychologist, a study physician, a research project coordinator, and two research technicians were assigned to the study. The study was funded by USAMRMC in the amount of $960K.

C. The "Coalition Warfare Program—return-to-duty" was an effort designed to produce a hardened device to be used in-theater to assess and treat military personnel experiencing balance issues following concussion. The result of this effort is a field-hardened version of the SensoryKinetics balance platform, which is under construction by Engineering Acoustics, Inc. One medical researcher, a psychologist, and two technicians were assigned to the study. This effort was funded by the Department of Defense in the amount of $950K.

D. The research project "Correlates of criminal propensity in Army populations with and without a history of deployment to a combat zone" explores the significant differences between criminal and non-criminal populations with and without combat experience. Two research psychologists and two research technicians are assigned to the study. Details of the study were presented at Military Health System and Research Symposium (MHSRS). The project was funded in FY13 through an In-house Laboratory Independent Research proposal in the amount of $165K.

E. "Development of a fitness-for-duty assessment battery for recovering dismounted warriors" determined whether shooting performance tests that are more realistic and dynamic (requiring more movement and coordination than traditional static range marksmanship) could be used to augment readiness assessments, and examined the effects of mild traumatic brain injuries (mTBI) on dynamic shooting tasks (for RTD applications). The study found that the kneeling-while-shooting task had the most promising test properties for future applications related to dynamic shooting research and training (e.g., improved Engagement Skill Trainer exercises). A study physician, a research project coordinator, an ombudsman, two research psychologists, and four research technicians were assigned to this study. Details of the study are published in USAARL Technical Report (TR) 2014-18. This study's total budget was funded by USAMRMC in the amount of $350K.

F. "Does susceptibility to concussion with loss of consciousness increase with multiple concussions? Examination of 20 years of mixed martial arts records" examined 20 years of archival data from mixed martial arts fights to determine if fighters were more susceptible to in-fight concussions (measured by knock-outs and technical knock-outs following blows to the head) following their first observed concussion. Two research psychologists and seven research technicians were assigned to the study. A report is being written. The protocol was funded by discretionary lab funds.

G. The research project titled "Effects of rifle handling, target acquisition, and trigger control on simulated shooting performance" utilized archival data from several simulated shooting experiments to analyze specific patterns among rifle handling and trigger control, and determined how the patterns affect reaction

time and accuracy among shooters of differing skills. Two research psychologists were assigned to this project. Details of the study are published in USAARL TR 2014-19. This study's total budget was funded by division discretionary funds.

H. "Evaluation of the military functional assessment program (MFAP): Preliminary assessment of the construct validity using an archived database of clinical data" explored the relationships between clinical assessments and novel military-specific tasks in order to provide evidence-based standards to eventually serve as criteria for operational competence and performance of a Soldier after injury. Three research psychologists and four research technicians were assigned to this study. Details of the study were presented at MHSRS and the National Neuroscience Symposium, as well as in the *Journal of Head Trauma Rehabilitation* (online only). Funding was not provided in FY14.

I. The "Evaluation of the military functional assessment program: A prospective, longitudinal study of the predictive validity of the military functional assessment program for return-to-duty success" study was an extension of the above study that incorporates longitudinal follow-up of Soldiers to assess their outcomes as related to their MFAP scores. Three research psychologists and four research technicians are assigned to this study. This study's total budget was funded by USAMRMC in the amount of approximately $720K.

J. The study "Fatigue assessment: Subjective peer-to-peer fatigue scoring" introduced a novel subjective peer-to-peer fatigue rating system recently demonstrated in a deployed military rotary-wing environment. A flight surgeon was assigned to this study. Details of the study are published in USAARL TR 2014-04 and in *Aviation, Space, and Environmental Medicine, 84*(10), 1105-1108.

K. The project titled "Investigation of the electrophysiological and psychophysiological correlates of fear conditioning in a military sample" investigated patterns of learning through the use of a fear-inducing auditory stimulus. The study incorporated electroencephalography to compare subjective subject predictions of the unpleasant stimulus with unconscious physiological reactions to the stimulus. Two psychologists and seven research technicians were assigned to the study. A manuscript is being written. The project was funded through an In-house Laboratory Independent Research proposal in the amount of approximately $70K.

L. The study "Modeling acceleration effects on spatial orientation" developed an improved mathematical model of orientation perceptions (and hazardous misperceptions) during various body acceleration stimuli impinging on pilots (and generally on vehicle passengers) under adequate and inadequate visual cueing conditions. An improved orientation model was developed that was able to simulate many quantified past illusions of self-orientation. A prototype software product was developed that has been used to assist with mishap analysis. The effort has now been transitioned successfully into a PEO Aviation Small Business Innovation Research effort that will yield further refinements of the model and ready it for full production. A research psychologist, a research engineer, a research medical scientist, and a research technician were assigned to this study. Details of the study are published in USAARL TR 2014-09 and USAARL TR 2014-10, as proceedings at the American Institute of Aeronautics and Astronautics and 18th International Symposium on Aviation Psychology, and as a presentation at the Aerospace Medicine Association meeting.

M. The project "Post-concussion tools to assist assessment, treatment, and return-to-duty" enhanced a quantitative test battery for evaluating neurophysiological balance dysfunction associated with concussive events of mTBI. A portable initial screening instrument was delivered to Biodex to be sold to the physiotherapy community as a treatment modality to restore balance function. One medical researcher, a research psychologist, a research coordinator, and two physiotherapists were assigned to this study. Details of the study were presented as proceedings at the 5th International Conference on Applied Human Factors and Ergonomics. This project was funded through the Congressionally Directed Medical Research Program in the amount of approximately $870K.

N. The study “Soldier beliefs about the readiness of military personnel with mild traumatic brain injury” examined military perceptions of Soldiers with mTBI. Findings indicated that when asked in a survey format, Soldiers expected peers and/or subordinates with mTBI to require special accommodations for reintegration, but in a performance task with a confederate posing as an injured/uninjured military partner, Soldiers showed no significant differences in performance ratings or actual performance related to their partner/team. Three research psychologists, a research project coordinator, and two research technicians were assigned to this study. Details of the study were published in USAARL TR 2014-20. This study’s total budget was funded by USAMRMC in the amount of $2.15M.

O. “The perception of looming tactile stimuli” study determined whether a tactile stimulus can be perceived as a meaningful cue conveying the perception of “approach” of/to significant environmental objects. A simple, localized vibration signal was identified that employed two tactors on one small area of skin. Results indicate that increasing the frequency of vibration over the period of stimulation was most effective in conveying a tacton consistent with looming. Two research psychologists, a research analyst, and four research technicians were assigned to this study. The study details were presented as proceedings at the 5th International Conference on Applied Human Factors and Ergonomics and the 17th International Conference on Human-Computer Interaction. The study was not funded in FY14.

P. “Traumatic brain injury effects on return-to-duty for specific military occupational specialties” included 10 years of epidemiological archival injury data across all military occupational specialties to identify the military occupations most affected by mTBI and neurosensory injuries, and to explore the likely injury-related job deficits that would be expected among a few of the most affected specialties selected for detailed study. Results of the study found that some Army occupations were more affected by mTBI and neurosensory injuries than others, and that the types of injuries incurred would be likely to disrupt the necessary duties of the affected jobs. A research scientist, two research psychologists, and two research technicians were assigned to this study. Details of the study were presented at the National Neurotrauma Society Conference and International Annual Meeting of Human Factors and Ergonomics Society meeting as well as published in USAARL TR 2014-08. This study’s total budget was funded by USAMRMC in the amount of approximately $800K.

Auditory Protection and Performance Division

During FY14, the division’s research objectives were to develop prevention-based strategies and medically-based solutions for auditory and vestibular injuries. Prevention and treatment of these common warfighter maladies is essential for combat readiness. The research accomplishments are as follows.

A. The objective of the “Aircrew occupational injury prevention and assessment of personal hearing protection in field environment” study was to develop the appropriate coefficients to use with a commercially-available system to permit evaluation of noise protection provided by standard expandable foam, pre-molded, and custom-molded eartips used with the Communications Earplug or Communication Enhancement and Protection System. A research psychologist, two research technicians, and an analyst were assigned to this study. Details of the study were presented at the National Hearing Conservation Association meeting, and a technical report is being written. This study’s total budget was funded by USAMRMC in the amount of approximately $220K.

B. “Assessment of the middle-ear assumption of the auditory hazard assessment algorithm for the human ear (AHAAH)” tested the warned-ear assumption(s) of the AHAAH, currently under consideration as a health hazard assessment method for determining risk of hearing loss from exposure to acoustic impulses. One research psychologist, a research assistant, and three engineers are assigned to this study. This study’s total budget is funded by USAMRMC in the amount of approximately $790K.

C. "Developmental testing for impulse noise assessments using an acoustic test fixture" supported the development of an impulse noise measurement technique utilizing an acoustic test fixture by examining the variability of hearing protection. Data collection is underway. One engineer is assigned to this study. This study's total budget is funded by USAMRMC in the amount of approximately $290K.

Enroute Care and Airworthiness Division

During FY14, ECAD's testing and evaluation objectives were to provide knowledge and expertise in planning and conducting studies to improve patient outcomes by addressing patient movement equipment and patient care capability gaps related to ground or rotary-wing transport. The studies included research, development, tests, and evaluation to (a) support the selection of medical devices used on air and ground ambulances, and (b) improve knowledge and treatment of injury and disease under the unique physical, mechanical, and physiological stresses of the patient movement environment. ECAD received core funding in the amount of $800K in FY14 to conduct internal test and evaluation. The testing and evaluation accomplishments are as follows.

A. The test plan for the aeromedical evacuation enroute critical care validation study evaluated the adequacy of space available for care providers to perform advanced medical treatment scenarios on simulated critical care patients in existing medical evacuation (MEDEVAC) aircraft. (b) (4) [redacted] One test manager, a flight medic, two project assistants, two aeromedical physician assistants, and three research engineers were assigned to the project. Testing was completed in FY14 and details about the equipment will be published in FY15. Testing was funded by the U.S. Army Medical Materiel Agency (USAMMA) in the amount of approximately $330K.

B. The Arcos, Inc. Burn Resuscitation Decision Support System – Mobile test assessed the fluid resuscitation algorithm software for airworthiness using commercial-off-the-shelf Panasonic Toughbooks® (models CF-19 and CF-H2). (b) (4) [redacted] A test manager, tester, a flight medic, a flight surgeon, a pilot, a copilot, a crew chief, a quality manager, and two test engineers were assigned to this project. Details of this testing are published in USAARL TR 2014-02. Testing was core funded in addition to approximately $33K received from USAMMA for external testing.

C. The Arizona Industries of the Blind-modified North Atlantic Treaty Organization 7309 standard and quad-fold patient litters were evaluated for fit, form, function, and material strength to be used during enroute patient transfer, including aboard U.S. Army rotary-wing aircraft. One test manager, a flight medic, a quality manager, two test engineers, and three testers were assigned to this project. The first phase of testing was completed in FY14. Testing was core funded in addition to approximately $18K received from U.S. Army Medical Materiel Development Activity (USAMMDA) for external testing.

D. The Baxter Sigma Spectrum Infusion Pump, B. Braun Medical Infusomat® Space Volumetric Infusion Pump, Caesarea Medical Electronics Infusion Pump, and Hamilton Medical T1 and IMPACT 731 EMV+ transport ventilators were tested on board the UH/HH-60A/L/M and UH-72 aircraft between 2013 and 2014. The device selection is scheduled for FY15. Two test managers, two test engineers, a tester, a flight medic, a flight surgeon, a pilot, a copilot, a crew chief, and a quality manager were assigned to this project. Details about the first three pumps are published as USAARL Technical Memorandum (TM) 2014-04, USAARL TM 2014-05, USAARL TM 2014-06, respectively. Testing was core funded in addition to approximately $158K received by USAMMA for external testing.

E. (b) (3) (B) [redacted] A test manager, a tester, a flight medic, a flight surgeon, a pilot, a copilot, a

crew chief, a quality manager, and two test engineers were assigned to this project. Testing was completed in FY14 and details about the equipment will be published in FY15. (b) (3) (B) [redacted]

F. Airworthiness testing of the Cardiac Science Powerheart® G3 Pro, Automated External Defibrillator was performed on the UH-72 helicopter to certify use onboard MEDEVAC helicopters. The device was added to the UH-72 airworthiness release (AWR). One test manager, a tester, a flight medic, a flight surgeon, a pilot, a copilot, a crew chief, a quality manager, and two test engineers were assigned to the project. Testing was core funded.

G. The Combat Medical Systems/FERNO Aviation, Inc. Tactical, Rapidly Installable, Medical Evacuation Rack (model FA582A100) was evaluated for fit, form, and function in conjunction with existing medical evacuation systems and determined the human factors impact of this configuration on patient care during aeromedical transport. One test manager, a tester, a flight surgeon, a pilot, a copilot, a crew chief, a quality manager, two test engineers, three flight medics, and six Soldiers were assigned to this project. Details of the evaluation are published in USAARL TR 2014-01. The tests and evaluations were core funded in addition to supplemental funding in the amount of approximately $120K.

H. Limited airworthiness testing of the Essex Cryogenics of Missouri, Inc. Mounted Medical Oxygen System provided USAMMA with data to support a test AWR for an initial MEDEVAC mission feasibility evaluation. One test manager, a tester, a flight medic, a flight surgeon, a pilot, a copilot, a crew chief, a quality manager, and two test engineers were assigned to this project. The testing was core funded in addition to approximately $10K received by USAMMA for external testing.

I. The induced environment qualification test plan for the Externally Powered Enhanced Mobile Equipment (EME) was conducted as a limited laboratory test to qualify an engineering change designed to provide external power to the EME through a connector mounted to the battery cover. One test manager, a flight medic, a pilot, a copilot, a crew chief, a quality manager, and two test engineers were assigned to this project. Details of the testing are published in USAARL TR 2014-17. The test was funded by the Air Warrior Program Management Office in the amount of $44K.

J. Development of a test method for the evacuation of eight current and developmental immobilization and vibration mitigation systems determined the effectiveness the systems when applied to healthy human volunteers (manikins) exposed to realistic ride profiles played through a multi-axis ride simulator. One medic, three research engineers, two study physicians, two motion simulator operators, and six research technicians were assigned to the test plan. Details of the tests were presented at MHSRS and the SAFE Symposium. The testing was funded by USAMMDA funded in the amount of approximately $93K.

K. Improved field management and safe ground transport of patients with head and spine injuries investigates the effect of transport forces acting on an animal model with head and spine injuries. A principal investigator, a flight surgeon, and two research engineers are assigned to this project. The testing is funded by USAMRMC in the amount of approximately $3M.

L. (b) (4) [redacted] A test manager, a tester, a flight medic, a flight surgeon, a pilot, a copilot, a crew chief, a quality manager, and two test engineers were assigned to this project. Device testing was completed during FY14 and details about the device will be published in FY15. The Air Combat Command, Office of the Surgeon General and the Air Force Medical Service, Air Force Medical Evaluation Support Activity funded the testing in the amount of approximately $61K.

M. Testing of the LifeBed™ Patient Vigilance System (consisting of the LifeBed™ display unit, LifeBed™ coverlet and bottom, and various accessories) included baseline, conducted emissions, radiated emissions, and

flight testing aboard a U.S. Army rotary-wing aircraft. One test manager, tester, flight medic, pilot, copilot, quality manager, and three volunteers were assigned to this project. Details of testing are published in USAARL TR 2014-23. The testing was core funded.

N. (b) (4) A publication is being drafted. A test manager, a tester, a flight medic, a flight surgeon, a pilot, a copilot, a crew chief, a quality manager, and two test engineers were assigned to this project. The testing was funded by the Marine Corps Systems Command in the amount of $56K.

O. The Mobile Oxygen Ventilation and External Suction (MOVES®) system SLC™ evaluated data that may lead to certifying the equipment and its accessories for U.S. Navy flight clearance through class desks at the Naval Air Systems Command (NAVAIR) and use aboard U.S. Army rotary-wing aircraft. One test manager, a tester, a flight medic, a flight surgeon, a pilot, a copilot, a crew chief, a quality manager, and two test engineers were assigned to this project. Details of the evaluation are published in USAARL TR 2014-21. Testing was funded by the Naval Health Research Center in the amount of approximately $164K.

P. (b) (4) (b) (4) One test manager, a tester, a flight medic, a flight surgeon, a pilot, a copilot, a crew chief, a quality manager, and two test engineers were assigned to this project. Testing was core funded.

Q. Testing of the Sensiotec, Inc. Virtual Medical Assistant® included baseline, conducted emissions, and radiated emissions for use during transport aboard U.S. Army rotary-wing aircraft. A test manager, a tester, a flight medic, a quality manager, and three volunteers were assigned to this project. Details of the project are described in USAARL TM 2014-11. The testing was core funded.

R. (b) (4) (b) (4) One test manager, a tester, a flight medic, a flight surgeon, a pilot, a copilot, a crew chief, a quality manager, and two test engineers were assigned to this project. A technical memorandum is being written. Testing was core funded.

S. The Thermal Angel and Ultra Battery tests assessed the airworthiness of an in-line, battery-powered disposable, lightweight, and completely portable blood and IV fluid warming device, capable of intravenous application and irrigation warming with its original lead-acid battery and an improved lithium-ion Ultra battery. The Thermal Angel will help care providers prevent fluid-induced hypothermia. The device with use of both batteries was approved for the Army's Air Ambulance set. One test manager, a tester, a flight medic, a flight surgeon, a pilot, a copilot, a crew chief, a quality manager, and two test engineers were assigned to this project. Details of this testing are published in USAARL TR 2014-06. Testing was core funded.

T. The Twin Star Extremity Compartment Monitoring system was tested and evaluated for airworthiness. A test manager, a tester, a flight medic, a flight surgeon, a pilot, a copilot, a crew chief, a quality manager, and two test engineers were assigned to this project. Details of the testing are published as a USAARL TM 2014-02. Testing was funded by the Combat Casualty Care Area Research Director Joint Program Committee-6 and Telemedicine and Advanced Technology Research Center in the amount of approximately $39K.

U. (b) (4) A test manager, a tester, a flight medic, a flight surgeon, a pilot, a copilot, a crew chief, a quality manager, and two test engineers were assigned to this project. Testing was completed

during FY14 and details will be published in FY15. The testing was core funded in addition to $85K received from USAMMA for external testing.

V. Testing was conducted on the U.S. Marine Corps litter support system to measure the vibration transfer function of the system in either the USAARL UH-60 or other aircraft using healthy humans and to extrapolate and merge injured animal vibration transfer function data to provide to materiel developers a software tool to assess material solutions associated with litter support systems, litters, etc. A principal investigator, a flight surgeon, and two research engineers are assigned to this project. The testing was funded by the U.S. Marine Corps in the amount of approximately $520K.

W. Testing of the Viasys Healthcare LTV 1200 Ventilator was completed and received aeromedical certification. One test manager, a tester, a flight medic, a flight surgeon, a pilot, a copilot, a crew chief, a quality manager, and two test engineers were assigned to this project. Details of testing are published in USAARL TR 2014-11. The test was core funded in addition to $210K received from USAMRMC for external testing.

X. (b) (4) (b) (4) A test manager, a tester, a flight medic, a flight surgeon, a pilot, a copilot, a crew chief, a quality manager, and two test engineers were assigned to this project. Testing was core funded.

Y. The Welch Allyn Model 01692-MC Thermometer Kit test assessed the airworthiness of the thermometer on U.S. Army UH-72A, CH-47F, and UH/HH-60A/L/M aircraft using the Joint Enroute Care Equipment Test Standard as guidance. (b) (4) A test manager, a tester, a flight medic, a flight surgeon, a pilot, a copilot, a crew chief, a quality manager, and two test engineers were assigned to this project. Details of this testing are published in USAARL TR 2014-03. Testing was core funded.

Z. The Welch Allyn Fiber Optic Laryngoscope Kit tests assessed the airworthiness of the laryngoscope with a limited test of the laryngoscope in a new kit to validate the equipment's performance compared to the previous version of the Welch Allyn Fiber Optic Laryngoscope. (b) (4) A test manager, a tester, a flight medic, a flight surgeon, a pilot, a copilot, a crew chief, a quality manager, and two test engineers were assigned to this project. Details of this testing are published in USAARL TR 2014-05. Testing was core funded.

AA. Test and evaluation of the ZOLL Medical Corporation Propaq® MD with configuration change was conducted to maintain certification of the equipment and accessories. One test manager a tester, a flight medic, a flight surgeon, a pilot, a copilot, a crew chief, a quality manager, and two test engineers were assigned to this project. Details of the project are published in USAARL TR 2014-15. The test and evaluation was core funded in addition to approximately $18K received from USAMMDA for external testing.

Injury Biomechanics Division

During FY14, the division's research objectives were to conduct research on Soldier injury mechanisms, human tolerance levels, injury-risk mitigation technologies, and health hazards present in the full spectrum of Army operational and training environments. The research accomplishments are as follows.

A. The goal of USAMRMC's Military Operational Medicine Research Program (MOMRP) task area Z1 is to develop injury assessment criteria and health hazard assessment methods for occupant seating systems in order to reduce spinal injury risks through improved seat performance standards. The total budget for these projects is in the amount of $677K.

   1) The vertical acceleration tower was completed and delivered to USAARL where system outfitting and instrumentation and training on system operation were administered. A review of Army aviation spinal injury resulting from crash exposures was initiated and is ongoing.

   2) The study titled "Patient litter evaluation in a CH-46 crash test" evaluated patient litter system performance during NASA's dynamic CH-46 helicopter crash test where IBD contributed manikins and high-speed cameras to measure dynamic occupant loads. Preliminary observations indicate considerable useful data were collected during the crash, and the information will be analyzed over the next year. Data collected will be used to compare manikin responses to injury risk criteria, while structural elements of the patient litter system will be compared against current equipment standards. A research mechanical engineer, two research technicians, and an analyst were assigned to this crash test.

   3) Ride exposure data from various Army tactical ground vehicles were collected at Fort Benning, KY. A research biomedical engineer, a research mechanical engineer, a research kinesiologist, two general engineers, an electrical engineer, and two research technicians were assigned to this program.

B. Head supported mass research focused on identifying the factors leading to acute and chronic neck/cervical spine injury in aviation and dismounted environments, respectively. Details about the study were presented at the SAFE conference, at the Air Medical Transport Conference, and collaborators from Medical College of Wisconsin presented at the American Association of Neurological Surgeons 82nd Annual Scientific Meeting. This program's total budget was in the amount of $116K.

C. The study titled "Evaluation of wearable dosimeter prototype sensor systems for measuring human exposures to blast events" evaluated the performance of several environmental sensors to simulated and live fire blast events. Data analysis will be completed in FY15. A research mechanical engineer, a biomedical engineer, a general engineer, an electrical engineer, and two research technicians were involved in this study. The study's total budget was funded by USAMRMC in the amount of $618K.

D. The study titled "Environmental sensors in training" evaluated, in controlled laboratory exposures to blunt impacts and indirect loading, the performance of five currently available environmental sensors. A research mechanical engineer, electrical engineer, Soldier, two general engineers, and two research technicians were involved in this study. The study resulted in a safety release for five environmental sensors in the combatives training environment. Details of the study were published as USAARL TM 2014-09 and presented at the MHSRS. The study's total budget was funded by USAMRMC in the amount of approximately $880K.

E. The study titled "Development of military-relevant mandible blunt impact injury criterion" investigated the tolerance of the constrained human mandible to blunt impact. This study established a contract for biological specimens; the design, fabrication, and testing of an impact test device; and biomechanical instrumentation was selected and procured. The primary challenge during this study was establishing a contract with biological specimen suppliers. Other studies included identifying musculoskeletal injury tolerance for the human skull and mandible, as well as developing injury criteria and performance assessment methods for use in medically based standards for future helmet and maxillofacial protection systems. The total budget for these projects was funded by USAMRMC in the amount of $355K.

F. The study titled "Aeromedical assessment of effects of aftermarket earcup components and inflatable bladder system on the lateral impact protection of the HGU-56/P aircrew integrated helmet system" investigated the use of several pieces of aftermarket equipment in the HGU-56/P Aircrew Integrated Helmet System. This study resulted in the approval of the aftermarket items for use by aviators assigned to the 160th SOAR(A). One aerospace engineer and two research technicians were assigned to this study. Details of the study are published in USAARL TR 2014-07. This study's total budget was funded by the 160th Special Operations Aviation Regiment (Airborne) in the amount of $23K.

G. Project Manager, Air Warrior originally requested assistance from the Visual Protection and Performance Division to test the Air Soldier System, which includes a Helmet Tracker Kit (HTK), Common Helmet Mounted Display (CHMD), and the HGU-56/P Rotary Wing Helmet (RWH). (b) (4) [redacted] Details of this effort were published as two USAARL TMs (2014-09, 2014-10). This effort's total budget was funded by the Project Manager, Air Warrior in the amount of $50K.

H. The proposal "Digitization and analysis of non-contact inertial loadings related to neurological injury" digitized the Biodynamics Data Resource special collection's various media types and identified matching pairs existing between the special collection impact acceleration runs and the human research volunteers and anthropomorphic test device impact acceleration runs. In addition, the NAVAIR/USAARL Biodynamics Data Resource (BDR) incorporated WIAMan data to integrate the vast amounts of biomechanical data being generated from the WIAMan program into the existing database to facilitate and support future research. The database structure is established, and data transfer and storage procedures are instituted. Additionally, a web-based user interface is entering the beta testing phase of development. Two research biomedical engineers, a research kinesiologist, a research biomathematician, a mathematician, two computer scientists, and three research technicians were assigned to both efforts. The total budget for this expansion was funded by USAMRMC and through the Defense Health Program in the amount of $4.1M.

Survival Analysis Division

During FY14, the division's objectives were to investigate ground and aviation accidents in support of the U.S. Army Combat Readiness Center (USACRC) and the Joint Combat Assessment Team, examine Warfighter personal protective equipment, identify injury mitigation strategies, develop criteria for design improvements, analyze aviation life support equipment, and track injury patterns. The division's accomplishments are as follows.

A. A case control study to investigate the risk factors for developing spinal injuries during helicopter mishaps allowed data collection from the USACRC database in accordance with the extant memorandum of agreement (MOA). An aerospace medicine engineer, a database architect, and a biomechanical engineer were assigned to this study. This study's total budget was funded by USAMRMC in the amount of $190K.

B. The study titled "Improving vehicular accident survivability through data analysis" detailed the division's capability to analyze High Mobility Multipurpose Wheeled Vehicle (HMMWV) rollover accidents reported to the USACRC and Mine Resistant Ambush Protected (MRAP) vehicle accidents with injury reported to the Joint Staff Readiness Division Deployments and Operations Task Force. The results confirmed the safety benefit of crew restraint use in HMMWV and MRAP rollovers. An injury epidemiologist, a technical writer, a database architect, a safety officer, a mechanical engineer, and a project manager were assigned to the study. Details of the study were published in the Survivability/Vulnerability Information Analysis Center Bulletin.

C. “Integration evaluation of the advanced mission extender device max” assessed the integration issues associated with use of the advanced mission extender device max (AMXD) in-flight urine collection device in U.S. Army helicopters. The lack of a U.S. Army airworthiness certification limited the test to a ground-based integration assessment. An aerospace medicine specialist, a mechanical engineer, and two research pilots were assigned to this study. Details of the study are published as USAARL TM 2014-01 and in USAARL TR 2014-16. This study’s total budget was funded by the USAMMDA in the amount of approximately $9K.

D. “Traumatic ear injuries among U.S. personnel, 2002-2011” described the comorbidity of traumatic ear injuries with other blast-induced ocular, acoustic, facial, and brain injuries among U.S. military personnel deployed to Operation Enduring Freedom, Operation Iraqi Freedom, and Operation New Dawn. An injury epidemiologist was assigned to this analysis during FY14. The analysis did not include audiometric data or information on hearing protection used at the time of blast exposure (Department of Defense Trauma Registry maintained by the Joint Trauma System/U.S. Army Institute of Surgical Research). Details of the study were presented at the Joint Defense/Veterans Audiology Conference. The study’s total budget was funded by USAMRMC in the amount of $1.5M.

E. Two accident investigations were supported by providing to the USACRC USAARL TMs (2014-07, 2014-12) on safety and protective equipment. Collaboration with the USACRC produced an instructional video for non-rated aviation crew members to demonstrate the proper fit and wear of aviation life support equipment. Community accident data procurement and analyses support was provided to the MRAP Joint Program Office and the Aviation and Missile Research, Development, and Engineering Center Tank Automotive Research, Development, and Engineering Center.

Visual Protection and Performance Division

During FY 14, the division’s research objectives were to investigate current and anticipated medical issues related to Warfighter protection with ballistic eye protection; RTD visual biomarkers with acute mTBI/concussion; effects of cockpit displays on aviator performance in degraded visual environments; effects of “step-up,” or transition lenses on Warfighter visual performance; effects of repetitive blast waves on the visual system; effects of blast vs non-blast mTBI on the visual system; and color vision tests for potential U.S. Army implementation. The research accomplishments are as follows.

A. “The Army color vison study” assessed nine color vision tests in Warfighters with and without color vision deficits. The results from this study will be given to senior leadership recommending implementing a new Army color vision test/standard. Two research optometrists, a clinical optometrist, a research psychologist, two research technologists, and an analyst were assigned to the study. A paper is currently being drafted for publication.

B. The study titled “Assessment of an alternative flight frame” addressed issues that were reported by aviation aircrew in a published survey. USAARL researchers assessed the viability of a current Air Force flight frame for improved aircrew ophthalmic standards. Data collection is complete and a paper is being written. This study’s total budget was funded by USAMRMC in the amount of $1M.

C. The study titled “Assessments of the pupillary light reflex and eye movements for early identification of Warfighters with acute mTBI/concussion” is assessing objective visual biomarker tests in Warfighters who have suffered an acute mTBI/concussion event. Two research optometrists, a clinical optometrist, neuropsychologist, and two research technicians are assigned to the study. Data collection is ongoing and should be completed in FY15. The study’s total budget is being funded by USAMRMC in the amount of approximately $350K.

D. The study titled “Blast wave pressure dynamics at the cornea as a function of eye protection” is an ongoing study that addresses the effects of the blast overpressure (BOP) wave while wearing Ballistic Eye Protection (BEP) of various styles; spectacles and googles. The study will result in an increased knowledge on the effects of BOP on current BEP with the potential of producing better designed BEP that will increase Warfighter protection against the primary blast wave. A research psychologist, a mechanical engineer, and an applied mathematician are assigned to this study. Preliminary results from the study were presented at MHSRS, and a paper is being written. This ongoing study’s total budget was funded by USAMRMC in the amount of $1.6M.

E. “The effects of repetitive low-level blast exposure on the visual system and ocular structures” assessed the effects of repeated blast exposure on Marine Corps Breacher Cadre during their training. This longitudinal study was performed over a 2-year period and involved a research optometrist, a research psychologist, three research technicians, and an analyst. Data collection was completed, and a report is being written. This study’s total budget was funded by USAMRMC in the amount of approximately $930K.

F. The “Evaluation of field-of-view in degraded visual environments” study assessed an emerging technology, developed by Army Night Vision Laboratory’s Air Systems Division, to test its ability to mitigate the effects of blowing sand, commonly referred to as ‘brownout,’ on helicopter landing operations. This study resulted in a knowledge product on ways to mitigate the effects of degraded visual environments on the aviator while using synthetic vision technology. A research optometrist, two research technicians, and an analyst were assigned to this study. A final report is being written. This study’s total budget was funded by Defense Advanced Research Projects Agency in the amount of approximately $400K.

G. The study titled “The methodology for assessing combat eye protection strategies to preserve visual sensitivity of Warfighters during abrupt changes in lighting” assessed the effects of wearing different types of transition protection lenses (e.g., step up filters, electronic) on the effects of Warfighter performance under different light conditions. The study resulted in the understanding of the capabilities of different “transition” protective lenses for Warfighters and new methodologies that could be used to perform subsequent testing. A research optometrist and two research technicians were assigned to the study. A paper is being written. The study’s total budget was funded by USAMRMC in the amount of approximately $600K.

H. “Visual dysfunctions in Warfighters during different stages following blast and non-blast mTBI” assessed the frequency and types of visual issues seen at different recovery stages following a non-blast and blast-induced mTBI. A research optometrist, two research psychologists, a research technician, and an analyst were assigned to this study. Details of the study were published in *Military Medicine 180*(2), 178-185, and a second paper is being written. This study’s total budget was funded by USAMRMC in the amount of approximately $200K.

I. The study titled “Adaptation to a simulated central scotoma during visual search training” evaluated an idealized condition in which a normal subject was practicing an isotropic search task with an isotropic simulated central scotoma. The study was performed at the University of Alabama, Birmingham where a vision scientist and vision scientist graduate student were assigned to the study. Details of the study are published in *Vision Research*. The graduate student had an Army scholarship to attend UAB and attain his Ph.D.

Research Support Division

A. The Flight Systems Branch supported a variety of USAARL research, testing, and evaluation projects using the Laboratory’s environmental research flight simulator and UH-60 Blackhawk helicopter. The “Synergy cueing solutions for degraded visual environments (DVE)” study, conducted in the simulator, examined three flight symbology sets paired with aural and tactile cues whilst the pilot performed DVE maneuvers.

The results of this study will help technology developers better understand which technology combinations enhance pilot situational awareness, mitigate workload and stress, and improve pilot performance. During FY14, the Blackhawk helicopter also supported missions for the U.S. Army Aviation Center of Excellence, including VIP, helicopter ferries, and training missions that benefit the Fort Rucker community.

B. The Science Information Center (SIC) contributed to the quantity and quality of USAARL research knowledge products to include technical reports, technical memoranda, open literature manuscripts, verbal presentations, and poster presentations; published a monthly newsletter to inform USAARL personnel of the laboratory's noteworthy knowledge products, activities, and events; published media articles to promote the research conducted by and the unique talents of USAARL scientists and engineers; managed numerous metrics contained in the laboratory's balance score card; responded to Freedom of Information Act requests; and maintained an archive of USAARL photos and documents dating back to 1962.

1) The SIC managed 7 Cooperative Research and Development Agreements and 23 Material Transfer Agreements that were negotiated between USAARL and its collaborators, including academic, industry, and foreign government entities. The laboratory executed an Education Partnership Agreement that resulted in the donation of excess computer equipment to an area school.

2) USAARL was actively engaged in the science, technology, engineering, and math (STEM) education of students of all ages. The SIC oversaw the Oak Ridge Institute for Science and Education (ORISE) program and the Gains in the Education of Mathematics and Science (GEMS) program.

a. The laboratory mentored 28 ORISE high school and college students, post-graduates, and post-doctoral fellows.

b. The SIC coordinated and implemented the GEMS summer program for school-aged students who are mentored by college students. USAARL offered to 5th and 6th graders Neuroscience GEMS and offered to 7th and 8th graders Biochemistry GEMS. A resource teacher, a Department of Defense Education Activity Observing Teacher, 5 mentors, 4 assistant mentors, and 178 students participated in the program.

B. The Regulatory Compliance Office provided to all principal investigators, associate investigators, and key research personnel nine educational sessions along with other research educational opportunities; provided to USAARL enlisted personnel ombudsman training, which is required when using and recruiting military personnel for voluntary participation in research; and performed post-Institutional Review Board approval monitoring of the USAARL investigators' master files and their subject files.

Resource Management and Budget

Program funding for FY13/FY14 (dollars in thousands)

R&D	FY13	FY14*	FY15*
6.1 Basic Research	169	167	0
6.2 Applied Research	6,692	4,238	4,128
6.3 Advanced Technology Development	3,279	4,811	3,646
6.4 Demonstration and Validation	218	0	0

6.5 Engineering and Manufacture Development	457	380	800
Other	2,678	5,980	1,677
TOTAL	$13,493	$15,576	$10,251

Note: USAARL funding is used over a 2-year period. Additional funding was received after submission of the FY13 Annual Report.
*Estimated funding for FY14-15

Information Management
N/A

Operations
N/A

Modernizations
N/A

Logistics
N/A

Construction
N/A

Health and Environment
N/A

Section 21

Fiscal Year 2014
Annual Historical Report

U.S. Army Institute of Surgical Research

Introduction

The U.S. Army Institute of Surgical Research is one of six research laboratories within the U.S. Army Medical Research and Materiel Command of the U.S. Army Medicine Command. The Institute is the Army's lead research laboratory for improving the care of combat casualties. The mission of the Institute is to "Optimize Combat Casualty Care".

The USAISR does this through three unique missions:

A. To provide requirements driven innovations in combat casualty care to advance medical care for injured service members.

B. As the only Burn Center in the DoD provide state of the art burn, trauma and critical care to injured war fighters and DoD beneficiaries around the world.

C. Through the Joint Trauma System provide a performance improvement system dedicated to ensuring that medical care is organized according to the needs of the patient.

The three primary missions of the U.S. Army Institute of Surgical Research work synergistically to improve care for combat wounded. The Joint Trauma System evaluates the current delivery of care in the deployed combat environment ensuring opportunities to improve care are recognized and acted upon. The information generated by the Joint Trauma System provides a picture of relevant battlefield medical problems. These problems in turn generate data driven questions. The questions feed into requirements driven combat casualty care research, developing products to improve care across the entire spectrum from self- and buddy-aid through definitive care. Finally, innovations in combat casualty care research are returned to the battlefield. These innovations return either through the Joint Trauma System or through the Burn Center. This approach enables the USAISR to; keep a finger on the pulse of current combat medical problems; develop solutions to these through research; and return solutions to benefit the warfighter.

The USAISR has a long history of burn care and burn research from WWII to the present day. Recently the Institute has led innovations in combat casualty care in the wars in Iraq and Afghanistan. Among the many areas the Institute has contributed are; hemostatic dressings; tourniquets; damage control resuscitation; 1:1 blood product use; extracorporeal organ support; pre-hospital lifesaving interventions; decision support technology to ensure expert medical decisions; and burn resuscitation and burn prevention.

The Institute has grown from a 12 person staff in 1943 to more than 700 military and civilian personnel focused on “Optimizing Combat Casualty Care”.

A. Mission: Optimizing Combat Casualty Care

B. Vision: Nation's premier joint research organization that integrates safety into planning and executing registry-based and translational research providing innovative solutions for burn, trauma, and combat casualty care from the time of injury through rehabilitation.

C. Organization (See Enclosure 1, Organizational Chart)

D. Key Staff Members, Figure 1.

FIGURE 1: Key Staff Members

Position	Staff Member
Commander	Colonel (b) (6), MC, MD, PhD
Deputy Commander	Lieutenant Colonel (b) (6), USAF, MC, MD, FACS
Chief of Staff	(b) (6)
Sergeant Major	Sergeant Major (b) (6)
Director of Research	Major (b) (6), PhD (Interim)
Joint Trauma System	Colonel (b) (6), MD, FACS
Director of the Burn Center	Colonel (b) (6), MC, MD
Chief Nurse	Lieutenant Colonel (b) (6), AN, RN
Company Commander	Captain (b) (6), MS
Company First Sergeant	First Sergeant (b) (6)

Clinical Division and Burn Center

A. The United States Army Institute of Surgical Research (USAISR) Burn Center serves as the sole facility caring for combat burn casualties, beneficiaries and civilian emergencies within the Department of Defense. The Burn Center provides interdisciplinary care by a team of approximately 300 medical professionals providing cutting edge surgical services and promoting optimal recovery, restoration of function, and community reintegration of our burn survivors.

B. Areas of Focus

1) Improved Care For Combat Wounded

State-of-the-art scientific care is coupled with combat casualty care research focused on the priorities of the Institute to improve battlefield care for our combat wounded. Since 2003, the Burn Center has provided care for more than 1,200 US military burn casualties injured in support of overseas contingency operations and more than 3,800 civilian burn victims.

2) More than 1,000 of these causalities have been transported by the Institute's Burn Flight Team which has completed more than 85 overseas missions to transport critically injured patients to the Burn Center for definitive care.

3) Prevention and mitigation of severe thermal injury is another important aspect of the Burn Center's ongoing mission.

4) Improvement in Soldier Equipment and Clothing

Collaborative efforts with the Army's Program Executive Office Soldier have resulted in improvement in soldier equipment and clothing to include the recently fielded Army Combat Shirt. The Army Combat Shirt provides enhanced thermal protection for the battlefield soldier through the use of improved fire

resistance materials coupled with basic body armament to provide the optimal level of protection against fire and flame related to explosions.

5) Physical and Occupational Therapy

The Burn Centers' rehabilitation staff continues to provide physical and occupational therapy designed to maximize return to duty of injured Soldiers as well as to maximize the long term functional outcomes of those soldiers who have been most severely injured by burns.

6) Burn Rehabilitation Improvements Through Collaborative Partnerships

The rehabilitation team continues to evaluate and improve methods of therapy to improve range of motion and functional outcome and has performed studies to ensure the most effective therapies are implemented as early as possible during the recovery process. The USAISR Burn Center is a member of the American Burn Association, a civilian credentialing agency, and has partnered with many military and civilian hospitals and universities to optimize reconstruction for burn patients.

C. Burn Center Workload

1) Figure 2 provides an overview of the clinical workload type and number of patient admissions for each.

FIGURE 2: Clinical Workload for Patient Admissions

Type	Number of Admissions
Grand Total Admissions	674
Acute Admissions	539
Non-Trauma Admissions	0
Readmissions	135
Burn Intensive Care Unit (BICU)	267
Ward 4 East	407
Transfer In	17
Discharges	552
Deaths	30

2) Figure 3 shows the type of residency types, numbers of those residencies and the medical program supported.

FIGURE 3: Residency Opportunities and Burn Training Rotations

Type	Quantity	Facility and/or Program
Students	10	Uniformed Services University of Health Sciences (USUHS)
	14	University of Texas Health Science Center, San Antonio (UTHSCSA)
Interns	19	Brooke Army Medical Center (BAMC)
Residents	3	Tripler Army Medical Center (TAMC)

	4	William Beaumont Army Medical Center (WBAMC)
	20	BAMC
	8	Scott and White Memorial Hospital, Temple Texas (Scott & White)
	4	Keesler USAF Medical Center (Keesler AFMC)
	1	SAUSHEC Surgical Critical Care (SCC)
	3	Scott & White Pulmonary Critical Care Medicine
	2	UTHSCSA SCC
	1	Walter Reed National Military Medical Center (NMMC)

D. Burn Clinic:

1) The Burn Clinic is a multidisciplinary outpatient ambulatory clinic. The focus is to continue care begun in the hospital or initiate treatment to direct clinic admissions to optimize longitudinal healing, recovery and community reintegration for burn survivors. The clinic provides consultative and follow-up care to eligible outpatients. These are active military personnel from all branches of the Department of Defense (DoD), their dependents, retirees and civilian emergency patients enrolled through the Secretary of the Army Designee program. They are evaluated by physicians, PAs and nurses for their daily plans of care. Physical therapy and occupational therapy see each patient, and behavior health, with referral to social services are available to each patient as needed. A Plastic Surgeon evaluates patients for reconstructive surgery, contracture release and laser treatments when clinically indicated. Clinic personnel also participate in institutional research begun as an inpatient and review treatments and technology. The clinic provides telephonic and limited on-site consultative services to all military hospitals in and outside of CONUS, and civilian hospitals in the southwest region of Texas. Additionally the clinic performs liaison services between USAISR and all civilian third party payer systems including Medicare, Texas Workers Comp and private insurance companies. Peer to peer consultations are performed, medical record documentation and paperwork is completed to authorize treatments and facilitate billing by SAMMC. Durable Medical Equipment (DME), home health care and outpatient therapy is ordered and monitored. The Secretary of the Army Designee program and other outside programs participating in patient care, such as Operation Mend, are administered.

2) There were 3,754 patient visits, including 652 procedures during the 2014 fiscal year.

3) Training includes Clinical Nurse Transition Program for all new nurses to USAISR, Vermont Nurses In Practice (VNIP) program, Burn Symposium and the PM&R resident rotation.

4) American Burn Association poster, Evaluation of Pulse Dye Laser Therapy Treatment for Burn Scar Erythema was submitted by the head nurse.

5) Figure 4 shows the Burn Clinic Staffing broken down by positions, types of employment and number of positions staffed.

FIGURE 4: Burn Clinic Staffing

Position	Type	Staffed
Physician, Chief	Lab Demo	1
Physician Assistant	Lab Demo	1
Physician Assistant	Contract	1
Registered Nurse, Head Nurse	Lab Demo	1
Registered Nurse	Contract	1
Licensed Vocational Nurse	Lab Demo	2
Licensed Vocational Nurse	Contract	3
Receptionist	Contract	1
NCOIC	Military	1

E. Nursing Services Branch

1) The USAISR Nursing Services comprises 20 to 25 percent of the total nursing workload at BAMC based upon the Workload Management System, Nursing - Internet (WMSNi) and Defense Medical Human Resource System – Internet (DMHRSi) data.

2) The BICU has transitioned to a model consisting of RNs as the predominant nursing staff on the ward. LVNs previously assigned to the BICU are now known as the Wound Care Team. Their primary duties consist of doing wound care for patients assigned to the BICU and to 4E. Additionally, as shown in Figure 4, the Wound Care Team also consults to SAMMC. The team visits BAMC patients requiring extensive wound care.

3) The BICU takes on the additional mission of performing Post Anesthesia recovery (PACU), a task normally accomplished in a structured PACU. The Burn Center does not have dedicated staff to man a traditional PACU.

4) Figure 5 reflects the workload of the Burn Intensive Care Unit (BICU) broken down by area or type of work and the various specified quantities associated with each.

FIGURE 5: Workload – Burn Intensive Care Unit (BICU)

Area or Type or Workload	Quantity
Average Daily Census	9.24 patients
Average Nursing Care Hours per Patient Days	432.63
Required Staff	89
Officers / RNs	14 personnel
NCOs / LVNs	4 personnel
Lab Demo / RNs	21 personnel
Contract / RNs	23 personnel
Contract / LVNs	1 person
Wound Care consults to SAMMC	5 hours per month
Actual required to Staff uncaptured workload	148 FTEs
Post-anesthesia Recovery Unit (PACU Recovery)	26 patients per month
Burn Flight Team training requirements for 13 members	104 hours per month
AMEDD Personnel Education and Quality System (APEQS)	90 hours per month
Staff Duty	8 hours per month
ExtraCorporeal Membrane Oxygenation (ECMO) Therapy	91 hours per month
Continuous Renal Replacement Therapy (CRRT)	472 hours per month

5) Figure 6 shows additional BICU workload not captured in WMNSi.

FIGURE 6: BICU Workload not captured in WMNSi

Area or Type or Workload	Quantity
BICU Nursing staff turn over	25%
Wound Care consults to SAMMC	5 hours per month
Post-Anesthesia Recovery Unit (PACU Recovery)	month
Burn Flight Team training for 13 members (20 per member goal)	104 hours per month
AMEDD Personnel Education and Quality System (APEQS)	90 hours per month
Staff Duty	8 hours per month
ExtraCorporeal Membrane Oxygenation (ECMO) Therapy	130 hours per month
Continuous Renal Replacement Therapy (CRRT)	168 hours per month

6) 4 East has transitioned to a progressive care unit or Intermediate Care unit and is now able to take higher acuity patients requiring an adjustment in the Team Nursing Patient Workload. Taking into account patient acuity the day shift nursing team shall not exceed a 4 to 5 patient to one nursing team member ratio. A nursing team is defined as 1 Registered Nurse (RN), 2 Licensed Vocational Nurses (LVN's) and 0.5 Certified Nursing Assistant (CNA).

7) 4 East teaches, instructs, guides and mentors three training programs. STAR-P, Sustainment of Trauma and Resuscitation Skills, is an Air Force program that sends airmen on the floor for several days to learn wound care. We see 1 to 4 airmen at a time usually once a quarter. 4 East also works with the US Army Medical Center and School in instructing the 68C (LVN) program. Finally, Ward 4 East also supports the CNTP which sends new Army Nurse Corp Officers for orientation.

8) Figure 7 reflects the workload of ward 4 East broken down by area or type of work and the various specified quantities associated with each.

FIGURE 7: Workload 4 East

Area or Workload	Quantity
Average Daily Census	13 patients
Avg. Nursing Care Hours per Patient Days	197.75
Officers / RNs	22 personnel
NCOs / LVNs	20 personnel
Certified Nursing Assistants (CNAs)	4 personnel
Clerks	2 personnel
PACU Recovery	252 hours
APEQS	3,129 hours
ANC-directed Patient Caring Touch and Joint Commission Compliance	1,920 hours
Licensed personnel covering ward clerks w/no replacement	648 hours
Wound Care consults to SAMMC	180 hours
Military training & compliance requirements (soldier competitions, ranges, urinalysis)	2,062 hours
After hour clinic support to patients	63 hours
Support from SAMMC nursing staff	3,156 hours
Support to SAMMC nursing staff	1,500 hours
Sick time hours	3,720 hours

F. Operating Room

1) The Burn OR patient population consists of a variety of burns, infectious skin diseases and polytraumas. The OR services the southern region of Texas as part of the burn center with ABA credentials. Currently the bulk of the OR patient load is that of civilians. The OR conducts an average of 800 cases a year with 2 suites. The OR is involved with research in developing treatments pertaining to grafting and healing of wounds.

2) Figure 8 reflects the workload of the OR broken down by area or type of work and the various specified quantities associated with each.

FIGURE 8: Operating Room (OR) Statistics

Month	OR Cases	Acute Pain Management	Total
October 2013	78	1	79
November 2013	75	4	79
December 2013	72	2	74
January 2014	72	0	72
February 2014	68	2	70
March 2014	64	5	69
April 2014	62	1	63
May 2014	37	0	37
June 2014	44	4	48
July 2014	45	0	45
August 2014	47	5	52
September 2014	56	0	56
Total Cases:	720	24	744

G. Clinical Training

1) Burn Management Symposium

The Burn Management Symposium is a comprehensive and effective opportunity to meet the educational needs of the multidisciplinary burn nursing team and ancillary healthcare providers. This comprehensive two day program is an chance to enhance knowledge about assessment, management and treatment modalities for burn injured patient during their first twenty-four hours and long term treatment and expand clinical judgment of the current practice, impact of care delivery in the world of burn treatment. The Symposium provides the needed information that will immediately applicable and pertinent to all aspect of burn care for the novice or experienced healthcare provider.

2) Figure 9 lists the Burn Management Symposium statistics for FY 2014.

FIGURE 9: Burn Management Symposium Statistics

Dates	Staff Attended	Contact Hours	Total Contact Hours
7 - 8 April 2014	22	14.25	313.5

3) Vermont Nurses In Practice (VNIP) 1 Day Course

   a. (The "Train the Trainer" Course condensed from 2 days to 1 day) The goal of the proposed evidenced based project is to implement an evidenced-based Precepting Program within the U.S. Army Institute of Surgical Research (USAISR) Burn Center to reduce the incidence of turnover of staff nurses within the demanding healthcare environment. Three staff were trained on 1 August 2014.

   b. Vermont Nurses in Practice (VNIP) 2 day course The learner used their self-awareness of personality, learning, conflict management and Critical thinking styles and strengths to support and improve experiential learning for the novices that they coach, within the parameters of agency protocol, resources and program framework. Primary audience included educators and managers that establish the system and resources for competency development / assessment. Secondary audience included all direct care providers that assist with student clinical experience, orientation, or work with those who provide this assistance. Ten staff received 14.5 contact hours on 11 and 12 September for a total of 80 contact hours provided.

4) Advanced Burn Life Support (ABLS) Provider Course: Instructor Simulation Training

   The goal of the training to integration simulation into the ABLS Provider Course through contribute to, and develop criteria for, simulation education based upon established guidelines set up by official accreditation organizations. Technique taught in observation, guidance and direction of military and civilian health care professionals and other simulation participant. Instructor also evaluated the effectiveness of the simulation programs conducted at the simulation center. This course is taught by the Defense Medical Readiness Training Institute (DMRTI).

5) ABLS Instructor Course

   This course is designed for those physicians, nurses, nurse practitioners, and physician assistants who have experience in daily patient management of burn injuries. The American Burn Association maintains the records of all persons who take the ABLS Instructor Course and provides a certificate of completion as an ABLS Certified Instructor. This course is taught by DMRTI.

6) Figure 10 details the student clinical education and training preceptorships and internships provided by the USAISR Nursing staff.

FIGURE 10: Student Clinical Education and Training Preceptorship / Internship

Area	Staff Attended	Hours per Student	Total Hours
4 East	6	320 hours	2,240 hours
BICU	13	320 hours	4,200 hours
BICU ECMO	1	560 hours	560 hours
Medical Students (USUHS), PGY[1] 4	7	Varies by student	1,620 hours
Medical Students (USUHS), PGY[1] 3	17	Varies by student	4,315 hours
Med Student (Rowan University /HPSP[2]) PGY[1] 4	1	120 hours	120 hours
Critical Care Air Transport Team (CCATT)[3]	5	64 hours	320 hours
STARS-P	15	16 hours	240 hours

[1]Post Graduate Year, [2]Health Professions Scholarship Program, [3]Predeployment

7) Figure 11 lists the burn outreach training provided to various audiences during FY 2014.

FIGURE 11: Burn Outreach Training

Course	Attendees	Hours
16 Jan 2014, Burns and Inflammatory Response	162	3 hours
9 Jun 2014, Burn Lecture	103	3 hours
16 Jun 2014, Fluid and Electrolytes	104	2 hours
23 Jun 2014, Burn Lecture	97	2 hours
27 Jun 2014, Team STEPPS[1] with Burns	97	3 hours
21 Jul 2014, Burn and BFT[2] Capabilities	65	2 hours

[1]Team Strategies and Tools to Enhance Performance and Patient Safety
[2]Burn Flight Team (Specialized Medical Response Capability - SMRC)

F. Respiratory Therapy Section

1) Respiratory Therapy (RT) is staffed with nine Soldiers, four Lab Demo, and seven contract employees. Our mission is to provide world class Respiratory Therapy to DOD personnel and central Texas civilian population; perform medical research in support of the growth of burn, trauma, and critical care medicine; serve as members of the Burn Special Medical Augmentation Response Team-Burn (SMART-B).

2) RT has engaged in research dealing with new humidification modalities, cuff leak research, and extubation protocols. RT continued involvement with Spontaneous Breathing Trial Research over the past year.

3) RT has completely rewritten the standard operating procedures throughout the department to ensure that procedures match the care provided. RT has taken an active role in the new ECMO program sending 4 staff to training. RT has 3 preceptors, provided training to 20 UTHSCSA RT students and 15 Military RT students. RT has provided 2 staff to the infection control team to help prevent hospital acquired diseases.

4) The RT lab has once again earned accreditation from CAP.

5) RT has developed a system for uploading pictures taken during bronchoscopy procedures to the Wound Flow system and into Essentris. This enabled the Burn Center staff to see the progression of healing in the patient airway.

6) Training provided by RT includes:

a. Association of the United States Army (AUSA) Medical Symposium

b. Burn Outreach

c. Preceptors to 68V Respiratory Therapy Students on Burn Respiratory Therapy Procedures

d. Quarterly USAISR Burn Symposiums

e. Preceptors to Critical Care Registered Nursing Students on Mechanical Ventilation and trach care

f. Pre-deployment seminars for Physicians and Nurses

g. Burn Rotation for University of Texas San Antonio Respiratory Therapy Students

h. Pre-deployment field training on mechanical ventilation to Joint Forces Tactical Medical Training

i. Consistent Resident Rotation teaching Mechanical Ventilation

G. Rehabilitation Section

1) The Rehabilitation Section provided rehabilitation care to patients with severe burns and poly- trauma in the critical care, intermediate care, and out-patient care settings to prevent contractures, deformity and optimize functional outcomes and promote patient independence. During the year 2014, the Burn Rehabilitation Section supported 721 total admissions and performed over 22,860 in-patient treatment sessions. Comprehensive inpatient rehabilitation services were provided 365 days a year and 17 hours a day. The rehabilitation out-patient services produced 4,236 visits. These services include the outpatient gym and burn clinic. In addition to the provision of care, the Rehabilitation Section developed, then conducted, clinical training programs for all levels of personnel; oriented military and civilian therapists, students, and other allied health personnel from various national and international areas; participated in, formulated and conducted research protocols related to rehabilitation; and assisted in clinical research of other health care professionals assigned to the burn center.

2) The Rehabilitation Section supported the U.S. Army Medical Specialist Corps' Doctor of Science in Occupational Therapy program educating six students on the "Management of Burns and Multiple Trauma." This series was the 5th year to support this program with lectures/labs and residency in the Burn Center.

3) The Rehabilitation Section provided clinical affiliation training to over 110 students in 2014. Clinical affiliations ranged from several weeks long to single day experiences. The following is a list of institutions the Rehabilitation section supported with clinical affiliations during Fiscal Year 2014:

a. US Army-Baylor University Doctorate of Physical Therapy Program

b. US Army-Baylor Doctorate of Occupational Therapy Program

c. US Army Physical Therapy Technician (303-N9) Program (METC)

d. US Army Occupational Therapy Technician (303-N3) Program (METC)

e. Department of Nursing, USAISR & Brooke Army Medical Center

f. University of TX San Antonio Masters of Occupational & Physical Therapy Programs

g. University of Maryland, Baltimore, MD

4) The Rehabilitation Section provided educational opportunities to other departments within the U.S. Burn Center by providing over 25 nurses to shadow therapists to promote cross training/ understanding roles and goals of different disciplines. The rehabilitation staff provided lectures in support of three Burn Symposiums and three lectures in support of the nursing preceptor program. Burn Rehabilitation staff supported the US Army Medical Department (AMEDD) Center and School with over twelve lectures to the Physical Therapy Program, Physical Therapy Assistant program (AMEDD & St. Phillips), the American Burn Association (two presentations, one poster) and the Southern Medical Association (one poster). Burn Rehabilitation staff provided seven occupational therapy platform presentations including American Occupational Therapy Association (One keynote, two presentations), Mid-Michigan Brain Injury Symposium (One keynote presentation), and Saginaw Valley State University Annual State Conference (One keynote presentation). The Rehabilitation Section provided lectures on occupational therapy in the military via video teleconference to nine Occupational Therapy (OT) schools.

5) The Rehabilitation Section engaged with the following protocols during FY14:

a. Burn patient acuity and rehabilitation treatment time related to patient outcomes.

b. Status: Data Analysis (Three abstracts presented at 2014 ABA conference) Lead: (b) (6)

c. Heterotopic Ossification: The ISR Experience Status: Manuscript Preparation Lead: (b) (6)

d. The Efficacy of Spray Silicone in the Alteration of Physical Burn Scar Characteristics; A Double Blinded Randomized Controlled Trial Status: Preparing for enrollment. Lead: (b) (6)

e. Multiple ascending sequential, placebo-controlled, double-blind study to assess safety, tolerability, and efficacy of BVS857 in severe burn patients PI: (b) (6)

6) Rehabilitation Section grants during FY 2014:

a. Burn patient acuity and rehabilitation treatment time related to patient outcomes. Status: Approved, Medical Research and Materiel Command (MRMC) Lead: (b) (6)

b. A Goniometry Paradigm Shift to Measure Burn Scar Contracture in Burn Patients. Status: Approved, Telemedicine and Advanced Technology Research Center (TATRC) Lead: (b) (6)

c. SBIR: Modifiable Electronic Body Diagram Template to Accommodate Varying Body Shapes. Lead: (b) (6) and (b) (6)

d. Early Exercise in the Burn Intensive Care Unit Decreases Hospital Stay, Improves Mental Health and Physical Performance. Lead: (b) (6)

7) Rehabilitation Section Process Improvement

a. Development of a Burn Rehabilitation Staffing, Workload and Productivity Model. P.I. CPT (b) (6)

b. Proper Accountability for USAISR Burn Rehabilitation Workload and Productivity Reporting. P.I. CPT (b) (6)

8) Rehabilitation Section Abstracts, National Presentations & other Publications

a. Richard R, Dewey WS, Anyan WR, Kemp-Offenberg J, Miller K, et al. Increased burn rehabilitation treatment time improves patient outcomes. J Burn Care Res 2014;35:S100.

b. Richard R, Dewey WS, Anyan WR, Kemp-Offenberg J, Miller K, et al. Cutaneous functional units relate better than total body surface area to burn patient outcomes. J Burn Care Res 2014:35:S77.

c. Richard R, Jones J, Parshley P. Hierarchical decomposition of burn body diagram based on cutaneous functional units and it utility. J Burn Care Res 2014:35:S195.

d. Dewey WS. Rehabilitation Options after Experiencing a Severe Hand Burn. Online journal for Phoenix Society: www.phoenix -society.org/downloads/resources/rehabilitation _after_severe_hand_burn_20130610_140702_1.pdf

e. Richard R. Burn therapist contributions to the American Burn Association and the Journal of Burn Care and Research: A 45th Anniversary review. J Burn Care Res 2014:35:465-469.

f. Richard R, Jones J, Parshley P. Hierarchical decomposition of burn body diagram based on cutaneous functional units and its utility. J Burn Care Res (accepted for publication).

g. Korp K, Richard R, Hawkins D. Refining the idiom “Functional Range of Motion” related to burn recovery. J Burn Care Res 2014 (accepted for publication).

H. Special Medical Response Capability (SMRC) -Burn Flight Team Missions

1) 28 and 29 June 2014, one BICU staff member was deployed for a USAF C-130 aircraft flight to transport one burn casualty from El Salvador to the USAISR.

2) 12 through 14 September 2014, one BICU staff member was deployed for a USAF C17 aircraft flight to transport one purpura fulminans patient from Tripler Army Medical Center to USAISR.

Joint Trauma System

The mission of the Joint Trauma System (JTS) is to improve trauma care delivery and patient outcomes across the continuum of care utilizing continuous performance improvement (PI) and evidence-based medicine driven by the concurrent collection and analysis of data maintained in the Joint Theater Trauma Registry (JTTR), renamed the Department of Defense Trauma Registry (DoDTR) in 2011.

A. JTS Divisions

The DoDTR is the data repository for DoD trauma-related injuries. The goal of this registry is to document, in electronic format, information about the demographics, injury-producing incident, diagnosis and treatment, and outcome of injuries sustained by US/Non-US military and US/Non-US civilian personnel in wartime and peacetime from the point of wounding to final disposition.

B. DoD Trauma Registry

1) Data Acquisition: Mines the medical records to abstract, code, and enters critical trauma data into the DoDTR database for use in support of the JTS mission.

2) Data Analysis: Develops queries and provides data from the DoDTR in response to requests for information. Conducts classified and non-classified data analysis.

3) Data Automation: Supports the information technology for the DoDTR and data-related special projects. Designs and implements special-project database applications, related architecture, and documentation. Handles documentation needs for JTS to maintain Program compliance with the Defense Health Agency.

C. Trauma Care Delivery

Maintains a database of operational and physiologic parameters related to delivery of en route care. Primary project has been to evaluate the validity of the "Golden Hour" standard for movement of casualties from point of injury to the first surgical capability. Future analysis will evaluate outcomes related to types of providers and interventions performed en route. Additionally, this division has established a Pre Hospital Trauma Registry (PHTR) to collect point of wounding information. A military en route care registry (MERCuRY) is also under way and this registry will allow capture for all ground, air and ship transport, so care in motion is captured.

D. Performance Improvement

1) Performance Improvement: Coordinates PI activities across the spectrum of trauma care. Participates in the development, maintenance, and adherence to Clinical Practice Guidelines (CPGs). Develops PI course content and training, and resolves trauma system patient care issues.

2) Education: Develops and conducts pre-deployment training of the CENTCOM Joint Theater Trauma System (JTTS) teams, DoDTR user training, and JTS staff training. Develops educational products for COCOM trauma system development. Secures continuing education credits and coordinates performance improvement and other trauma related courses.

E. Staffing

1) COL (b) (6) retired from the JTS in the spring of 2014 so there was a reduction of one military person in the organization.

2) LTC (b) (6) replaced COL (b) (6) as the Chief of the Trauma Care and Delivery Division.

3) The JTS lost several key staff members in 2014 who were Government Service (GS) and the leads in their task areas. Multiple contract staff also left and when inquiring into the reason, all were due to better salaries and better professional development.

F. In Tactical Combat Casualty Care (TCCC):

1) (b) (6) organized and conducted 2 Committee on TCCC meetings:

   a. 4 through 5 February 2014 in Tampa, Florida.

   b. 5 through 6 August 2014 in Atlanta, Georgia.

2) (b) (6) served as the Chief Editor for the Military Version of the Eighth Edition of the Prehospital Trauma Life Support Textbook and participated in the second meeting Hartford Consensus Working Group to help transition military advances in trauma care to the victims of Active Shooter and terrorist-related mass casualties in the civilian sector.

3) (b) (6) was a major contributor to the Defense Health Board report on the Trauma Care Lessons Learned from the Iraq and Afghanistan conflicts and oversaw the update of the TCCC combat medic and all combatants training curricula. He co-authored the Wilderness Medical Society Practice Guidelines on the management of eye emergencies in austere environments.

4) Three new changes to the TCCC Guidelines were made that included:

   a. Hemostatic dressings

   b. Fluid resuscitation

   c. Optimizing tourniquet use

G. The JTS Data Acquisition Branch (DAB) coordinated the absorption of the work from the redeploying CENTCOM JTTS Team beginning March 2014, began working on a new ROLE 2 database and continued training on ICD-10 to the JTS staff. The DAB also provided data evaluation and data mapping for the ROLE 2 database, data evaluation on the Prehospital Trauma Registry (PHTR), diagnosis and scoring for the TACEVAC project and multiple data cleaning projects. The DAB also provides oversight to all the specialty modules such as Infectious Disease, orthopedics, acoustics, etc.

H. The Acoustics Module, a specialty clinical module of the (DoDTR), was designed to capture all granular data on patients with any type of hearing injury or loss, to include audiograms, specific locations of bone fractures, etc. The contract was awarded and staff reported for work on 21 July 2014.

I. The Trauma Continuum of Care Conference had 2,081 attendees and provided 768 participants Continuing Medical Education (CME) credits at 217 sites. An additional performance improvement conference for mortality cases was developed in conjunction with Armed Forces Medical Examiner with 71 cases having been presented.

J. Forty-one clinical practice guidelines (CPGs) have been monitored using 129 core measures. New pre-hospital audit filters have been identified and developed.

K. In terms of information technology, the team continues to work with the AMEDD Operational Architecture Team to create drawings reflecting the DoDTR web version, complete and submit the Business Processes Reengineering questionnaire to MEDCOM, DIACAP process and POA&M documentation. Also, the team completed and coordinated approval of the Privacy Impact Assessment (PIA) and FISMA/PIA Compliance Assertion Checklist, and began planning/testing of servers for migration to virtual servers. All reporting tools were presented for action, including DHP-SIRT, Medical Systems Inventory Repository (MSIR), Defense Business Certification (DBC), Military Health Systems (MHS), architecture requirements, and all certifications. The team achieved PKE compliance for the DoDTR. Two new clinical registries, Acoustics and Infectious Disease, were incorporated into the DoDTR and the owners are actively adding data. The PHTR is successfully operating in the proof of concept phase.

L. The JTS Data Analysis Branch received approximately 131 requests for information/data. 42% of the requests were related to research projects and 12% were related to performance improvement projects either internally or theater approved PI. JTAPIC, Operational/Clinical and media requests were also supported. Of specific interest were amputation and genitourinary injuries. Three contract positions were converted to government civilian positions. An improved MOU process with MRMC with development of

template cut approval time in half. The JTS, in specific relationship to the Data Analysis Branch, also conducted an open review of all research projects and their methodology. The research component of the JTS with reorganized with Jean Orman, PhD, so that all the PhD level work was planned, reviewed and coordinated with her oversight.

M. Multiple publications were accepted:

1) Bennett, B., Littlejohn, L., Kheirabadi, B., et al, Management of external hemorrhage in Tactical Combat Casualty Care: chitosan-based hemostatic gauze dressings-TCCC Guidelines-Change 13-05. J Spec Oper Med 2014;14:40-57

2) Butler, F., Holcomb, J., Schreiber, M., et al, Fluid Resuscitation for hemorrhagic shock in Tactical Combat Casualty Care: TCCC Guidelines Change14-01- 2 June 2014. J Spec Oper Med 2014;14:13-38

3) Butler, F.K., Beadling, C., Medical Support of Special Operations. In Conflict and Catastrophe Medicine; Ryan, J.M., Buma, A., Beadling, C.W., Mozunder, A., Nott, D.M., eds; Springer-Verlag; London; 2014

4) Butler, F.K., Kotwal, R.S., Buckenmaier, C.C. III, Edgar, E.P., O'Connor, K.C., Montgomery, H.R., Shackelford, S.A., Gandy, J.V. III, Wedmore, I.S., Timby, J.W., Gross, K.R., Bailey, J.A., A Triple-Option Analgesia Plan for Tactical Combat Casualty Care. J Spec Operations Med 2014;14:13-25

5) Butler, F.K., Kotwal, R.S., Buckenmaier, C.C., Edgar, E.P., O'Connor, K.C., Montgomery, H.R., Shackelford, S.A., Gandy, J.V., Wedmore, I.S., Timby, J.W., Gross, K.R., Bailey, J.A., A Triple-Option Analgesia Plan for Tactical Combat Casualty Care. TCCC Guidelines-Proposed Change 13-04. Journal of Special Operations Medicine. 2014;14;1. pp13-25

6) Davis, J., Satahoo, S., Butler, F., et al, An analysis of prehospital deaths: who can we save? J Trauma Acute Care Surg 2014;77:213-218

7) Deuster, P.A., Lindsey, A.T., Butler, F.K., The 10 Commandments of Nutrition: 2014.J Spec Oper Med 2014 Fall;14(3):80-9

8) Hooper, T., Nadler, R., Badloe, J., Butler, F., Glassberg, E., Implementation and Execution of Military Forward Resuscitation Programs. Shock 2013; Shock. 2014 May;41 Suppl 1:102-3

9) Jenkins, D.H., Rappold, J.F., Badloe, J.F., Berséus, O., Blackbourne, L., Brohi, K.H., Butler, F.K., Cap, A.P., Cohen, M.J., Davenport, R., DePasquale, M., Doughty, H., Glassberg, E., Hervig, T., Hooper, T.J., Kozar, R., Maegele, M., Moore, E.E., Murdock, A., Ness, P.M., Pati, S., Rasmussen, T., Sailliol, A., Schreiber, M.A., Sunde, G.A., van de Watering, L.M.G., Ward, K.R., Weiskopf, R.B., White, N.J. Strandenes, G., Spinella, P.C., THOR Position Paper on Remote Damage Control Resuscitation: Definitions, Current Practice and Knowledge Gaps. Shock. 2014 May;41 Suppl 1:3-12

10) Kotwal, R.S., Butler, F.K., Gross, K.R., Kheirabadi, B.S., Baer, D.G., Dubick, M.A., Rasmussen, T.E., Weber, M.A., Management of Junctional Hemorrhage in Tactical Combat Casualty Care. J Spec Oper Med. 2014 Fall;14(3):40-57

11) Mazzoli, R.A., Gross, K.R., Butler, F.K., The Use of Rigid Eye Shields (Fox Shields) at the Point of Injury for Ocular Trauma in Afghanistan. Journal of Trauma and Acute Care Surgery, 2014:77; supplement 2. ppS156-S162

12) Powell-Dunford, N., Quesada, J.F., Malsby, R.F., Gerhardt, R.T., Gross, K.R., Shackelford, S.A., Risk Management in Air Ambulance Blood ProductAdministration. Aviation, Space and Environmental Medicine.2014;85:1130-1135

13) Remick, K.N., Wong, E., Chep, C.C., Morton, R.T., Monsour, A., Fisher, D., Oh, J.S., Wilson, R., Malone, D.L., Branas, C., Elster, E., Gross, K.R., Kushner, A.L., Development of a Novel Global Trauma System Evaluation Took and Initial Results of Implementation in the Republic of South Sudan. Injury. 2014;45: 1731-1735

14) Sauer, S.W., Robinson, J.B., Smith, M.P., Gross, K.R., Kotwal, R.S., Mabry, R.L., Butler, F.K., Stockinger, Z.T., Bailey, J.A., Saving Lives on the Battlefield (Part II) – One Year Later: A Joint Theater Trauma System & Joint Trauma System Review of Pre-Hospital Trauma Care In Combined Joint Operating Area – Afghanistan (CJOA-A); USCENTCOM/JTS Report; May 2014

15) Shackelford, S.A., Butler, F.K., Kragh, J.F., Stevens, R.A., Seery, J.M., Parsons, D.L., Montgomery, H.R., Kotwal, R.S., Mabry, R.L., Bailey, J.A., Optimizing the use of Limb Tourniquets in Tactical Combat Casualty Care: TCCC Guidelines Change 14-02; accepted for publication in Journal of Special Operations Medicine

N. The JTS was awarded three honors in 2014 comprised of the 4th Quarter and Annual Wolf Pack Awards presented by the Office of The Surgeon General (OTSG), and the Force Health Protection Award presented by Association of Military Surgeons of the United States (AMSUS) during the annual AMSUS conference in November 2013.

Research

A. Epidemiology and Biostatistics

Chief: (b) (6), ScD, MPH

1) Overview:

a. The USAISR Epidemiology and Biostatistics Office (EPI/BIOSTATS) historically provides essential support for ISR research. This support includes assisting investigators with research design, protocol writing, data analysis and interpretation, and presentation/manuscript preparation. During the past year, the capabilities of the EPI/BIOSTATS office have increased significantly. With guidance and support from (b) (6), former Director of Research (DOR), and MAJ (P) (b) (6) current Acting DOR, (b) (6), senior epidemiologist and Chief, has assembled a team of epidemiologist/ biostatisticians. These highly skilled research professionals are uniquely trained in both *Epidemiology*, the branch of medicine that studies causes, risk factors, and treatment of disease and injury, and in *Biostatistics*, the field of statistics specific to biological and medical data. With the addition of these staff, the EPI/BIOSTATS Office is now focused exclusively on clinical and epidemiologic research (statistical support for preclinical research is now provided separately by (b) (6) In addition, a halftime data management specialist from UTHSCSA is leading efforts to modernize ISR data collection efforts. Also this year, the EPI/BIOSTATS Office began providing support to the Joint Trauma System (JTS); thus staff time is shared between ISR and JTS. With the exception of (b) (6) and one contractor, the team is comprised of ORISE postdoctoral and half-time graduate student fellows. An important goal for the coming year will be to stabilize the team by hiring select staff into more permanent positions.

b. The capabilities of the team and their value to the ISR, MRMC and the Department of Defense have been evidenced by a) Demonstrated ability to write or assist in preparing successful grant proposals; increased capacity to assist ISR investigators and demonstrated ability to independently conduct epidemiologic studies from design through manuscript preparation; c) quality of the resulting publications, with two manuscripts prepared with EPI/BIOSTATS team statistical support having been reviewed or currently under review by *NEJM* and one first-authored publication under review by *JAMA*.

2) Key capability improvements

a. Advanced research methods:

i. Enhanced research design: Increased focus on clear conceptualization of the study design and application of appropriate epidemiologic methods; application of longitudinal (cohort) study

designs to research on genitourinary injury outcomes and the effects of combat-related injury on the long term risk of chronic disease.

ii. Complex biostatistical analysis: Application of Cox proportional hazard modeling for survival analysis; mixed and marginal structural models using generalized estimating equations. Not previously applied to research at the ISR, survival analysis is the preferred method for assessing risk factors for mortality, an important focus of ISR research. It provides stronger evidence for associations where time-to-event data, also referred to as time dependent variables, for example time from injury to death, are available.

iii. Advanced statistical programming: Use of iterative processing, macros and arrays for time-dependent data and coding of complicated variables such as TBI severity based on ICD-9-CM Barell Matrix code implementation; Acute Kidney Injury (AKI) diagnosis based on full hospital creatinine values for each patient; iterative processing for simulating the number of deaths under different evacuation time scenarios (used for evaluating the impact of the Golden Hour policy).

iv. The complex biostatistical analyses described above could not be appropriately implemented without this advanced programming capability.

v. Efficient data collection and management systems: Introduction of the NIH-recommended research electronic data capture system (REDcap).

b. Expanded clinical and epidemiologic research support

i. Joint Trauma System: As mentioned above, the EPI/BIOSTATS team now supports the Joint Trauma system as well as the USAISR.

ii. TCCC Task Area: The EPI/BIOSTATS team is now actively involved in advising on the methods and analyzing data for multiple studies led by the TCCC Task Area and/or (b) (6) . In the past, support for this research was provided by statisticians outside of the ISR.

iii. Burn rehabilitation: A halftime ORISE fellow will focus specifically on advancing the research design and analytic methods applied to research to evaluate burn rehabilitation techniques.

c. Response to MRMC and ISR leadership requests:

i. Comprehensive DODTR report: (requested by COL (b) (6)) With assistance from COL (b) (6) prepared a detailed outline. She later prepared and submitted a DODTR data request, and prepared and submitted a protocol. DODTR is currently pulling the data for the report.

ii. Genitourinary injury in OEF/OIF: (Initiated by MG Caravalho, currently directed by LtCol (b) (6)). (b) (6) prepared a BAMC IRB-approved protocol, recruited collaborators from UTHSCSA and worked with them and BAMC urologists to prepare a $3.4 million grant proposal for the Trauma Outcomes and Urogenital Health Project (TOUGH), the proposal, submitted to the MRMC BAA, received a score of 1.8 and funding is pending. Through (b) (6) participation in joint meetings both in the UK and at the ISR, UK GU injury researchers are now collaborators on the TOUGH project. (b) (6) also collaborated with colleagues at the South Texas VA to analyze data regarding neuropscychiatric and other adverse outcomes of GU injury in OEF/OIF Veterans receiving VA care. These data were presented at the 2014 MHSRS conference. Following MHSRS, at the request of (b) (6) of USAMMDA, (b) (6) performed detailed analyses of the epidemiology of severe GU injury using DODTR data; the results are being used to help guide decisions regarding proposed penile transplantation efforts. (b) (6) and MAJ (b) (6) , the BAMC urologist involved in research on this topic, were invited to present results from the DODTR and VA studies at a special convening sponsored by the Bob Woodruff Foundation.

iii. Economic impact of combat-related injury: (Requested by COL (b) (6)) MAJ (b) (6) , who conceptualized this project, received assistance from (b) (6) in identifying a civilian injury economist to consult on the development of a grant proposal to support this work. The proposal, submitted to the MRMC BAA, is waiting funding.

iv. Polytrauma and TBI: (Requested by COL (b) (6) and (b) (6) (b) (6) and (b) (6) were asked to a) provide data on the prevalence of polytrauma among OEF/OIF injured service members to (b) (6) of WRAIR; to meet this request, results of (b) (6) publication on TBI in OEF/OIF were sent to (b) (6) ; b) Prepare a protocol to further investigate polytrauma among OEF/OIF injured SMs, using DODTR data. A draft concept for such a study is in preparation and will be sent to COL (b) (6) for input before the final protocol is prepared. (b) (6) will then submit the protocol and data request and (b) (6) will analyze the data for this project.

v. NATO meeting presentation: (Requested by (b) (6)). (b) (6) will attend the NATO meeting in Warsaw, Poland in April 2015 and will present on GU injury and extremity trauma. (b) (6) is analyzing the data for this presentation.

vi. Response to departure of (b) (6) : (Requested by JTS and ISR leadership): (b) (6) has assisted by rewriting the job description for JTS statistical support and with recruitment, hiring, initial training and ongoing mentoring. With her assistance, two highly qualified JTS epidemiologist/biostatisticians (b) (6)) have been hired and are now housed in the EPI/BIOSTATS area. (b) (6) played a key role in reviewing all of the manuscripts published as a PhD by (b) (6) . He also reanalyzed the JTS data on TXA and survival (manuscript is currently under review).

d. Successful grant proposals

i. DHP 6.7: Burn Outcomes Database Project (PI: (b) (6))

ii. MRMC BAA: Trauma Outcomes and Urogenital Health (TOUGH Project). (PI: (b) (6) , PhD, University of California, Davis [formerly UTHSCSA]; Co -Investigator: (b) (6) , ScD

- Requested funding: $3.4 million (award pending)

iii. BAA Economic Impact (PI: (b) (6) , PhD, Pacific Institute for Research and Evaluation). Co-Investigators: (b) (6) , PhD; (b) (6) , ScD

- Requested funding: $3.5 million (award pending)

3) Accepted Abstracts

a. (b) (6) En Route Blood Transfusion from Point of Injury in a Theater of Operations Positively Impacts Shock Index. Poster presentation at Military Health System Research Symposium, Ft. Lauderdale, FL. August 2014.

b. (b) (6) Evidence of an association between ADHD medications and diminished bone health in children and adolescents. Poster presentation at San Antonio Postdoctoral Research Forum, University of Texas Health Science Center, San Antonio, TX. September 2014.

c. (b) (6) , et al. Multidisciplinary Treatment of Patients with Persistent Post Concussive Complaints Significantly Reduces Symptom Burden. Poster presented at the 2nd Annual San Antonio Post-Doctoral Forum, San Antonio, TX, September 2014

d. (b) (6) , et al. Neuropsychiatric Outcomes of Genitourinary Injury in OEF/OIF Veterans. Oral presentation at the Military Health System Research Symposium, Ft. Lauderdale, FL. August 2014.

e. (b) (6) Genitourinary Injuries in OEF/OIF: What do we know, and where do we go? Presented at the Bob Woodruff Foundation Intimacy After Injury Convening, Washington, DC, December 2014.

4) Courses Taught

a. (b) (6) Geographic Information Systems for Population Science. DEM7093. UTSA. Summer 2014.

5) Lectures

a. (b) (6) Statistics in Clinical Science. WHASC Clinical Investigation Research Training (CIRT) meeting. September 2014.

6) Board and Committee Membership

a. (b) (6)

i) Editorial Board Member, *Journal of Head Trauma Rehabilitation*

ii) Assistant Editor, *Injury Epidemiology*

iii) Member, JPC-6 Neurotrauma Steering Committee

7) Faculty Appointments

a. (b) (6)

i) Adjunct Professor, Department of Epidemiology and Biostatistics, UT Health Science Center at San Antonio

ii) Adjunct Professor, University of Texas School of Public Health at San Antonio

8) Peer-Reviewed Journal Reviewer:

a. (b) (6)

i) Journal of Women's Health Care

ii) Journal of Occupational and Environmental Medicine

iii) Journal of Biosafety and Health Education

b. (b) (6)

i) Aging: Clinical and Experimental Research

ii) American Journal of Epidemiology

iii) Journal of Head Trauma Rehabilitation

B. Tactical Combat Casualty Care Research

Task Area Manager: (b) (6), PhD

1) CCCRP IPR Review of Task Area 2

a. Received high priority for continued core funding

2) Published manuscripts in peer-reviewed scientific and clinical literature:

a. In two separate 2014 Journal of Applied Physiology articles, TCCCR validated lower body negative pressure (LBNP) as an experimental human model of hemorrhage and demonstrated the importance of compensatory reserve index (CRI) in the estimation of individual-specific progression to cardiovascular instability using arterial waveforms.

3) (b) (4)

a. (b) (4) [redacted]

b. (b) (4) [redacted]

4) Strategic: Compensatory Reserve Index (CRI) research and development recognized as an Army medical requirement in a Requirements Adjudication Team (RAT) memorandum released by the AMEDDC&S Directorate of Combat and Doctrine Development (DCDD) for early triage decision support.

5) Personnel: (b) (6) [redacted] Ph.D., senior research physiologist and TCCCR Task Area manager at the U.S. Army Institute of Surgical Research (USAISR)

   a. Received the 2013 Outstanding Distinguished Alumnus Award from the College of Biological Sciences at the University of California at Davis

   b. Received the 2013 EMS Today Top Ten Innovator Award for development of diagnostic (Compensatory Reserve Index) and therapeutic (Intrathoracic Pressure Regulation Therapy) technologies for use in patients with hemorrhage

   c. Received the 2014 Honor Award from the Texas Regional Chapter of the American College of Sports Medicine for "outstanding contributions to exercise science and sports medicine in the state of Texas"

   d. Received the 2014 US Army Institute of Surgical Research Commander's Award

   e. Was invited as a keynote speaker at the following venues:

      i) Hennepin County Medical Center, Minneapolis, MN

      ii) Korea Centers for Disease Control Trauma Conference, Seoul, Korea

      iii) Department of Emergency Medicine, Seoul National University Hospital, Seoul, Korea

      iv) Department of Engineering, Worcester Polytechnic Institute, Worcester, MA

      v) American Heart Association Resuscitation Science Symposium, Dallas, TX

      vi) Raven Lecture, Texas Chapter of the American College of Sports Medicine, Fort Worth, TX

      vii) Journal of EMS International Webinar, US Army Institute of Surgical Research

      viii) National Park Service Search & Rescue Medical Expert Panel Working Group Meeting, Tucson, AZ

      ix) Allina Hot Topic EMS Pulse Check Conference, St. Paul, MN

6) Publications:

   a. Convertino, V.A., G.Z. Grudic, J. Mulligan, S. Moulton. Estimation of individual-specific progression to cardiovascular instability using arterial waveforms. *J. Appl. Physiol*. 115:1196-1202, 2013.

   b. Moulton, S.L., J. Mulligan, Grudic, G.Z., Convertino, V.A. Running on empty? The compensatory reserve index. *J. Trauma Acute Care Surg*. 75:1053-1059, 2013.

   c. Hinojosa-Laborde, C., Shade, R.E., Muniz, G.W., Bauer, C., Goei, K.A., Pidcoke, H.F., Chung, K.K., Cap, A.P., Convertino, V.A. Validation of lower body negative pressure as an experimental model of hemorrhage. *J. Appl. Physiol*. 116:406-415, 2014.

   d. Rickards, C.A., Vyas, N., Hurst, G.M., Barrera, C.R., Ward, K.R., Ryan, K.L., Convertino, V.A. Bleeding or active? Validation of a machine-learning algorithm for determination of blood volume status: application to remote triage. *J Appl. Physiol.* 116:486-494, 2014.

e. Carter, R. III, Hinojosa-Laborde, C., Convertino, V.A. Heart rate variability in patients being treated for dengue viral infection: New insights from mathematical correction of heart rate. *Front. Clin. Trans. Physiol.* 5(Art. 46):1-4, 2014.

f. Convertino, V.A. Neurohumoral mechanisms associated with orthostasis: reaffirmation of the significant contribution of the heart rate response. *Front. Integrat. Physiol.* 5(Art. 236):1-8, 2014.

g. Hinojosa-Laborde, C., Ryan, K.L., Rickards, C.A., Convertino, V.A. Resting sympathetic baroreflex sensitivity in subjects with low tolerance and high tolerance to orthostatsis induced by lower body negative pressure. *Front. Integrat. Physiol.* 5(Art. 241):1-6, 2014.

h. Nadler, R., Convertino, V.A., Gendler, S., Lending, G., Lipsky, A.M., Cardin, S., Lowenthal, A., Glassberg, E. The value of non-invasive measurement of the compensatory reserve index in monitoring and triage of patients experiencing minimal blood loss. *Shock* 42:93-98, 2014.

i. Johnson, B.D., van Helmond, N., Curry, T.B., Convertino, V.A., Joyner, M.J. Reductions in central venous pressure by lower body negative pressure or blood loss elicit similar hemodynamic responses. *J. Appl. Physiol*. 117:131-141, 2014. 8.

j. Wampler, D., Convertino, V.A., Weeks, S., Hernandez, M., Larrumbide, J., Manifold, C., Lurie, K.G. Use of an impedance threshold device in spontaneously-breathing patients with hypotension secondary to trauma: an observational cohort feasibility study. *J. Trauma Acute Care Surg*. 77:S140-S145, 2014.

k. Schlader, Z.J., Rivas, E., Soller, B.R., Convertino, V.A., Crandall, C.G. Tissue oxygen saturation during hyperthermic progressive central hypovolemia. *Am. J. Physiol*. 307:R731-736, 2014.

C. Extremity Trauma and Regenerative Medicine

Task Area Manager: (b) (6) , PhD

1) **Accomplishments**

a. Notable Research and Development Accomplishments: In an ongoing series of rodent studies aimed at understanding and treating volumetric muscle loss (VML) we have discovered that improvements in muscle function can be made by surgically implanting either an FDA approved biological scaffold (b) (4) or autologous minced muscle graft. We have partnered with (b) (4) to further improve their product for this application. Work with autologous muscle graft to explore dilution with collagen with the goal of reducing donor site morbidity is ongoing. There was a proof of concept study performed in a large animal VML model which indicated that minced muscle graft was effective in larger injuries in a non-rodent model.

b. Through continued collaboration with Vanderbilt University ((b) (6) , Chemical and Biomolecular Engineering), current research includes the development of a novel injectable scaffolding system for the delivery of stem cells for use in bone regeneration. We have investigated the incorporation of bone marrow mesenchymal stem cells (BMSCs) into an injectable, settable polyurethane scaffold. Research has included: 1) optimization of cell viability during polyurethane curing (setting) from injectable to solid scaffold; 2) initial investigation of cell attachment to scaffold during maturation; 3) initial studies of osteogenic differentiation of cells within scaffold for future use in bone regeneration applications.

c. With external grant funding, a laboratory and clinical research team was established at the USAISR which enrolled over 100 subjects across two prospective human clinical research protocols for full pharmacokinetic sampling of approximately 15 different antimicrobials. The objective is to determine the adequacy of current antimicrobial dosing strategies in burn, trauma and other critically ill patients, and explore the penetration of antimicrobials across wounds by sampling wound effluent. These efforts have resulted in collection of evidence supporting a role for Augmented Renal Clearance compromising the efficacy of piperacillin-tazobactam therapy in

Trauma and Surgical ICU patients. This has illustrated the need for real-time antibiotic monitoring with a point-of-care device in the ICU, a technology which does not currently exist but could be encouraged through future SBIR funding. In burn patients treated with high-volume Continuous Venovenous Hemofiltration (CVVH), we provided evidence that current dosing with imipenem (500mg q6h) appears to be adequate despite filtration losses. Colistin was sampled in two patients receiving CVVH, which has been rarely reported in the literature. Additional unpublished observations include: (1) absence of antifungal drug levels (Amphotericin B) in the wound effluent of blast-injured combat casualties with invasive fungal infection (abstract submitted to MHSRS 2014), (2) potentially subtherapeutic doxycycline levels in wound effluent associated with completion of post-deployment malaria chemoprophylaxis which could potentially promote the development of resistance, (3) correlation of measured vancomycin AUC to trough values in 17 patients to examine the validity of current trough-based national dosing guidelines. In addition, basic science work has uncovered a new method using FTIR spectroscopy to determine plasma concentrations of colistin, a drug which is notoriously difficult to determine by current HPLC methods.

d. The standard of care for diaphyseal long bone fractures in adults is implantation of an intramedullary nail (IM nail). The IM nail functions to stabilize the fracture with the appropriate length, rotation and alignment and acts as a load-bearing device while the bone heals. The introduction of biomaterials, to include metallic implants, into the body is known to promote the onset of infection. Infection around the implant can be catastrophic, resulting in implant failure, subsequent surgeries, and sepsis. Treatment for implant related infections include removal of the infected implant, debridement and systemic antibiotic therapy. These infections could have originated directing, either at the time of injury or during surgery, or from a hematogenous source, such as through an abscess in the gums. A model has been developed to investigate osteomyelitis that is facilitated by the presence of an IM nail. This model will allow for further research involving multiple treatment mechanisms.

e. Spinal injury and pain are often treated with surgical intervention. Posteolateral intratransverse process fusion is the most common type of fusion performed in the lumbar spine. An animal model is being adapted here at the ISR that involves testing materials for spinal fusion. In addition, the model is being expanded to evaluate materials with potential anti-microbial capabilities. Surgical-site infections can be as high at 8.2% in spinal surgeries. New materials are being developed that can reduce the occurrence of SSI which encouraging fusion of the transverse processes. A proof-of-concept data suggests that an antibiotic can be added to this material to prevent infection or during revision surgeries.

2) Notable Research Transitions:

a. The positive results, high amount of muscle regeneration and restoration of muscle strength in a challenging rodent model and a large animal model, encourage to an observational clinical trial.

b. Transition of the injectable scaffold project has included the investigation of the addition of osteogenic agents (specifically, Lovastatin – a suitable, affordable, and FDA-approved agent that promotes osteogenic differentiation of stem cells) in the scaffolds to maximize the use of the injectable vehicle as a drug delivery system as well as a cell delivery system. This study has transitioned to using bone autograft. The goal is to be able to use less graft from the patient and to protect it from resorption.

c. The ETRM Task Area has initiated efforts to transition into addressing wound healing following polytraumatic injury. Our current focus is on the initial development and characterization of a rat model of polytrauma. Military-relevant injuries incorporated into this IACUC-approved model include fracture, blunt chest trauma, and a burn injury. Initial studies have focused on characterizing the systemic inflammatory response that initially follows polytrauma. Currently we are evaluating correlates of wound healing. Future studies will evaluate wound healing following immunomodulating therapies. Funding from an UFR has been used for these initial studies. We

demonstrated that dysregulated inflammation results in delayed healing of bone defects. Modulating the immune response with cellular and/or pharmacological therapies will be explored in the future.

d. Ischemia-reperfusion injury accompanies compartment syndrome and surgical procedures that accompany muscle transfer. We expanded on our previous research and experience utilizing stem cells in skeletal muscle to identify a clinically relevant methodology to utilize freshly isolated bone marrow-derived cells for the treatment of ischemia-reperfusion injury. VML impairs negatively impacts a service member's ability to restore limb function. Research efforts have significantly improved our understanding of the etiology of VML injury, and this knowledge was used to identify therapeutic targets. For example, insufficient vascularity was identified as a potential factor that leads to fibrosis and impaired myogenesis. To address this, microvessels from adipose tissue were as a means to improve tissue perfusion within VML defects.

e. The current standards of care for skin replacement are either commercially available or skin grafts from the patient. The off-the-shelf approach is not vascularized, and adherence around the joints and infection are constant issues. The skin graft approach can only cover a very small area initially, increases morbidity, and takes an extremely long time to obtain complete coverage. This staged coverage approach increases the mortality rate because of the increased chance of infections. (b) (6) has spearheaded a tissue engineered and regenerative medicine solution that will utilize a composite scaffold that quickly vascularizes. Many of the approaches in the realm of regenerative medicine research do not have a realistic pathway to translate the findings to the clinic; this is generally because the approaches have an incredibly small chance of being FDA approved. (b) (6) has developed an effective therapy that is utilizing mature technologies. The devices are either already approved for clinical use or will have a short regulatory path.

f. (b) (6) is the program manager and GOR for the Major Extremity Trauma Research Consortium, which has 13 clinical trials ongoing. Over 2,500 patients have been enrolled to date. Enrollment should be complete next year on several studies.

3) Notable Products Completed:

a. The large, multi-center clinical trial that investigated the effects of pressure and irrigants has reached its enrollment goal of 2,520 patients in 2013 and one-year follow up was completed late in 2014. Brooke Army Medical Center was the only military hospital involved in this study, and work from our task area helped shape the study design.

b. Freshly isolated bone marrow-derived cells improved functional recovery following ischemia-reperfusion injury. Cells were isolated and delivered on the day of injury. This was the first study to demonstrate a functional improvement with the use of bone marrow-derived cells, and that their systemic delivery was superior to direct delivery. Microvessels from adipose tissue effectively improved perfusion in large VML defects. This study identifies microvessels from adipose tissue as a suitable platform for both VML and other orthopaedic injuries.

4) Significant Awards or Honors Received:

a. (b) (6) was a moderator at the Word Stem Cell Conference.

b. (b) (6) was the IACUC Chairman.

c. The Skin Replacement Project has been designated a Science Technology Objective (STO) by the Clinical and Rehabilitative Medicine Research Program.

5) Publications:

a. Rathbone C.R., Guda, T., Singleton, B., Oh, S., Appleford, M.R., Ong, J.L., Wenke, J.C. Cell-seeded hydroxyapatite scaffolds modify bone regeneration in the rabbit radius in vivo J Biomed Mater Res A. 2013 J Biomed Mater Res A. 2014 May;102(5):1458-66.

b. Krueger C.K., Wenke, J.C., Cho, M., Hsu, J.R. Common Factors and Outcome in Late Upper Extremity Amputations Following Military Injury. J Orthop Trauma. 2014 Apr;28(4):227-31.

c. Guda T., Walker, J.A., Hernandez, J., Singleton, B., Appleford, M.R., Oh, S., Ong, J.L., Wenke, J.C. Hydroxyapatite scaffold pore architecture effects in large bone defects in vivo. J Biomater Appl. 2014 Mar;28(7):1016-27.

d. Krueger, C.A., Wenke, J.C. Initial injury severity and social factors determine ability to deploy after combat-related amputation. Injury. 2014 Feb 15. pii: S0020-1383(14)00079-5. doi: 10.1016/j.injury.2014.02.008.

e. Guda T., Darr, A., Silliman, D.T., Magno, M.H., Wenke, J.C., Kohn, J., Brown Baer, P.R. Methods to Analyze Bone Regenerative Response to Different rhBMP-2 Doses in Rabbit Craniofacial Defects. Tissue Eng Part C Methods. 2014 Mar 3.

f. Akers K.S., Mende, K., Cheatle, K.A., Zera, W.C., Yu, X., Beckius, M.L., Aggarwal, D., Li, P., Sanchez, C.J., Wenke, J.C., Weintrob, A.C.,Tribble, D.R., Murray, C.K. Infectious Disease Clinical Research Program Trauma Infectious Disease Outcomes Study Group. Biofilms and persistent wound infections in United States military trauma patients: a case-control analysis. BMC Infect Dis. 2014 Apr 8;14(1):190.

g. Tennent, D.J., Wenke, J.C., Rivera, J.C., Krueger, C.A. Characterisation and outcomes of upper extremity amputations. Injury. 2014 Jun;45(6):965-9.

h. Brown K.V., Penn-Barwell, J.G., Rand, B.C., Wenke, J.C. Translational research to improve the treatment of severe extremity injuries. J R Army Med Corps. 2014 Jan 24. doi: 10.1136/jramc-2013-000235.

i. Sanchez C.J., Akers, K.S., Romano, D., Woodbury, R., Hardy, S., Murray, C.K., Wenke, J.C. D-amino acids enhance the activity of antimicrobials against biofilms of clinical wound isolates of Staphylococcus aureus and Pseudomonas aeruginosa. Antimicrob Agents Chemother. 2014 Aug;58(8):4353-61.

j. Penn-Barwell, J.P., Rand, B.C., Brown, K.V., Wenke, J.C. A versatile model of open-fracture infection: A contaminated segmental rat femur defect. Bone Joint Res. 2014 Jun;3(6):187-92.

k. Krueger, C.A., Ficke, J.R., Wenke, J.C. Amputation characteristics vary by branch of service. J Surg Orthop Adv. 2014 Summer;23(2):57-63.

l. Cardile, A.P., Sanchez, C.J. Jr, Samberg, M.E., Romano, D.R., Hardy, S.K., Wenke, J.C., Murray, C.K., Akers, K.S. Human plasma enhances the expression of Staphylococcal microbial surface components recognizing adhesive matrix molecules promoting biofilm formation and increases antimicrobial tolerance In Vitro. BMC Res Notes. 2014 Jul 17;7:457. BMC Res Notes. 2014 Jul 17;7:457. doi: 10.1186/1756-0500-7-457.

m. Cardile, A.P., Sanchez, C.J. Jr, Hardy, S.K., Romano, D.R., Hurtgen, B.J., Wenke, J.C., Murray, C.K., Akers, K.S., Dakin solution alters macrophage viability and function. J Surg Res. 2014 Jul 18. pii: S0022-4804(14)00656-8.

n. Shah, A.R., Wenke, J.C., Agrawal, C.M., Manipulation of Human Primary Endothelial Cell and Osteoblast Coculture Ratios to Augment Vasculogenesis and Mineralization. Ann Plast Surg. 2014 Aug 20.

o. Corona, B.T., Ward, C.L., Baker, H., Walters, T.J., Christ, G.J., Implantation of in vitro tissue engineered muscle repair constructs and bladder acellular matrices partially restore in vivo skeletal muscle function in a rat model of volumetric muscle loss injury. Tissue Eng Part A. 2014 Feb;20(3-4):705-15.

p. Corona, B.T., Garg, K., Roe, J.L., Walters, T.J., The effect of recombinant human MG53 protein on tourniquet-induced ischemia reperfusion injury in rat muscle. Muscle Nerve. 2014 Jun;49(6):919-21.

q. Corona, B.T., Rathbone, C.R., Accelerated functional recovery following skeletal muscle ischemia-reperfusion injury using freshly-isolated bone marrow cells. Journal of Surgical Research, J Surg Res. 2014 May 1;188(1):100-9.5.

r. Baumann, C.W., Green, M.S., Doyle, J.A., Rupp, J.C., Ingalls, C.P., Corona, B.T., Muscle injury after low intensity downhill running reduces running economy. J Strength Cond Res. 2014 May;28(5):1212-8.

s. Pilia, M., McDaniel, J.S., Guda, T., Chen, X.K., Rhoads, R.P., Allen, R.E., Corona, B.T., Rathbone, C.R., Transplantation and perfusion of microvascular fragments in a rodent model of volumetric muscle loss injury. Eur Cell Mater. 2014 Jul 14;28:11-24.

t. Guda, T., Darr, A., Silliman, D.T., Magno, M.H., Wenke, J.C., Kohn, J., Brown Baer, P.R., Methods to Analyze Bone Regenerative Response to Different rhBMP-2 Doses in Rabbit Craniofacial Defects. Tissue Eng Part C Methods. 2014 Mar 3.

u. Corona, B.T., Ward, C.L., Baker, H., Walters, T.J., Christ, G.C., Implantation of in vitro tissue engineered muscle repair constructs and bladder acellular matrices partially restore in vivo skeletal muscle function in a rat model of volumetric muscle loss injury. Tissue engineering Part A 20: 705-715, 2014.

v. Rathbone, C.R., Guda, T., Singleton, B., Oh, S., Appleford, M.R., Ong, J.L., Wenke, J.C., Cell-seeded hydroxyapatite scaffolds modify bone regeneration in the rabbit radius in vivo J Biomed Mater Res A. 2013 J Biomed Mater Res A. 2014 May;102(5):1458-66.

w. Krueger, C.K., Wenke, J.C., Cho, M., Hsu, J.R., Common Factors and Outcome in Late Upper Extremity Amputations Following Military Injury. J Orthop Trauma. 2014 Apr;28(4):227-31.

x. Guda, T., Walker, J.A., Hernandez, J., Singleton, B., Appleford, M.R., Oh, S., Ong, J.L., Wenke, J.C., Hydroxyapatite scaffold pore architecture effects in large bone defects in vivo. J Biomater Appl. 2014 Mar;28(7):1016-27.

y. Krueger, C.A., Wenke. J.C., Initial injury severity and social factors determine ability to deploy after combat-related amputation. Injury. 2014 Feb 15. pii: S0020-1383(14)00079-5. doi: 10.1016/j.injury.2014.02.008.

D. Clinical Trials in Burns and Trauma (CTBT)

Task Area Manager: LTC (b) (6), MD

1) Accomplishments

The overarching goal of the CTBT Task Area is to revolutionize burn and trauma care by optimizing burn wound outcomes, executing studies that advance the prevention, early detection, and treatment of organ failure, and accelerating the road to full functional recovery. In order to accomplish our goal, the task area integrates and balances three focus areas; definitive burn wound coverage, end organ support and rehabilitation, reconstruction and resilience. Collaboration and funding through the Armed Forces Institute of Regenerative Medicine (AFIRM) has resulted in many productive clinical research trials for burn wound coverage such as STRATAGRAFT Skin Tissue alternative to autografting, Autologous FAT Transfer to prevent scar formation and remodeling and the ReCell Device. Funding from the American Burn Association (ABA) was used in on-going work on end organ support to evaluate the hemofiltration in adult burn patients with septic shock and acute renal failure and to evaluate restrictive vs. traditional blood transfusion practices in burn patients. We currently are recruiting for a clinical trial to demonstrate the feasibility of the CytoSorb system to filter myoglobin in patients with Rhabdomyolysis.

2) Notable Research Transitions: N/A

3) Notable Products Completed: Two studies stand out as notable products completed. The first is "A Comparative Study Of The ReCell® Device And Autologous Split-Thickness Meshed Skin Graft In The Treatment Of Acute Burn Injuries" called ReCell and the second is "An Open-Label, Controlled, Randomized, Multicenter, Dose Escalation Study Evaluating The Safety and Efficacy of STRATAGRAFT Skin Tissue in Promoting the Healing of the Deep Partial-Thickness Component of Complex Skin Defects as an Alternative to Autografting" called StratGraft.

   a. The (b) (4) study, sponsored by (b) (4), was a randomized, within-patient controlled study to compare the clinical performance of the (b) (4) with that of Split-thickness Meshed Skin Grafts (STMSG) for the treatment of second degree burns. This multi-center investigation included patients with injury patterns such that two, 100-320 cm2 regions (not necessarily contiguous) of second degree burn injury in comparable skin locations were available for treatment with ReCell and the STMSG control. A total of 18 patients were enrolled from the USAISR Burn Center and recruitment was only stopped because the company completed the study. To date 12 subjects have completed the full year follow up requirements, 5 subjects remain in the study to complete their follow up year, and only 1 subject withdrew from the study. ReCell® is currently available at the USAISR Burn Center for compassionate use.

   b. The StrataGraft study, sponsored by the (b) (4), was also a randomized, within-patient controlled study in order to compare StrataGraft tissue or an autologous skin graft. Two donor sites were designated in a randomized fashion to provide a source of autograft skin for the control treatment site and, if needed, the StrataGraft treatment site. Both the StrataGraft skin tissue and autograft control were placed on the treatment sites immediately after surgical excision of non-viable tissue. Five subjects were enrolled and all of the subjects completed the full year required visits.

   Both companies have indicated their desire to have CTBT involved in future studies. The next iteration of ReCell® is currently in development.

4) Support Provided to Operational Units: N/A

5) Significant Awards or Honors Received: The Army Medical Department's Annual Wolf Pack Award was presented for the Burn Resuscitation Decision Support System which was a cross task area multidisciplinary collaborative effort. LTC (b) (6), Task Area Manager for Clinical Trials in Burns and Trauma, received The Surgeon General's 'A' Designator which is the Highest Recognition for Professional Excellence in Army Medicine. He also received the Presidential Citation at the Society for Critical Care Medicine and was the invited speaker for the MG Jack Gamble Memorial Lecture at Madigan Army Medical Center at Joint Base Lewis McCord, Washington. LTC (b) (6) received the Defense Meritorious Service Medal for her service as the final Human Protections Administrator in Afghanistan and was a guest lecturer at the Southern Illinois University School of Medicine, Department of Plastic Surgery in Springfield, Illinois. (b) (6) received an Achievement Award for Civilian Service. (b) (6) and (b) (6) presented at the 27th Annual Southern Regional Burn Conference. (b) (6) presentation won First place for Non-physician abstract and presentation. These achievements demonstrate the expertise, flexibility and research experience of the task area's personnel.

6) Publications:

   a. Malin, E.W., Galin, C.M., Lairet, K.F., Huzar, T.F., Williams, J.F., Renz, E.M., Wolf, S.E., Cancio, L.C., Silver-coated Nylon Dressing Plus Active DC Microcurrent for Healing of Autogenous Skin Donor Sites. Ann Plast Surg. 2013 Nov;71(5):481-4. doi: 10.1097/SAP.0b013e31829d2311 PMID:23903090 [PubMed - in progress]

   b. Lester, M.E., Hazelton, J., Dewey, W.S., Casey, J.C., Richard, R. Influence of upper extremity positioning on pain, paresthesia, and tolerance, advancing current practice. J Burn Care Res.

2013 Nov-Dec;34(6):e342-50. doi: 10.1097/BCR.0b013e3182788f52. PMID: 23702855 [PubMed - in process]

c. Wilton, J.C., Hardin, M.O., Ritchie, J.D., Chung, K.K., Aden, J.K., Cancio, L.C., Wolf, S.E., White, C.E., Outcomes after Cardiac Arrest in an Adult Burn Center. J. Burns 2013

d. Madson, A.Q., Tucker, D., Aden, J., Hale, R.G., Chan, R.K., Non-battle craniomaxillofacial injuries from U.S. military operations. J Craniomaxillofac Surg. 2013 Dec;41(8):816-20. doi: 10.1016/j.jcms.2013.01.035. Epub 2013 Apr 3

e. Richard, R., Niszczak, J., Burns. In Jacobs MA, Austin NM (Eds.). Splinting The Hand And Upper Extremity: Principles and Process, 2nd Edition. Lippincott Williams & Wilkins, Philadelphia, 2014

f. Richard, R.L., Ward, R.S., Burns. In O'Sullivan SB, Schmitz TJ, Fulk GD (Eds) Physical Rehabilitation (6th Ed). FA Davis, Philadelphia, 2014, 1090-1121.

g. Martini, W.Z., Chung, K.K., Dubick, M.A., Differential changes in hepatic cynthesis of albumin and fibrinogen after severe hemorrhagic shock in pigs. Shock 2014 Jan; 41(1) 67-71 doi: 10.1097/SHK000071 PMID: 24351528

h. Liu, U.T., Holcomb, J.B., Wade, C.E., Batchinsky, A.L., Cancio, L.C., Darrah, M.I., Salinas, J., Development and validation of a machine learning algorithm and hybrid system to predict the need for life-saving interventions in trauma patients. Med Biol Eng Comput. 2014 Feb;52(2): 193-203. doi: 10.1007/s11517-013-1130x

i. Linden, K.,Stewart, I.J.,Kreyer, S.F., Scaravilli, V., Cannon, J.W., Cancio, L.C., Batchinsky, A.L., Chung, K.K., Extracorporeal blood purification in burns: A Review: Burns 2014 Feb 15. PII: So305-4179 (14) 00026-6.doi: 10.1016/J. Burns. 2014.01.013

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7) Presentations:

a. Escolas, S.M., Walker, S.L., Tyrell, K.M., Chung, K.K., Escolas, H.D., Hatem, V.D., Orman, J.A., Renz, E.M., Post-discharge cause-of-death in combat burn casualties, American Burn Association Conference, Boston, Massachusetts, March 27, 2014

b. Jackson, B.A., King, B.T., Jones, J., Escolas, S.M., Shiels, M.E., Renz, E.M., Chung, K.K., Cancio, L.C., Comparison of military outcomes to the National Burn Repository (NBR), American Burn Association Conference, Boston, Massachusetts, March, 2014

c. Richard, R., Dewey, W.S., Anyan, W.R., Kemp-Offenberg, J., Miller. K., et al., Increased burn rehabilitation treatment time improves patient outcomes. (Top six abstract selection), American Burn Association Annual Meeting, Boston MA - March 28, 2014

d. Richard, R., Dewey, W.S., Anyan, W.R., Kemp-Offenberg, J., Miller, K., et al., Cutaneous functional units relate better than total body surface area to burn patient outcomes, American Burn Association Annual Meeting, Boston MA - March 26, 2014

e. Richard, R., Jones, J., Parshley, P., Hierarchical decomposition of burn body diagram based on cutaneous functional units and it utility. (Burke/Yannas Bioengineering Best Paper Award), American Burn Association Annual Meeting, Boston MA - March 27, 2014

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g. Charo-Griego, S., Patino, I.F., Mueller, M.R., Willenberg, S., Mann-Salinas, E.A., Allen, D.A., Shingleton, S.K., Development of an Evidenced Based Comprehensive Pressure Ulcer Prevention Program in a Burn Intensive Care Unit, TriService Nursing Research/Evidence Based Practice Dissemination Course, 16-17SEPT2014, San Antonio TX

E. Battlefield Pain Management Task Area

Task Area Manager: COL (b) (6), MD, MPH, FACP

1) Notable Research and Development Accomplishments: The task area was successful in continuing work on the funding awards from the Combat Causality Care Research Program (CCCRP) and Defense Health Program (DHP). These funds are being used on-going work to examine the effects of administration of peripheral analgesic compounds on pain behaviors in a rat model of partial thickness thermal injury. Utilizing funding from a second DHP grant the task area remains involved in a retrospective analysis of the incidence of use of regional anesthesia on the battlefield and during hospitalization, to determine the effects of regional anesthesia on patient outcomes. The pain task area has continued to increase joint service, universities and private sector industry collaboration by

submitting several original grants. The pain task area has been highly successful in securing funding through several CRADA agreements from three industrial partners to test novel analgesic compounds on pain behaviors in the rat model of partial thickness thermal injury. These continued successes are instrumental in shaping the pain task area into a world renowned basic and clinical pain research organization.

2) Notable Research Transitions: The pain task area, in an effort led by (b) (6), has been working on administering a small business innovation research (SBIR) award for the development of biocompatible dressings for the delivery of analgesics to burn wounds. The projects aim to further accelerate healing, active wound dressings have been developed that provide controlled local delivery of therapeutic agents, such as biological growth factors and antimicrobial agents, while keeping the wound surface moist, removing exudates, inhibiting bacterial invasion and allowing oxygen permeation. (b) (6) serves as tech base rep/SME for the Sufentanil nanotab IPT team, which has recently achieved Milestone B approval from the MDA, Dr. Kenneth Bertram.

3) Notable Products Completed: The rat model of full thickness thermal injury continues to be a novel model for the investigation of burn/trauma multimodal pain.– The task area developed this animal model of thermal hyperalgesia and mechanical allodynia evoked by full thickness thermal injury that shares pathological characteristics with full thickness burns in patients.

4) Support Provided to Operational Units: (b) (6) participated in a process improvement project led by Col. (b) (6), USAF, to analyze analgesic use and effects on physiological parameters in the field. This PI project has resulted in an accepted publication to Military Medicine. It has also informed work that resulted in the updated TCCC guidelines for analgesia.

5) Significant Awards or Honors Received: (b) (6) received her certificate for five years of continued service to ISR.

6) Publications:

   a. Nyland, J.E., McLean, S.A., Averitt, D.R., Sub-chronic stress prior to injury intensifies pain associated with thermal burn injury. Journal of Pain (Submitted)

   b. Nyland, J.E., Alexander, D. N., Grigson, P.S., Reward comparison in rats with lesions of the trigeminal orosensory area in a runway apparatus. Behavioral Neuroscience (Submitted)

   c. McGhee, L., Maani, C.V., Garza, T., Slater, T., Petz, L.N., Fowler, M., The intraoperative administration of ketamine to burned US service members does not increase the incidence of posttraumatic stress disorder. Military Medicine 2014 Aug;179(8 Suppl):41-6

   d. Shackelford, S.A., Fowler, M., Schultz, K., Summers, A., Galvagno, S.M., Gross, K.R., Mabry, R.L., Bailey, J.A., Kotwal, R.S., Butler, F.K., Prehospital pain medication use by US Forces in Afghanistan. In press, Mil Med

   e. Clifford, J.L., Fowler, M., Hansen, J.J., Cheppudira, B., Nyland, J.E., Salas, M.M., McGhee, L.L., Petz, L.N., Loyd, D.R. Advances in treating pain in wounded service members: A decade at war. Journal of Trauma and Acute Care Surgery, 2014, 77(3), S228-S236

F. Coagulation and Blood Research

Task Area Manager: LTC (b) (6), MD, PhD, FACP

1) Notable Research and Development Accomplishments:

   a. The Coagulation and Blood Research Task Area addresses battlefield mortality due to hemorrhage with a focus on developing diagnostics and therapeutics to treat life-threatening blood loss with safe and effective blood products delivered far-forward. Major capability gaps are identified through constant interactions with stakeholder communities including experts in operational medicine and the military blood banking community. Blood product availability in the far-forward setting, closest to

point of injury, remains a challenge, but research demonstrates that early treatment of hemorrhage saves lives.

b. Platelets are critical for hemorrhage control and are difficult to supply at all levels of care due to short lifespan (5 days) and current storage approaches (22°C on an agitator). Available platelet products carry a risk of bacterial contamination and may not be optimal for treatment of hemorrhage and coagulopathy of trauma (COT). We developed a collaboration with multiple academic, research, and industry partners to test potential strategies for optimizing storage and found that refrigerated platelets in platelet additive solution (PAS) represent the most promising candidate technology to date. Our own research and additional efforts in collaboration with UTSA-Biomedical Engineering demonstrate that refrigerated platelets have better function and form stronger clots whether stored as whole blood or as platelet components. These results led to the formation of a Joint Working Group to coordinate an Army/Defense Health Program (DHP) program on implementation of platelet refrigeration for the battlefield. Additionally, the Coagulation and Blood Research Task Area has been specifically designated as the lead for platelet work in the DoD, and the project has been accorded the status of a Strategic Technology Objective (STO).

c. In line with the platelet effort, we are also investigating deployable plasma products, a component of blood that, like platelets, is critical to clot formation and hemorrhage control. We continue to work with SOCOM and the French Military to provide freeze-dried plasma (FDP) to Special Forces units with plans for a wider roll-out in the future. Another notable effort includes the ongoing observational clinical trial assessing coagulation changes during large tissue resections in burn and other soft tissue injury patients, which promises to provide important information regarding the early changes associated with massive bleeding, as well as a new model for testing novel therapeutics in a clinical setting of severe hemorrhage. This would represent a major innovation in trauma research, because the severe nature of injuries leading to acute hemorrhage, and the unavailability of family members to provide consent, significantly limit trauma-related clinical investigations.

d. Another major research focus focuses on development of a better understanding of the mechanisms underlying Acute Traumatic Coagulopathy (ATC), present in 25% of bleeding trauma patients, and associated with a high risk of death. The diagnostic criteria for ATC are imprecise and risk stratification of patients is unavailable. We lack targeted therapeutics, and overall, there is no standard of care for ATC. We hope to provide solutions through the characterization of early changes in coagulation due to severe bleeding in part through the clinical study mentioned previously. Basic science investigations conducted at our laboratory suggest that platelet dysfunction may be a major component of the etiology of ATC; this effort is thus closely linked to our platelet research. Finally, we previously collaborated with an industry partner, TerumoBCT, on grant-funded research to test whole blood quality after pathogen reduction treatment (PRT) with riboflavin and ultraviolet light, which non-specifically targets parasites, bacteria, and viruses. A follow-up study, similarly grant-funded, is currently underway to test blood component quality (platelets, plasma and pRBCs) after PRT, and further work on a refrigerated, PRT-treated apheresis platelet product is underway. The net result of all these efforts will be better and more widely available transfusion products, mitigation of the infectious potential of those products, diagnostics and other therapeutics to treat severe hemorrhage, and a better understanding of the mechanisms underlying ATC. Select projects are highlighted below.

2) Animal Models of ATC (b) (6) , PhD): Acute coagulatopahy of trauma (aCOT) is a main focus of our group. We have successfully developed a rat model of severe trauma and hemorrhage that demonstrates ATC. This has allowed us to develop a mechanistic understanding of the coagulopathy and revealed potential approaches to refining diagnostic criteria. Our results document an early increase in plasmin activity; in other words, the coagulopathy appears to be predominantly fibrinolytic in nature. We are currently testing anti-fibrinolytic therapy in our rat model, which has unexpectedly born other fruit to study. Severe trauma and hemorrhage in this rat model also leads to a sequela of symptoms seen in human trauma patients, including acute renal failure, acute lung failure (2nd to the trauma), a systemic inflammatory response syndrome (SIRS), and a compensatory anti-inflammatory

response syndrome (CARS). The development of therapies for the combination of these pathologies will improve the care of combat wounded soldiers.

3) Platelet Contributions to Hemostasis in ATC ([redacted], PhD): In vitro models of acute traumatic coagulopathy (ATC) were used to demonstrate the highly effective contribution of platelets to hemostasis; the presence of even a moderate number of platelets was sufficient to overcome very high (superphysiological) levels of activated protein C (aPC), an anticoagulant protein which has been shown to be elevated in trauma patients experiencing coagulopathy. aPC prevents coagulation primarily through inactivation of coagulation factor V (FV); while the FV present on the surface of platelets makes up only 20% of the total FV, this fraction has demonstrated its resistance to inactivation by aPC.

   Because magnesium plays important roles in platelet function (and has deleterious effects at concentrations which are higher or lower than normal), we investigated the use of supplemental magnesium in stored platelets. The citrate anticoagulant used in blood product storage chelates not only the calcium but also the magnesium; recent studies with various platelet additive solutions have shown that those which incorporate magnesium into their milieu result in better functional performance. The use of magnesium was therefore tested on platelets stored in citrated plasma at both room temperature and refrigerated (4 °C). Over an eight day testing period, platelets stored at 4 °C with supplemental magnesium had significantly improved collagen adhesion responses, an important test in determining the usefulness of the transfusion of these platelets into a bleeding patient. Overall, these results indicate opportunities for improving platelet storage and delivering hemostatically optimal products to the battlefield.

4) In Vitro Studies of Fibrinolysis ([redacted], MD): Fibrinolysis has been identified as a critical component of ATC. The CRASH-2 study established the usefulness of tranexamic acid (TXA), a lysine analog antifibrinolytic, in the treatment of bleeding trauma patients. Early treatment with TXA reduces mortality in this population. Identification of patients with clinically relevant fibrinolysis is challenging. Viscoelastic methods like thromboelastography (TEG) may be insensitive to early changes caused by the consistently observed increase in tissue plasminogen activator (tPA) in severe trauma. Using several in vitro approaches, we characterized the thresholds of TEG sensitivity to tPA-induced fibrinolysis and determined the effects of TXA on clot structure and biomechanical properties. Our results indicate that TEG is insufficiently sensitive to detect early fibrinolytic changes following trauma. We also showed that TXA not only inhibits fibrinolysis, but also reduces thrombin-activated clot time and produces stronger and thicker fibrin clots.

5) Notable Research Transitions: As noted above, our task area uses an integrated approach to address the problems of platelet and plasma availability, safety, and functionality in far forward settings, closest to the point of injury. Our work on platelet storage has been designated an Army Strategic Technology Objective. Efforts to further expand our effective use of funding have led to collaborations with many other task areas, and university, and industry partners. We maintain collaborations with the entities as shown in Figure 12.

FIGURE 12: Collaborating Entities

Entity	Entity	Entity
CICR	Clinical Trials	CTIR
DCR	Emory U	French Military
Haemonetics	IDF	JTS/JTR
Mosaic Biosciences	Norwegian Military	ROTEM
SAMMC	SOCOM	SwRI
TC3	TerumoBCT	Texas Biomedical Research Institute
U Washington/PSBS	USAMMDA	UTHSC-Houston
UTHSCSA-Surgery	UTSA-Biomedical Engineering	UT Southwestern
Washington U		

6) We continue to develop our relationship with the Israeli Defense Forces (IDF), building on assignment of IDF Surgical Fellows to the USAISR for one year internships focused on developing therapeutic strategies to mitigate acute traumatic coagulopathy. This exchange and continuing collaborations have resulted in abstracts and oral presentations at various medical and scientific meetings and peer-reviewed journal publications.

7) Notable Products Completed:

   a. Storage of apheresis platelets in additive solution (PAS platelets) allows storage under refrigeration with reduced formation of aggregates and enhanced preservation of function. This is due to dilution of fibrinogen from plasma; fibrinogen binding by primed cold platelets leads to progressive activation and reduced storage life.

   b. Development of a thrombin/plasmin activity ratio assay reveals key changes in coagulation function during ATC and may provide the basis for a new diagnostic assay.

   c. We established the efficacy of Mirasol PRT for inactivation of Ebola virus in whole blood and plasma.

8) Support Provided to Operational Units:

   a. French Freeze-Dried Plasma (FDP): This product is fielded by USASOC under an FDA Expanded Access IND protocol; a program expansion is underway which will provide US-sourced plasma for lyophilization in France. LTC (b) (6) led a site qualification and planning visit to FT Bragg Blood Donor Center and hosted BG Anne Sailliol of the French Army. The Blood Research Program coordinated a study with the Army Blood Program and USASOC which established the feasibility of recruiting suitable donors, collecting plasma, shipping it to France, and ultimately taking receipt of an FDP product that meets all release criteria.

   b. LTC (b) (6) took part in the PACOM Blood planning conference and serves as an advisor to PACOM-JTS. He is working with PACOM Navy Special Warfare to develop emergency transfusion and hemostasis protocols for implementation far-forward.

c. LTC (b) (6) participated as faculty in the annual medic training exercise of 2nd Battalion, 75th Ranger Regiment. He assisted the Regimental Surgeon, MAJ(P) (b) (6), in development of an emergency whole blood transfusion protocol to be used throughout the Ranger Regiment. LTC (b) (6) also assisted other USASOC elements, including 10th SFG in development of their transfusion guidelines.

d. LTC (b) (6) served as faculty for the Joint Forces Combat Trauma Management Course and for several JTS Trauma conferences.

e. The Blood Research Program trained deploying members of a Blood Support Detachment en route to Liberia during Operation United Assistance in use of the Mirasol Pathogen Reduction (PRT) technology in the event this technology would be required for treatment of blood collected in Liberia during the Ebola virus epidemic. The Blood Research Program also assisted the EUCOM/AFRICOM Joint Blood Program Officer in testing the feasibility of shipping apheresis platelets in various storage configurations over long distances (trans-Atlantic shipping). LTC (b) (6) served as the USAISR and Combat Casualty Care Research Program representative to the MRMC Ebola Task Force.

9) Significant Awards or Honors Received: (b) (6) received the Commander's Award for Civilian Service for development of a rat model of acute traumatic coagulopathy. (b) (6), PhD Candidate/UTSA Biomedical Engineering and a member of the USAISR Blood Research Program, received a travel award from the American Society of Hematology for her presentation on conservation of platelet inhibitory signaling in cold-stored platelets. (b) (6), a graduate student member of the Blood Research Program, completed her MS in Biotechnology and began the PhD program in Biomedical Engineering at UTSA. She will continue her research at USAISR.

10) Publications:

a. Nair, P.M., Pidcoke, H.F., Cap, A.P., Ramasubramanian, A.K., Effect of cold storage on shear-induced platelet aggregation and clot strength., J Trauma Acute Care Surg. 2014 Sep;77(3 Suppl 2):S88-93. doi: 10.1097/TA.0000000000000327.PMID:25159368

b. Galvin, J.W., Freedman, B.A., Schoenfeld, A.J., Cap, A.P., Mok, J.M., Morbidity of early spine surgery in the multiply injured patient. Arch Orthop Trauma Surg. 2014 Sep;134(9):1211-7. doi: 10.1007/s00402-014-2068-7. Epub 2014 Jul 31.PMID:25077784

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G. Ocular Trauma

Task Area Manager: COL (b) (6) , MD

1) Mission: The Ocular Trauma task area is composed of laboratory scientists and clinical researchers, utilizing state of the art equipment and techniques seeks to better comprehend, model, detect, and treat the full range of diseases and conditions that influences that ability of the warrior to see optimally and function on the modern battlefield, and that adversely influences their ability to return to duty after injury. With a research lineage evolved from the Walter Reed Army Institute of Research's Ocular Hazard Division, we likewise continue to investigate non-ionizing directed energy bioeffects for force protection measures.

2) Background: Within the USAISR, Ocular Trauma Research Division is dedicated to providing cutting edge research to improve the clinical outcomes of ocular injuries sustained fragmentary munitions and blast, and to improve the treatment of severe ocular surface diseases of patients in our burn center.

3) Major Accomplishments:

   a. Developed a method to differentiate human induced pluripotent stem (iPS) cells into retinal progenitors under a xeno-free 3D condition.

   b. Derived photoreceptors from human iPS cells.

   c. Detailed the dynamics of extracellular matrix remodeling during *in vitro* retinogenesis.

   d. Developed an in vitro model of proliferative vitreoretinopathy using retinal pigmented epithelium derived from iPS cells

   e. Demonstrated apoptosis in the retina and optic nerve for rats subjected to repeated low blast overpressure

   f. Provisional Patent Award: (b) (6) . Unique loading and preservation of amniotic membrane for us in ocular trauma and therapeutics. Provisional Application for US Patent filed: 5/2013.

   g. Provided the scientific input that allowed for updating the ANSI Z136.1 – American National Standard for Safe Use of Lasers.

   h. Completed 2 CDMRP research projects

4) Publications:

   a. Muñiz, A., Greene, W. A., Plamper, M. L., Choi, J.H., Johnson, A. J., Tsin, A., Wang, H.C., Retinoid Uptake, Processing and Secretion in Human iPS-RPE Support the Visual Cycle. Invest Ophthalmol Vis Sci. 55(1):198-209. 2014

   b. Greene, W. A., Muñiz, A., Plamper, M. L., Kaini, R.R., Wang, H.C., MicroRNA expression profiles of human iPS cells, retinal pigment epithelium derived from iPS, and fetal retinal pigment epithelium. J Vis Exp June 24(88):e51589. 2014

   c. Pocock, G.M., Lavey, B. J., Boretsky, A., Gupta, P., Vargas, G., Zhang, W., Wang, H.C., Motamedi, M., In Vivo Multimodal Imaging of NF-κB (p5) Spatial and Temporal Activation Following Light Injury in the Mouse Retina. DoD Technical Information center (DTIC) A595708. Jan 15, 2014

   d. Wang, H.C. et al, Pathophysiology of blast-induced ocular Trauma with apoptosis in the retina and optic nerve. Mil Med 178(8 Suppl):34-40, 2014

   e. Wang, H.C., Greene, W.A., Kaini, R.R., Shen-Gunther, J., Chen, H.I., Cai, H., Wang, Y., Profiling the microRNA expression in human iPS and iPS-derived retinal pigment epithelium. Cancer Inform. 2014; 13 (Suppl 5):25-35

   f. Muñiz, A., Kaini, R. R., Greene, W.A., Choi, J.H., Wang, H.C., Deriving retinal pigment epithelium (RPE) from induced pluripotent stem (iPS) cells by different sizes of embryoid bodies. J Vis Exp (in press)

g. Friedrich, E.E., Sun, L.T., Natesan, S., Zamora, D.O., Christy, R.J., Washburn, N.R., Effects of hyaluronic acid conjugation on anti-TNF-α inhibition of inflammation in burns. (J Biomed Mater Res A, 2014; 102(5):1527-36)

h. Cornell, L.E., DeSilva, M., Johnson, A.J., Zamora, D.O., Magnetic Nanoparticles as a potential vehicle for corneal endothelial repair. (Submitted Dec. 2014 to Journal of Military Medicine)

i. Lund, B.J., Lund, D.J., Edsall, P.R., Gaines, V.D., "Laser-induced retinal damage threshold for repetitive-pulse exposure to 100-ms pulses," J Biomed Opt 19(10): 105006 (2014)

j. Lund, B.J., Lund, D.J., Edsall, P.R., "Damage threshold from large retinal spot size repetitive-pulse laser exposures," Health Physics 107(4), 292-299 (2014)

k. Lund, B.J., Rule, G.T., "Pressure wave dosimetry for 'Retinal ganglion cell damage in an experimental rodent model of blast-mediated traumatic brain injury'," Invest Ophthalmol Vis Sci 55(3), 1348-1349 (2014)

l. Sherwood, D., Sponsel, W.E., Lund, B.J., Gray, W., Watson, R., Groth, S.L., Thoe, K., Glickman, R.D., Reilly, M.A., "Anatomical manifestations of primary blast ocular trauma observed in a postmortem porcine model," Invest Ophthalmol Vis Sci 55(2), 1124-1132 (2014)

5) Poster Presentations:

a. Zamora, D.O., DeSilva, M.N., Glickman, R.D., Wang, H.H., Johnson, A.J., The Effects of Magnetic Nanoparticles on Human Corneal Epithelial Cell Viability. (Tissue Engineering and Regenerative Medicine International Society; Poster, Atlanta, GA; November 2013)

b. Zamora, D.O., DeSilva, M.N., Cornell, Wang, H.H., Cleland, J.M., Johnson, A.J., Potential Use of Magnetic Nanoparticles to Deliver Endothelial Cells to the Inner Cornea. (RegenMed-SA; Poster, San Antonio, TX; February 2014)

c. Wehmeyer, J.L., Christy, R.J., Johnson, A.J., Zamora, D.O., Supercritical CO2-treated Amniotic-Membrane and its Utility of Ocular Regenerative Medicine. (RegenMed-SA; Poster, San Antonio, TX; February 2014)

d. Zamora, D.O., DeSilva, M.N., Cornell, L.E., Glickman, R.D., Wang, H.H., Johnson, A.J., Characterization of Magnetic Nanoparticle Loaded Corneal Endothelial Cells. (ARVO: Poster #1916363, Orlando, FL; May 2014)

e. Chou, C., Cornell, L.E., Zamora, D.O., Toxicity Assay of Iron- and Magnetic Nanoparticle-Loaded Corneal Endothelial Cells. (ISR Summer Student Symposium, Ft. Sam Houston, TX Aug 2014)

f. Cornell, L.E., DeSilva, M., Wang, H.C., Johnson, A.J., Zamora, D.O., Magnetic Nanoparticle Based Approach for Externally Controlled Corneal Endothelial Repair. (MHSRS: Poster #501, Ft. Lauderdale, FL Aug 2014)

g. Cornell, L.E., Johnson, A.J., Zamora, D.O., Use of Nanoparticles to Magnetically Target and Repair the Corneal Endothelium. (San Antonio Post-Doctoral Research Forum; Poster, UTHSCSA San Antonio, TX; Sept 2014)

h. Griffith, G.L., Wirostko, B., Lee, H.K., Zamora, D.O., Johnson, A.J., Model Development: Use of Thiolated Hyaluronic Acid for the Treatment of Corneal Epithelial Wounds. (San Antonio Post-Doctoral Research Forum; Poster, UTHSCSA San Antonio, TX; Sept 2014

6) Awards:

a. "Retinoid Uptake, Processing and Secretion in Human iPS-RPE Support the Visual Cycle. Invest Ophthalmol Vis Sci. 55(1):198-209. 2014 "was listed as top 10 articles at the MDLinx Ophthalmology"

b. Travel award from ARVO 2014 meeting: “Assessment of damage along the optic nerve after low-level repeated blast exposure,” Primary Author: (b) (6)

c. 3rd place poster award from San Antonio Postdoctoral Research Forum: “The development of an *in vitro* model of proliferative vitreoretinopathy using retinal pigmented epithelium derived from induced pluripotent stem cells". Primary author (b) (6)

d. Regenerative Medicine Prize from World Stem Cell Submit 2014: “Matrix Proteins and Retina Development in a 3-D in-vitro system” Primary Author: (b) (6)

e. CO-PIs ((b) (6)) for an extramural award titled as “Vision Restoration with Granulocyte Colony-Stimulating Factor Following Traumatic Injury”

H. Damage Control Resuscitation

Task Area Manager: (b) (6) , PhD

1) History and Mission: In 2006, the Damage Control Resuscitation (DCR) Task Area was created to integrate the research efforts of the Hemostasis and Resuscitation task areas within the ISR. It also invited participation by the Resuscitation and Blood Products research groups at WRAIR. With the implementation of BRAC, the Blood Research Task Area was moved to ISR and efforts were made to utilize the expertise of investigators in both task areas to address issues related to Trauma-induced Coagulopathy. In addition, BRAC also relocated the Complement research group at WRAIR to ISR, as part of DCR. The emphasis of DCR is to combine efforts in hemostatic resuscitation with the previous research effort in hypotensive resuscitation and is based on the premise inherent in damage control surgery, i.e., stay out of trouble rather than getting out of trouble. The mission of the Damage Control Resuscitation task area is to identify solutions to deficits associated with the control of bleeding and the stabilization of injured Soldiers, with the emphasis on treatments far forward of fixed medical facilities.

2) The goals of the program are: 1. To investigate improved methods of hemorrhage control and hemostasis at the point of injury, 2. To develop pre-hospital resuscitation strategies that simultaneously restore coagulation and metabolic function and replace the intravascular volume deficit; 3. To understand the inflammatory response to trauma and investigate the potential benefit of immune modulation as part of the resuscitation and 4. Investigate potential benefits of small volume resuscitation adjuncts, including anti-shock and cytoprotective agents for tissue stabilization and casualty survivability. To this end, research in the task area includes studies of hemostatic mechanisms under normal and coagulopathic conditions, evaluation of different ratios of currently available blood products, including whole blood, as resuscitation strategies, as well as continued research into new hemostatic products, including products for junctional and non-compressible bleeding. The new emphasis over the past year and extending into 2015 is the gap fills in light of prolonged or extended prehospital times until the casualty can reach a treatment facility.

3) Damage Control Resuscitation Personnel were involved or investigators in several protocols based on 8 proposals. These protocols investigate new hemostatic dressings and drugs, the genetic and epigenetic responses to hemorrhage, relationships between coagulation and the immune system and various resuscitation strategies related to the use of blood products and adjuncts. These protocols include 1 observational study in theater investigating various aspects of the use of blood products, including massive transfusion practices, as well as determining the coagulation and immune status of combat casualties.

4) Major Accomplishments:

a. In a study of physicians and medics, it was determined that the Combat Ready Clamp and SAM Junctional tourniquet were easiest to apply and were favored by the users.

b. Verified the importance of the windlass in improving efficacy of limb tourniquets and in response to the Boston Marathon bombings, determined that as a group, improvised tourniquets were ineffective in stopping arterial hemorrhage.

c. Determined that Voluven, a synthetic starch compound of lower molecular weight than Hextend, was no better in resuscitating rabbits from an uncontrolled hemorrhage and had similar effects on hemostasis as Hextend, contrary to claims.

d. Determined that the ability of RBCs to restore the endothelial glycocalyx after loss from hemorrhage in rats, may relate to the presence of a small volume of plasma in the RBC fraction, as this benefit was lost upon washing the RBCs.

e. Observed that hypotensive resuscitation with 15 ml/kg blood products, in line with TCCC recommendations, was insufficient to maintain survival in a swine severe uncontrolled hemorrhage model

f. Determined that recommended doses of fibrinogen as concentrate or as cryoprecipitate could reduce blood loss and improve survival in a swine severe uncontrolled hemorrhage model, but high dose fibrinogen did not offer additional benefit.

g. Assisted TCCC committee in adding Chitogauze and Celox Gauze to Combat Gauze as recommended hemostatic dressings.

5) Awards:

a. (b) (6) received a Presidential Citation from the Society of Critical Care Medicine

b. (b) (6) received a Commander's Award for Civilian Service

6) Information Productivity: 26 Manuscripts, 9 published abstracts and 18 presentations at major national and international scientific meetings, including the DoD's MHSRS.

7) Damage Control Resuscitation Task Area Personnel:

a. DCR personnel included 6 PhD or MD scientists. In addition, there are 7 bachelors or masters' level research and surgical technicians and 1 DVM

b. Significant personnel additions: None.

c. Significant personnel losses: (b) (6) retired (b) (6) were converted to PI emeritus to consult and help transition the loss of 3 senior investigators and help to publish their final research efforts.

8) Presentations:

a. Damage Control Resuscitation Task Area personnel had presentations at the Annual Shock Meeting, MHSRS (formerly ATACCC) 2014, AAST, Experimental Biology Annual Meeting, Critical Care Medicine and Innsbruck Winter Symposium on Coagulation. In addition, Dr. Kheirabadi made 2 presentations of efficacy and safety of hemostatic agents to the FDA Division of Cardiovascular Devices, part of CDRH.

9) Service to the Institute and MRMC:

a. (b) (6) continued to serve as the Damage Control Resuscitation Task Area Manager.

b. DCR investigators continued to review proposals, pre-proposals and SBIR and STTR submissions for MRMC, and served on RAD II strategic planning committees.

c. (b) (6) was appointed to the Hemorrhage and Resuscitation Steering Committee at MRMC.

d. (b) (6) has consulted with the Swedish Navy, Danish Marines, Belgian Special Forces, and Norweigan Special Forces regarding use of Junctional Tourniquets.

e. (b) (6) serves as the Laboratory Program Representative for the Institute's Postdoctoral fellowship program through the National Research Council of the National Academy of Sciences.

f. (b) (6) served on the ISR IACUC as member or alternate member.

g. (b) (6) served on the MRMC IRB committee.

h. DCR personnel served as COR or GOR for CDMRP, DARPA and SBIR, STTR projects and extramural contracts.

i. (b) (6) served as advisors for the DARPA Wound Stasis program.

j. (b) (6) served on the advisory committee of the Norwegian Blood Far Forward program.

k. (b) (6) served as a reviewer for the CDMRP Joint Fighter Medical Research Program

l. (b) (6) served as a reviewer for the USSOCOM Extramural Biomedical Research and Development Program

m. (b) (6) consulted with Naval Medical Research Center, Silver Spring and Naval Medical Research Unit San Antonio regarding studies with Oxygen Therapeutics.

10) Related Activities/Accomplishments:

a. (b) (6) serves on the editorial board of the journal Shock

b. (b) (6) is a founding editorial board member for the International Journal of Burns and Trauma.

c. (b) (6) completed his term as regional editor of the Brazilian journal, Clinics.

d. (b) (6) serves on the editorial board of the journal MedicalExpress

e. (b) (6) is an associate editor of the Journal of Special Operations Medicine

f. (b) (6) serve on an advisory panel for the FDA's CDRH.

g. (b) (6) served as an editorial consultant of the hypothermia module for the American College of Surgeons- Physicians Information and Education Resource (PIER)

h. (b) (6) serves a member of an NIH (NIGMS) study section on Surgery, Anesthesiology and Trauma

i. (b) (6) continued to serve as a consultant to a European clinical trial on the use of fibrinogen as therapy.

j. (b) (6) participated in a consensus conference on Viscoelastic Test Based Transfusion Guidelines for Early Trauma Resuscitation

k. (b) (6) is an Adjunct Professor in the Department of Surgery, University of Texas Health Science Center, San Antonio.

l. (b) (6) is an Associate Professor in the Department of Surgery, USUHS.

m. (b) (6) continued to serve as a Science and Policy Advisor to the American Council for Science and Health.

n. (b) (6) served as a member of the Awards Committee and became a Minorities Diversity Program Mentor for the Shock Society.

o. (b) (6) served on the Program Committee of the Society of Critical Care Medicine.

p. (b) (6) was appointed to the Military Liaison Committee of the American Association for the Surgery of Trauma

q. (b) (6) serves on the PhD committee of a bioengineering graduate student at UTSA.

r. (b) (6) served as a judge at the 2nd Annual UTHSCSA Post-doctoral Research Forum.

s. (b) (6) was appointed to the Development Committee of the Microcirculatory Society.

11) DCR personnel served as ad-hoc reviewers for the following journals:

a. Critical Care Medicine
b. Journal of Trauma
c. Annals of Surgery
d. Experimental Biology and Medicine
e. American Journal of Physiology
f. Shock; Thrombosis Research
g. Blood Coagulation and Fibrinolysis, Thrombosis and Haemostasis
h. Military Medicine
i. Journal of Emergencies, Trauma and Shock
j. Scandanavian J Trauma, Resuscitation, Emergency Med
k. Biomaterials
l. J Special Operations Medicine
m. Resuscitation
n. British J Anesthesiology
o. European J Applied Physiology and Clinics

12) Publications:

a. Martini, W.Z., Chung, K.K., Dubick, M.A., Differential changes in hepatic synthesis of albumin and fibrinogen after severe hemorrhagic shock in pigs. Shock 2014:41:67-71
b. Sondeen, J.L., Prince, M.D., Polykratis, I.A., Hernandez, O., Torres-Mendoza, J., de Guzman, R., Aden, J.K., Dubick, M.A., Swine blood banking techniques for plateletpheresis. J Am Assoc Lab Animal Sci (JAALAS) 2014:53:307-316
c. Chung, K.K., Dubick, M.A., Building the case towards a definitive clinical trial: Saline vs. Plasma-lyte. Crit Care Med 2014:42:1009-1110
d. Kragh, J.F. Jr, Wallum, T.E., Aden, J.K. III, Dubick, M.A., Baer, D.G., Emergency tourniquet effectiveness in four positions on the proximal thigh. J Spec Oper Med 2014:14(1): 26-29 (Spring issue)
e. Kragh, J.F. Jr, Parsons, D.L., Kotwall, R.S., Kheirabadi, B.S., Aden, J.K., Gerhardt, R.T., Baer, D.G., Dubick, M.A., Testing of junctional tourniquets to control simulated groin hemorrhage in normal military medics. J Spec Oper Med, 2014 in press
f. Dubick, M.A., Poli de Figueiredo, L.F., Kramer, G.C., Use of small volume hypertonic acetate dextran during aortic occlusion in pigs: assessment of blood flow and antioxidant status in tissues. Medical Express 2014:1:47-52
g. Kheirabadi, B.S., Terrazas, I.B., Miranda, N., Estep, J.S., Corona, B.T., Kragh, J.F. Jr, Dubick, M.A., Long-term effects of Combat Ready Clamp (CRoC) application to control junctional hemorrhage in swine. J Trauma Acute Care Surg (3 Suppl 2) 2014:77:S101-S108
h. Martini, A.K., Rodriguez, C.M., Cap, A.P., Martini, W.Z., Dubick, M.A., Acetaminophen and meloxicam inhibit platelet aggregation and coagulation in blood samples from humans. Blood Coagulation Fibrinolysis (Epub 3 Jul 2014)

i. Kragh, J.F. Jr, Steinbaugh, J., Parsons, D.L., Mabry, R.L., Kheirabadi, B.S., Dubick, M.A., A manikin model for study of wound-packing interventions to control out-of-hospital hemorrhage. Am J Emerg Med 2014:32(9):1130-1131 (Epub 21 May 2014)

j. Uwaydah, N.I., Hoskins, S.L., Bruttig, S.P., Farrar, H., Cooper, N.C., Deyo, D.J., Dubick, M.A., Kramer, G.C., Intramuscular vs intraosseous delivery of nerve agent antidote pralidoxime chloride in swine. Prehosp Emerg Care, in press

k. Hackman, R.M., Aggarwal, B.B., Applebaum, R.S., deVere White, R.W., Dubick, M.A., Heber, D., Ito, T., Johnson, G.H., Keen, C.L., Winters, B.H., Stohs, S.H., Forecasting nutrition research in 2020. J Am Coll Nutr 2014:33(4):340-346(Epub 21 Aug 2014)

l. Torres, L.N., Sondeen, J.L., Dubick, M.A., Torres, I., Systemic and microvascular effects of resuscitation with blood products after severe hemorrhage in rats. J Trauma 2014:77:716-723

m. Kragh, J.F. Jr, Dubick, M.A., Aden, J.K., McKeague, A.L., Rasmussen, T.E., Baer, D.G., Blackbourne, L.H., US military use of tourniquets from 2001 to 2010. Prehosp Emerg Care, in press

n. Kragh, J.F. Jr, Darrah, M., Gradilla, C., Salinas, J., Aden, J.K. III, Dubick, M.A., An intelligent tourniquet system to stop traumatic extremity bleeding. Am J Emerg Med, in press (Epub 8 Aug 2014)

o. Bennett, B.L., Littlejohn, L.F., Kheirabadi, B.S., Butler, F.K., Kotwal, R.S., Dubick, M.A., Bailey, J.A., Management of external hemorrhage in tactical combat casualty care: Chitosan-based hemostatic gauze dressing. TCCC Guidelines-Change 13-05. J Spec Oper Med 2014 :14(3):40-57,Fall issue

p. Hourigan, L.A., Omaye, S.T., Keen, C.L., Jones, J.A., Dubick, M.A., Vitamin and trace element loss from negative pressure wound therapy. Adv Skin Wound Care, in press

q. Martini, W.Z., Deguzman, R., Rodriguez, C.M., Guerra, J., Martini, A.K., Pusateri, A.E., Dubick, M.A., Effect of ibuprofen dose on platelet aggregation and coagulation in blood samples from pigs. Milit Med (Suppl), in press

r. Kragh, J.F. Jr, Parsons, D.L., Kotwal, R.S., Kheirabadi, B.S., Aden, J.K. III, Gerhardt, R.T., Baer, D.G., Dubick, M.A., Testing of junctional tourniquets by military medics to control simulated groin hemorrhage. J Spec Oper Med 2014:14 (3):58-63, Fall issue

s. Harcke, H.T., Mazuchowski, E., Brunstetter, T., Diaz, G., Burrows, S., Hart, S., Kragh, J.F. Jr., Feedback to the Field #16: Junctional Emergency Treatment Tool: Observations. US Armed Forces Medical Examiner Service. 2014

t. Johnson, J.E., Sims, R.K., Hamilton, D.J., Kragh, J.F., Safety and effectiveness evidence of SAM Junctional Tourniquet to control inguinal hemorrhage in a perfused cadaver model. J Spec Oper Med. 14(2):21-5, 2014

u. Klotz, J.K., Leo, M., Anderson, B.L., Nkodo, A.A., Garcia, G., Wichern, A.M., Chambers, M.J., Gonzalez, O.N., Pahle, M.U., Wagner, J.A., Robinson, J., Kragh, J.F. Jr., First case report of SAM Junctional Tourniquet use in Afghanistan to control inguinal hemorrhage on the battlefield. J Spec Oper Med. 14(2):1-5, 2014

v. Torres, L.N., Spiess, B.D., Torres Filho, I.P., Effects of Perfluorocarbon emulsions on microvascular blood flow and oxygen transport in a model of severe arterial gas embolism. Journal of Surgical Research 2014:187(1):324–333

w. Tiba, M.H., Draucker, G.T., Barbee, R.W., Terner, J.T., Torres Filho, I.P., Romfh, P., Vakhshoori, D., Ward, K.D., Tissue oxygenation monitoring using resonance Raman spectroscopy during hemorrhage. Journal of Trauma and Acute Care Surgery 76(2): 402-408

x. Torres Filho, I.P., Pedro, J.R.P., Narayanan, S.V., Nguyen, N.M., Roseff, S.D., Spiess, B.D., Perfluorocarbon emulsion improves oxygen transport of normal and sickle cell human blood in vitro. Journal of Biomedical Materials Research Part A 2014:102(7):2105-2115

13) Published Abstracts

a. Barr, J., Jacobson, D., Grubbs, D., Dubick, M.A., Antioxidant activity of currently available resuscitation fluids in vitro. FASEB J 28:1157.5, 2014

b. Torres Filho, I., Torres, L., Sondeen, J., Salgado, C., Dubick, M.A., In vivo effects of blood products on the endothelial glycocalyx, microvascular permeability and coagulation in severe hemorrhagic shock. FASEB J 28:676.15, 2014

c. Torres. L., Sondeen, J., Salgado, C., Dubick, M., Torres Filho, I., Comparison of plasma and 5% albumin resuscitation on preserving endothelial glycocalyx and microvascular permeability in vivo after severe hemorrhagic shock in rats. FASEB J 28:676.12, 2014

d. Torres, L.N., Sondeen, J., Salgado, C., Valdez, C., Dubick, M.A., Torres Filho, I., Endothelial glycocalyx (EG) after severe hemorrhagic shock (HS) followed by plasma volume expansion with normal saline. Shock 41(Suppl 2):26 (Abstract 40), 2014

e. Dubick, M.A., Li, Y., Grubbs, D.L., Barr, J.J., Dalle Lucca, J.J., Inflammatory responses in brain from swine subjected to traumatic hemorrhage and treated with a C1 inhibitor. Shock 41(Suppl 2):64 (Abstract P98), 2014

f. Martini, W.Z., Chung, K.K., Dubick, M.A., Comparisons of normal saline and lactated Ringer's in normal and hypotensive resuscitation in pigs after hemorrhagic shock. Shock 41(Suppl 2):94 (Abstract P183), 2014

g. Belenkiy, S., Park, T., Baker, W., Jordan, B., Dubick, M., Salinas, J., Cancio, L., A Batchinsky, Assessing hemorrhage severity with continuous automatic heart-rate-complexity monitoring in swine. Crit Care Med 42 (12 Suppl): Abst 186, 2014

h. Park, T., Batchinsky, A., Baker, W., Belenkiy, S., Jordan, B., Dubick, M., Salinas, J., Cancio, L., Resuscitative endovascular balloon occlusion of the aorta improves survival in lethal hemorrhage. Crit Care Med 42 (12 Suppl): Abst 248, 2014

i. Dubick, M., Scaravilli, V., Grubbs, D., Cancio, L., Batchinsky, A., Tissue inflammation in awake sheep subjected to extracorporeal acid load CO_2 removal (ALCO2R). Crit Care Med 42 (12 Suppl): Abst 683, 2014

14) Presentations

a. Martini, W.Z., Dubick, M., Fibrinogen concentrate administration inhibits fibrinogen synthesis in pigs after traumatic hemorrhage. Presented at the 73rd Annual Meeting of the American Association for the Surgery of Trauma, Philadelphia PA, 10-13 September 2014

b. Dubick, M.A., Berry, J.S., Grubbs, D.L., Barr, J.L., Batchinsky, A.I., Cancio, L.C., Indices of inflammatory responses and oxidative stress in tissues from pigs subjected to exsanguination shock. Presented at the 73rd Annual Meeting of the American Association for the Surgery of Trauma, Philadelphia PA, 10-13 September 2014

c. Kheirabadi, B.S., Miranda, N., Terrazas, I.B., Gonzales, M.D., Dubick, M.A., Does limited prehospital resuscitation with colloids or crystalloids influence hemostasis and survival in rabbits with an untreated non-compressible hemorrhage?, Presented at the 73rd Annual Meeting of the American Association for the Surgery of Trauma, Philadelphia PA, 10-13 September 2014

d. Kragh, J.F. Jr., A keynote talk entitled " Efficacy and Safety Assessment of Hemostatic agents for treating traumatic hemorrhage" was given at FDA Hemostatic Devices Workshop, Silver Spring, MD, Sept3-4, 2014

e. Kragh, J.F. Jr., Tourniquets Today, Idaho EMS, Boise ID, Grand Rounds 2014

f. Kragh, J.F. Jr., Tourniquets Today. MHSRS 2014 Breakout presentation in hemorrhage control.

15) MHSRS Presentations

a. Dalle Lucca, J.J., Slack, J., Simovic, M., Waldrep, K., Sondeen, J., Dubick, M.A., C1 inhibitor improves survival, reduces resuscitation fluid requirement and tissue damage in swine model of traumatic hemorrhage

b. Dubick, D.A., Li, Y., Grubbs, D.L., Barr, J.L., Dalle Lucca, J.J., The effects Of A C1 Inhibitor On Inflammatory Responses in Brain From Swine Subjected To Traumatic Hemmorrhage

c. Martini, W., Chung, K., Dubick, M.A., Comparisons of Normal Saline and Lactated Ringer's in Normal and Hypotensive Resuscitation after Hemorrhagic Shock in Pigs

d. Del Junco, D., Bulger, E., Fox, E., Holcomb, J., Brasel, K., Hoyt, D., Grady, J., Duran, S., Klotz, P., Dubick, M., Wade, C., When randomized trauma trials and bias collide: The trouble with subgrouping on surrogates for severity

e. Kheirabadi, B.S., Terrazas, I.B., Miranda, N., Gonzales, M.D., Sondeen, J.L., Dubick, M.A., Splenectomy Appears Necessary for Creating a Lethal Uncontrolled Hemorrhage Model with Limited Resuscitation in Swine

f. Torres Filho, I., Torres, L., Salgado, C., Valdez, C., Sondeen, J., Dubick, M.A., Effects of resuscitation fluids on endothelial glycocalyx (EG) and microvascular permeability studied by intravital microscopy: Integration of systemic and local parameters in vivo

g. Salgado, C., Valdez, C., Sondeen, J., Dubick, M., Torres Filho, I., In Vivo Microvascular Effects Associated With Prehospital 0.9% Saline (Ns) And 3% Hypertonic Saline (Hts) Resuscitation Regimen In A Hemorrhagic Shock (Hs) Model In Rats

h. Dalle Lucca, J.J., Pusateri, A., Valiyaveettil, M., Slack, J., McCarthy, J., Schwacha, M., Cap, A., Baer, D., Dubick, M.A. Profile of Early Immune and Coagulation Response to Trauma at a Level 1 Trauma Center in San Antonio Texas

i. Ritter, J., Kragh, J.F., Gross, K., Quantitative Anatomy of the Greater Trochanter and the Common Femoral Artery as to Guide Pelvic Binder and Junctional Tourniquet Placement

j. Khard, C.U., Tubb, C.C., Gross, K., Kragh, J.F. Evaluation of Prehospital Pelvic Binder Usage in US Military Casualties with Pelvic Fractures

k. Vega, S., Prat, N., Salinas, J., Dubick, M.A., Cap, A., Blackbourne, L., Decision Support for TEG Analysis

16) Patent Disclosure: Smart TEG- With CICR and Blood Research Task Areas

I. Systems of Care for Complex Patients (SCCP)

Task Area Manager: LTC (b) (6) , PhD, RN

1) Accomplishments Narrative

a. Notable Research and Development Accomplishments:

i) TATRC/JPC 6 Award for Development of En Route Burn Guidelines ($425K). Project is moving along very well and phase 2 expected to begin Q3 FY2014.

ii) Cooperative Communication Systems Phase 1 Completed (JPC-1 funded).

iii) Phases of Illness Paradigm project started Q1 FY2014. (TATRC funded).

iv) TriService Nursing Program (TSNRP) Development of an Evidence Based Practice Nurse Precepting Program concluded May 2014. Multiple dissemination efforts to include podium presentations at ABA 2014, Iowa Evidence Based Practice Conference 2014, manuscript published Journal BURNS 2014, The Surgeon General of the Army and Army Nurse Corps Chief and staff presentations.

v) Sepsis alerts started in Burn ICU Q4 FY2013, evaluation underway.

vi) Pathogenic bacteria on CAC/Identification cards completed – discovered CAC/ID cards safe to use in the Burn ICU environment, do not harbor pathogenic bacteria, and weekly cleaning reduces bacterial contamination of ID cards by 50%. Poster presentation 2014 ABA, podium and poster presentations at Tri-Service Nursing Research Conference 2014.

vii) Decontamination of skin for human transplant project completed and manuscript accepted for publication in JBCR 2014.

viii) Preliminary evaluation of the Joint Trauma System "Burn Care" Clinical Practice Guideline and Burn Flow Sheet completed Fall 2014. This process has already resulted in modifications to the CPG and supplemental materials have been added to the JTS site for currently deployed medical teams.

ix) Multicenter clinical trial underway in 4 Texas burn centers to identify burn sepsis related biomarkers. (DHP funded).

x) Comparison of teaching methods for extracorporeal membrane oxygenation (live tissue versus high-fidelity simulation) underway (JPC-1 funded).

b. Notable Research Transitions: Nurse Precepting Program briefed to The Surgeon General of the Army and Army Nurse Corps Chief and senior leaders for transition to facilities MEDCOM-wide**.**

c. Notable Products Completed: NA

d. Support Provided to Operational Units: LTC (b) (6) deployed in support of the Joint Combat Casualty Research Team from July to December 2013 as Site Lead for medical research at Bastion Hospital and Camp Leatherneck Afghanistan.

2) Significant Awards or Honors Received:

a. LTC (b) (6) member of the US Army Medical Command/ The Surgeon General of the Army's "Wolf Pack Award", 2014 (Annual Award and 1st Quarter 2014)

b. LTC (b) (6) received the Joint Service Commendation Medal, Army Achievement Medal, NATO Service Medal and Afghanistan Campaign Medal for deployment in support of the JC2RT at Camp Leatherneck, Afghanistan, July through December 2013

c. LTC (b) (6) was inducted as Fellow of the American College of Critical Care Medicine January 2014

3) Invited Lectures/Presentations:

a. "Nurse's Role in the Identification and Management of Sepsis", Research Seminar, University of Texas School of Nursing, Houston, TX, 7 March 2014

b. "Advances in Burn Fluid Resuscitation and Application to Military Medicine" and "Evidence Based Practice for Advancing Burn Care" Grand Rounds, Oregon Burn Center, Portland Oregon, 25 February 2014

c. "The Need for Smarter Monitors: Nurse Perspective", Smart Monitoring 2014, Ft Lauderdale, FL, 16-17 August 2014

d. “Military Advances in Burn Fluid Resuscitation” Research Seminar, University of Texas School of Medicine, Houston, TX, 6 June 2014

4) Scientific Presentations

a. “Discovering Complexities in Critical Care and their Challenges to Health IT Design in a Burn ICU” Pamplin, J., Anders, S., Brown, J., Crandall, B., Grome, A., Chung, K., Mann-Salinas, E., Nemeth, C., Society of Critical Care Medicine 43rd Congress, San Francisco, CA, 9-13 January 2014

b. “Prospective Clinical Evaluation of Delirium Screening in a Burn Intensive Care Unit”, Gallagher, S., Flores, D ., Gomez, C., Dunham, K., Robbins, J., Pamplin, J., Mann-Salinas, E., 46th Annual American Burn Association Meeting, Boston, MA, 25-28 March 2014

c. “High Fidelity Human Patient Simulation: Bridging Burn Care Education with Modern Technology”, Hayes, E., Coffman, R., Serio-Melvin, M., Valdez-Delgado, K., Mann-Salinas, E., 46th Annual American Burn Association Meeting, Boston, MA, 25-28 March 2014

d. “Demonstrated Benefits of an Evidence-Based Burn Precepting Program”, Robbins, J., Hayes, E., Valdez-Delgado, K., Sabido, J., Yoder, L., Greeley, H., Mann-Salinas, E., 46th Annual American Burn Association Meeting, Boston, MA, 25-28 March 2014

e. “Continuous Renal Replacement Therapy Sustainability in a Burn ICU: A Coordinator Perspective”, Rodriguez, J.G., Edgecombe, H.P., Wallace, A., Robbins, J.R., Renz, E.M., Mann-Salinas, E., Chung, K.K., 46th Annual American Burn Association Meeting, Boston, MA, 25-28 March 2014

f. “Developing an Evidence Based Practice (EBP) Nursing Precepting Program” , Hayes, E.J., Robbins, J., Mann-Salinas, E., Yoder, L., Valdez-Delgado, K., Sabido, J., Allen, D., Feider, L., 21st National Evidence-Based Practice Conference, Iowa City, IA, 24-25 April 2014

g. “Determination of the Optimal Delirium Screening Tool for Burn Intensive Care Unit Patients”, Mann-Salinas, E.A., Gallagher, S.P., Flores, D., Lopez, C., Dunham, K., Robbins, J., Pamplin, J., 2014 Military Health System Research Symposium, Ft. Lauderdale, FL, 18-21 August 2014

h. “Developing a Cognitive and Communications Tool for Burn ICU Clinicians” Nemeth, C ., Pamplin, J., Anders, S., Strouse, R., Grome, A., Crandall, B., Salinas, J., Mann-Salinas, E., 2014 Military Health System Research Symposium, Ft. Lauderdale, FL, 18-21 August 2014

i. “Bridging Combat Causality Burn Care Education with High Fidelity Human Patient Simulation”, Hayes, E.J., Serio-Melvin, M., Valdez-Delgado, K., Coffman, R.L., Mann-Salinas, E.A., 2014 Military Health System Research Symposium, Ft. Lauderdale, FL, 18-21 August 2014

j. “Unit Practice Council Successful Efforts for Implementing Alcohol Impregnated Port Protectors”, Mitchell, C., Martino, A., Fields, J., Martinez, D., Hatem, A ., Bang, S., Mann-Salinas, E., 2014 Military Health System Research Symposium, Ft. Lauderdale, FL, 18-21 August 2014

k. “Burn Intensive Care Unit Multidisciplinary Approach Facilitates Adult Extracorporeal Life Support Therapy” Mitchell, C., Muller, M., Negaard, K., Mann-Salinas, E., Renz, E., King, B., Chung, K., Cannon, J., 2014 Military Health System Research Symposium, Ft. Lauderdale, FL, 18-21 August 2014

l. “Implementation of an Evidence-Based Burn Precepting Program on a Progressive Care Unit: A Coordinators Perspective.” Barba, M., Robbins, J., Hayes, E., Valdez-Delgado, K., Vanfosson, C., Mann-Salinas, E., 2014 TriService Nursing Research and EBP Dissemination Course, San Antonio, TX, 15-18 September 2014

m. “Development of an Evidence-Based Comprehensive Pressure Ulcer Prevention Program in a Burn Intensive Care Unit.” Shingleton, S., Charo-Griego, S., Patino, I., Mueller, M., Willenberg, S.,

Mann-Salinas, E., Allen, D., 2014 TriService Nursing Research and EBP Dissemination Course, San Antonio, TX, 15-18 September 2014

n. "Are Common Access Cards the Fomites of Military Medicine?" Caldwell, N., Guymon, C., Aden, J., Chafin, K., Mann-Salinas, E., 2014 TriService Nursing Research and EBP Dissemination Course, San Antonio, TX, 15-18 September 2014

o. "Unit Practice Council Initiatives to Introduce Alcohol Impregnated Port Protectors are Effective in Reduction of Central Line Infection Rates." Thompson, L., Mitchell, C., Martino, A., Fields, J., Martinez, D., Hatem, A., Bang, S., Mann-Salinas, E., 2014 TriService Nursing Research and EBP Dissemination Course, San Antonio, TX, 15-18 September 2014

p. "Transforming Care at the Bedside: Implementation of a Midline Intravenous Catheter for Burn Patients to Decrease Frequent Peripheral Sticks and Infection Risk." Robbins, J., Phillips, S, Vanfosson, C., Peak, T., Mittelsteadt, P., Riley, N., Palacios, R., Valdez-Delgado, K., Caldwell, N., Mann-Salinas, E., 2014 TriService Nursing Research and EBP Dissemination Course, San Antonio, TX, 15-18 September 2014

q. "Comprehensive Evaluation of the Joint Trauma System Burn Documentation Process." Mann-Salinas, E., Serio-Melvin, M., Caldwell, N., Garcia, A., Jackson, B., Chung, K., Cancio, L., Salinas, J., 2014 TriService Nursing Research and EBP Dissemination Course, San Antonio, TX, 15-18 September 2014

r. "High Fidelity Human Patient Simulation: Bridging Burn Care Education with Modern Technology." Serio-Melvin, M., Hayes, E., Coffman, R., Valdez-Delgado, K., Mann-Salinas, E., 2014 TriService Nursing Research and EBP Dissemination Course, San Antonio, TX, 15-18 September 2014

5) Poster Presentations

a. "Secondary Validation of Novel Predictors of Sepsis in the Burn Patient", Mann-Salinas, E.A., Chang, S., Bartels, J., Hurst, K., Batchinsky, A., Society of Critical Care Medicine 43rd Annual Congress, San Francisco, CA, 9-13 January 2014

b. "Deployment of a Mobile Decision Support System in a Burn Intensive Care Unit" Salinas, J., Serio-Melvin, M., Fenrich, C., Driscoll, I., Garcia, A., Mann-Salinas, E., Cancio, L ., Chung, K., Society of Critical Care Medicine 43rd Congress, San Francisco, CA, 9-13 January 2014

c. "Discovering Complexities of Information Sources in a Burn ICU & Implications for Heath IT Design" Nemeth, C., Pamplin, J., Anders, S., Brown, J., Crandall, B., Grome, A., Chung, K., Mann-Salinas, E., Society of Critical Care Medicine 43rd Congress, San Francisco, CA, 9-13 January 2014

d. "Using Electromagnetic Guidance for Successful Placement of Enteral Tubes by Nurses in Burn Patients", Robbins, J., Shields, B., Allen, D., Wallace, A., Sabatino, B., Phillips, S., Mann-Salinas, E., King, B., 46th Annual American Burn Association Meeting, Boston, MA, 25-28 March 2014

e. "Implementation of a Nurse-Led Burn Wound Care Team: Lessons Learned", Campbell, M.A., Meisner, J.R., Trichel, R., Rodriguez, J.G., Mann-Salinas, E., Peak, T.F., Shingleton, S., 46th Annual American Burn Association Meeting, Boston, MA, 25-28 March 2014

f. "Implementation of a Midline Intravenous Catheter for Burn Patients to Decrease Frequent Peripheral Sticks and Infection Risk", Robbins, J., Phillips, S., Vanfosson, C., Peak, T., Mittelsteadt, P., Riley, N., Palacios, R., Valdez-Delgado, K., Caldwell, N., Mann-Salinas, E., 46th Annual American Burn Association Meeting, Boston, MA, 25-28 March 2014

g. "Pathogenic Bacteria on Common Access and Identification Cards: A Search for Badge Bugs", Caldwell, N., Guymon, C.H., Aden, J., Chafin, K., Mann-Salinas, E., 46th Annual American Burn Association Meeting, Boston, MA, 25-28 March 2014

h. “Demonstrated Benefits of an Evidence-Based Precepting Program”, Robbins, J.R., Valdez-Delgado, K., Sabido, J.M., Yoder, L.H., Mitchell, C., Barba, M.G., Shingleton, S.K., Mann-Salinas, E.A., 2014 Military Health System Research Symposium, Ft. Lauderdale, FL, 18-21 August 2014

i. “Card Sorts Help “Unpack” Clinician Perspectives on Patient Condition and Treatment Priorities”, Pamplin, J., Murray, S., Chung, K.K., Huzar, T., Wolfe, W., Mann-Salinas, E., Nemeth, C., 2014 Military Health System Research Symposium, Ft. Lauderdale, FL, 18-21 August 2014

j. “Developing Cognitive Aides according to the Phases of Illness Paradigm for use in the Burn ICU”, Murray, S., Chung, K., Mann-Salinas, E., Caldwell, N., Huzar, T., Wolfe, W., Nemeth, C., Pamplin, J., 2014 Military Health System Research Symposium, Ft. Lauderdale, FL, 18-21 August 2014

k. “Deployment of a Mobile Decision Support System in a Burn ICU: A Case Series”, Serio-Melvin, M., Fenrich, C.A., Driscoll, I., Garcia, A., Mann-Salinas, E., Chung, K.K., Cancio, L.C., Salinas, J., 2014 Military Health System Research Symposium, Ft. Lauderdale, FL, 18-21 August 2014

l. “Practice Transformation: An Evidence-Based Practice Nurse Precepting Program.” Robbins, J., Hayes, E., Valdez-Delgado, K., Sabido, J., Yoder, L., Greeley, H., Mitchell, C., Mann-Salinas, E., 2014 TriService Nursing Research and EBP Dissemination Course, San Antonio, TX, 15-18 September 2014

m. “Implementation of an Evidence-Based Burn Precepting Program on a Progressive Care Unit: A Coordinators Perspective.” Barba, M., Robbins, J., Hayes, E., Valdez-Delgado, K., Vanfosson, C., Mann-Salinas, E., 2014 TriService Nursing Research and EBP Dissemination Course, San Antonio, TX, 15-18 September 2014

n. “Development of an Evidence-Based Comprehensive Pressure Ulcer Prevention Program in a Burn Intensive Care Unit.” Shingleton, S., Charo-Griego, S., Patino, I., Mueller, M., Willenberg, S., Mann-Salinas, E., Allen, D., 2014 TriService Nursing Research and EBP Dissemination Course, San Antonio, TX, 15-18 September 2014

o. “Are Common Access Cards the Fomites of Military Medicine?” Caldwell, N., Guymon, C., Aden, J., Chafin, K., Mann-Salinas, E., 2014 TriService Nursing Research and EBP Dissemination Course, San Antonio, TX, 15-18 September 2014

p. “Nurse Placed Enteral Feeding Tube: A Practical Solution for the Critical Care Environment.” Wallace Jr., A., Sabatino, B., Shields, B., Robbins, J., Phillips, S., Mann-Salinas, E., King, B., 2014 TriService Nursing Research and EBP Dissemination Course, San Antonio, TX, 15-18 September 2014

q. “Unit Practice Council Initiatives to Introduce Alcohol Impregnated Port Protectors are Effective in Reduction of Central Line Infection Rates.” Thompson, L., Mitchell, C., Martino, A., Fields, J., Martinez, D., Hatem, A., Bang, S., Mann-Salinas, E., 2014 TriService Nursing Research and EBP Dissemination Course, San Antonio, TX, 15-18 September 2014

r. “Transforming Care at the Bedside: Implementation of a Midline Intravenous Catheter for Burn Patients to Decrease Frequent Peripheral Sticks and Infection Risk.” Robbins, J., Phillips, S., Vanfosson, C., Peak, T., Mittelsteadt, P., Riley, N., Palacios, R., Valdez-Delgado, K., Caldwell, N., Mann-Salinas, E., 2014 TriService Nursing Research and EBP Dissemination Course, San Antonio, TX, 15-18 September 2014. *First Place Award, EBP Poster Category*

s. “Comprehensive Evaluation of the Joint Trauma System Burn Documentation Process.” Mann-Salinas, E., Serio-Melvin, M., Caldwell, N., Garcia, A., Jackson, B., Chung, K., Cancio, L., Salinas, J., 2014 TriService Nursing Research and EBP Dissemination Course, San Antonio, TX, 15-18 September 2014

t. "Prospective Clinical Evaluation of Delirium Screening in a Burn Intensive Care Unit." Gallagher, S., Flores, D., Gomez, C., Dunham, K., Robbins, J., Pamplin, J., Mann-Salinas, E., 2014 TriService Nursing Research and EBP Dissemination Course, San Antonio, TX, 15-18 September 2014

u. "High Fidelity Human Patient Simulation: Bridging Burn Care Education with Modern Technology." Serio-Melvin, M., Hayes, E., Coffman, R., Valdez-Delgado, K., Mann-Salinas, E., 2014 TriService Nursing Research and EBP Dissemination Course, San Antonio, TX, 15-18 September 2014

6) Publications

a. Mann-Salinas, E.A., Hayes, E.J., Robbins, J.R., Sabido, J.M., Feider, L.L., Allen, D.A., Yoder, L.H., "Systematic Review of the Literature to Support an Evidence-Based Precepting Program:" 2014, *Burns, 40(3): 374-387*

b. Mann-Salinas, E.A., Kragh Jr, J.F., Dubick, M.A., Baer, D.G., Blackbourne, L., "Assessment of Users to Control Simulated Junctional Hemorrhage with Combat Ready Clamp (CRoC), *2013, Intern J Burns Trauma,* 3:1, 49–54

c. Shields, B.A., Brown, J.N., Aden, J.K., Salgueiro, M., Mann-Salinas, E.A., Renz, E.M., Chung, K.K., "A Pilot Review of Gradual versus Goal re-Initiation of Enteral Nutrition after Burn Surgery in the Hemodynamically Stable Patient", 2014, *J Burns 2 July e pub ahead of print; doi:10.1016/jburns.2014.02.015*

d. Schmidt, P., Mann-Salinas, E.A., "Evolution of Burn Management in the United States Military: Impact on Nursing", 2014, *Annual Rev Nursing Research,* 32(1): 25-39

e. Nemeth, C., Anders, S., Grome, A., Crandall, B., Dominguez, C., Pamplin, J., Mann-Salinas, E., Serio-Melvin, M., "Support for ICU Resilience: Using Cognitive Systems Engineering to Build Adaptive Capacity", Conference proceedings of the 2014 IEEE International Conference on Systems, Man and Cybernetics

f. Caldwell, N.W., Guymon, C.H., Aden, J.K., Akers, K., Mann-Salinas, E.A., "Bacteria on Burn Unit Employee Identity Cards", in press *J Burn Care Research*

J. Comprehensive Intensive Care Research (CICR)

Task Area Manager: (b) (6) **, PhD**

1) Accomplishments Narrative

a. Notable Research and Development Accomplishments: The CICR Task Area has continued efforts to set up, test, and validate several decision support systems and devices for the critical care environment. Additionally, work on the basic research to characterize the performance of several extra-corporeal life support devices on animal models has continued to be performed using funding obtained from both core and extra-mural sources. Over the last year, the CICR task area has continued to support an FDA compliant infrastructure within the USAISR for full testing, validation, and verification of software based medical devices. This new infrastructure has been used for validation of 2 devices developed within this task area (IDEA, BRDSS-C). We continue to work and collaborate with the FDA as we transition new automation and decision support system to human trial that require potential FDA regulatory oversight. In addition to development of these devices, we have continued testing a new resuscitative endovascular balloon occlusion of the aorta (REBOA) device that provides easy access and placement of the catheter without a wire guide in a patient that has

noncompressible torso hemorrhage. This device has been tested in animal model of severe hemorrhage.

b. Using our existing collaborations with several European and US research institutes, we have also continued testing the use of the Maquet and Hemolung extra corporeal membrane oxygenation (ECMO) device for potential use as adjuncts to mechanical ventilation in patients with acute respiratory distress syndrome (ARDS). These devices provide additional ventilation and/or oxygenation of the patient through the use of minimally invasive catheters placed in one of several arterial and/or venous access points.

2) Notable Research Transitions: We have initiated product transitions for advanced development of the following products:
   a. Extra Corporeal Member Oxygenation (ECMO) – This product will provide military critical care providers the ability to support patients diagnosed with acute respiratory distress syndrome (ARDA). The ECMO devices will serve as adjuncts to mechanical ventilators for patients starting at Role 3.
   b. Intelligent Focused Assessment with Sonography for Trauma (iFAST) – We have developed a new system to provide advanced diagnostic capability of portable ultrasound video and imagery using advanced image processing algorithms for automated detection of hemo-thorax and pneuno-thorax injuries.
   c. Smart Thromboelastograph (smartTEG) – This product will provide clinicians in the far forward environment the ability to interpret coagulation status of critical care patients through the use of pattern recognition software. The smartTEG system provides an interface into the TEG device to process the output data and generate both a diagnosis and treatment recommendation based on multiple coagulation parameters derived through the device data stream.
   d. Ventilator Decision Support System (Ventilizer) – This device will provide users with recommendations for better ventilator management based on standard guidelines. Using existing clinical practice recommendations, the system allows for better ventilator management of critical care patients.
   e. IDEA (Integrated Data Exchange and Archival) System: The system received a US Army Certificate of Networthiness (CoN) to allow for full deployment in an Army facility.
3) Notable Products Completed: Burn Resuscitation Decision Support System – Clinical Variant (BRDSS-C): The BRDSS-C device received full FDA 510(k) clearance in December 2014.
4) Support Provided to Operational Units: We have supported both Landstuhl Regional Medical Center (LRMC) and AF CCATT units as part of the current ECMO program to test ECMO devices during overseas evacuation.
5) Significant Awards or Honors Received: The BRDSS-C and Burn Navigator team received the annual AMEDD Wolf Pack ward as recognition of the work to develop and field the Burn Navigator system.

K. Publications:

1) Nitzschke, S.L., Aden, J.K., Serio-Melvin, M.L., Shingleton, S.K., Chung, K.K., Waters, J.A., King, B.T., Burns, C.J., Lundy, J.B., Salinas, J., Wolf, S.E., Cancio, L.C., Wound healing trajectories in burn patients and their impact on mortality, Journal of Burn Care & Research 35 (6), 474-479
2) Belenkiy, S.M., Batchinsky, A.I., Park, T.S., Luellen, D.E., Serio-Melvin, M.L., Cancio, L.C., Pamplin, J.C., Chung, K.K., Salinas, J., Cannon, J.W., Automated inhaled nitric oxide alerts for adult extracorporeal membrane oxygenation patient identification, Journal of Trauma and Acute Care Surgery 77 (3), S184-S189
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Dental and Trauma Research Detachment (DTRD)

Mission: Provide militarily relevant research and solutions to treat and rehabilitate craniomaxillo-facial trauma and prevent infectious dental disease.

Major Accomplishments from the fiscal year 2014 included:

A. Dental Epidemiology: Our group has published five articles and submitted another in the continuation of our dental DNBI study. The articles consisted of a study of the financial impact of treating dental emergencies and the cost to units of time lost due to emergency visits. The second was a retrospective study of the frequency and rates of dental emergencies and diagnoses in theater for three years of deployment in OIF and OEF, comparing active duty, reserve, and national guard US Army components. This consisted of analysis of over 31,000 dental encounters.

B. Antiplaque chewing gum: Phase 1/2a clinical trials still are being conducted at the OralHealth Research Institute, Indiana University (IU). Completed preparation of IND for electronic FDA filing for the testing of antiplaque gum.

C. Anti-Biofilm Treatment Evaluations: Further work on determining dose-response curves for antimicrobial therapies (using: selected antimicrobial peptides and conventional antibiotics; quorum-sensing inhibitors; and biofilm-disrupting agents) for controlling mono-and mixed-species biofilm formation (consisting of commonly found wound pathogens) using a well-established i*n vitro* biofilm assays under static and flow conditions.

D. Antimicrobial Peptides Adjuncts: Tested protease inhibitors to prevent degradation of antimicrobial peptides in the presence of trypsin, chymotrypsin, and elastase as part of the formulation development for the thermo-sensitive wound gel containing PLGA micro-encapsulated antimicrobial peptides.

E. Pro-resolution of Inflammation: Obtained ISR-IACUC approval (Dec 2012) of animal protocol A-13-010 "Exacerbated Inflammation in a Rabbit (*Oryctolagus cuniculus)* Ear Wound Model" for a model of pathologically inflamed wounds to screen for pro-resolving mediators that return inflammation to homeostasis. Craniofacial Bone Regeneration.

F. Armed Forces Institute of Regenerative Medicine II:

1) Bone Regeneration: The Dental and Trauma Research Detachment of the Institute of Surgical Research, through our collaboration with institutions of the Armed Forces Institute of Regenerative Medicine II, successfully maintained collaborations with three institutions of the Armed Forces Institute of Regenerative Medicine (AFIRM) to evaluate and translate materials to regenerate bone more predictably and in shorter time than the current clinically available options. Initiated pre-clinical animal models to mimic severe injuries of our wounded warriors to best test the clinical bone regenerative potentials of these biomaterials. The combination of the advanced bone regenerative materials and animal models are critical to translate better clinical options for the surgeons working to restore battle-injured soldiers' oral facial form and function.

2) Skin Regeneration: DTRD established a collaborative network consisting of US Army Institute of Surgical Research, Southwest Research Institute, Rochal Industries, and Walter Reed National Medical Center. The proposed research aims to address the maxillofacial tissue repair and regeneration problem by developing a bi-layered mask for high quality skin restoration. The scope of this clinically-relevant applied research effort is to produce develop a "Biomask for Skin Regeneration," to support full-thickness skin regeneration of the face.

G. Joint-Service Projects and Major Collaborations:

1) US Navy: *A Novel Bioactive Chitosan-Fibrinogen Wound Healing Dressing for Craniofacial Injuries*. Wound healing scientists from DTRD have formed a joint research team with researchers from the Navy Medical Research Unit-San Antonio to engineer a novel resorbable wound bandage which releases temporally-essential growth factors and/or antimicrobial agents. The objective of this project is to fabricate a biomimetic active wound healing dressing based on a nanofibrous scaffold with extracellular matrix (ECM) morphology and composition. Specifically, we will create a nanoscaffold capable of sustained release of platelet-derived growth factor (PDGF). The nanofibrous dressing will be formulated with chitosan and fibrinogen. In addition to growth factor release, it will have the added benefits that a physical dressing provides in wound healing, such as emollient, demulcent, astringent, antimicrobial, and anti-inflammatory properties. The wound dressing will serve to improve wound-healing time, potentially reduce scar formation, and control for altered physical parameters that exist at the wound site.

2) US Navy: *Evaluation of the Immune Response Associated with Maxillofacial Bone Regeneration and Wound Healing in a Porcine Model of Maxillofacial Osteogenesis.* The long term goals of this project are to (1) establish immune profiles for a mandibular bone defect which will set the foundation for developing future immunomodulatory therapeutics for mandibular bone defects and (2) to identify immune biomarkers that are associated with various stages of maxillofacial bone regeneration which could be utilized for enhancing the osteogenesis process leading to improvements in standard of care, while minimizing invasive procedures. The research objectives of this project are to identify immune biomarkers that are associated with various stages of maxillofacial bone regeneration including what cytokines and chemokines are involved, when they are involved, and sample sources in which they can be detected. Our central hypothesis is that key immune biomarkers are associated with various stages of maxillofacial bone regeneration and wound healing, and the biomarkers can be utilized for diagnosing the osteogenesis process leading to improvement in standard of care, while minimizing invasive procedures.

3) US Air Force - US Navy - Brooke Army Medical Center: *Regeneration of the Facial Nerve Following Tissue Avulsion in a Murine Model*. A Collaboration between DTRD, US Army Institute of Surgical Research and Surgeons from the US Navy and US Air Force in the Department of Otolaryngology, San Antonio Military Medical Center.

4) Uniformed Services University of the Health Sciences: COL (b) (6) was appointed as a member of the Committee on Faculty Appointments and Promotions, Postgraduate Dental College.

5) Media Event: *San Antonio Express-News – Health Care*: "Plaque-fighting chewing gum could aid deployed soldiers"; August 11, 2014; (b) (6)

6) International Meetings: *U.S. Delegation to the NATO Workshop on Regenerative Medicine* (030792 NATO STO HFM-243), in cooperation with Julius Wolff Institute and Center for Regenerative Medicine Therapies, Charlité-Universitätsmedizin Berlin, Germany Workshop on Regenerative Medicine: COL (b) (6) Chaired Session on "Diagnostic Methods, Biomarkers and Monitoring Techniques."

H. Leadership

1) COL (b) (6) assumed command of DTRD on September 29, 2014.

2) COL (b) (6) appointed to Dental Corps Executive Committee and Consultant for Dental Research.

I. Staffing

1) Arrivals:

a. Post Doctorate: (b) (6)

b. Visiting Scientist/Clinician: (b) (6), Doctor of Dentral Surgery (DDS) from the University of Japan. (b) (6) was participating in the Oak Ridge Institute for Science and Education (ORISE), a U.S. Department of Energy institute focused on scientific initiatives to research health risks from occupational hazards, assess environmental cleanup, respond to radiation medical emergencies, support national security and emergency preparedness, and educating the next generation of scientists.

c. Enlisted Soldiers: SPC (b) (6); SPC (b) (6); PFC (b) (6) PV2 (b) (6)

d. Military Officers: MAJ (b) (6) (Physiologist); CPT (b) (6) (Microbiologist)

2) Departures:

a. Post Doctorate: (b) (6), Biologist

b. Government Employees: (b) (6)

c. Enlisted Soldiers: SFC (b) (6), SSG (b) (6) both to USAISR.

d. Military Officers: COL (b) (6), DDS, outgoing Commander of DTRD

J. Information Productivity is shown in Figure 13.

FIGURE 13: Information Productivity

Type	Quantity
Abstracts	6
New protocols (approved in 2014)	9
Posters presented	10
Presentations given	9
Publications accepted	14

Resource Directorate

The USAISR Resource Directorate is managed by the Resource Director who also serves as the USAISR Chief of Staff. The Resource Directorate is comprised of five divisions from Security, Training and Operations; Research Regulatory Compliance; Information Management; Logistics; and Personnel; as well as three offices from Safety; Public Affairs; and Occupational Health. The Resource Directorate oversees the day-to-day operation of the USAISR.

1. Information Management Division
    a. The Information Management Division provides a broad range of capabilities to include: database design, analysis and management, technical support, data management, coordination of data communication activities, planning and programming for automation enhancements, information resource access, information assurance security and risk management, and review and analysis of workflow performance improvement activities, media informatics support, and library research services.
        i. The Information Management Office provides directed technical support in concert with the MEDCOM Enterprise Service Desk (ESD) to clinical, research, Department of Defense Trauma Registry (DoDTR), and administrative support missions through the utilization of clinical and research instrumentation and data acquisition, database development and linkage to external systems of record, and support of the research data needs in development of protocols and analytical tools and software. This includes Bio-Medical Engineering interfacing of medical devices for experimental procedures and operations, and the development of mathematical or software solutions or troubleshooting through applied computer techniques.
        ii. Desktop workstations were replaced as part of the planned and implemented lifecycle management in standardizing IT/IS equipment. Improvements were also made in upgrading and support, networking, operating system environment, and commercial off-the-shelf software where possible. Windows Servers were not completely migrated to Windows 2008R2 operating systems from Windows 2003 due to continued staffing vacancies for the duration of the entire year. Migration of the DoDTR system from the old physical server platform to our VMWare virtual environment was postponed due to lack of skilled staff to perform the job.
        iii. A major emphasis on network and information security has resulted in providing a computer system network and communications environment more stable and less vulnerable to external attacks and disruptions of computer services. The ACAS implementation was postponed by USAMITC due to lack of skilled staff on their part to complete the project on time.

iv. The initial implementation of a dedicated laboratory instrument vlan and laboratory information system was accomplished during this period. We leveraged the existing DAQ data collection technology with some custom programming to permit laboratory instruments to relay information to the protected network while maintaining flexibility and security. This has initially reduced human transcription of results from two instruments and is being expanded to other instruments. This will eliminate the need for transferring data to CD and then to a networked computer improving time efficiency and security.

v. The Integrated Research Database (IRDB) continued to advance, adding additional datasets and instrumentation feeders into a stable Oracle 11g database structure for future research information processes.

vi. A nationwide search finally yielded a new LabView programmer who is EE qualified. This new person enabled the IMO Bio-medical Branch to continue development for the Data Acquisition (DAQ) station and increase research data acquisition capabilities while providing a high level of station standardization with COTS software and off-the-shelf components from National Instruments. Higher demands on acquisition automation, more medical devices in OR and ICU integrated with the DAQ system, and improved automation and control have increased demand for use of these data stations. The new software developments have provided a modular code structure, expandable features, very efficient run time modules, voice capable recording, and adaptable for video/ imaging functions. All features are database capable with a real-time playback process for digital and multimedia data

b. Media Informatics Branch / Knowledge Management (MIB/KM): MIB/KM continues to seek better Knowledge Management (KM) practices within MIB and the institute. This includes the KM practices associated with documents, forms, publications and the institute's history. MIB operational oversight includes the content development for the public web site and the institute's intranet.

i. MIB manages the imagery used in support of the institute missions in both clinical and research operations. This includes consultation for collection methods and technologies, management of imagery and records archival, and the support of presentation output to include imagery prints, media and output for submissions for publication and/or display.

ii. The release of clinical imagery is managed in accordance with AR 40-66, Medical Record Administration and Health Care Documentation, in support of patient and legal requests submitted to BAMC Patient Administration Division.

iii. The DICOM imagery collection from Theater is no longer expanding. The legacy system was housed in a MedWeb system that has been superceded by an Orthanc system. Orthanc is open source and allows us to customize the data index for AISR unique research requirements. The legacy DICOM images are currently being imported into the Orthanc system.

iv. MIB/KM continues responsibility for records management and office symbols.

c. Research Library: The Library is responsible for providing services to the Research Directorate and the clinical Trauma Division. These services include literature searches, bibliography preparation, interlibrary loan service, collection development with textbooks and current references, and maintenance of a print periodical collection. Reference and research publication holdings and materials are determined based upon Combat Casualty Care and Patient Care Research programs. Additionally the USAISR Library coordinates with the Army Library Program Manager, the MRMC Command Librarian, state and regional library consortia and groups, and IMD resources to provide database access to online journal content.

i. A definitive intranet resource site continues to be developed to contain all updated database and content links. This resource gives a one stop entry point to the majority of online resources available to the ISR staff. It also displays topical news and information on library activities.

ii. Interlibrary loan activities continue to maintain pace with previous years. Networking and electronic access are vital components of patron education and services. Conversely, barriers to access are instigated at various levels by publishing interests and upgrades to security. The challenges of the librarian/technical information specialist changes dynamically as we seek to improve customer access and service.

2. Logistics Division

a. Mission: The Logistics Division provides an extensive array of support services to the USAISR that include receiving Class VIII supplies and equipment for issue and turn-in, coordinating the reutilization of excess equipment, conducting medical equipment maintenance and repair services, managing facility services, maintaining temporary storage areas, processing unit supply requirements for the enlisted Soldiers, and supporting Joint Service Operations. The Logistics Division maintains liaison with MEDCOM, HQ MRMC, and BAMC Logistics personnel to ensure an optimum support operation.

b. Organization: In FY14, the Logistics Division was staffed by the Chief of Logistics, Property Book Officer, two Facility Managers, Logistics NCOIC, two 68J, one 68A, four Medical Equipment Repairers, two General Supply Specialists, and five Supply Technicians.

c. Significant Accomplishments:

i. Equipment Management:

1. The value of the property book at year-end close was $40,870,727.34.

2. The number of items on the property book at year-end close was 8,384.

ii. Facility Management:

1. Repair Fire Alarm System in building 3611. This project is currently in the Design Phase. The existing fire alarm system is not equipped with mass notification which is essential to the safety of personnel. This is a vital requirement which will allow the unit to receive and/or transmit information to Fort Sam Houston during an emergency situation. The total cost of this project will be $1,127,587.00.

2. Latrine Renovation in building 3611. This project is currently in progress. The existing latrines are in need of renovation to repair all deteriorated lavatories and tile. The latrines will be fully equipped with new water saving plumbing fixtures and energy efficient lighting. The total cost of this project is $1,057,500.00.

3. Replace Interior Wooden Doors and Hardware in Vivarium of building 3611. This project is currently in the submittal phase. The existing doors and hardware have exceeded life expectancy and require constant maintenance. The total cost of this project was $274,148.00.

3. Operations, Training and Security Division

a. The current staff is comprised of the Chief, Operations, Security, & Training, the Training Coordinator, the Operations NCO, the DTMS Administrator and an Administrative Clerk shared with the reception desk. The Division stood an MRMC OIP inspection and did very well with only one area with a minor deficiency which has since been corrected.

b. Operations

i. To date, reviewed over 831 abstracts, posters and publications.

ii. Participated in two MASCAL exercises generated by Brooke Army Medical Center while serving as the Commander's representative in the Emergency Operations Center, while utilizing the Send Word Now program.

iii. Coordinated and initiated Quarterly Training Briefs by establishing formats and data sets based on directives from the Institute Commander.

iv. Processed 14 personnel for deployments to various theaters of operation (TCS orders).

v. Provided input and submitted requirements utilizing the Defense Readiness Reporting System-Army (DRRS-A) program.

vi. Provided oversight and review of 94 contracts relative to Operations Security and Anti Terrorism and Force Protection.

vii. Reviewed and certified over 2,900 Government Credit Card single line items as a Billing Official utilizing GFEBS, Access Online and PCOLS.

viii. Participated in 3 Joint Base San Antonio (JBSA) force protection exercises while proving the command team with updates utilizing the WEBEOC computer program.

ix. Served as the Civilian Awards Board Chairman and processed over 78 awards.

x. Prepared for and participated in the MRMC OIP inspection.

c. Security

i. Maintained the Anti-Terrorism plan for the organization.

ii. Conducted training on safeguarding classified information and the proper use of secure systems to the staff of the Joint Theater Trauma Registry.

iii. Provided security plans and assisted with details for ISR events and functions.

iv. Processed over 675 VIP parking requests through the BAMC Provost Marshal's office; received over 8,684 visitors to the facility in 2014.

d. Training

i. Continued Birth Month based Training throughout the organization with a continued reduction of delinquencies. This process is still very successful and is keeping training delinquencies to less than 3% in most categories.

ii. Continued a block scheduling for all face-to-face training. The annual classes are held together and taken in the birth month. This has reduced delinquencies and made tracking more efficient.

iii. The Training Coordinator provides weekly reports to MRMC for deployments, schools and current training status.

iv. The Training Coordinator provides weekly Training rosters to supervisors and management to assist with bringing staff up to current training status.

v. The Digital Training Management System Administrator (DTMS) completes approximately 8,000 transactions of all completed mandatory training for assigned personnel.

vi. Incorporated DA directed face to face TARP training. Completed over 40 sessions resulting in 99% of the staff attending this training requirement.

vii. In and out-processed approximately 496 personnel and submitted 360 requests for background checks.

e. OCONUS Travel

i. Provides personnel requesting OCONUS Temporary Duty (TDY) or Leave instructions regarding necessary requirements. Approximately 38 OCONUS leaves and TDY's were taken by ISR personnel in 2014.

ii. Tracked packet completions and submitted packets to MRMC for approval and State Department clearances. Conducts follow up appointments with each traveler to inform them of the status of their clearance. Ensured no personnel traveled without proper paperwork and clearance.

iii. Provided Pre-Deployment packets, assisted in packet completion, readiness and SRP issues, made CRC reservations for 14 deploying soldiers.

4. Personnel Division

a. Mission: The Personnel Division manages, coordinates, executes and provides oversight for the military and civilian human resource management functions. This division analyzes current personnel capabilities, organizational design, mission requirements and assets to produce a personnel management strategic master plan. The plan identifies the most efficient organization that is within fiscal and manpower constraints; and one that will meet mission requirements. This office provides solutions to management problems and programs such as military and civilian pay, civilian appraisal, promotions, assignments, enlisted and officer efficiency reports (NCOERs and OERs), incentive awards, records management, suspense tracking system, civilian recruitment (utilizing the Defense Civilian Personnel Data System (DCPDS)), employee relations, training and updates military personnel information into EMILPO.

b. Organization: In FY 2014, the Division was staffed by the Chief of Personnel ((b) (6) , one Military Personnel Technician ((b) (6) , one Administrative Support Specialist ((b) (6)) and one Contract Assistant ((b) (6)), who transitioned to civil service as a Human Resources Specialist (Military) on September 8, 2014.

c. Human Resources

i. Significant Personnel Gain: None

ii. Significant Personnel Loss: None

d. Balanced Scorecard: The primary areas associated with the Personnel Division are R 1.0: Optimize Resources and LG 2.0 Train and Develop the Force. Both areas are an ongoing initiative associated with personnel throughout the command. However, in FY 14, Army, MEDCOM and MRMC placed increased emphasis on civilian training, encouraging all employees to seek opportunities and complete their CES target course.

e. Significant Accomplishments:

i. Military Personnel: The Personnel Division Human Resource (Military) clerk continuously expressed the importance of the timely submission of NCOERs and OERs to the Human Resources Command (HRC). The timely submission of awards, especially for departing Soldiers was a high priority, not only for the organization, but for HQ, MRMC and MEDCOM as a whole. The Division continued to work closely with the USAISR Company Commander and First Sergeant to improve support to Officers and Soldiers.

ii. Civilian Personnel: By serving as the focal point for the Personnel Demonstration Project, maintaining a current awareness of all changing procedures/policies and providing professional service and assistance to the employees and supervisors on all civilian

personnel issues continues to improve the confidence rating of this Division. This division continues to maintain an excellent liaison with Fort Detrick Civilian Personnel Advisory Center - thus resolving problems immediately and keeping abreast of new and changing personnel regulations.

iii. On April 1, 2014, the Army began using the Evaluation Entry System (EES) to process all Officer Evaluation Reports. This undertaking required all officers to be trained on the new system and was accomplished without any issues.

iv. In FY 2013, MEDCOM directed that the twelve funded Individual Mobilization Augmentee (IMA) positions at the USAISR be unfunded. This action became effective October 1, 2014, and though the positions will remain required on the USAISR MOBTDA, it eliminated all drilling IMA positions at the USAISR. As of September 30, 2014, the USAISR has one IMA assigned. He will be removed from the position no later than September 30, 2015.

v. In FY 2014, the USAISR on-boarded 5 new civilian employees.

f. Requirements And Authorizations at the end of the year are listed in Figure 14.

FIGURE 14: Requirements and Authorizations FY14

	MC	DC	VC	MS	AN	SP	EN	CIV	CON	TOTAL
REQUIRED	28	6	4	14	23	5	167	293	59	599
AUTHORIZED	22	6	4	12	21	3	151	79	59	357

5. Quality Assurance (QA) Division

a. Mission: QA ensures the quality of human, animal, laboratory, and medical device research activities by providing oversight and assuring compliance with applicable federal laws, Department of Defense (DOD) Regulations, and United States Army Medical Research and Material Command (USAMRMC) and United States Army Institute of Surgical Research (USAISR) command policies/Standard Operating Procedures (SOPs).

b. Organization: During FY14, QA was staffed by 5 contract QA Specialists ((b) (6)) of whom (b) (6) continued the Lead QA position in the interim.

c. Significant QA Personnel Gain: (b) (6)

d. Significant QA Personnel Losses: (b) (6)

e. Significant Accomplishments:

i. Integrated Data Exchange and Archival (IDEA) System was registered with FDA

ii. Burn Resuscitation Decision Support System – Clinical (BRDSS-C) full validation completed full validation completed

iii. BRDDS –C 510k submission

iv. Woundflow 513(g) submission

v. FDA "friendly" visit (23-24 January 2014)

vi. QAD Intranet revision

vii. Quality Policy and Quality System Framework Policy memorandum revision and implementation (14-074)

viii. USAISR quality improvement data collection (Resource Directorate)

f. Animal Protocol Audits:

i. Administrative PAMs: protocols 47, Type Protocols 11, Type Studies 25

ii. Procedures PAMs: Protocols 30, Type Protocols 2, Type Studies 15

g. Human Protocol Audits (Open):

i. 14 out of 16 Greater than minimal risk

ii. 26 out of 74 minimal risk

iii. 0 out of 7 non- human research (NHR)

iv. 40 out of 97 total

h. Human Protocol Audits (Closed)

i. 1 Greater than minimal risk

ii. 3 minimal risks

iii. 4 total

6. Resource Management

a. The ISR managed approximately $60 million in FY14 in direct support of Combat Casualty Care research. Total funding, sources, and change from FY13 are listed below:

i. Combat Casualty Care Research (2040/2-yr appropriation): $30.3M ($1M decrease)

ii. Joint Trauma System (0130/1-yr appropriation): $10.6M ($227K increase)

iii. Burn Center Operations (0130/1-yr appropriation): $9.9M ($464K increase)

iv. Facility Projects/Utilities (0130/1-yr appropriation): $3.2M ($925K increase)

v. DHP Research (0130/2-yr appropriation): $5.6M ($3.8M increase)

vi. Flight Team Operations/Training (2020/1-yr appropriation): $20K ($49K decrease)

b. The ISR processed approximately $4M in incoming and $5.3M in outgoing Military Interdepartmental Purchase Requests (MIPR), respectively. The Institute also managed approximately $1.7M in Cooperative Research and Development Agreement (CRADA) funding.

c. The ISR experienced no shortfalls in mission or programs because of funding changes, and internal resources were allocated similar to FY13. The ISR is not expecting any major funding changes in FY15.

7. Research Regulatory Compliance Division

a. Mission: The Research Regulatory Compliance Division (RRCD) provides regulatory guidance to the USAISR Command and research staff as to applicable Federal laws, Department of Defense regulations, and USAMRMC Policies relevant to the performance of research involving human and animal subjects. The RRCD maintains various Assurances to Federal agencies that allow the performance of research involving human and animal subjects, and provides regulatory oversight for all research performed within the USAISR.

b. Services: RRCD provides a variety of services to USAISR investigative staff to support their research endeavors. Such services include: oversight of research protocols involving human subjects to include submission to appropriate Institutional Review Boards (IRBs); determinations of the applicability of IRB review for specific projects (e.g., performance improvement or quality improvement projects); the administration of an Institutional Animal Care and Use Committee (IACUC) for oversight of research protocols involving animal subjects; oversight of laboratory-based protocols; provision and tracking of required training for ethical use of animal and human subjects, as well as training required for FDA-regulated studies (e.g., Good Clinical Practice); and, processing scientific work products (abstracts, posters, presentations, and manuscripts) through required approvals prior to public dissemination.

c. Organization: In FY14, the RRCD was staffed by the Chief ((b) (6) , Ph.D.), three Human Subjects Protections Scientists ((b) (6)), one IACUC Administrator ((b) (6)), one Regulatory Compliance Specialist for animal research ((b) (6)), and one Publications Specialist ((b) (6) (Cherokee Nation contractor).

   i. Significant Personnel Gains: None

   ii. Significant Personnel Loss: (b) (6) Human Subjects Protections Scientist

d. Significant Accomplishments:

   i. Activities to Support Human Subjects Research: RRCD maintained the DoD Assurance for the Protection of Human Research Subjects as well as the Federalwide Assurance for the Protection of Human Subjects. RRCD administered protocol lifecycle events and provided oversight for 132 human use protocols during FY14.

   ii. Activities to Support Research Using Animal Subjects: RRCD maintained the USAISR Animal Welfare Assurance received from the Office of Laboratory Animal Welfare (OLAW) and all other applicable DoD and Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) accreditations. The RRCD supported a growing cadre of principal investigators and postdoctoral research fellows, providing oversight for 129 animal use protocols and 95 type studies during FY14.

   iii. Educational Activities: The RRCD provided one full-day Research Orientation Course for newly assigned research staff, as well as hosted a GCP course consisting of one full-day course for investigators new to the GCP environment and a half-day refresher course for those already working in this environment. RRCD also provided one 32-hour orientation course for the Joint Combat Casualty Care Research Team. In addition, RRCD began a series of informational seminars/training sessions for investigational staff and the IACUC. These included: "The Ins and Outs of Peer Review, Part 1: Scientific Review of Research Protocols" (1 hr); "Writing an Effective Protocol: Tips to Get It Approved the First Time" (1 hr); "Demystifying the ISR IACUC Process" (1 hr); "You've Got the Power: DIY Literature Searches for Protocols" (1 hr); and, "All About IACUC (At ISR)" (4 hrs). All slide sets were made available on the RRCD revised intranet site for subsequent use by investigative staff.

USAISR Presentations

Aden, JK., Waters, A., Belenkiy, S.M., Cancio, L.C., Chung, K.K., Partition Analysis Reveals the Complexity of Concomitant Risk Factors in Mechanically Ventilated Burn Patients (Poster) American Burn Association 46th annual conference (24 - 28 Mar 14)

Akers, K.S., Antimicrobial PK/PD in Burn and Trauma ICU Patients (Presentation) Texas Infectious Disease Society Annual Meeting (13 - 15 Jun 14)

Akers, K.S., Cota, J.M., Chung, K.K., Waters, J.A., Murray, C.K., Pharmacokinetics and Pharmacodynamics (PK/PD) of Piperacillin in Critically Ill Patients (Poster) 43rd Critical Care Congress (9 - 13 Jan 14)

Akers, K.S., Niece, K.L., Mende, K., Chung, K.K., Murray, C.K., Antifungal Wound Penetration of Amphotericin B and Voriconazole in Two Blast-Injured Combat Casualties (Poster) MHSRS 2014 (18 - 21 Aug 14)

Allen, K.C., Homeyer, D.C., Niece, K.L., Romano, D.R., Hardy, S.K., Sanchez, C.J., Wenke, J.C., Akers, K., Voriconazole Induces Markers of Osteogenesis and Stress in Human Osteoblasts Suggesting a Role in Periostition (Poster) Texas Infectious Disease Society Annual Meeting (13 - 16 Jun 14)

Aurora, A., U S Army Institute of Surgical Research (Presentation) 2nd Annual Post-doctoral Meeting (16-Sep-14)

Aurora, A., Roe, J., Corona, B.T., Walters, T.J., Extracellular Matrix Scaffold For Traumatic Muscle Injuries (Poster) San Antonio Post-doctoral Research Forum 2014 (16-Sep-14)

Bailey, J., Battle Scars: Lessons Learned from Modeling and Developing the Military Trauma System? (Presentation) A Regional Emergency Healthcare Systems Conference (5-May-14)

Bailey, J., Prehospital Trauma Care (Presentation) AAST (10-Sep-14)

Bailey, J., Stockinger, Z., Kotwal, R., Bolenbacher, R., Lira, J., Apodaca, A., JTS Transexamic Acid Monitoring & Evaluation (Presentation)

Barba, M., Robbins, J., Hayes, E., Valdez-Delgado, K., Vanfosson, C., Mann-Salinas, E., Implementation of an Evidence-Based Burn Precepting Program on a Progressive Care Unit: A Coordinators Perspective (Presentation) TriService Nursing Research and EBP Dissemination Course (15 - 18 Sept 14)

Barba, M.G., Robbins, J.R., Hayes, E.J., Valdez-Delgado, K.K., VanFosson, C.A., Mann-Salinas, E.A., Implementation of an Evidence-Based Burn Precepting Program on a Progressive Care Unit: A Coordinator's Prospective (Poster) TriService Nursing Research and EBP Dissemination Course (15 - 18 Sept 14)

Barnard,E.B.G., Ervin, A.T., Mabry, R.L., Bebarta, V.S., Prehospital and En Route Cricothyrotomy Performed in the Combat Setting: a Prospective, Multicenter, Observational Study (Poster) MHSRS (18 - 21 Aug 14)

Barr, J.L., Jacobson, D.B., Grubbs, D.L., Dubick, M.A., Antioxidant Activity of Currently Available Resuscitation Fluids in Vitro (Poster) Experimental Biology 2014 (26 - 30 Apr 14)

Batchinsky, A., Minimally Invasive Extracorporeal Life Support for Lung Failure: what it is and what it isn't? (Presentation) Invited Presentation at the Conference on High Frequency Ventilation (28 Mar 14)

Batchinsky, A., Acute Respiratory Distress Syndrome due to Inhalation Injury and Trauma: models and emerging treatments (Presentation) Invited Presentation at the Chlorine Center for Excellence Research Conference (30 - 31 Jan 14)

Batchinsky, A., Minimally Invasive Extracorporeal Life Support: devices, approaches and clinical impact (Presentation) 30th Annual CNMC Symposium (23 - 27 Feb 14)

Batchinsky, A., Low Flow Lung Support Systems and their Future (Presentation) A Invited presentation at the European Extracorporeal Life Support Meeting (21 - 24 May 14)

Batchinsky, A., Acute Respiratory Distress Syndrome due to Inhalation of Chlorine Gas in Sheep: a multi-day clinically relevant animal ICU study (Presentation) Chlorine Center for Excellence Research Conference (10-Jul-14)

Batchinsky, A., Minimally Invasive Extracorporeal Life Support Technology (Presentation) Eisenhower Critical Care Conference (2-May-14)

Baylan, J.M., Chambers, A., McMullin, N., Chan, R.K., Posterior interosseous flap for defects of dorsal ulnar wrist using previously burned skin (Poster) Annual Meeting (25 - 28 Mar 14)

Bedigrew, K., Shiels, S., Sanchez Jr, C., Loose, C., Wang, H., Stachowski, M., Wenke, J., Controlled-Release Antimicrobial Coating Prevents Hardware Infection (Poster) American Academy of Orthopaedic Surgeons, (10 - 14 Mar 14)

Belmont Jr., P.J., Goodman, G.P., Nelson, J.H., Black, M., Burks, R., Schoenfeld, A.J, "The Influence of Musculoskeletal Conditions, Behavioral Health Diagnoses and Socio-Economic Status on Injury-related Outcome in a High-Demand Population" (Presentation) American Academy of Orthopaedic Surgery (11 - 15 Mar 14)

Bridges, E., Beilman, G., Occult Hypoperfusion in Seriously Injured Combat Casualties (Pre-Post MEDEVAC) (Poster) Society of Critical Care Medicine (9 Jan 14)

Burmeister, D., Roy, D., Natesan, S., Christy, R., Shanmugasundaram, N., Porcine Large Total Body Surface Area (TBSA) Contact Burn for Investigating Immunomodulators to Reduce Systemic Inflammatory Response Syndrome (SIRS) (Presentation) MHSRS (18 - 21 Aug 14)

Burmeister, D.M., Roy, D.C., Ford, B.M., Coronado, R.E., Natesan, S., Christy, R.J., Plasma-based hydrogels for the treatment of deep partial thickness burns (Presentation) Society for Biomaterials (16 - 19 Apr 14)

Burmeister, D.M., Roy, D.C., Natesan, S., Christy, R.J., Porcine Large Total Body Surface Area (TBSA) Contact Burn for Investigating Immunomodulators to Reduce Systemic Inflammatory Response Syndrome (Poster) UTHSCSA POSTDOC (16-Sep-14)

Butler, F., Junctional Tourniquets 6 January 2014 (Presentation) MRMC Hemostatics Working Group Mtg (7 - 8 Jan 14)

Bynum, J.A., Meledeo, M.A., Getz, T.M., Cap, A.P., Pidcoke, H.F., 4°C Platelet Storage Reduces Reactive Oxygen Species, Preserves Mitochondrial Function, and Reduces Fibrinolysis (Presentation) MHSRS (18 - 21 Aug 14)

Caldwell, N.W., Guymon, C.H., Aden, J.K., Chafin, K.N., Mann-Salinas, E.A., Are Common Access Cards the Fomites of Military Medicine? (Poster) TriService Nursing Research and EBP Dissemination Course (18 Sep 14)

Caldwell, N.W., Guymon, C.H., Aden, J.K., Chafin, K.N., Mann-Salinas, E.A., Are Common Access Cards the Fomites of Military Medicine? (Presentation) TriService Nursing Research and EBP Dissemination Course (18 Sep 14)

Caldwell, N., Guymon, C.H., Aden, J., Chafin, K., Mann-Salinas, E.A., Pathogenic Bacteria on Common Access and Identification Cards: A Search for Badge Bugs (Poster) Quality Improvement & Patient Safety Symposium and American Burn Association 46th Annual Conference (6 Mar 14/25 - 28 Mar 14)

Campbell, M.A., Mann-Salinas, E.A., Jones, J.A., Serio-Melvin, M.L., Rodriguez, J.G., Peak, T.F., Shingleton, S.K., Implementation of a Nurse-Led Wound Care Team: Lessons Learned (Poster) ABA (25 - 28 Mar 14)

Cancio, L., Burrows, J.M., Khan, M.N., Salinas, J., Kramer, G.C., Stemming the Tide of Fluid Creep: New Metrics for Early Identification of Burn Patients at Risk of Over-Resuscitation (Poster) Society of Critical Care Medicine (9 - 13 Jan 14)

Cancio, L.C., Blast Injuries in Austere Environments (Presentation) J Burn Care Res special issue

Cancio, L.C., "Burns on the battlefields of Iraq and Afghanistan: DOD Trauma Registry analysis" (Presentation) Madrid Burns Symposium (5 - 7 Apr 14)

Cancio, L.C., Toxic Industrial Chemical Injuries in the Austere Environment (Presentation) J Burn Care Res special issue

Cannon, J., Batchinsky, A., Luellen, D., Serio-Melvin, M., Cancio, L., Pamplin, J., Chung, K., Salinas, J., Electronic iNO Alerts for Adult ECMO (Poster) SCCM (9 - 13 Jan 14)

Cap, A., Optimal Far-Forward Resuscitation of the Coagulopathic Patient? (Presentation) Remote Damage Control Resuscitation Symposium (8 - 11 Jun 14)

Cap, A.P., Reddoch, K., Montgomery, R., Pidcoke, H.F., Ramasubramanian, A., Shumeev, A., Filkina, Y., Llyin, L., Herschel, LH., Waters, SL., Dumont, LJ., Functionality of Chilled Platelets Stored under Hyperbaric Xenon (Poster) AABB (12 - 15 Oct 13)

Carlisle, P., Localized Low Dose rhBMP-2 if Effective at promoting Bone Regeneration in a Pre-clinical Mandibular Segmental Defect Model (Presentation) MHSRS (18 - 21 Aug 14)

Carlisle, P.L. ., Silliman, D.T., Aden, J., Brown Baer, P.R., Owens, D.S., Bioavailability Of Fentanyl And Buprenorphine Sustained-Release Drugs: A Comparison Of Pain Control Modalities In Sinclair Miniature Pigs. (Presentation) American College Veterinary Internal Medicine Forum (7 Jun 14)

Carlisle, P., Silliman, D., Tucker, D., Hale, R., Owens, D., Guelcher, S.A., Brown-Baer, P., Localized Low Dose rhBMP-2 is Effective at Promoting Bone Regeneration in a Pre-Clinical Mandibular Segmental Defect Model (Poster) 2nd Annual Postdoc Research Forum (16 Sep 14)

Carter III, R., Hinojosa-Laborde, C., Convertino, V.A., Gender Differences in Muscle Sympathetic Nerve Activity (MSNA) and Arterial Pressure Oscillations during Progressive Central Hypovolemia (Poster) MHSRS (18 - 21 Aug 14)

Carter III, R., Hinojosa-Laborde, C., Convertino, V.A., Variability in Mechanisms associated with tolerance to progressive reductions in central blood volume: role for the compensatory reserve index (Poster) MHSRS (18 - 21 Aug 14)

Carter, R., Hinojosa-Laborde, C., Convertino, V.A., Gender Differences in Muscle Sympathetic Nerve Activity (MSNA) and Arterial Pressure Oscillations during Progressive Central Hypovolemia (Poster) Experimental Biology (26 Apr 14)

Carter, R., Hinojosa-Laborde, C., Convertino, V.A., Variability in Mechanisms associated with tolerance to progressive reductions in central blood volume: role for the compensatory reserve index (Poster) Experimental Biology (26 Apr 14)

Chan, R.K., Prospective Multicenter Randomized Split Thickness Skin Graft Cover Dressing Trial (Presentation) MHSRS (18 - 21 Aug 14)

Charo-Griego, S., Patino, I.F., Mueller, M., Willenberg, S., Mann-Salinas, E.A., Allen, D.A., Shingleton, S., Development of an Evidence-Based Comprehensive Pressure Ulcer Prevention Program in a Burn Intensive Care Unit (Presentation) TriService Nursing Research and EBP Dissemination Course (15 - 18 Sept 14)

Charo-Griego, S., Willenberg, S., Patino, I.F., Mueller, M., Mann-Salinas, E., Allen, D.A., Shingleton, S., Development of an Evidence-Based Comprehensive Pressure Ulcer Prevention Program in a Burn Intensive Care Unit (Poster) TriService Nursing Research and EBP Dissemination Course (18-Sep-14)

Chen, J., Nadler, R., Dagan, Tien H., Cap, A.P., Glassberg, E., Needle Thoracostomy for Tension Pneumothorax: The Israeli Defense Force experience (Poster) MHSRS (18 - 21 Aug 14)

Chen, J., Wu, X., Keesee, J.D., Darlington, D.N., Cap, A.P., Coagulation Function after Cold (4°C) Storage of Whole Rat Blood (Poster) MHSRS (18 - 21 Aug 14)

Chen, J., Wu, X., Keesee, J.D., Darlington, D.N., Cap, A.P., Platelet Function after Cold (4°C) Storage of Whole Rat Blood (Poster) A-14-012 MHSRS (18 - 21 Aug 14)

Cheng, X.G., Yoo, J.J., Hale, R.G., Davis, M.R., Kang, H.W., Lee, S.J., 3D Printed Biomaterials for Maxillofacial Tissue Engineering and Reconstruction- a review (Presentation) Journal of Biomedical Materials Research

Cheppudira, B.P., Antinociceptive Effects of a9a10 Nicotinic Acetylcholine Receptor (a9a10 nAChR) Antagonists in a Thermal Injury-induced Full-thickness Rat Pain Model (Presentation) MHSRS (18 - 21 Aug 14)

Choi, J.H., Novak, J., Burke, T.A., Lund, B.J., Johnson, A.J., Cleland, J.M., Wang, H.C., Assessment of damage along the optic nerve after low-level repeated blast exposure (Poster) MHSRS (18 - 21 Aug 14)

Choi, J.H., Novak, J., Burke, T.A., Lund, B.J., Johnson, A.J., Cleland, J.M., Wang, HC., Assessment of apoptosis along the optic nerve after low-level repeated blast exposure (Poster) ARVO (4 - 8 May 14)

Christy, S., Rose, L., Carlsson, A., Leung, K., Isolation of RNA in porcine models (Poster) Biomedical Engineering Society Annual Meeting (22 - 25 Oct 14)

Clifford, J.L., Curcumin: A Prototype Anti-inflammatory Therapeutic for Burn Pain and Wound Healing (Presentation) Invited Talk at Louisiana State University School of Veterinary Medicine (1 May 14)

Clifford, J.L., Preemptive bupivacaine treatment blocks long-term allodynic responses in a rat spinal nerve ligation model for neuropathic pain (Presentation) 2014 Military Health System Research Symposium (MHSRS) (18 - 21 - Aug 14)

Johnson, A., US Army Institute of Surgical Research The division of Ocular Trauma (Presentation) Regenerative Medicine in Ophtamology Conference (23 - 24 June 14)

Cornell, l.E., DeSilva, M.N., Wang, H.H., Johnson, A.J., Zamora, D.O., Magnetic Nanoparticle Based Approach for Externally Controlled Corneal Endothelial Repair (Poster) MHSRS (18 - 21 Aug 14)

Corona, B.T., Rivera, J.C., Owens, J.G., Wenke, J.C., Rathbone, C.R., Volumetric muscle loss leads to permanent disability following extremity trauma (Poster) MHSRS (18 - 21 Aug 14)

Cunningham, C., Ritter, J., Kragh, J.F., Gross, K., Quantitative Anatomy of the Greater Trochanter and the Common Femoral Artery as to Guide Pelvic Binder and Junctional Tourniquet Placement (Poster) MHSRS (18 - 21 Aug 14)

Darlington, D.N., Keesee, J.D., Wu, X., Cap, A.P., Platelet Function after Polytrauma and Hemorrhage in Rats (Poster) SHOCK (7 - 10 Jun 14)

Darlington, D.N., Wu, X., Cap, A., Anti-coagulant and Fibrinolytic Acitivity in Plasma After Polytrauma and Hemorrhage in Rats. (Poster) HEMISTASIS (15 May 14)

Darlington, D.N., Wu, X., Cap, A.P., Fibrinolytic Activity in Plasma after Polytrauma and Hemorrhage in Rats (Poster) SHOCK (7 - 10 Jun 14)

Darlington, D.N., Wu, X., Cap, A.P., Thrombin Inhibition after Polytrauma and Hemorrhage in Rats (Poster) SHOCK (7 - 10 Jun 14)

Davids, N.B., Gross, K.R., Kragh, J.F., Molter, N.C., Association Between Amputations and Pelvic Fractures Requiring Massive Transfusion in Dismounted Blast Injury in Operation Enduring Freedom Casualties (Poster) Special Operations Medical Association/ the office at the JTTS headquarters. (13 - 18 Dec 13)

De Lorenzo, R., Getting DoD to Fund Your Research (Presentation) GSS 2014 (2 - 4 Mar 14)

DeLorenzo, R., Challenges to Improving Combat Casualty Survival on the Battlefield (Presentation) Military Medicine

DeNicolo, P., Colthirst, P.M., Simecek, J.W., The Dental Emergency Rate of U.S. Army Personnel in Garrison (Poster) American Association of Dental Research Conference (19 - 22 Mar 14)

Dubick, M.A., Li Y., Grubbs, D.L., Barr, J.L., Dalle Lucca, J.J., Inflammatory Responses in Brain from Swine Subjected to Traumatic Hemorrhage and Treated with a C1 Inhibitor (Poster) Shock (7 - 10 Jun 14)

Dubick, M.A., Fluids! (Presentation) Resuscitation Symposium (16 - 17 Nov 13)

Dubick, M.A., Berry, J.S., Grubbs, D.L., Barr, J.L., Batchinsky, A.I., Cancio, L.C., Indices Of Inflammatory Responses And Oxidative Stress In Tissues From Pigs Subjected To Exsanguination Shock (Poster) American Association for Surgery of Trauma (10 - 13 Sept 14)

Dubick, M.A., Li, Y., Grubbs, D.L., Barr, J.L., Dalle Lucca, J.J., Inflammatory Responses In Brain From Swine Subjected To Traumatic Hemorrhage And Treated With A C1 Inhibitor (Poster) MHSRS 2014 meeting (18 - 21 Aug 14)

Dubick, M.A., Li, Y., Grubbs, D.L., Simovic, M., Barr, J.L., Dalle Lucca, J.J., Indices of inflammation in swine subjected to trauma/hemorrhage and treated with a C1 inhibitor (Poster) Critical Care Medicine (9 - 13 Jan 14

Dukes, S.F., Risk Factors for Pressure Ulcer Development in CCATT Patients (Presentation) MHSRS (18 - 21 Aug 14)

Escolas, S.M., Chung, K.K., Hansen, J.J., Rauschendorfer, C., Sweet, R., Walker, S., Jones, J., Attachment Style and Pain (Presentation) Behavioral Health Webinar Series (5 Nov 13)

Escolas, S.M., Walker, S.L., Tyrell, K.M., Chung, K.K., Escolas, H.D., Hatem, V.D., Orman, J.A., Renz, E.M., "Post-discharge cause-of-death in combat burn casualties" (Presentation) ABA (25 - 28 Mar 14)

Evans Jr., T.W., McNamee, I.L., Propper, B.W., Arthurs, Z.M., Mental Health Co-morbidities of Service Members with Extremity Vascular Injuries Acquired in Iraq and Afghanistan (Poster) Society of Trauma Nurses 17th Annual Conference (2 - 5 Apr 14)

Fang, R., Markandaya, M., DuBose, J.J., Cancio, L.C., Blackbourne, L.H., Early in-theater management of combat-related traumatic brain injury: A prospective, observational study to identify opportunities for performance improvement (Presentation) MHSRS (8 - 21 Aug 14)

Fenrich, C, Shingleton, S., Serio-Melvin, M.L., Salinas, J., An Electronic Wound Mapping System (Poster) MHSRS (18 - 21 Aug 14)

Gallagher, S., Flores, D., Lopez, C., Dunham, K., Robbins, J., Mann-Salinas, E., Pamplin, J., Determination of the Optimal Delirium Screening Tool for Burn Intensive Care Unit Patients (Poster) TriService Nursing Research and EBP Dissemination Course (18 Sep 14)

Gerhardt, B., Murphy's Laws of Tactical Medicine (Presentation) Special Operations Medical Association Scientific assembly (13 - 18 Dec 13)

Getz, T.M., Montgomery, R.K., Rodriguez, A.C., Cap, A.P., Storage of Platelets at 4°C in Platelet Additive Solutions Prevents Aggregate Formation and Preserves Platelet Functional Responses (Presentation) MHSRS (18 - 21 Aug 14)

Gibbons, R.V., Salas, M.M., Jones, J., Fowler, M., Petz, L.N., Hansen, J., Bakewell, T., Orman, J., Clifford, J.L., USAISR Burn Pain Medication Usage Patterns for Severely Burned Military Service Members (Poster) 2014 Military Health System Research Symposium (MHSRS) (18 - 21 Aug 14)

Gibbons, R.V., Salas, M.M., Jones, J., Fowler, M., Petz, L.N., Hansen, J., Bakewell, T., Orman, J., Clifford, J.L., USAISR Burn Pain Medication Usage Patterns for Severely Burned Military Service Members (Poster) 2014 Military Health System Research Symposium (MHSRS) (18 - 21 Aug 14)

Gibson, R.S., Rodriguez, C., Bice, L., Martini, W.Z., Dubick, M.A., Effect of Acidosis and Hypothermia on Coagulation, in Vitro (Poster) Summer Student Poster Presentations (8 Aug 14)

Greene, W., Muniz, A., Johnson, A.J., Wang, Heuy-C.H., Development of an in vitro model of proliferative vitreoretinopathy using retinal pigment epithelium derived from induced pluripotent stem cells (Poster) Association for Research in Vision and Ophthalmology annual meeting (3 - 8 May 14)

Greene, W., Muniz, A., Johnson, A.J., Wang, Heuy-Ching H., Development of an in vitro model of proliferative vitreoretinopathy using retinal pigment epithelium derived from induced pluripotent stem cells (Poster) MHSRS (18 - 21 Aug 14)

Griffith, G.L., Wirostko, B., Lee, H.K., Zamora, D.O., Johnson, A.J., Model Development: Use of Thiolated Hyaluronic Acid for the Treatment of Corneal Epithelial Wounds (Poster) UTHSCSA Post Doc Symposium (16-Sep-14)

Griffith, G.L., Wirostko, B., Lee, H.K., Zamora, D.O., Johnson, A.J., Model Development: Use of Thiolated Hyaluronic Acid for the Treatment of Corneal Epithelial Wounds (Poster) San Antonio Post-doctoral Research Forum 2014 (16 Sep 14)

Gross, K., Joint Trauma System Functional Efforts to Impact Combat Casualty Care Outcomes (Presentation) MHSRS (18 - 21 Aug 14)

Gross, K., Deployed Surgeon Military Occupational Specialty Identifier (Presentation) Military Liaison Committee of American Association for the Surgery (10-Sep-14)

Gross, K., Butler, F., Kotwal, R., Apodaca, A., Lira, J., Bailey, J., Rasmussen, T., Tactical Combat Casualty Care Guidelines Recommending Hetastarch Use at Point of Injury Do Not Require Revision (Presentation) MHSRS (18 - 21 Aug 14)

Gross, K., Shackelford, S., Powell-Dunford, N., Orman, J., Howard, J., Quesada, J., Bailey, J., En Route Blood Transfusion from Point of Injury in a Theater of Operations Positively Impacts Shock Index (Poster) MHSRS (18 - 21 Aug 14)

Guda, T., Silliman, T., Carlisle, P., Hale, R.G., Brown-Baer, P., Spinal Bone Healing in a Bone Notch Model in Pigs: A Clinical CT Analysis (Poster) TERMIS (10 - 13 Nov 13)

Hansen, J.J., Read, M.D., Alphonso, C., Lai, D., Fowler, M., Use of Transesophageal Echocardiography in a Burn Operating Room (Poster) American Burn Association (25 - 28 Mar 14)

Hardy, S.K., Cardile, A., Akers, K.S., Murray, C.K., Wenke, J.C., Sanchez Jr, C.J., Pre-clinical Evaluation of the Local Delivery of Rifamycins for the Treatment of Staphylococcus aureus Biofilms (Poster) 2nd Annual San Antonio Postdoctoral Research Forum (12-Sep-14)

Hayes, E., Coffman, R., Serio-Melvin, M., Valdez-Delgado, K.K., Mann Salinas, E., High Fidelity Human Patient Simulation: Bridging Burn Care Education with Modern Technology (Presentation) ABA (25 - 28 Mar 14)

Hayes, E., Coffman, R., Serio-Melvin, M., Valdez-Delgado, K.K., Mann Salinas, E., Bridging Combat Casualty Burn Care Education with High Fidelity Human Patient Simulation (Presentation) 2014 Military Health System Research Symposium (18 - 21 Aug 14)

Hayes, E., Coffman, R., Serio-Melvin, M., Valdez-Delgado, K.K., Mann Salinas, E., High Fidelity Human Patient Simulation: Bridging Burn Care Education with Modern Technology (Presentation) TriService Nursing Research and EBP Dissemination Course (15 - 18 Sep 14)

Heafner, T., Lewis, C., Abercrombie, J., Propper, B., Arthurs, Z., Quantitative in vitro model for the study of bacterial attachment on vascular conduits (Presentation) SMS (2 - 5 Apr 14)

Heafner, T.A., Lewis, C., Abercrombie, J., Leung, K., Propper, B., Arthurs, Z.M., Quantitative in vitro model for the study of bacterial attachment on vascular conduits (Poster) SAUCHEC Day (24 Apr 14)

Hinojosa-Laborde, C., Validation of Lower Body Negative Pressure as an Experimental Model of Hemorrhage (Presentation) EXPERIMENTAL BIOLOGY (26 - 30 Apr 14)

Hinojosa-Laborde, C., Mulligan, J., Grudic, G.Z., Convertino, V.A., Comparison of Compensatory Reserve Index During Lower Body Negative Pressure and Hemorrhage in Baboons (Poster) 2014 Military Health System Research Symposium (18 - 21 Aug 14)

Hinojosa-Laborde, C., Shade, R.E., Muniz, G.W., Bauer, C., Goei, K.A., Pidcoke, H.F., Chung, K.K., Cap, A.P., Convertino, V.A., Validation of Lower Body Negative Pressure as an Experimental Model of Hemorrhage (Poster) Experimental Biology 2014 (26 - 30 Apr 14)

Houston, R., Soko, K., Spencer, J., Watson, D.B., Morrison, J.J., Rasmussen, T.E., The Trauma Specific Vascular Injury Shunt (TS-VIS): Proof Of Concept And Function (Poster) EAST Annual Scientific Assembly (14 - 18 Jan 14)

Howard, J.T., Walick, K.S., Rivera, J.C., Evidence of an Association Between ADHD, Medications and Diminished Bone Health in Children and Adolescents (Poster) MHSRS (18 - 21 Aug 14)

Hurst, D., Differences in PTSD, Depression, Post Concussive Symptoms, and Concussion Severity resulting from Blast Versus Non-blast mild Traumatic Brain Injury (Presentation) International Society for Traumatic Stress Studies Annual Meeting (6 - 8 Nov 14)

Hylden, C., Johnson, A., Rivera, J., Comparison of Female and Male Casualty Cohorts from Conflicts in Iraq and Afghanistan (Poster) Musculoskeletal Sex Difference Throughout the Lifespan Research Symposium (30 Jul - 01 Aug 14)

Isaac, K.M., Christy, R.J., Wrice, N.L., Roy, D.C., Evaluating the Ability of Ciprofloxacin-loaded Keratose Hydrogels to Support Healing in a Porcine Infected Burn Model (Poster) Undergraduate Intern Poster Session (13 Aug 14)

Ivo Torres, F., Thrombus Formation and Platelet Adhesion: A Quantitative System to Evaluate Platelet Function in vivo (Poster) MHSRS (18 - 21 Aug 14)

Jackson, B.A., King, B.T., Jones, J., Escolas, S.M., Shiels, M.E., Renz, E.M., Chung, K.K., Cancio, L.C., Comparison of Military Outcomes to the National Burn Repository (NBR) (Poster) ABA 46th Annual Meeting (25 - 28 Mar 14)

Jackson, BA., King, BT., Jones, JA., Escolas, SM., Shiels, ME., Renz, EM., Chung, KK., Cancio, LC10 Year Comparison of Military Outcomes to the National Burn Repository (NBR) (Poster)N/A MHSRS (18 - 21 Aug 14)

Janak, J.C., Cooper, D.B., Bowles, A.O., Orman, J., Multidisciplinary Treatment of Service Members with Persistent Postconcussive Complaints Significantly Reduces Symptom Burden (Poster) San Antonio Postdoctoral Forum (16 Sep 14)

Johnson, A., Military Applications of Collagen Crosslinking Technology (Presentation) American Society of Cataract and Refractive Surgeons (25 - 29 Apr 14)

Johnson, A., Lewis, A., DeMartelaere, S., Cho,R., Ching Wang, H., Kim, M., Grimm, R.C., Choi, J.H., Redmond, R., Vereter, E., Kochevar, I., Cross-linked vs. Cryopreserved Amniotic Membrane for the Treatment of Severe Exposure Keratopathy in the New Zealand White Rabbit (Poster) ARVO (4 - 8 May 14)

Kaini, R.R., Johnson, A., Burke, T.A., Golden, D., Wang, H.H., Xeno-Free 3D Retinal Differentiation of Human Induced- Pluripotent Stem Cells (Poster) ARVO (4 - 8 May 14)

Kaini, R.R., Johnson, A.J. Burke, T.A. Golden, D., Wang, H-C.H., Xeno-Free 3D Retinal Differentiation of Human Induced-Pluripotent Stem Cells (Poster) ISSCR Meeting (18 - 21 Jun 14)

Kharod, C.U., Tubb, C.C., Gross, K., Kragh, J.F., Evaluation of Prehospital Pelvic Binder Usage in US Military Casualties with Pelvic Fractures (Poster) MHSRS (18 - 21 Aug 14)

Kheirabadi, B.S., Miranda, N., Terrazas, I.B., Gonzales, M.D., Dubick, M.A., Does Limited Prehospital Resuscitation with Colloids or Crystalloids Influence Hemostasis and Survival of Rabbits Subjected to Lethal Uncontrolled Hemorrhage? (Poster) 2014, AAST annual meeting (10 - 13 Sept 14)

Kheirabadi, B.S., Terrazas, I.B., Miranda, N., Gonzales, M.D., Sondeen, J.L., Dubick, M.A., Splenectomy Appears Necessary for Creating a Lethal Parenchymal Hemorrhage in Normal Pigs (Poster) MHSRS (18 - 21 Aug 14)

Kragh, J.F., "Advancements in Tourniquets 2014" (Presentation) Remote Damage Control Resuscitation (RDCR) (10 Jun 14)

Kragh, J.F., Junctional Tourniquets Today (Presentation) MHSRS (18 - 21 Aug 14)

Krueger, C.A., Stinner, D.J., Patzkowski, J.C., Blank, R.V., Bedigrew, K., Owens, J.G., Hsu, J.R., "Limb salvage versus amputation: What we thought we knew" (Presentation) AAOS 2014 annual meeting (11 - 15 Mar 14)

Laborde, A., Natesan, S., Christy, R.J., Burmeister, D.M., Split Thickness Skin Graft versus MatriStem® for the treatment of deep partial thickness burns (Poster) Undergraduate Research Fellow Posters (13-Aug-14)

Liu, N.T., Branson, R.D., Enkheebetaar, P., Patel, N., Salter, M.G., Kramer, G.C., Salinas, J., Kinsky, M.P., Closed-loop FiO2 smart oxygenation system to detect pulmonary injury (Poster) 2014 Military Health System Research Symposium (18 - 21 Aug 14)

Liu, N.T., Kramer G.C., Khan, M.N., Kinsky, M.P., Salinas, J., Blood pressure and heart rate can reliably estimate cardiac output in a conscious sheep model of multiple hemorrhages and resuscitation using computer machine learning approaches (Poster) 2014 Military Health System Research Symposium(18 - 21 Aug 14)

Liu, N.T., Kramer, G.C., Khan, M.N., Kinsky, M.P., Salinas, J., Utility of vital signs, heart-rate variability and complexity, and machine learning for identifying the need for life-saving interventions in trauma patients (Presentation) 2014 Military Health System Research Symposium (18 - 21 Aug 14)

Liu, N.T., Holcomb, J.B., Wade, C.E., Darrah, M.I., Salinas, J., Performance of life-saving interventions in trauma patients is associated with data quality in the prehospital and clinical environments (Poster) 2014 Military Health System Research Symposium (18 - 21 Aug 14)

Luellen, D.E., Sosnov, J., Serio-Melvin, M.L., Chung, K.K., Salinas, J., Stewart, I., Results of a Retrospective Electronic AKIN Alert Analysis (Poster) MHSRS (18 - 21 Aug 14)

Mann-Salinas, E., Military Approach to Burn Care & What's New with Burn Fluid Resuscitation (Presentation) Nursing Grand Rounds, Oregon Burn Center (20 Feb 14)

Mann-Salinas, E.A., The Nurse’s Role in the Identification and Management of Sepsis: Harnessing the Power of Technology (Presentation) Nursing Research Lecture (7-Mar-14)

Mann-Salinas, E.A., Gallagher, S.P., Flores, D., Gomez, C., Dunham, K., Robbins, J., Pamplin, J., Prospective Clinical Evaluation of Delirium Screening in a Burn Intensive Care Unit (Presentation) ABA (25 - 28 Mar 14)

Mann-Salinas, E.A., Gallagher, S.P., Flores, D., Gomez, C., Dunham, K., Robbins, J., Pamplin, J., "Determination of the Optimal Delirium Screening Tool for Burn Intensive Care Unit Patients" (Presentation) MHSRS (18 - 21 Aug 14)

Mann-Salinas, E.A., Serio-Melvin, M., Caldwell, N., Garcia, A., Jackson, B., Shields, M., Chung, K., Cancio, L., Salinas, J., Comprehensive Evaluation of the Joint Trauma System Burn Documentation Process (Poster) TriService Nursing Research and EBP Dissemination Course (15 - 18 Sept 14)

Mann-Salinas, E.A., Serio-Melvin, M., Caldwell, N., Garcia, A., Jackson, B., Shiels, M., Chung, K., Cancio, L., Salinas, J., Comprehensive Evaluation of the Joint Trauma System Burn Documentation Process (Poster) TriService Nursing Research and EBP Dissemination Course (18-Sep-14)

Mann-Salinas, E.A., Serio-Melvin, M., Caldwell, N., Garcia, A., Jackson, B., Shiels, M., Chung, K., Cancio, L., Salinas, J., Comprehensive Evaluation of the Joint Trauma System Burn Documentation Process (Presentation) TriService Nursing Research and EBP Dissemination Course (15 - 18 Sept 14)

Marrs, J., Investigation of Angiogenesis in a Porcine Mandible Injury Model (Presentation) UTHSCSA Dental School Student Research Training Program (26 Jun 14)

Martini, W., Chinkes, D., Dubick, M., Fibrinogen Concentrate Administration Inhibits Endogenous Fibrinogen Synthesis in Pigs after Traumatic Hemorrhage (Presentation) AAST (10 Sep 14)

Martini, W.Z., Chung, K.K., Dubick Comparisons of Normal saline (NS) and Lactated Ringer’s Solution (LR) in Normal or Hypotensive Resuscitation after Severe Hemorrhagic Shock in Pigs (Poster) SHOCK 2014 (7 - 10 Jun 14)

Martini, W.Z., Chung, K.K., Dubick, M.A., Comparisons of Normal saline (NS) and Lactated Ringer’s Solution (LR) in Normal or Hypotensive Resuscitation after Severe Hemorrhagic Shock in Pigs (Poster) MHSRS (18 - 21 Aug 14)

McDaniel, J.S., Pilia, M., Pollot, B.E., Rathbone, C.R., Stem Cells From Microvascular Fragments Contain Resident Mesenchymal Stem Cell Characteristics Resemblant Of Adipose Derived Stem Cells (Poster) Orthopaedic Research Society (15 - 18 Mar 14)

McDaniel, J.S., Pilia, M., Walker, J.A., Corona, B.T., Rathbone, C.R., Use Of Microvascular Fragments For Improving Regeneration In Musculoskeletal Defects (Poster) MHSRS (18 - 21 Aug 14)

Meledeo, A., Campbell, J.E., Rodriguez, A.C., Valenciana, M.V., Cap, A.P., Comparative Response of Platelet fVa and Plasma fVa to aPC and Relevance to a Model of ATC (Presentation) UTHSCSA Clot Club, (27 Jan 14)

Meledeo, A., Campbell, J.E., Rodriguez, A.C., Valenciana, M.V., Cap, A.P., MgSO4 Supplementation Promotes Cold-Stored Platelet Function (Poster) MHSRS (18 - 21 Aug 14)

Meledeo, A.M., Campbell, J., Rodriguez, A., Valenciana, M., Cap, A.P., MgSO4 Supplementation Promotes Cold-Stored Platelet Function (Poster) UTHSCSA Postdoctoral Research Forum (16 Sep 14)

Meyer, A.D., Kamucheka, R., Nair, P., Reddoch. K.M., Montgomery, R.K., Parida, B.K., Cap, A.P., Mackman, N., Ramasubramanian, A.K., ECLS Device Shear Stresses Induce Prothrombotic Microparticle Formation (Poster) MHSRS (18 - 21 Aug 14)

Miller, C.L., Chen, T., Leung, K.P., Identification of novel small RNAs in Pseudomonas aeruginosa involved in biofilm formation, antibiotic tolerance, and mixed-species interactions using RNA sequencing (Poster) 114th General Meeting of the American Society for Microbiology (17 - 20 May 14)

Miller, D.L., Russell, A.R., Evans Jr, T.W., Propper, B., Arthurs, Z.M., Vascular discharge education and follow-up care subsequent to wartime vascular trauma (Poster) SAMMC Nurses Week event (6 May 14)

Miller, S., Arthur, Z., Corpus, R., Russell, A., Vascular discharge education and follow-up care subsequent to wartime vascular trauma in injured Service Members (Presentation) Society of Vascular Nurses (7 May 14)

Mitchell, C., Martino, A.L., Fields, J.L., Martinez, D., Hatem, A.M., Bang, S., "Successful Outcomes Associated with Implementing the Use of Alcohol Impregnated Port Protectors in a Burn Unit" (Presentation) ABA (25 - 28 Mar 14)

Mitchell, C., Martino, A.L., Fields, J.L., Martinez, D., Hatem, A.M., Bang, S., Castillo, M.A., Allen, D.A., Successful Outcomes Associated with Implementing the Use of Alcohol Impregnated Port Protectors in a Burn Unit (Poster) Evidence Based Practice Project/ Nurse Week (8 May 14)

Mitchell, C., Martino, A.L., Fields, J.L., Martinez, D.M., Hatem, A.M., Bang, S., Mann-Salinas, E.A., Unit Practice Council Successful Efforts for Implementing Alcohol Impregnated Port Protectors" (Presentation) MHSRS (18 - 21 Aug 14)

Mitchell, C., Muller, M., Negaard, K., Peak, T., Mann-Salinas, E., Renz, E., King, B., Chung, K., Cannon, J., "Burn Intensive Care Unit Multidisciplinary Approach Facilitates Adult Extracorporeal Life Support (ECLS) Therapy" (Presentation) MHSRS (18 - 21 Aug 14)

Mitchell, C., Peak, T., Mueller, M.R., Negaard, K.A., King, B.T., Chung, K.K., Cannon, J.W., Renz, E.M., Incorporating an Adult Extra Corporal Life Support Program in the Burn Intensive Care Unit (Poster) ABA (25 - 28 Mar 14)

Mitchell, T., Aortic Occlusion As An Adjunct Of Resuscitation For Combat Wounded: An Eight-Year Review Of OEF and OIF Resuscitative Thoracotomies (Presentation) ASGBI (30 Apr - 2 May 14)

Morris. R.S., Schaffer, B.S., Lundy, J.B., Pidcoke, H.F., Cap, A.P., Schwacha, M.G., Immunopathological Response to Severe Trauma and Burn: Changes in Platelet Activity in Acutely Burned Patients (Poster) MHSRS (2014 18 - 21 Aug 14)

Muniz, A., Greene, W.A., Plamper, M.L., Choi, J.H., Johnson, A.J., Tsin, A.T., Wang, H.C.H., Retinoid Uptake, Processing and Secretion in Human iPS-RPE Support the Visual Cycle (Poster) ARVO (4 - 8 May 14)

Muniz, G.W., Poh, P., Carter III, R., Hinojosa-Laborde, C., Mulligan, J., Grudic, G.Z., Convertino, V.A., Respiratory Pump Contributes to Increased Physiological Reserve for Compensation during Simulated Hemorrhage (Poster) MHSRS (18 - 21 Aug 14)

Murray, S.J., Pamplin, J., Chung, K., Mann-Salinas, E., Serio-Melvin, M., Huzar, T., Wolf, S., Nemeth, C Developing Cognitive Aides According to the Phases of Illness Paradigm for use in the Burn ICU (Poster) MHSRS (18 - 21 Aug 14)

Nair, P., Pidcoke, HF., Cap, A., Ramasubramanian, AK Biophysical Effects of Low Temperature Storage on Platelets for transfusion (Poster) URSA COS Research Conference (18 Oct 13)

Nair, PM., Reddoch, K., Pidcoke, HF., Cap, AP., Ramasubramanian, AK Improved clot strength of 4°C-stored apheresis platelets (Presentation) MHSRS (18 - 21 Aug 14)

Natesan, S., Wehmeyer, JL., Coronado, RE., Wrice, NL., Christy, RJ Supercritical CO2-Treated Human Amniotic Membrane and Adipose Derived Stem Cells based Epithelial Autograft for Wound Regeneration (Presentation) TERMIS (10 - 13 Nov 13)

Nemeth, C., Anders, S., Brown,J., Crandall,B., Grome, A., Chung, K., Mann-Salinas, E., Pamplin, J Discovery of Burn ICU Critical Care Complexities and their Implications for Health IT Design. (Poster) 43rd Critical Care Congress (9 - 13 Jan 14)

Nemeth, C., Pamplin, J Developing a Cognitive and Communications Tool for Burn ICU Clinicians (Presentation) MHSRS (18 - 21 Aug 14)

Nyland, J.E., Garza, T.H., Bakewell, T.M., Fowler, M., Clifford, J.L., Petz, L.N., Averitt, D.R., Development of Opioid Tolerance in a Rat Model of Full Thickness Thermal Injury (Poster) Society for Neuroscience Meeting (9 - 13 Nov 13)

Nyland, J.E., McLean, S.A., Clifford, J.L., Fowler, M., Petz, L.N., Loyd, D.R., Prior Stress Exposure Increases Pain Behaviors in a Rat Model of Full Thickness Thermal Injury (Poster) MHSRS (18 - 21 Aug 14)

Orman, J.A., "Neuropsychiatric Diagnoses Associated with Genitourinary Injury in Male OEF/OIF Veterans Receiving Care at VA Health Care Facilities" (Presentation) MHSRS (18 - 21 Aug 14)

Pamplin, J., Murray, S.J., Chung, K., Mann-Salinas, E., Serio-Melvin, M., Huzar, T., Wolf, S., Nemeth, C., Card Sorts Help “Unpack” Clinician Perspectives on Patient Condition and Treatment Priorities (Poster) MHSRS (18 - 21 Aug 14)

Pamplin, J.C., Nemeth, C., "Discovering Complexities in Critical Care and Their Challenges to Health IT Design" (Presentation) 43rd Critical Care Congress (9 - 13 Jan 14)

Parida, B.K., Garrastazu, H., Aden, J., Cap, A.P., McFaul, S.J., Silica Beads are Superior to Polystyrene for Sizing Cellular Microvesicles (Poster) AABB (12 - 15 Oct 13)

Park, T., Cancio, L., Jordan, B.S., Belenkiy, S., Baker, W., Voelker, C., Myers, B., Batchinsky, A., Automatic heart-rate complexity monitoring in a swine model of massive exsanguination (Poster) 13th SCAI (31 Jul - 3 Aug 14)

Pedersen, A.R., Stinner, D.J., McLaughlin, H.C., Bailey, J.R., Walter, J.R., Hsu, J.R., Pelvic Fractures And Associated Genitourinary Injuries During Operation Iraqi Freedom And Operation Enduring Freedom (Presentation) Society of Military Orthopaedic Surgeons (13 - 18 Dec 13)

Peterson, W.C., Cancio, L.C., Kay, A., Jennes, S., Managing the burn wound (surgery and dressings) (Presentation) Development of Evidence-Based Guidelines for the management of severely Burnt Patients. Burnt Patients (8 - 9 Sept 14)

Peterson, W.C., Cancio, L.C., Kay, A., Jennes, S., Overview Of Definitive Care (Presentation) Development of Evidence-Based Guidelines for the management of severely Burnt Patients. (8 - 9 Sept 14)

Peterson, W.C., Cancio, L.C., Kay, A., Jennes, S., Managing the burn wound (surgery and dressings) (Presentation) NATO (8 Sep 14)

Petz, L.N., Tyner, S., Barnard, E., Ervin, A., Mora, A., Clifford, J., Fowler, M., Bebarta, V.S., Prehospital and En Route Analgesic use in Traumatically Injured Patients in the Combat Setting (Poster) MHSRS (18 - 21 Aug 14)

Pidcoke. H., Herzig, M., Schaffer, B., Fedyk, C., Garrastazu, H., Montgomery, R., Parida, B., Prat, N., Aden, J., Salinas, J., Cap, A., A Prospective Observational Study of Changes in Coagulation during Tissue Excisions Causing Significant Bleeding: A Model for Severe Bleeding in the Pre-hospital Setting? (Presentation) RDCR Symposium (10 Jun 14)

Pidcoke, H., Shade, R., Herzig, M., Schaffer, B., Stewart, K., Fedyk, C., Prat, N., Parida, B., Aden, J., Anderson, S., Reddick, R., Cap, A., A Third Generation Perfluorocarbon Causes Thrombocytopenia, Platelet Dysfunction and Changes in Blood Morphology in a Baboon Model of Systemic Inflammation (Poster) ASH (6 - 11 Dec 13)

Pidcoke,H., Herzig, M., Schaffer, B., Fedyk, C., Garrastazu., H., Prat, N., Chung, K., Aden, J., Cap, A., A Prospective Observational Study of Changes in Coagulation during Tissue Excisions Causing Significant Bleeding: A Model for Severe Bleeding in the Pre-hospital Setting? (Presentation) MHSRS (18 - 21 Aug 14)

Pilia, M., McDaniel, J., Corona, B., Rathbone, C., Transplantation of Microvascular Fragments for Volumetric Muscle Loss (Presentation) TERMIS (10 - 13 Nov 13)

Pilia, M., McDaniel, J.S., Rathbone, R., Microvascular Fragments Improve Vessel Density Of Allograft Bone In Vivo (Poster) MHSRS (18 - 21 Aug 14)

Poh, P.Y., Carter III, R., Hinojosa-Laborde, C., Mulligan, J., Grudic, G.Z., Convertino, V.A., Respiratory Pump Contributes to Increased Physiological Reserve for Compensation during Simulated Hemorrhage (Poster) EXPERIMENTAL BIOLOGY (26 - 30 Apr 14)

Prat, N., Montgomery, R., Cap., A.P., Sarron, J.C., Descombe, C., May, P., Magnan, P., Isolated Primary Blast Injury is not associated with acute Coagulopathy of Trauma in pigs.(Poster) MHSRS (18 - 21 Aug 14)

Pruitt, B.A., "A Decade of ABA Burn Prevention Award Winning Posters 2004 - 2013" (Poster) ABA (25 - 28 Mar 14)

Rathbone, C., Applications For Microvascular Fragments In Orthopaedic Trauma (Presentation) Biomaterials Day (9 Jun 14)

Rathbone, C., Translational Approaches for Skeletal Muscle Regeneration (Presentation) MHSRS (18 - 21 Aug 14)

Reddoch, K., Cold-activated platelets respond normally to homeostatic regulation (Presentation) Clot Club UTHSCSA (5 May 14)

Reddoch, K., Montgomery, R., Nair, P., Fedyk, C., Pidcoke, H., Ramasubramanian, A., Cap, A., Platelets Stored for 14 Days at 4°C are Comparable to Standard Room Temperature Storage for 5 Days (Poster) AABB Annual Meeting (12 - 15 Oct 13)

Reddoch, K., Montgomery, R., Pidcoke, H., Ramasubramanian, A., Cap, A., Apoptosis-related events in refrigerated platelets for transfusion (Poster) MHSRS (18 - 21 Aug 14)

Reddoch, K., Montgomery, R., Rodriguez, A., Meledeo, M., Pidcoke, H., Ramasubramanian, A., Cap, A., The Response of Refrigerated Platelets to Physiologic Inhibitors (Poster) MHSRS (18 - 21 Aug 14)

Richard, R.L., Jones, J.A., Parshley, P., Hierarchical Decomposition of Burn Diagram Based on Cutaneous Functional Units and Its Utility (Poster) American Burn Association (26 Mar 14)

Rivera, J.C., Johnson, A.F., The Military Orthopaedic Trauma Registry: Quality Data Now Available (Presentation) Military Health System Research Symposium (18 - 21 Aug 14)

Rivera, J.C., Krueger, C.A., Johnson, A.E., Female Combat Amputees have Higher Rates of PTSD Disability (Poster) AAOS/CORR/ORS/CMH-UCD/SWHR Musculoskeletal Sex Difference Throughout the Lifespan Research Symposium/Military Health System Research Symposium (30 JUL - 01AUG 14/ 18 - 21 Aug 14)

Rivera, J.C., Krueger, C.A., Wenke, J.C., Hsu, J.R., Limb Salvage versus Amputation: Trading Disabilities for the Same Outcomes? (Presentation) Society of Military Orthopedic Surgeons (9 - 13 Dec 13)

Robbins, J., Hayes, E., Valdez-Delgado, K., Greeley, H., Mitchell, C., Barba, M., Peak, T., Shingleton, S., Phillips, S., Yoder, L., Mann-Salinas, E., "Demonstrated Benefits of an Evidence-Based Precepting Program" (Presentation) ABA 46th Annual Meeting (25 - 28 Mar 14)

Robbins, J., Hayes, E., Valdez-Delgado, K., Greeley, H., Mitchell, C., Barba, M., Peak, T., Shingleton, S., Phillips, S., Yoder, L., Mann-Salinas, E., Practice Transformation: An Evidence-Based Nurse Precepting Program (Presentation) TriService Nursing Research and EBP Dissemination Course (18 Sep 14)

Robbins, J., Phillips, S., Vanfosson C., Peak, T., Mittelsteadt, P., Riley, N., Palacios, R., Valdez-Delgado, K., Caldwell, N., Mann-Salinas, E., Practice Transformation: Implementation of a Midline Intravenous Catheter to

Decrease Frequent Peripheral Sticks and Infection Risk (Presentation) TriService Nursing Research and EBP Dissemination Course (15 - 18 Sept 14)

Robbins, J., Shields, B., Allen, D., Wallace, A., Sabatino, B., Phillips, S., Mann-Salinas, E., King, B., Using Electromagnetic Guidance for Successful Placement of Enteral Tubes by Nurses in Burn Patients (Poster) American Burn Association meeting (25 - 28 Mar 14)

Robbins, J., Shields, B., Allen, D., Wallace, A., Sabatino, B., Phillips, S., Mann-Salinas, E., King, B., Using Electromagnetic Guidance for Successful Placement of Enteral Tubes by Nurses in Burn Patients (Poster) ABA (25 - 28 Mar 14)

Robbins, J.R., Hayes, E.J., Valdez-Delgado, K.K., Sabido, J.M., Yoder, L.H., Greeley, H.L., Demonstrated Benefits of an Evidence-Based Precepting Program (Poster) Evidence Based Practice Project/ Nurse Week (8 May 14)

Robbins, J.R., Hayes, E.J., Valdez-Delgado, K.K., Sabido, J.M., Yoder, L.H., Greeley, H.L., Mitchell, C., Barba, M.G., Shingleton, S.K., Peak, T.F., Vanfosson, C.A., Phillips, S.A., Mittelsteadt, P.B., Mann-Salinas, E.A., Practice Transformation: An Evidence-Based Practice Nurse Precepting Program (Poster) TriService Nursing Research and EBP Dissemination Course (15 - 18 Sept 14)

Robbins, J.R., Hayes, E.J., Valdez-Delgado, K.K., Sabido, J.M., Yoder, L.H., Greeley, H.L., Mitchell, C., Barba, M.G.,Shingleton, S.K., Peak, T.F., Vanfosson, C.A., Phillips, S.A., Mittelsteadt, P.B., Mann-Salinas, E.A., An Evidence-Based Burn Precepting Program Improves Transition to Specialty Practice (Poster) MHSRS (18 - 21 Aug 14)

Robbins, J.R., Phillips, S.A., Vanfosson, C.A., Peak, T.F., Mittelsteadt, P.B., Riley, N.J., Palacios, R.G., Valdez-Delgado, K.K., Caldwell , N.W., Mann-Salinas, E.A., Implementation of a Midline Intravenous Catheter for Burn Patients to Decrease Frequent Peripheral sticks and Infection Risk (Poster)ABA 46TH ANNUAL MEETING (25 - 28 Mar 14)

Robbins, J.R., Phillips, S.A., Vanfosson, C.A., Peak, T.F., Mittelsteadt, P.B., Riley, N.J., Palacios, R.G., Valdez-Delgado, K.K., Caldwell , N.W., Mann-Salinas, E.A., Transforming Care at the Bedside: Implementation of a Midline Intravenous Catheter for Burn Patients to Decrease Frequent Peripheral Sticks and Infection Risk (Poster) TriService Nursing Research and EBP Dissemination Course (15 - 18 Sept 14)

Rodriguez, J.G., Edgecombe, H.P., Wallace, A., Robbins, J.R., Renz, E.M., Mann-Salinas, E., Chung, K.K., "Continuous Renal Replacement Therapy Sustainability in a Burn ICU: A Coordinator Perspective" (Presentation) ABA 46th Annual Meeting (25 - 28 Mar 14)

Rose, L.F., Wu, J., Tucker, D., Chan, R.K., Characterization of the Role of Hypodermis in Contraction (Poster) MHSRS (18 - 21 Aug 14)

Roy, D., Burmeister, D., Natesan, S., Meng, H., Ellenburg, M., Burnett, L., Tomblyn, S., Saul, J., Christy, R., Release of Functional Antibiotics from a Keratin Hydrogel to Treat Cutaneous Wound Infection (Poster) TERMIS-AM (10 - 13 Nov 13)

Roy, D., Ellenburg, M., Burnett, L., Tomblyn, S., Saul, J., Christy, R., Antibiotic-loaded Keratin Hydrogels Prevent Infection in a Full-thickness Porcine Excision Wound (Poster) MHSRS (18 - 21 Aug 14)

Saini, T., Ritter, J., Walker, T., Norton, N., Incidental Asymptomatic Radiolucent Lesions of Clivus (Poster) American Association of Maxillofacial Radiology Conference (25 - 27 Sept 14)

Saini, T.S., Federal Services Dental Symposium (Presentation) Federal Services Dental Symposium (17 - 20 Sept 14)

Salas, M.M., Greer, A., Fowler, M., Petz, L.N., Clifford, J.L., Curcumin Attenuates Thermal Hyperalgesia in a Rat Full Thickness Thermal Injury Model by Influencing Inflammation Signaling (Poster) MHSRS (18 - 21 Aug 14)

Salas, M.M., Greer, A., Fowler, M., Petz, L.N., Clifford, J.L., Curcumin Attenuates Thermal Hyperalgesia in a Rat Full Thickness Thermal Injury Model by Influencing Inflammation Signaling (Poster) SA Post Doc Research Forum UTHSCSA (16 Sep 14)

Salas, M.M., Jones, J., Fowler, M., Averitt, D.L., Petz, L.N., Renz, E.M., Maani, C.V., Garza, T.H., Sueltenfuss, M., Orman, J., Clifford, J.L., Pain Medication Profile for Severely Burned Military Service Members in OIF and OEF (Poster) Society for Neuroscience (9 - 13 Nov 13)

Salinas, J., Information technology and the military critical care patient Presentation (Presentation) FDA (23 Apr 14)

Salinas, J., Fenrich, C.A., Waters, J.A., Serio-Melvin, M.L., Cancio, L.C., Kramer, G.C., Driscoll, I., Chung, K.K., Full-Thickness Burn Size: More Important Than Total Burn Size in Determining Fluid Needs During Burn Resuscitation? (Presentation) ABA 2014 (25 - 28 Mar 14)

Salinas, J., Fenrich, C.A., Waters, J.A., Serio-Melvin, M.L., Cancio, L.C., Kramer, G.C., Driscoll, I., Chung, K.K., Full-Thickness Burn Size: More Important Than Total Burn Size in Determining Fluid Needs During Burn Resuscitation? (Presentation) MHSRS (18 - 21 Aug 14)

Salinas, J., Serio-Melvin, M.L., Fenrich, C.A., Driscoll, I., Garcia, A., Mann-Salinas, E., Cancio, L.C., Chung, K.K., A Case Series on Deployment of a Mobile Decision Support System in a Burn ICU (Poster) Society for Critical Care Medicine Conference (9 - 13 Jan 14)

Salinas, J., Waters, J.A., Fenrich, C.A., Serio-Melvin, M.L., Cancio, L.C., Kramer, G.C., Driscoll, I., Peterson, W., Chung, K.K., Validating the Correlation Between Resuscitation Fluid Volumes and Intra-abdominal Hypertension (Poster) ABA 2014 (25 - 28 Mar 14)

Samberg, M.E., Becerra, S.C., Cap, A.P., Christy, R.J., Effect of Platelet Incorporation within Human Plasma Hydrogels on Human Adipose-derived Stem Cell Differentiation (Poster) TERMIS (10 - 13 Nov 13)

Sanchez Jr, C.J., Hardy, S.K., Romano, D.R., Ward, C.L., Murray, C.K., Wenke, J.C., Effects of Local Release of D-/L- Tryptophan from Collagen Hydrogels on Infection in Mouse Full Thickness Dermal Wounds (Poster) 2nd Annual San Antonio Postdoctoral Research Forum (16 Sep 14)

Sanchez Jr., C.J., Prieto, E.M., Krueger, C.A., Zienkiewicz, K.J., Romano, D.R., Ward, C.L., Akers, K.S., Effects of Local Delivery of D-Amino Acids from Biofilm-Dispersive Scaffolds on Infection in Contaminated Rat Segmental Defects (Poster) Orthopaedic Research Society Annual Meeting (11 - 15 Mar 14)

Sanchez Jr., C.J., Prieto, E.M., Krueger, C.A., Zienkiewicz, K.J., Romano, D.R., Ward, C.L., Akers, K.S., Guelcher, S.A., Wenke, J.C., Effects of Local Delivery of D-Amino Acids from Biofilm-Dispersive Scaffolds on Infection in Contaminated Rat Segmental Defects (Poster) American Academy of Orthopaedic Surgeons Annual Meeting (12 - 14 Mar 14)

Sanchez Jr., C.J., Prieto, E.M., Krueger, C.A., Zienkiewicz, K.J., Romano, D.R., Ward, C.L., Akers, K.S., Guelcher, S.A., Wenke, J.C., Effects of Local Delivery of D-Amino Acids from Biofilm-Dispersive Scaffolds on Infection in Contaminated Rat Segmental Defects (Poster) Orthopaedic Research Society Annual Meeting (11 - 15 Mar 14)

Scaravilli, V., Kreyer, S., Linden, K., Jordan, B., Pesenti, A., Cancio, L.C., Batchinsky, A.I., Effects of recirculation of dialysate on carbon dioxide removal capabilities of a membrane lung (Poster) MHSRS (18 - 21 Aug 14)

Serio-Melvin, M., Great Balls of Fire! Care of the Burn Patent and Implications for Case Managers (Presentation) Alamo Chapter Case Management Society of America (Oct 14)

Serio-Melvin, M.L., Caring for our Wounded Warriors in the US Army Burn Center (Presentation) Smart Monitoring 2014 (16 - 17 Aug 14)

Serio-Melvin, M.L., Fenrich, C.A., Driscoll, I., Garcia, A., Mann-Salinas, E., Chung, K.K., Cancio, L.C., Deployment of a Mobile Decision Support System in a Burn ICU: A Case Series (Poster) MHSRS (18 - 21 Aug 14)

Serio-Melvin, M.L., Hayes, E., Coffman, R., Mann-Salinas, E., High Fidelity Human Patient Simulation: Bridging Burn Care Education with Modern Technology (Poster) TriService Nursing Research and EBP Dissemination Course (18 Sep 14)

Shields, B., Doty, K.A., Chung, K.K., Wade, C.E., Aden, J.K., Jones, J.A., Wolf, S.E., Determination of Resting Energy Expenditure after Severe Burn (Presentation) ABA (25 - 28 Mar 14)

Shiels S.M, Tomblyn S, Pattison L, Burnett L, Wenke J.C., Injectable Keratin-Based Gel for rhBMP-2 Delivery in a Critical Size Defect Model (Poster) MHSRS (18 - 21 Aug 14)

Silliman, D., Carlisle, P., Owens, D., Tucker, D., Hale, R., Brown-Baer, P., Segmental Mandibular Defects in Sinclair Miniature Pigs Mimic Human Mandibular Reconstruction Cases (Poster) MHSRS (18 - 21 Aug 14)

Simecek, J.W., Wojcik, B., Humphrey, R., Guerrero, A., Fedorowicz, A., Szeszel-Fedorowicz, W., Colthirst, P.M., DeNicolo, P., The Severity of Dental Disease Non-battle Injuries in Deployed US Army Personnel May 2009-December 2012 (Poster) MHSRS (17 - 22 Aug 14)

Simecek, J.W., Wojcik, B., Humphrey, R., Guerrero, A., Fedorowicz, A., Szeszel-Fedorowicz, W., ColthirsT, P.M., DeNicolo, P., The Severity of Dental Disease Non-battle Injuries in Deployed US Army Personnel May 2009-December 2012 (Presentation) MHSRS (18 - 21 Aug 14)

Sine, C.R., Belenkiy, S.M., Buel, A.R., Henderson, J.L., Waters, J.A., Batchinsky, A., Cannon, J.W., Lundy, J.B., Aden, J.K., Renz, E.M., Chung, K.K., Acute Respiratory Distress Syndrome In Burns: Application Of The Berlin Defination (Presentation) 43RD Critical Care Congress (9 - 13 Jan 14)

Sine, C.R., Buel, A.R., Henderson, J.L., Waters, J.A., Batchinsky, A., Cannon, J.W., Acute Respiratory Distress Syndrome In Burns: Application Of The Berlin Definition (Poster) 43rd Critical Care Congress (9 - 13 Jan 14)

Stockinger, Z., CPGs in the Joint Trauma System (Presentation) 46th Annual Meeting of the American Burn Association (25 - 28 Mar 14)

Stone II, R., Rathbone, C.R., A Pilot Study: Evaluation Of Microvascular Fragments For Improved Flap Survival Using A Rat Dorsal Skin Flap Model (Poster) 2nd Annual San Antonio Postdoctoral Research Forum (16 Sep 14)

Summers, S., Chin, E., Salinas, J., Blackbourne, L., Grisell, R., Automated Detection of Pneumorthorax with Ultrasound (FAST) (Poster) MHSRS (18 - 21 Aug 14)

Tennent, D.J., Wenke, J.C., Rivera, J.C., Krueger, C.A., Characterizations and Outcomes of Upper Extremity Amputees (Poster) MHSRS (18 - 21 Aug 14)

Thomas, M., Wallum, T., White, C., Bailey, J., Blackbourne, L., Murray, C., Impact of a Post-Splenectomy Vaccination Clinical Practice Guideline (Presentation) SAUSHEC Research Day (24 Apr 14)

Thompson, L.M., Mitchell, C., Martino, A.L., Fields, J.L., Martinez, D., Hatem, A.M., Bang, S., Unit Practice Council Initiatives to Introduce Alcohol Impregnated Port Protectors are Effective in Reduction of Central Line Infection Rates (Poster) TriService Nursing Research and EBP Dissemination Course (15 - 18 Sept 14)

Thompson, L.M., Mitchell, C., Martino, A.L., Fields, J.L., Martinez, D.M., Hatem, A.M., Bang, A.M., Mann-Salinas, E.A., Unit Practice Council Initiatives to Introduce Alcohol Impregnated Port Protectors are Effective in Reduction of Central Line Infection Rates (Presentation) TriService Nursing Research and EBP Dissemination Course (15 - 18 Sept 14)

Torres Filho, I., Thrombus Formation and Platelet Adhesion: A Quantitative System to Evaluate Platelet Function in vivo (Presentation) MHSRS (18 - 21 Aug 14)

Torres Filho, I., Torres, L., Sondeen, J., Salgado, C., Dubick, M., In vivo effects of blood products on endothelial glycocalyx, microvascular permeability and coagulation in severe hemorrhagic shock (Poster) EB2014 (26 - 30 Apr 14)

Torres, L., Endothelial Glycocalyx After Hemorrhagic Shock Followed By Volume Expansion With Normal Saline (Presentation) 36th Annual Conference on SHOCK (7 - 10 Jun 14)

Torres, L., Salgado, C., Valdez, C., Sondeen, J., Dubick, M., Torres Filho, I., Effects Of Resuscitation Fluids On Endothelial Glycocalyx And Microvascular Permeability Studied By Intravital Microscopy: Integration Of Systemic And Local Parameters In Vivo (Poster) MHSRS (18 - 21 Aug 14)

Torres, L., Salgado, C., Valdez, C., Sondeen, J., Dubick, M., Torres Filho, I., In Vivo Microvascular Effects Associated With Prehospital 0.9% Saline (NS) And 3% Hypertonic Saline (HTS) Resuscitation Regimen In A Hemorrhagic Shock (HS) Model In Rats (Poster) MHSRS (18 - 21 Aug 14)

Torres, L., Sondeen, J., Salgado, C., Dubick M., Filho, I.T., Comparison of plasma and 5% albumin resuscitation on preserving endothelial glycocalyx (EG) and microvascular permeability in vivo after severe hemorrhagic shock (HS) in rats (Poster) Experimental Biology 2014 (26 - 30 Apr 14)

Van Laar, T.A., Chen, T., Leung, K.P., Transcriptome Analysis of Persister Cells of Pseudomonas aeruginosa (Poster) American Society for Microbiology General Meeting (17 - 20 May 14)

Van Laar, T.A., Chen, T., Leung, K.P., Sublethal Concentrations of Carbapenems Change Cell Morphology and Genomic Expression of Klebsiella pneumoniae biofilms (Poster) MHSRS (18 - 21 Aug 14)

Vega, S., Prat, N., Salinas, J., Dubick, M., Cap, A., Blackbourne, L., Decision Support for TEG Analysis (Poster) MHSRS (18 - 21 Aug 14)

Wallace Jr, A., Sabatino, B.J., Shields, B.A., Robbins, J.R., Phillips, S.A., Mann-Salinas, E.A., King, B.T., Nurse Placed Enteral Feeding Tube: A Practical Solution for the Critical Care Environment (Poster) TriService Nursing Research and EBP Dissemination Course (18 Sep 14)

Walters, T.J., Aurora, A., Corona, B.T., Physical Rehabilitation Improves Skeletal Muscle Function following Volumetric Muscle Loss Injury in Rats (Poster) MHSRS (18 - 21 Aug 14)

Wang, H.C., Stem Cell Applications in Ocular Trauma (Presentation) UTSA College of Science Conference (18-Oct-13)

Wang, H.C., Choi, J.H., Novak, J., Burke, T.A., Kim, M., Lund, B.J., Johnson, A.J., Neutrophil infiltration induced by low-level single and repeated blast exposure in the rat cornea (Poster) AARVO (4 - 8 May 14)

Ward, C.L., Corona, B.T., Expanded Autologous Minced Muscle Grafts Promote De Novo Regeneration after Volumetric Muscle Loss (Poster) MHSRS (18 - 21 Aug 14)

Ward, C.L., Guo, R., Guelcher, S.A., Wenke, J., Development of a Cell Delivery Scaffold for Tissue Regeneration (Poster) MHSRS (18 - 21 Aug 14)

Ward, C.L., Guo, R., Wenke, J.C., Guelcher, S.A., Development of an Injectable and Settable Polyurethane Cell Delivery System for Tissue Regeneration (Poster)2013 Annual Meeting of the Tissue Engineering and Regenerative Medicine Society (TERMIS) (10 - 13 Nov 13)

Waters, .JA., Stewart, I.J., Kaplan, D.M., Aden, J.K., Cannon, J.W., Batchinsky, A., Sine, C.R., Chung, K.K., "Impact of Acute Respiratory Distress Syndrome and Acute Kidney Injury In Burns"(Poster) ABA (24 - 28 Mar 14)

Welsh, E., Burn Rehabilitation (Presentation) N/A (19-Nov-13)

Wood, L.A., Aden, J.K., Morris, M.J., Bell, D.G., Convertino, V.A., Chung, K.K., Correlation of Transcutaneous to Arterial Carbon Dioxide Levels in Shock: A Prospective Observational Study (Presentation) MHSRS (18 - 21 Aug 14)

Wood, L.A., Aden, J.K., Morris, M.J., Bell, D.G., Hunninghake, J.C., Convertino, V.A., Chung, K.K., Utility of a Near-Infrared Reflectance Spectroscopy (NIRS) Oximeter in Shock (Presentation) MHSRS (18 - 21 Aug 14)

Wright, Z., Stewart, I., Sosnov, J., Pidcoke, H., Fedyk, C., Kwan, H., Heegard, K., White, C., Chung, K., Cap, A., A Prospective Evaluation of Acute Traumatic Coagulopathy and Effects of Damage Control Resuscitation in Military Trauma Patients in Afghanistan (Poster) American Society of Hematology (6 Dec 14)

Wu, J.C., Rose, L.F., Tucker, D.I., Leung, K.P., Hale, R.G., Chan, K.K., The Impact of Full Thickness Burn on Skin Graft Contraction and Skin Quality (Poster) MHSRS (18 - 21 Aug 14)

Wu, X., Chen, J., Darlington, D.N., Cap, A.P., Schwacha, M.G., Polytrauma and Hemorrhage Elevates Plasmin and Thrombin Activity in Rats (Poster) MHSRS (18 - 21 Aug 14)

Wu, X., Darlington, D.N., Cap, A.P., Polytrauma and Hemorrhage Elevates Protein C in Rats (Poster) MHSRS (18 - 21 Aug 14)

Wu, X., Darlington, D.N., Schwacha, M.G., Cap, A.P., The Development of Acute Lung Injury After Polytrauma and Hemorrhage in Rats (Poster) SHOCK (7 - 10 Jun 14)

Wu, X., Keesee, J.D., Darlington, D.N., Cap, A.P., Schwacha, M.G., Polytrauma, without Resuscitation, Leads to Acute Lung Injury in Rats (Poster) MHSRS (18 - 21 Aug 14)

Yoder, L.H., "Should a Military Version of the Burn Specific Health Scale be Developed?" (Presentation) ABA (25 - 28 Mar 14)

Zaar, M., Fedyk, C.G., Pidcoke, H.F., Scherer, M.R., Ryan, K.L., Rickards, C.A., Hinojosa-Laborde, C., Convertino, V.A., Cap, A.P., Platelet activation after presyncope by lower body negative pressure in humans (Poster) Annual San Antonio Postdoctoral Research Forum at UTHSCSA (16 Sep 14)

Zamora, D.O., DeSilva, M.N., Cornell, L.E., Glickman, R.D., Wang, H.H., Johnson, A.J., Characterization of Magnetic Nanoparticle Loaded Corneal Endothelial Cells (Poster) ARVO (3 - 6 May 14)

Zamora, D.O., DeSilva, M.N., Glickman, R.D., Wang, H.C., Johnson, A.J., The Effects of Magnetic Nanoparticles on Human Corneal Epithelial Cell Viability (Poster) TERMIS (9 - 13 Nov 13)

USAISR Articles/Letters to Editor/Book Chapters

Summers, N., JTS News Letter (Letter) (10/1/2013)

Kragh, J.F., It’s exciting and important to have a journal so focal and unique (Interview) (10/4/2013)

Kragh, J.F., It’s exciting and important to have a journal so focal and unique (Letter) (10/4/2013)

Kragh, J.F., My name, F, just that one letter (Interview) (10/4/2013)

Kragh, J.F., Train to failure (Interview) (10/4/2013)

Kragh, J.F., Who owns battlefield medicine? (Interview) (10/4/2013 0:00)

Kragh, J.F., People that say “No!” irritate me., we should say “yes”.(Interview) (10/11/2013)

Summers, N., Intratheater Transport of the Critically Ill or Injured Patient from Role 1, 2, and 3 MTFs (Letter) (10/22/2013)

Summers, N., Management of Patients with Severe Head Trauma (Letter) (10/22/2013)

Summers, N., Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) for Hemorrhagic Shock (Letter) (10/22/2013)

Summers, N., JTS OP1 DA4700 TCCC-AAR v20131204 form Medical Record-Supplemental Medical Data (Letter) (12/10/2013)

Summers, N., The JTS Newsletter (Letter) (12/23/2013)

Akers, K.S., Cardile, A.P., Wenke, J.C., Murray, C.K., Biofilm Formation by Clinical Isolates and its Relevance to Clinical Infections (Chapter/Review) (5/6/2014)

Summers, N., West, S., DoDTR Data Request Form (Letter) (5/14/2014)

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Section 22

Fiscal Year 2014
Annual Historical Report

U.S. Army Medical Research Institute of Chemical Defense

Mission

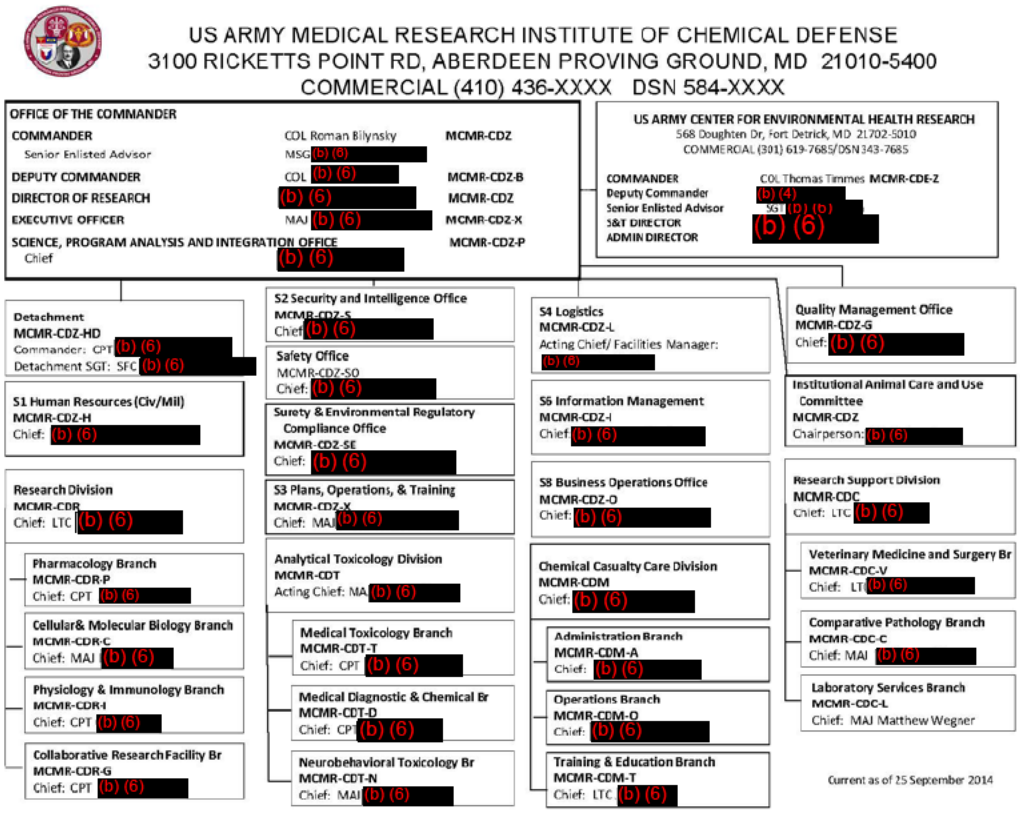
The mission of the US Army Medical Research Institute of Chemical Defense (USAMRICD) is to discover and develop medical products and knowledge solutions against chemical and biochemical threats through research, education and training, and consultation.

Organization and Personnel

Organization

A. Figure 1 illustrates the organization of the Institute at the end of fiscal year (FY) 2014, with key leaders identified.

FIGURE 1: Organization of the USAMRICD



B. Significant changes within the organization of the USAMRICD

1) Effective 1 July 2014, the S2/Safety, Surety, Security and Intelligence Office was reorganized into the Surety and Environmental Regulatory Compliance Office, the Safety Office, and the S2, Security and Intelligence Office. Additionally, the public affairs officer was aligned under the Science, Program Analysis and Integration Office (SPAIO). The safety and security managers began reporting directly to the Commander, USAMRICD, for all safety and security matters, but for administrative purposes began being rated by the Deputy Commander. The Safety Office was established to meet the requirements of Army Regulation 385-10, The Army Safety Program (November 27, 2013), and the S2, Security and

Intelligence Office was established to align with ATTP 5-0.1, Command and Staff Officer Guide (September 2011) .

Personnel

A. Changes to Key Leadership

1) On 22 July 2014, COL Roman O. Bilynsky assumed command of the USAMRICD. See photo Appendix A.

2) (b) (6) was appointed as Director of Research (DoR) on 17 November 2013 upon the departure of (b) (6) was acting DoR until until his permanent appointment on 28 July 2014. He continues as the acting chief of the Science, Program Analysis and Integration Office (SPAIO).

3) MSG (b) (6) was assigned as Senior Enlisted Advisor on 3 July 2014.

4) (b) (6) was appointed as Chief, Logistics on 1 May 2014.

5) MAJ (b) (6) arrived on 25 August 2014 and assumed the duties as the Deputy Chief, SPAIO.

6) MAJ (b) (6) was assigned as Chief, Laboratory Services Branch on 1 October 2013.

7) MAJ (b) (6) assigned as Chief, Cellular & Molecular Biology Branch on 4 October 2013.

8) MAJ (b) (6) assigned as Chief, Comparative Pathology Branch on 1 May 2014.

9) LTC (b) (6) was assigned as Chief, Veterinary Medicine & Surgery Branch on 16 June 2014.

10) MAJ (b) (6) was assigned as acting Chief, Analytical Toxicology Division on 1 August 2013.

11) SFC (b) (6) was assigned as Detachment Sergeant on 7 August 2014.

B. Civilian Human Resources

1) Civilian personnel strength is at 152.

2) A listing of civilian awards for 2014 is in Figure 2 at the end of this section.

3) Labor-Management Relations.

a. A Labor-Management Partnership Forum charter was signed on 27 May 2015. The USAMRICD, as represented by the Deputy Commander, COL (b) (6), was one of five Army organizations at APG to partner with the National Federation of Federal Employees local 178 to sign the charter.

4) Fiscal Year 2014 Government Shutdown

a. Because no continuing resolution authorization was in place on 1 October 2013, federal employees were furloughed. However, the USAMRICD and other laboratories within the US Army Medical Research and Materiel Command that had multiyear funding accounts were able to maintain the vast majority of their civilians on the payroll using the balance of FY 2013 money.

C. Military Personnel Resources

1) The Detachment is authorized 25 Army officers and 36 enlisted. Total strength at the end of fiscal year 2014 was 57 Soldiers. Personnel strength figures are shown in Figure 3 at the end of this section.

2) Military awards presented this fiscal year are listed in Figure 4 at the end of this section.

3) The Veterinary Medicine and Surgery Branch received its first Laboratory Animal Medicine (LAM) residency residents in 10 years in June 2014: CPT (b) (6) and MAJ (b) (6). The LAM

residency director is LTC (b) (6). The Department-of-Defense -structured portion of the residency occurred at Fort Detrick and the Walter Reed Army Institute of Research on Tuesdays, and an internally structured portion occurred on the USAMRICD campus on all other days of the week.

4) The NCO of the year was SSG (b) (6). There was no Soldier of the Year for 2014.

FIGURE 2: Civilian Awards Issued, FY14

Award	Number Awarded
Meritorious Civilian Service	1
Superior Civilian Service	5
Commander's Award for Civilian Service	26
Achievement Medal for Civilian Service	5
Certificate of Achievement	6
Certificate of Appreciation	29
Special Act	14
On-The-Spot	16
Time Off	147
Performance	116
Quality Step Increase	33
Patent	1
Federal Executive Board Career Service	15
Order of Military Medical Merit	8
AMEDD 30-Year Medallion	2
AMEDD Regimental Affiliation for Civilians	5
Distinguished Member of the Regiment	7
Friend of the Regiment	2
Honorary Member (Spouse) of the Regiment	6

FIGURE 3: Military Personnel Strength, end of FY14

Officers	Required	Authorized	Actual
Branch Immaterial (AI)	2	2	2
Medical Corps	3	3	3
Medical Service Corps	10	10	9
Veterinary Corps	10	10	11
Nurse Corps	1	1	2
Total Officers	26	26	27
Total Enlisted Soldiers	37	37	30

FIGURE 4: Military Awards Issued, FY14

Awards	Number Awarded
Legion Of Merit	2
Meritorious Service Medal	6
Army Commendation Medal	8
Army Achievement Medal	10
Military Outstanding Volunteer Service Medal	1
Certificate of Achievement	26

Statistical Data

Adjutant/Detachment Commander Office/Human Resources (S1)

A. Awards. The Military Human Resources (S-1) office received and processed 53 awards.

B. Personnel Actions. The Military Human Resources prepared over 200 requests for personnel actions.

C. Finance and Personnel Records Audit. The Military Human Resources conducted a mandatory review of 63 Soldiers' records during a Department of the Army mandated Finance and Personnel Records Audit. During the review the S-1 records manager individually sat down with each Soldier to go over every document in their Official Military Personnel File.

Editorial Office

A. Approximately 145 abstracts and 34 manuscripts were edited. Approximately 20 animal use and nonanimal use protocols as well as approximately 85 miscellaneous documents to include award nominations, standard operating procedures and memoranda were edited.

B. Seventy laboratory notebooks were issued to the research staff.

C. The Institute staff authored, or were coauthors on, 31 open literature articles and book chapters, and 113 abstracts were presented at various professional meetings and seminars around the world, including the Institute-hosted nineteenth biennial Medical Defense Bioscience Review, held in May 2014. A list of published journal articles, technical reports, and book chapters can be found in Appendix B. A list of presentations is at Appendix C.

D. Twenty-one news articles were prepared by USAMRICD staff in FY14, with additional articles about members of the staff prepared by other publications, such as the APG News.

Statistician

A. During FY14, statistical support to the Institute included working with approximately 32 principal investigators and technicians on analysis of data, experimental designs, reviewing and researching new statistical methods, and reviewing 25 manuscripts, abstracts and technical reports and contributing to several manuscripts as coauthor. As a member and full-time chair of the IACUC, the statistician attended 16 meetings and reviewed and participated in discussion of all new protocols and protocol amendments, and other IACUC policies, documents, and protocol templates. Additional IACUC duties included performing 5 annual reviews of protocols and participating in 2 semiannual facility inspections and program reviews.

Research Support Division

A. Comparative Pathology Branch

1) 2,847 samples arrived in the branch, of which 119 were diagnostic, 83 were quality control, 14 were training and 2,631 were for research protocols

2) 289 necropsies performed, of which 111 were diagnostic, 83 were quality control, 4 were training and 91 were for research protocols

3) 13,831 blocks trimmed for processing

4) 14,216 blocks processed and paraffin embedded

5) 23,099 slides cut from paraffin blocks

6) 420 cryosections produced

7) 12,417 slides stained with hematoxylin and eosin (H&E) stain

8) 1,232 slides stained with special stains

9) 909 slides stained with immunohistochemical stains
10) 24,106 slides delivered, 10,420 to veterinary pathologists and 13,686 to Principal Investigators (PIs)
11) 184 samples processed for electron microscopy
12) 367 tissue sections produced for electron microscopy
13) 690 electron microscopy digital micrographs acquired
14) 10,777 slides read by veterinary pathologists

B. Laboratory Services Branch
1) 390 complete blood counts performed
2) 811 serum chemistries performed
3) 900 microbiology cultures performed
4) 250 ova and parasite fecal samples examined
5) 381 chemistry controls performed
6) 2,732 total samples were tested by the branch

C. Veterinary Medicine and Surgery Branch
1) 9780 rodents provided with comprehensive veterinary medical and husbandry care (with an average daily census of 815).
2) 16 rabbits provided with comprehensive veterinary medical and husbandry care (with an average daily census of 16).
3) 77 nonhuman primates provided with comprehensive veterinary medical and husbandry care (with an average daily census of 71).
4) 95 swine provided with comprehensive veterinary medical and husbandry care (with an average daily census of 15).

Safety Program

A. Inspections
1) Internal Inspections of laboratories, administrative, mechanical, and warehouse space - 408
2) Subordinate site safety inspection of US Army Center for Environmental Health Research - 4
3) Automated External Defibrillator daily inspections for proper operation - 724
4) Safety Shower weekly flow testing to ensure proper operation - 2,652

B. Document Review
1) Internal Memoranda - 2
2) Policies – 8
3) Army Regulations - AR385-61, Chemical Agent Safety
4) DoDM 6055.09 V6.E4-DoD Chemical Agent Safety Standard
5) Standard Operating Procedures - 31

C. Chemical Agent, Biological Agent, Radiation Hazardous Materials Permits Issued – 49

Health Care Delivery

N/A

Training and Education

USAMRICD Training Mission – Chemical Casualty Care Division

The Chemical Casualty Care Division delivers graduate level continuing education and training, provides consultative services, contributes subject matter expertise, develops educational products, and advances initiatives. In FY14, 35 training iterations were offered, and 1,759 medical individuals were trained, resulting in the awarding of 12,532 professional credits.

A. Training and Education
   1) Medical Management of Chemical and Biological Casualties Course (MCBC)
      a. In-house - 7 iterations; 312 medical personnel trained; 8,032.53 professional credits awarded
      b. Off-site - 2 iterations (Republic of Korea and Fort Bragg, NC); 264 medical personnel trained; 444 professional credits awarded
   2) Field Management of Chemical and Biological Casualties Course (FCBC)
      a. In-house - 5 iterations; 365 medical personnel trained; 2,770 professional credits awarded
   3) Hospital Management of Chemical, Biological, Radiological/Nuclear and Explosive Incidents Course (HM-CBRNE)
      a. In-house - 2 iterations; 101 medical personnel trained; 1,120.24 professional credits awarded
   4) Emerging Threats Classified Course
      a. In-house - 8 iterations; 235 medical personnel trained.
   5) Webinar Training via Defense Connect Online (DCO)
      a. In-house - 11 total offerings; 482 medical personnel trained; 165 professional credits awarded

B. Training Products - 5 key products produced by the Chemical Casualty Care Division (CCCD)
   1) M50 Mask Computer Based Training Module
   2) FCBC Leaders Guide
   3) FCBC Training Exercise Casualty Care Pack
   4) Military Working Dog Field Medical Card
   5) Wide Area Virtual Environment (WAVElet)
   6) Numerous publications

C. Consultative Services on the Medical Management of Chemical Agents
   1) Joint Program Executive Office (JPEO)
   2) Fort Bragg Special Operations Command
   3) 22nd Chemical Battalion
   4) 38th Parallel Healthcare Operational Training in Yongsan, Korea
   5) 1st Area Medical Lab APG-North

6) 82nd Airborne Division, Fort Bragg
7) Delaware and Wisconsin Civil Support Teams
8) Federal Bureau of Investigation (FBI)
9) Aberdeen Proving Ground (APG) Chemical Accident Incident Response and Assistance (CAIRA)
10) Joint Special Operations Command (JSOC)
11) Edgewood Chemical Biological Center (ECBC)
12) Request from the US Army Office of The Surgeon General to attend the Bio Surveillance Baseline Operational Assessment Tabletop Exercise at the Dougherty Conference Center, Offutt Air Force Base (AFB), Nebraska
13) 20th Support Command

Required and Optional Training of USAMRICD Personnel

A. Training, Plans & Operations
   1) S3 oversees mandated training on behalf of the USAMRICD Command.
      a. HQDA mandatory face-to-face training
         i) Trainings are tracked through the Enterprise Safety Applications System (ESAMS), the Digital Training Management System (DTMS), and sign-in rosters
         ii) There are 6 of these trainings
         iii) The USAMRICD average was 86.9%
      b. HQDA mandatory online training
         i) Training are through ESAMS and DTMS based on submitted certifications
         ii) There are 3 of these trainings
         iii) The USAMRICD average was 87%
      c. USAMRICD mandatory training
         i) Trainings are tracked through ESAMS, DTMS, submitted certifications, and sign-in rosters
         ii) There are 107 of these training
         iii) The USAMRICD average 93%
   2) There were numerous opportunities for military education
      a. Professional Development Courses
         i) 1 Soldier graduated from the Warrior Leader Course
         ii) 1 Soldier graduated from the Advanced Leader Course and the Platoon Sergeant Course
         iii) 1 Soldier graduated from the Senior Leader Course
      b. Courses required for additional duty
         i) Master Fitness: 1 Soldier graduated
         ii) Master Resilience Training: 2 Soldiers graduated
         iii) Unit Prevention Leader : 2 Soldiers obtained certification

iv) Armor: 1 Soldier graduated

B. Adjutant/Detachment Commander Office

1) The detachment conducted Army Warrior Task Training (AWTT) on 25 April 2014 at the USAMRICD Chemical Casualty Care Division field site to build and test leader confidence, promote esprit-de-corps, and train Soldiers to support Professional Filler System (PROFIS), Special Medical Augmentation Response Teams (SMART), augmentee, and contingency operations worldwide. Forty-five Soldiers from the USAMRICD attended AWTT. The mission was accomplished, resulting in 45 Soldiers qualifying for AWTT. Soldiers were trained on reacting to contact, establishing security, performing actions as a member of a mounter patrol, and evacuating a casualty. Soldiers were also educated in supervising casualty treatment and evacuating and developing a security plan for a Command Post.

2) In the absence of weapons and ammunitions 10 Soldiers participated and qualified on the M16 and/or M9 during two ranges held by other APG commands. Because USAMRICD does not have any authorized weapons or allotment of ammunition assigned, the Institute is included on ranges offered by other APG units. During the end of FY 14, the unit submitted a request to gain access to the Total Ammunition Management Information System (TAMIS) to obtain ammunition.

C. Civilian Human Resources

1) Onsite leadership development training.

a. Employee Performance Conversations, Strategic Initiatives Consulting Group, 24 hours

b. Federal Employees Benefits Seminar, Federal Benefits Advocates, 8 hours

c. Federal Retirement Seminar, Kissinger Financial Services, 16 hours

d. It's Okay to be the boss; CRM Learning, 1 hour

e. Leadership and Management Skills for Non-Managers, Management Concepts, 24 hours

f. Leadership and Teamwork Presentation, GoRuck Special Forces, 3 hours

g. Leading and Managing High-Performing Project Teams, UMBC Training Centers, 16 hours

h. Professional Government Supervision Program, Management Concepts, 40 hours

i. Scientific Writing Course, Franklin Covey, 16 hours

2) Certifications

a. Twenty-five percent of acquisition members are certified. The remaining 75% are required to be certified by January 2016

D. Quality Management Office

1) The Quality Management Office provided USAMRICD scientific staff members with the opportunity to take annual Good Laboratory Practice (GLP) training.

E. Chemical Surety Personnel Reliability Program Training

1) The SERCO wrote and provided training materials to the Certifying Official of the USAMRICD Chemical Surety Personnel Reliability Program (CPRP). This program consists of eleven Institute employees who must adhere to the highest levels of reliability standards to qualify as a member of this program. This training is required annually and exceeds training standards as dictated by AR 50-6, Chemical Surety. The Certifying Official's training session for CPRP personnel was held on 9 October 2013.

F. Safety Program

1) Toxic Aid – 112 employees trained

2) Blood Borne Pathogen – 73 employees trained

3) Hearing Conservation – 28 employees trained

4) Fire Marshall training (prepares staff for conducting building life-safety inspections) – 6 employees trained

5) New Hire Orientations – 68

G. Security and Intelligence

1) In 2014 security personnel conducted face-to-face security training in the areas of personnel, operations security (OPSEC), information security, classified spillage, and antiterrorism to all USAMRICD personnel. The goal of these trainings was to foster a more personal approach versus the online training, tailor the training to the USAMRICD mission and security infractions, and allow personnel to ask questions. The training was well received and reporting of security issues significantly increased.

H. Research Support Division

1) Comparative Pathology Branch

a. One pathologist passed the American College of Veterinary Pathology exam and became board certified in veterinary anatomic pathology 19 September 2014. All the pathologists in the Institute are now board certified in veterinary anatomic pathology.

b. Two pathologists attended the American College of Veterinary Pathology conference 16-21 November 2013.

c. One pathologist attended the Western Veterinary Conference 15-20 February 2014.

d. One pathologist attended the Society of Toxicologic Pathology 22-26 June 2014.

2) Laboratory Services Branch (LSB)

a. MAJ (b) (6) continues to provide didactic training on "Military Working Dogs and the Chemical, Biological, Radiological, Nuclear and Explosives (CBRNE) environment" for the Institute's Medical and Field Management of Chemical and Biological Casualties (MCBC and FCBC) courses.

b. MAJ (b) (6) developed hands-on training utilizing canine first aid manikins to further enhance the training provided in the MCBC and FCBC Field Training Exercises (FTXs).

c. The LSB technicians are assistant instructors for the hands-on MCBC and FCBC FTXs.

3) Veterinary Medicine and Surgery Branch

a. CPT (b) (6) met all milestones for residency progress for the Laboratory Animal Medicine (LAM) residency program. She developed her hypothesis and experimental design for her hypothesis-based research project for the LAM residency program, a major step in completing this significant residency requirement.

b. Two team members achieved Laboratory Animal Technologist (LATG) certification through the American Association of Laboratory Animal Science (AALAS).

c. One team member achieved Laboratory Animal Technician (LAT) certification through AALAS.

d. One team member achieved Institute of Laboratory Animal Management (ILAM) certification through AALAS.

e. One team member achieved Certified Manager of Animal Resources (CMAR) certification through AALAS

f. RSD and the IACUC worked closely together to develop a new proficiency-based program for training USAMRICD animal users and animal caregivers. The comprehensive program includes, at its foundation, on-line and classroom didactic classes and species-specific introductory animal

handling and use workshops taught by VMSB personnel. The program utilizes individual training records to document the user's progress through several stages of proficiency, with each level qualifying the user for a higher level of autonomy. The program further requires potential trainers to demonstrate proficiency not only in performing the individual procedures, but also in teaching/training those procedures to pothers. Once fully implemented, each lab group will have certified trainers on their research teams who can train and certify users in the procedures that are specific to that group. Full implementation of the program is expected to take approximately 2 years to complete.

g. 11 Animal Care and Use Briefings conducted to train 25 people.

h. 3 Swine Handling Classes conducted to train 3 people.

i. 11 Small Animal Handling Workshops conducted to train 54 people.

j. 3 Non Human Primate Handling Courses conducted to train 5 people.

k. 7 Herpes B Classes conducted to train 87 people.

l. 4 Aseptic Techniques Workshops conducted to train 8 people.

m. 2 Rabbit Handling Courses conducted to train 7 people.

n. 1 Mouse Tail Nick training conducted to train 5 people.

o. Collaborated with a Charles River Laboratories to provide an Animal Models seminar for 18 institute personnel.

I. Analytical Toxicology Division

1) (b) (6) obtained recertification as a Diplomat with the American Board of Toxicology (DABT). This and his certification in Intermediate Nuclear Weapons Orientation with the Defense Threat Reduction University makes him the only USAMRICD employee with both of these two certifications.

Research and Development

Science, Program Analysis and Integration Office (SPAIO)

The Science, Program Analysis and Integration Office (SPAIO) serves as the Institute's focal point for coordinating and integrating the intramural and extramural science programs, consultative services, and international scientific activities.

A. Efforts funded by the Defense Threat Reduction Agency (DTRA)/Joint Science and Technology Office (JSTO)

1) The USAMRICD received funding from DTRA/JSTO for six multidisciplinary research areas encompassing the development of botulinum neurotoxin inhibitors; centrally acting nerve agent treatments; animal models for developing chemical warfare agent therapeutics; emerging chemical threats; and the creation of the Absorption, Distribution, Metabolism, Excretion and Toxicity Center of Excellence.

2) The USAMRICD received >$30M from DTRA/JSTO in FY14. Also during this period, USAMRICD investigators prepared required quarterly reports that were utilized by DTRA/JSTO program managers to inform requirements for FY15 statements of work.

B. Inter-Agency Agreements (IAAs) between the USAMRICD and the Office of Biodefense Research (OBR), National Institute of Allergy and Infectious Disease (NIAID).

1) FY14 marked the start of the eighth year of IAAs between USAMRICD and the NIAID.

2) In April, the NIAID awarded USAMRICD 16 projects that fell under one of the four umbrella IAAs: Anticonvulsants/Neuroprotectants, Toxic Vesicants and Industrial Chemicals (TICs), Cyanide, and Pulmonary Toxicant Gases. Total funding for the projects was $9M, an increase of $2M over the previous funding cycle.

Analytical Toxicology Division

A. Absorption, Distribution, Metabolism, Excretion and Toxicology (ADMET) Center of Excellence

1) (b) (6) and (b) (6), along with other USAMRICD investigators ((b) (6), CPT (b) (6) and (b) (6)), continued efforts to stand up the ADMET Center of Excellence. The center, established in response to Joint Science and Technology Office's (JSTO) new initiative, is a cross-divisional effort focused on streamlining the time and expense involved in drug development by determining critical characteristics of potential countermeasures prior to animal testing. The center continued securing more than $5M research funding, while the research under this new initiative was focused on accelerating the delivery of scopolamine and a catalytic bioscavenger to Milestone A by integrating into current efforts specific components of absorption, distribution, metabolism, and excretion to further current knowledge regarding the behavior and mechanism of action of these compounds in vivo.

B. Two Division principal investigators, (b) (6) and (b) (6), travelled to the Defence Science and Technology Laboratory (Dstl) in Porton Down, United Kingdom, to discuss progress and future work on contract W81XWH-12-C-0259, a swine phosgene exposure model, in support of the National Institute of Health (NIH) funded phosgene interagency agreement (IAA). The IAA requires USAMRICD scientists to verify use of state-of-the-art procedures and technology purchased with NIH funds at the Dstl. In FY13, Dstl finalized model development to include the addition of telemetry to monitor cardiac parameters and establishment of a phosgene dose to evaluate therapeutics. In the first option year (FY14), the Dstl team evaluated valproic acid (VPA) as a therapeutic for phosgene poisoning. Scientific discussions focused on evaluation of FY13 data, mitigation of possible setbacks, and plans for moving forward for the Dstl contract. The USAMRICD scientists found that the project was on track and that the the investigators have a solid plan for the year.

C. The (b) (6) team, in collaboration with the University of Colorado, spent much of 2014 evaluating compounds for their efficacy in reducing acute lung injury and chronic mortality resulting from sulfur mustard (HD) exposure. They discovered that tissue plasminogen activator (tPA, a fibrinolytic drug) significantly increases survival against lethal doses of HD in mice and that acute treatment with tPA eliminated HD-induced mortality in 28-day studies. Previous studies demonstrated that delayed lethality was due primarily to pulmonary fibrosis and bronchiolitis obliterans, and tPA was selected to combat these effects. During other studies on phosgene-induced pulmonary injury in mice, they also discovered that Sildenafil, a phosphodiesterase-5 inhibitor, and Captopril, an ACE (angiotensin-converting-enzyme) inhibitor, greatly improved survival following phosgene exposure. They plan on screening additional drugs, with the most effective examples proceeding to further testing at Dstl, UK. The objective of this research is to develop effective medical countermeasures against toxic lung injury.

D. (b) (6) research team, including recent additions (b) (6) and (b) (6), characterized the toxicology and inhalational lethality of gaseous phosphine, revealing increases in apoptotic cell death biomarkers in the mitochondria of cardiac tissue; additional tests revealed increases in immune responses, inflammation, general cell signaling, metabolism, and cancer. Preliminary studies of liver mitochondrial metabolism suggest that ATP production may be decreased. In addition to developing a custom ammonia inhalational exposure pathway for unanesthetized rodents, the team developed and validated a custom-designed head-out nerve agent inhalation system for conscious rats, which they've used to investigate differences in mammalian responses to aerosolized versus vaporized nerve agents.

E. (b) (6) continued his animal work in support of several USAMRICD research groups. His work helped to define the length of time that Reactive Skin Decontamination Lotion (RSDL), in conjunction with therapy, can be used to keep guinea pigs alive following cutaneous exposure to nerve agents. This can assist the Warfighter and civilians alike in the event of a nerve agent exposure without identification of the specific time of occurrence.

F. The wound healing and decontamination team, led by (b) (6), initiated a new partnership with US Army Medical Materiel Agency (USAMMA) to serve as an authority for wound healing efficacy assessment. They pioneered a new model of HD exposure and treatment using Yucatan miniature pigs and began a comparative study on wound healing in four different research-relevant strains. (b) (6) and contract employee (b) (6) also were called upon as subject matter experts to assist in evaluating a next-generation wound dressing for future advanced wound care applications. In addition, the team is close to completing their first fully USAMMA-funded wound healing project, an integration of non-invasive biophysical analysis and multivariate statistical modeling system, in the coming year.

G. During 2014, BB Team analytical chemists collaborated with Institute PIs on several research projects as subject matter experts in mass spectrometry. An anti-inflammatory cytokine, TSG-6, was characterized by on-column tryptic digestion-liquid chromatography-mass spectrometry, and a rapid quantitative method was developed for human and mouse TSG-6 based on six characteristic tryptic digest peptides which provide 20 percent sequence coverage. Three peptides were conserved and three were not conserved. The method will be used to quantify TSG-6 in culture media of mesenchymal stem cells exposed to chemical agent. Two SNAP-25 (synaptosomal protein of 25 kDa) epimers containing the cleavage site for botulinum A toxin and their respective cleavage products were also characterized, and a quantitative LC/MSMS method was developed. The methods have been used recently to evaluate the in vitro enzyme kinetics of candidate small molecule and peptide botulinum A toxin inhibitors. A quantitative air sampling/GC/MS method for over 35 chemical warfare agents was developed and is being validated to measure inhalation dosing and to provide standard operating procedures (SOP) monitoring. (It has been used to determine inhaled doses of a classified compound in a current USAMRICD protocol.)

H. (b) (6) and co-workers worked diligently during FY14 to establish a consortium for the development of botulinum neurotoxin (BoNT) antagonists with the Defense Threat Reduction Agency; collaborators are from the Naval Research Laboratory, Montclair State University, Brookhaven National Laboratory, Institute for Advanced Sciences, Moulder Center for Drug Discovery (Temple University), Hawaii Biotechnology, the Walter Reed Army Institute of Research, and the Israeli Institute of Biological Research. During the year, the consortium synthesized and tested 18 hydroxamate and 15 peptide inhibitors of BoNT serotype A (BoNT/A). The crystal structure of the most effective cyclic peptide has provided insights into the inhibitor-active site interactions and will guide future peptide and small molecule inhibitor synthesis

I. (b) (6) and his research group had a productive FY14. As part of the Botulinum Neurotoxin Consortium, they are investigating the efficacy of insulin-like growth factor-1 (IGF-1) as a countermeasure for botulinum neurotoxin serotype A (BoNT/A) intoxication. This is the first treatment that has been shown to accelerate recovery from BoNT-induced paralysis. (b) (6) and (b) (6) led a Commander's Innovative Research and Development project entitled "Investigation of Cellular Mechanisms in Soman-Induced Seizures in Rats Treated with Phytocannabinoids Using Electrophysiology and Calcium Imaging." Their findings indicate that cannabidiol is effective in preventing soman-induced hyperexcitability in rat hippocampal slices; furthermore, phytocannabinoids may be an important adjunct to standard therapy for soman-induced central nervous system hyperexcitability. The (b) (6) group has continued a very valuable and productive collaboration with the laboratory of (b) (6) of the Uniformed Services University of the Health Sciences, investigating the efficacy of antagonists of kainite receptors containing the glutamate receptor kainite 1 (GluK1) subunit to counteract the seizures and neuropathology caused by the nerve agent soman. The project is funded by the NIH CounterACT program.

J. (b) (6) group completed a project funded by Biomedical Advanced Research and Development Agency (BARDA), which showed that pre-weanling rats are highly susceptible to the lethal effects of

exposure to chemical warfare nerve agents (CWNA), consistent across agents and routes of exposure. Another BARDA-funded project evaluating the long-term effects of exposure to sublethal and lethal doses of chemical warfare nerve agent in rats and nonhuman primates was initiated by (b) (6) and (b) (6) . Drugs with anticholinergic and NMDA (N-methyl-D-aspartate) antagonistic effects administered as adjunct therapy to standard medical countermeasures against toxic doses of soman in rats were shown to reduce seizure activity, reduce performance deficits and protect the brain. Graduate studen (b) (6) led a related investigation of GD-induced impairment of sensory-motor gating. (b) (6) led the Lange group project demonstrating that aged rats had lower LD50 values for soman exposure compared to adults and had lower plasma carboxylesterase and brain acetylcholinesterase levels, which may partially account for the increased sensitivity to GD. In other projects, the (b) (6) group established a rodent model of percutaneous exposure to chemical nerve agents and demonstrated the efficacy of RSDL decontamination in combination with medical countermeasures. They also demonstrated the beneficial effects of catalytic bioscavenger in combination with medical countermeasures against the toxic effects of percutaneous VX. The (b) (6) group external collaborators include the US Army Center for Environmental Health Research, the National Center for Toxicological Research, the Walter Reed Army Institute of Research, the UCLA School of Medicine/VA Medical Center, the US Air Force at Wright Patterson Air Force Base, and the US Army Edgewood Chemical Biological Center.

K. (b) (6) group had numerous collaborative research projects and other work. They continued to advance the welfare of large animals at the Institute through active leadership of the Large Animal Working Group, which has provided core hands-on training, videos, and SOPs for working with nonhuman primates (NHPs) and swine. (b) (6) team in collaboration with (b) (6) and (b) (6) has provided time-course, safety, and efficacy data to advance the proof-of-concept for use of adenovirus-mediated expression of human butyrylcholinesterase (bioscavenger) in a NHP species against otherwise lethal soman (GD) challenge. (b) (6) completed two large studies that provided behavioral support for analysis of rodent performance to evaluate scopolamine and pyridostigmine bromide following subcutaneous agent exposure ((b) (6)) or inhalation exposure (b) (6)), and are now elaborating the behavioral efficacy of the centrally active oxime 80A. In support of an NIH IAA, (b) (6) evaluated behavioral protection afforded by the centrally active oxime monoisonitrosoacetone (MINA) following sarin, VX, and pesticide challenge in collaboration with (b) (6) . This work has complemented (b) (6) ongoing work with MINA in macaques. The (b) (6) group is also working on an NIH IAA to examine the oral toxicity of two poisons in rats, partnering with (b) (6) to conduct a cyanide study funded by DTRA, performing anthrax research with National Institute of Allergy and Infectious Disease (NIAID), and taking a role in the emerging threats program area.

L. (b) (6) cyanide team had many accomplishments. The group continued developing and testing a hydrogen cyanide inhalation delivery system for use with mice. Their work with countermeasures further characterized the in vivo efficacy of the novel cyanide countermeasure dimethyl trisulfide in mouse and rabbit models and demonstrated additive in vivo efficacy of the combination of two novel cyanide countermeasures dimethyl trisulfide and cobinamide in mouse and rabbit models. Additionally, this hard-working group developed a smaller, second-generation Cyanalyzer, a sensor designed to detect cyanide in biological fluids, such as blood, in near real-time (less than 30 seconds). The (b) (6) group's newest study generated preliminary data characterizing cyanide-induced biological pathway disruption, using mouse cardiac and neural tissue. (b) (6) was also a co-inventor on one provisional patent submission as part of a technology transfer initiative with Sam Houston State University.

Research Division

During the fiscal year 2014, the Toxicants, Bioscavenger and the Centrally Active Nerve Agent Treatment System (CANATS) research programs were executed by the Research Division. One of the challenges for all programs was that performance year (PY) was out of sync with the fiscal year (FY). For all programs, the PY for 2013 ended on 31 March 2014, and the succeeding PY was scheduled to end 31 December 2014, three months after the end of the fiscal year, on 30 September 2014. The government shutdown in October 2013 also created difficulties for the programs. When the federal government entered the shutdown, the length of the shutdown was completely unknown, and no prediction could be made to estimate the length. Unable to plan around this, researchers could not order animals unless they knew the animals would be housed and fed. A third challenge to research was extremely bad weather. Weather does not normally have a significant impact on research conducted indoors; however, the severe weather between November 2013 to March 2014 resulted in at least six lost working days as a result of Aberdeen Proving Ground closing, while several other working days were shortened. Despite these challenges, the programs made considerable progress.

A. The Bioscavenger research group continued efforts to develop and test enzymes that are capable of both persisting in the circulation for extended times and rapidly converting organophosphorus (OP) nerve agents into non-toxic products. We designed new enzymes with enhanced activity against different classes of OPs, we tested novel approaches for administering candidate enzymes, and we developed innovative methods for increasing the circulatory stability of lead candidate enzymes. Finally, in addition to showing that bioscavenger can provide protective efficacy when administered prior to OP exposure, we established that combining catalytic enzymes with conventional anti-OP therapeutic drugs after OP exposure affords better recovery than either approach alone. These projects were conducted with support from both the Defense Threat Reduction Agency and the National Institutes of Health.

B. The CANATS research program focuses on evaluating centrally active compounds that have broad-spectrum efficacy against all classes of chemical nerve agents (CNAs). When used either as a pretreatment or as an adjunct to post-exposure medical countermeasures, CANATS will improve survival, reduce morbidity and decrease neurological damage. In FY 14, we conducted studies to evaluate the contribution of scopolamine as an adjunct to current medical countermeasures. Guinea pigs were pretreated with pyridostigmine bromide (PB) or saline (vehicle for PB) 30 min prior to CNA challenge (2.0 LD50). At 1 min after CNA administration, guinea pigs were given atropine sulfate (0.5 mg/kg), 2-PAM (25 mg/kg), and midazolam (0.66 mg/kg) with or without scopolamine (0.10 mg/kg). Results indicate that PB in combination with scopolamine provided 100% survival against VX and sarin; PB in combination with scopolamine provided 83% and 75% survival against soman and cyclosarin, respectively; and scopolamine treatment alone improved survival from 67% to 92% against tabun. Although scopolamine increased survival, it had no advantage in reducing neuropathology. The observed improvement of neuropathology was primarily due to the anticonvulsive property of midazolam.

C. The Toxicants program also continued to make progress. (b) (6) group conducted high throughput screening approaches and small animal models to identify therapeutic targets and to evaluate countermeasures for injuries caused by chemical agents and industrial toxicants. (b) (6) team continued their research to establish stem cell-derived models for evaluation of neurotoxin's toxicity and potential treatment. (b) (6) team performed mechanistic studies and examined potential therapeutic chemicals for phosgene and phosphine.

Research Publications and Presentations

Listings of the 2014 open literature publications and technical reports is at Appendix B; presentations are at Appendix C.

Resource Management and Budget

A. The USAMRICD has historically obligated its financial program at the command target. Fiscal year (FY) 2014 was an exception as the Institute reported a 70% obligation rate at the end of the FY. This was due to several factors, the most critical being the change in performance year directed by our primary funding agency, DTRA. This change moved the performance year six months off the FY and made it impossible to execute to the established command targets. Adjustments to correct the performance year back to align with FY will be implemented in FY15.

B. Future funding is expected for the continued construction of our new facility as well as for its initial outfitting.

C. Research funding continued to be a high priority when out-year programming showed a significant decline in resources (both fiscal and human) for FY15-19. This caused an overall in-depth financial and research impact analysis to be performed so that an information paper could be prepared and provided to USAMRMC HQ. The FY14 program was not in place until February 2014, putting a severe strain on all Institute resources and program plans, since research cannot continue or begin because of the lack of direction being provided by the primary funding agent. We continue to pursue additional funding opportunities, and negotiations with NIH are expected to begin in early 2015.

D. Financial Management. The FY14 Command Budget Estimate (CBE) was developed based on DTRA-accepted research program submissions. Funding was received from DTRA via USAMRMC. The FY13 and FY14 programs are shown below:

FIGURE 5: Breakout of the The FY13 and FY14 programs

Programs	FY13	FY14
In-house Laboratory Independent Research (6.1/91C)	204	196
Defensive Countermeasures to Toxins of Biological Origin Medical Chemical Defense - Exploratory (6.2/TC2) Development	20,795	20,185
Medical Chemical Defense Life Support (6.3/TC3)	17,881	8,920
Materiel - Non-systems Advanced Development Exploratory Studies for the Development (6.2/TB2) of Medical Defensive Countermeasures to Toxins of Biological Origin	0	0
Advanced Studies (Non-systems Development) (6.3/TB3) on Toxins of Biological Origin Advanced Development	0	0
Threat Area Sciences (CB1)	0	0
Threat Area Sciences (CB2)	0	0
Infrastructure (LS6)	500	0
Operation & Maintenance, Army	11.5	0
Defense Health Program	1,923.5	3,331
Defense Health Program, Initial Outfitting & Transition	4,745.5	7,360
Totals	46,060.5	39,992

E. The USAMRICD programs and executes its resources by research and capability areas and assigns funding at the research project level. The CBE and work breakdown structures were prepared to make project level reporting possible. A continuing concern of the USAMRICD is the planning and programming for research and how strategic planning cannot be performed when funding decisions arrive so late in the fiscal year and multiple year projects are not considered. Additionally, the requirement to compete for funding research projects that are burdened with the core capability and infrastructure costs continues to be a major concern. We are working with JSTO/DTRA to secure and maintain a funding level that supports these costs.

F. The FY13 program build continued our approach to assign costs via Activity Based Costing to more accurately reflect the true cost of each science project. We will continue to refine this methodology in future costing tools.

G. Personnel Augmentation Programs. The Business Operations Office maintains Institute administrative oversight and contract management of extramural contracts and many of the personnel augmentation contracts as well as program administration of the National Research Council Program, the Non-Personal Services and Requirements Contract Programs, the Battelle Summer Employment Program, and the Scientific Technical Analysis Services Program.

H. The Office of Research and Technology Application (ORTA) group negotiated and prepared a variety of contract agreements and intellectual property actions during 2014:

1) Cooperative Research and Development Agreements (CRADAS) – 9
2) Cooperative Research and Development Agreement (CRADA) Modifications – 1
3) Memorandums of Understanding (MOU) – 2
4) Memorandums of Agreement (MOA) – 8
5) Material Transfer Agreements (MTA) – 15
6) Inter-Agency Agreements (IAA) – 5
7) Commercial Test Agreements (CTA) – 0
8) Non-Disclosure Agreements (NDA) – 1
9) Invention Disclosures – 0
10) Inventions approved for full patent – 1
    a. Measurements of the inhibition of synaptic activity to detect, study, and evaluate all active botulinum neurotoxin serotypes (McNutt/Beske).
11) Inventions approved for provisional patent – 0
12) Our new partners during 2014 are
    a. National Strategic Research Institute
    b. BeneChill
    c. Texas A&M
    d. AstraZeneca
    e. Oligasis, LLC
    f. Biomedical Advanced Research and Development Authority

I. The annual Command Plan, 0116 Peacetime and Mobilization Designee (MOBDES) Tables of Distribution and Allowances (TDA) were submitted and approved. The manpower mission was impacted by the receipt of the results from our Manpower Survey. An out-of-cycle TDA was submitted (0216) to document

additional changes. The TDA allows for military manpower requisitioning and civilian and contractor resourcing, and provides management with a tool for the decision-making process.

J. The Managers' Internal Control Program audit was completed, and the Annual Statement of Assurance was signed by the Commander and submitted to USAMRMC. Responsibility for annual training, reviews and assessments is maintained and directed from S8. A new five-year plan was developed, and the next annual review is scheduled for February 2016.

K. We continued to develop the MRICD Resource Planning Portal (MRPP) for costing of projects and proposals. The costs in this tool are based on our Activity-Based Costing reports and are updated annually.

Information Management

A. The installation of several systems occurred in the USAMRICD Recapitalization Project. Wired and wireless local area network was installed in the facility. The Building Automation System (BAS) was installed to monitor various building components to include the HVAC system, air handler, ventilation, laboratory equipment and other sensors throughout the facility. Facility Commander and Ultra View were installed in the Security Office; these two systems control access and video surveillance for all of the entryways to the facility. This upgraded technology allows for increased capabilities to ensure the security and safety of our facility and personnel.

B. The Information Management Office consulted with USAMRICD Logistics to construct camera mounts in building E3156 for the animal behavioral laboratory. The animal behavioral system was relocated from E3100 to E3156 and the Stoelting software was upgraded.

C. A new lab surveillance system for a non-human primate protocol was configured. The project involved five Ethernet cameras controlled from a PC with a fully configured backup PC.

D. The Army Virtual Battle Space 3 simulator was installed for the Chemical Casualty Care Division.

E. Upgraded Defense Medical Logistics Standard Support (DMLSS) portable data assistant (PDA) scanners for the S4 Property Management team were configured and deployed. The project included new software, new PDA scanners and CAC authentication sleds.

F. A new iStat blood analyzer and PC-controlled Central Data Station was configured in the BB area secure labs, by working with Abraxus vendor.

G. An upgrade of FileMaker Pro 13 was completed on 12 machines and the server.

H. The Institute transitioned from the use of Retina for Information Assurance Vulnerability Alerts (IAVA) scanning to the Assured Compliance Assessment Solution (ACAS) tool. The transition involved mapping of USAMRICD's assets to assist with the configuration of the new tool as well as face-to-face training for all ACAS users. The first scan using ACAS occurred in August 2014. The project involved defining a network map, scan zones, and scanning points of contact (organizational leads, managers, and users in each zone).

I. During USAMRICD's annual training week, a Cybersecurity presentation for US Army Medical Command's first Cybersecurity Awareness Month was prepared and presented.

J. The Goal 1 waiver process was fully implemented. The Goal 1 Waiver process is an Army-approved waiver for information technology (IT) purchases which cannot be acquired via a CHESS vendor. This involved conducting a training course for USAMRICD customers and implementing a process for customer consultations to facilitate the composition of the Statement of Non-Availability (SoNA) and Goal 1 Waiver. Along with the implementation of the Goal 1 Waiver process, USAMRICD also completed its transition to the use of the Medical System Information Repository with 153 entries. The creation of our Goal 1 process assisted the United States Army Medical Research Acquisition Activity Contracting Officers by alleviating this step from their process and speeding up the acquisition of information technology products.

K. The Information Management Office assisted the US Army Public Health Command with the transition of the Defense Information Assurance Certification and Accreditation Process (DIACAP) to Enterprise Mission Assurance Support Service (eMASS). The Information Assurance manager attended the mandatory online and face-to-face training and will be updating USAMRICD assets within the eMASS.

Operations

A. Chemical Accident or Incident Response and Assistance (CAIRA) Exercises: The USAMRICD executed four CAIRA exercises during the period 1 October 13 – 30 September 14. Three of the exercises were tabletops, and one was a live exercise encompassing all APG Garrison response forces to include Kirk US Army Health Clinic and the APG Directorate of Emergency Services (fire and emergency services/law enforcement). Notes on the After-Action Review are at Appendix D.

B. The S2, Security and Intelligence Office, participated in the Aberdeen Proving Ground Garrison's annual antiterrorism (AT) exercise, "Raven Keep," which allowed us to evaluate our shelter-in-place procedures in our 14 buildings. This exercise provided invaluable information to USAMRICD's antiterrorism program, leading changes to our program in such areas as priorities of communication, accountability, establishment of a USAMRICD Emergency Operations Center, and personnel responsibilities during an active shooter scenario.

C. Personnel from the Analytical Toxicology Division supported the Army Test and Evaluation Center's mission at Dugway Proving Ground (DPG) by sending two subject matter expert scientists to perform physical inventory of the DPG Combined Chemical Test Facility (CCTF) agent stocks.

Modernization

Adjutant/Detachment Commander Office/Human Resources (S1)

A. Military Human Resources Work Order System. The Military S-1 is working with the S-6 office to establish an online Military Human Resources Work Order System. The system will be designed as an electronic system for the Soldiers to submit personnel actions to the Military S-1 Section. We conducted a testing of the system with 13 Soldiers in USAMRICD in July 2014. Because of changes in the lead contractor the release date for the system has been pushed to the right. When the system becomes operational, the Military S-1 Section will be in line with the Commander's mission to transition to an electronic-based office.

Research Division/Cellular and Molecular Biology Branch

A. In 2014, CMBB acquired the following major equipment:

1) Zeiss LSM 710 Confocal Microscope
2) 2200 TapeStation for RNA quality control
3) ACEA xCELLigence RTCA Cardio System, a high throughput instrument for assessing clinical potential for drugs to induce arrhythmia using in vitro models
4) Pearl Imaging System with anesthesia suite for real-time imaging of anesthetized animals with edema, inflammation, and other pathological indicators
5) Odyssey CLx Premium Imaging System that provides an open platform for multiple applications to include Western blot analysis, In-Cell and On-Cell Westerns, protein arrays, ELISA, tissue section analysis
6) Nikon C2+ Point Scanning Confocal Microscope

Logistics

A. Medical Maintenance Section. The Medical Maintenance Section completed 3,422 services (preventive maintenance, safety inspections, repairs, and calibrations) during 2014. Through the Aberdeen Proving Ground support group, 53 calibrations of test, measurement and diagnostic equipment were completed.

B. Supply/Property Management Section. The property account is valued at nearly $42M with 6,402 pieces of equipment. There are 67 line items with a unit price greater than $100,000. The number of hand receipts is 70. The Government Purchase Card Program continued to be a success with purchases valued in excess of $6.3M. Over 582 property book items were processed for turn-in or redistribution.

C. Facilities Section. The number of facilities maintenance service/work orders processed and completed was 2,603. The following projects were completed were completed in our current facilities:

1) Building E3100 – replacement of chilled water coils in 2 air handling units.

2) Building E3081 – replacement of exhaust fan supporting vault room.

3) Building E3244 – replacement of exhaust fan.

4) Building E3081 – rebuild of exhaust fan supporting critical mission area.

5) Building E3081 – repair of the damaged epoxy flooring throughout vivarium areas.

Construction

The USAMRICD Military Construction (MILCON)/Recapitalization Project

A. The MILCON/Recapitalization project for USAMRICD consists of 525,255 gross square feet of medical research laboratory including neat and dilute agent laboratories, vivarium, animal procedure rooms, administrative and logistical areas and a support Central Utility Plant. The project completion is anticipated for first quarter of FY15 with the first occupant relocation into the facility scheduled for April 2015. Approximately $7M in laboratory support equipment was procured and installed in the facility, which included a nuclear magnetic resonance spectrometer, one transmission electron microscope and one scanning electron microscope.

Health and Environment

A. Fourteen (14) ergonomic assessments were conducted to prevent repetitive injuries.

B. Occupational medical exams for chemical, biological, radiation, and animal workers numbered 230 in FY14.

C. Fifty-three (53) industrial hygiene surveys were conducted to ensure safe working levels of chemical exposure and sound levels.

Other

Research Program-Related Activities

A. Fourth Biomedical Confidence Building Exercise conducted by the Organization for the Prohibition of Chemical Weapons (OPCW).

1) The Medical Diagnostics Team ((b) (6) [redacted] were one of twenty-one international laboratories nominated to participate in the Fourth Biomedical Confidence Building Exercise conducted by the Organization for the Prohibition of

Chemical Weapons (OPCW). All of the participating laboratories received six human plasma samples prepared by the OPCW Laboratory. The laboratories were tasked with analyzing the samples for the presence or absence of nerve agents. (b) (6) , members of the USAMRICD analytical chemistry group, had 28 days to conduct studies and prepare a detailed report of their methods and findings. Using immunomagnetic beads, the team separated the enzyme butyrylcholinesterase from the plasma. They broke down the protein to isolate the active site peptide, and used liquid chromatography-tandem mass spectrometric (LC-MS-MS) analysis to detect whether nerve agent was bound to that active site, thus verifying exposure and identifying the specific nerve agent. Out of nineteen laboratories that submitted reports, the USAMRICD was one of ten to correctly identify all the chemical warfare agents spiked into the samples received. Although not required for the exercise, the team went a step further and quantified the samples, correctly calculating numerical concentration values for the agent content in the samples. The accomplishments made through this exercise were significant in that it demonstrated the Medical Diagnostics Team's proficiency and accuracy in detecting nerve agent exposure in biological samples. The team's identification of the unknown compounds in pre-spiked samples underscored the capacity of the USAMRICD to participate in high-profile exercises across the international spectrum.

B. Hosted Scientific Meetings

1) The SPAIO hosted the fall and spring Semiannual Commander's Reviews in October and April, respectively.

   a. The primary purpose of the Commander's Semi-Annual Reviews is for the USAMRICD's program advisors to report progress on currently funded research projects to the command staff, program managers, funding agencies and stakeholders. These reviews are the most efficient way to disseminate this type of information and also provide a venue for our stakeholders and funding agencies to meet, facilitating discussion of programmatic issues of interest as well as concerns.

   b. The review conducted in the fall is an internal review with no outside guests, whereas key stake holders from within the Department of Defense Chemical and Biological Defense Program (CBDP) are invited to the spring event. Key leaders from the DTRA/JSTO, the Joint Requirements Office-Chemical, Biological, Radiological, and Nuclear Defense, and the Joint Program Executive Office for Chemical and Biological Defense are invited and are often in attendance. This venue allows for the key stake holders of the CBDP to see first-hand the science and technology (S&T) efforts in chemical warfare agent (CWA) therapeutic development that support the overarching goals of the CBDP enterprise.

2) 19th Biennial Medical Defense Bioscience Review, Advances in Medical Chemical Defense, from 11 to 15 May 2014

   a. Over 300 scientists from government, academic and commercial organizations within the United States and seven other countries attended to survey the latest research to develop medical countermeasures to protect against the effects of chemical warfare agents and biological neurotoxins.

   b. (b) (6) , professor of pathology and laboratory medicine at the University of Pennsylvania, provided this year's keynote lecture, "Vector Platforms for Biodefense and Pandemics."

   c. The Clarence A. Broomfield Award recipient was Professor (b) (6) of the Weizmann Institute of Science in Israel. The title of (b) (6) award lecture was "Acetylcholinesterase - From 3D Structure to Function: Impact on Drug Discovery and Protection against Chemical Threat Agents."

   d. Attendees also participated in several breakout sessions and workshops, to include an educational experience provided by the USAMRICD's Chemical Casualty Care Division (CCCD), for which participants earned continuing educational credits. In the two-hour, hands-on workshop, "From the

Laboratory to the Aid Station: A Crash Course in Chemical Casualty Simulation," the division's Field Training Team provided instruction on cutting edge, high fidelity casualty simulation practices.

C. Trip of the USAMRICD Commander, COL Bruce Schoneboom, and the Institute Director of Research ([redacted] to the United Kingdom (UK), November 2013.

1) On 5 November 2013, the Commander and DoR visited the Defence Science and Technology Laboratory (Dstl, Ministry of Defence, UK) facilities at Porton Down, Wiltshire, accompanied by COL (b) (6) from the Defense Threat Reduction Agency's Joint Science and Technology Office (DTRA-JSTO). The visit consisted of (a) an overview of Dstl from senior management; (b) tours of their high containment facility, sample reception facility (where we discussed the possibility of sharing their human biological samples for validation of USAMRICD's forensic/analytical techniques), marmoset colony, *in vitro* laboratory, and inhalation toxicology laboratory; and (c) classified discussions on medical countermeasures against chemical threats of mutual concern.

2) On 6 November 2013, the DoR and the Commander attended the second day of the two-day XVIth International CBRN Symposium at the Defence Capability Centre (DCC), Defence Academy, Shrivenham, UK. One outcome of this meeting and visit to Dstl was the opportunity to test our fielded analytic fibers on human urine samples that were collected after the sarin attacks in Syria.

3) On 7-8 November 2013, the Commander and DoR attended the Chemical Biological Review (CBR) of the Dstl. The meeting was held at the DCC.

D. Quadrilateral Medical Countermeasures Consortium (Quad MCMC)

1) (b) (6), the Director of Research, attended various Quadrilateral Medical Countermeasures Consortium (Quad MCMC) meetings as the US Scientific and Technical Lead, while the Deputy Commander attended various Quad MCMC meetings as a Task Group member. The Quad MCMC facilitates the exchange information, identify areas for collaboration and identify opportunities for burden sharing across the nations for development of medical countermeasures between the United States, Australia, Canada, and the United Kingdom.

E. The SPAIO chief, (b) (6), coordinated USAMRICD responses to questions asked by auditors from the US Government Accountability Office (GAO), which was conducting a review of the Department of Defense's chemical and biological infrastructure capabilities in response to a Congressional request from the Chairman and Ranking Member of the House Armed Services Subcommittee on Intelligence, Emerging Threats and Capabilities.

F. The Quality Management Office started talks with the Joint Program Executive Office for Chemical and Biological Defense, Joint Project Manager-Medical Countermeasures Systems, about bringing an advanced development capability to the USAMRICD.

Institutional Animal Care and Use Committee (IACUC)

A. During the year, (b) (6) served as the Institutional Animal Care and Use Committee (IACUC) chair and biostatistician. Federal law mandates IACUC review and approval of proposed activities that are related to the care and use of animals.

B. The full committee met 19 times within the last year and reviewed 138 amendments (5 Full Committee Review [FCR], 46 Designated Member Review [DMR], and 87 minor [54 chair & veterinarian; 33 coordinator]) to current protocols and 12 new protocols (11 FCR, 1 DMR). The committee takes approximately 45 minutes to review each new protocol, of which approximately 30 minutes are devoted to direct questioning of the principal investigator (PI). Fifty-seven annual reviews of protocols were conducted and two semiannual facility inspections and program reviews were conducted. Thirty-four adverse events (AE) were received and reviewed by the IACUC. Seven Post-Approval Monitoring (PAM) memorandums were submitted and reviewed by the IACUC.

C. The IACUC conducted and reported the results of two semiannual inspections (1 to 30 October 2013 and 1 to 30 April 2014) of its animal care and use program and facilities. These inspections were performed using the Animal Welfare Act, the Guide for the Care and Use of Laboratory Animals, and appropriate Department of Defense and Army regulations to verify compliance.

D. The IACUC reported 12 protocol noncompliance incidents to the Office of Laboratory of Animal Welfare (OLAW) (and copied the Animal Care and Use Review Office [ACURO] at the US Army Medical Research and Materiel Command).

E. The IACUC received full-accreditation from the Association for the Assessment and Accreditation of Laboratory Animal Care (AAALAC) International (18 November 2013).

F. The IACUC completed the following annual reports:

1) US Department of Agriculture (USDA) animal use for FY 2013 to include all species except mice and rats (completed 21 November 2013).

2) USAMRMC version of the USDA report to include all species including mice and rats (completed 21 November 2013).

3) Office of Laboratory Animal Welfare (OLAW) annual report (completed 27 January 2014).

4) AAALAC International report (28 January 2014).

G. The following IACUC policy letters were established and/or revised:

1) Guidelines for Housing of Social Species

2) Guidelines Regarding the Distinction of Significant (Major) and Minor Changes and Respective Approval Process

3) Policy on Notification and Supervision of Proposed Surgery and/or Anesthesia of Non-Rodent (large animal) Species

4) IACUC Member Training

5) Guidelines for Food and Water Restriction for Animals Used in Research

6) Policy on Prolonged Restraint

7) Procedures for Review and Approval of Protocol Amendments

8) Guidelines for Reporting Adverse Events

9) Guidelines for Designated Member Review and Approval of Protocols

10) Guidelines on Tissue Sharing

11) IACUC Standard Operating Procedure

H. Two alternative attending veterinarians (AV) were replaced as a result of a permanent change of their duty station, and one new alternate AV was appointed. The USAMRICD change of command also led to a change in the Institutional Official.

I. Each year new IACUC members receive a minimum of eight hours training on animal care and use issues. Training was accomplished by meeting with the IACUC chair, who reviewed all USAMRICD IACUC policies, guidance and SOPs, attending the in-house Animal Care and Use Brief, and reviewing and the taking the exams for the American Association for Laboratory Animal Science (AALAS) Learning Library courses “Animal Welfare Act Regulations,” “Guide to the Care and Use of Laboratory Animals” and “Essentials for IACUC Members.” In-house and on-line training cover the key components of an animal care and use program, IACUC functions, program evaluations and inspections, protocol review and personnel qualifications and training. IACUC members and the coordinator also attend training courses that included seminars and webinars conducted by Scientist Center for Animal Welfare, AALAS, Public Responsibility in

Medicine and Research, Association for Assessment and Accreditation of Laboratory Animal Care International, and Office of Laboratory Animal Welfare. Also, various articles relating to animal care and welfare were discussed with the IACUC members throughout the year. Several webinars were sponsored this year that helped meet this requirement.

Security and Intelligence Programs

A. Antiterrorism/Force Protection.

1) The USAMRICD established a protection working group. Members consist of command, division, laboratory, staff, and safety personnel. This group meets quarterly and discusses various topics such as antiterrorism (AT), operations security (OPSEC), the Continuity of Operations Program (COOP), and various threat topics. Thus far the group has offered up numerous ideas that were implemented into USAMRICD's AT, OPSEC, COOP, and intelligence programs. This group also provided comment to a first ever USAMRICD criticality assessment, which identified significant gaps in our AT and physical security program that the group was able to later leverage.

B. Chemical Agent Security.

1) FY14 was a challenge to our chemical surety material (CSM) program. During this FY the civilian security guards (CSG) that were charged with the protection of our CSM were moved to the access control points, and security response was replaced with federal police. Additional changes include decrements in the APG Table of Distributions and Allowances for CSG and police assets, removal of a dedicated response force, and CSG random patrols and security checks.

2) In early FY14 the Department of the Army issued a change to the postulated threat, which forced the USAMRICD to conduct a full-scale vulnerability assessment (VA). The changes with security forces on Aberdeen Proving Ground as well as the change of the Edgewood Chemical Biological Center's (ECBC) single small-scale facility from a schedule II to a schedule III chemical agent facility fostered a joint VA between the ECBC and the USAMRICD. The joint VA was a huge success as a result of the inclusion of security, facility, safety, and laboratory subject areas from ECBC and the USAMRICD to address like vulnerabilities with each other and address similar gaps with the degradation of APG security assets. It also save resources by allowing Garrison assets to attend one VA versus two separate VAs.

C. Intelligence. During the summer of 2014 the S2, Commander, Deputy Commander, and Director of Research visited the National Ground Intelligence Center (NGIC). The meeting allowed the USAMRICD and NGIC to provide mission briefs and to open up dialogue on how best to serve one another. Since this meeting, the S2 has been receiving better intelligence support from NGIC and other members of the intelligence community (IC), which is strengthening our programs and interaction with members of the IC.

D. Personnel Security. In 2014, the USAMRICD finalized all processes with the Department of Defense childcare background investigation. In 2014 alone the S2 processed 42 personnel for childcare background investigations in support of numerous science and engineering development programs.

E. Physical Security. Members of the S2 met with the APG Special Reactions Team (SRT). The meeting was to introduce the new SRT Commander to key leaders of the USAMRICD, allow the SRT to tour USAMRICD facilities, and to war-game various scenarios should the SRT need to respond to the USAMRICD. The S2 team furnished the SRT with floor plans as well as security badges and keys to facilitate a faster response to the USAMRICD.

Inspections

A. The US Army Medical Command Surety Management Review (SMR), 14-18 July 14, identified zero deficiencies in surety management.

B. The following environmental inspections occurred. No major deficiencies were noted.

1) 13 December 13 – APG Garrison quarterly inspections of 90-day sites
2) December 13 – USAMRICD internal inspections of all Satellite Accumulation Sites
3) 20 March 14 – APG Garrison quarterly inspections of 90-day sites
4) March 14 – USAMRICD internal inspections of all Satellite Accumulation Sites
5) 28-29 May 14 – Annual APG Garrison inspections of all Satellite Accumulation Sites
6) Week of 26 May 14 – Organizational Inspection Program (OIP) Multimedia Inspection
7) Week of 16 June 14 – Environmental Performance Assessment System (EPAS) inspection to include hazardous waste, hazardous materials, pollution prevention, and air quality
8) 16 June 14 – APG Garrison quarterly inspections of 90-day sites
9) 16-19 September 14 – Environmental Protection Agency (EPA) inspections of the USAMRICD 90-day sites and unannounced EPA multimedia inspection
10) 27-30 September 14 – USAMRICD internal inspections of all Satellite Accumulation Sites

C. The USAMRICD passed site assessment conducted on 27 August 2014 by the Army Human Research Protections Program, and USAMRICD's assurance was renewed.

D. The Chemical Surety Program underwent a Surety Management Review by the US Army Medical Command in July with no findings or deficiencies. The BB Team Agent Inventory and Accountability Program was commended for its accounting and inventory system. During 2014, the BB Team issued over 400 dilute chemical surety material (XCSM) and 250 CSM samples to provide agent for USAMRICD research protocols. The BB Team performed routine monthly XCSM lot analyses and requested ultradilute and XCSM analyses to ensure agent stock quality for Institute PIs.

Internship and STEM Programs

A. SPAIO sponsors several internship programs, which are managed by the marketing director.

1) Ninety-six (96) students in the fifth to seventh grades, over a three-week period, were accepted into the 2014 Gains in the Education of Mathematics and Science (GEMS) program. The students performed mission-relevant hands-on experiments in labs at the Science, Technology, Engineering, and Mathematics (STEM) Center at Aberdeen Proving Ground North. Experiments included a mystery artifact scientific method challenge, DNA extraction, snap circuits, fingerprinting, blood typing, biochemistry, a manikin demonstration, a three-dimensional modeling demonstration, and an electron microscopy demonstration.

2) The USAMRICD hosted more than 62 students ranging from bachelor's degree to the post-doctorate level through the Oak Ridge Institute for Science and Education (ORISE) program. Students were brought on board for full-time, part-time and interim appointments that support the research efforts conducted by USAMRICD investigators.

External Employee Recognition

A. For her extraordinary volunteer efforts, SPC (b) (6), a medical laboratory technician, received the prestigious American Legion Spirit of Service Award (Army), as well as the title of APG Military Volunteer of the Year; additionally, her charitable efforts and those of her family earned the (b) (6) the honor of being the APG Military Family of the Year.

B. Chemical Casualty Care Division's COL (b) (6) was recognized by the American Medical Writers Association (AMWA) for her contributions to two military books published by the Borden Institute. COL (b) (6) was executive medical editor for *Emergency War Surgery* Book, 2013, which took first place in the

Physician category, and she was director and editor in chief of *Medical Consequences of Radiological and Nuclear Weapons*, which received an honorable mention in the Physician category.

C. Several USAMRICD employees were recognized by the Baltimore Federal Executive Board:

1) Gold: (b) (6), Outstanding Para-Professional (Non-Supervisory) Technical, Scientific & Program Support

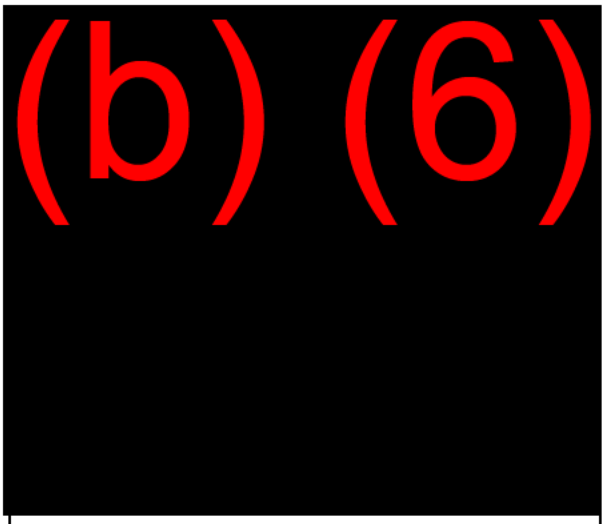
2) Silver: CPT (b) (6) Outstanding Supervisor, GS 12 and below; (b) (6), Outstanding Professional (Non-Supervisory), Technical, Scientific and Program Support; Neuro-Stem Cell and Molecular Biology Team (a 10-member research team led by (b) (6) and including co-researchers (b) (6)), Outstanding Para-Professional (Non-Supervisory), Technical, Scientific and Program Support - Team; (b) (6), Distinguished Public Service Career; (b) (6), Rookie Employee of the Year - Technical, Scientific and Program Support.

3) Bronze: (b) (6), Outstanding Supervisor, GS 13 and above; (b) (6), Outstanding Professional (Non-Supervisory), Administrative Management & Specialist; (b) (6), Outstanding Para-Professional (Non-Supervisory), Administrative/Management Analyst; (b) (6), Outstanding Administrative Assistant/Management Assistant - Individual; S1, Civilian Human Resources Office (b) (6), Outstanding Administrative Assistant/Management Assistant - Work Group or Team; (b) (6) Outstanding Trades and Crafts (Non-Supervisory); SPC (b) (6), Volunteer Service - Individual; Morale, Welfare and Recreation Committee (b) (6), MAJ (b) (6), CPT (b) (6), CPT (b) (6), SFC (b) (6), SFC (b) (6), SSG (b) (6), SSG (b) (6), SSG (b) (6), SGT (b) (6) SGT (b) (6), SPC (b) (6), SPC (b) (6), SPC (b) (6), SPC (b) (6), SPC (b) (6), SPC (b) (6), PFC (b) (6)), Volunteer Service - Team; (b) (6), Rookie Employee of the Year - Administrative/Management Analyst.

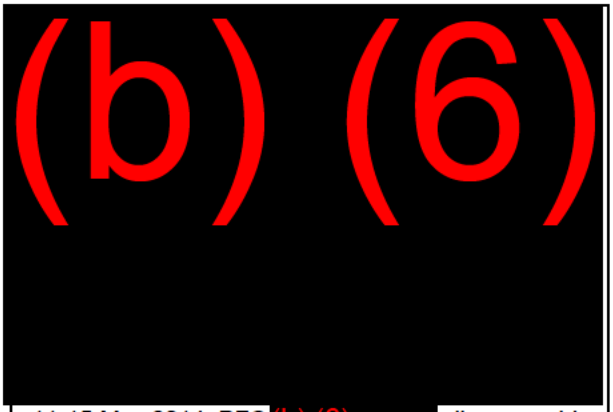
D. (b) (6) earned Best Post-Doctoral Poster recognition at the Medical Defense Bioscience Review in May.

E. (b) (6) was invited to join the F1000 Research Advisory Editorial Board and was elected secretary for the Society for *In Vitro* Biology.

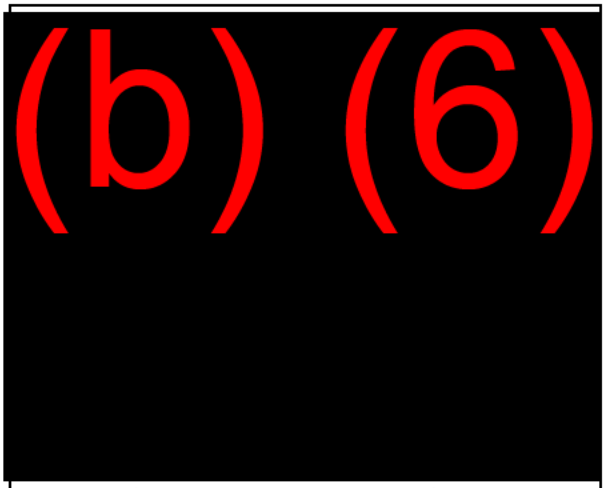
Appendix A – Photos



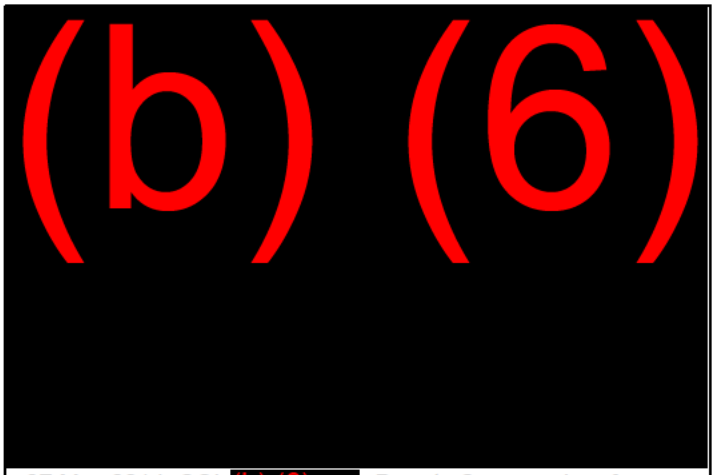
22 July 2014, COL Roman O. Bilynsky assumed command of the USAMRICD; after special permissions were obtained, the ceremony was held in the Institute's new facility.



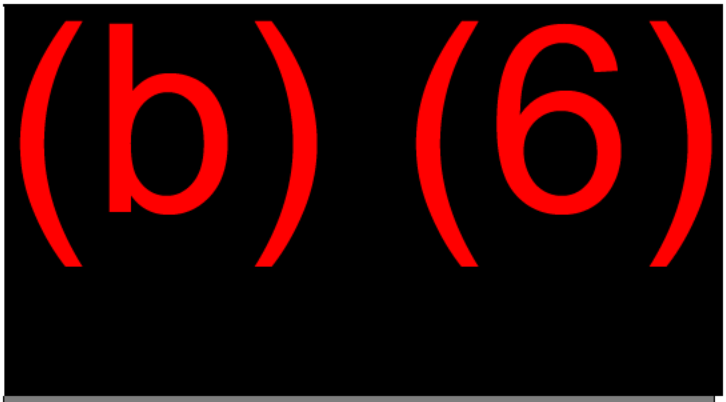
11-15 May 2014, PFC (b) (6) discusses his poster at the USAMRICD-hosted biennial Medical Defense Bioscience Review held in Hunt Valley, Md.



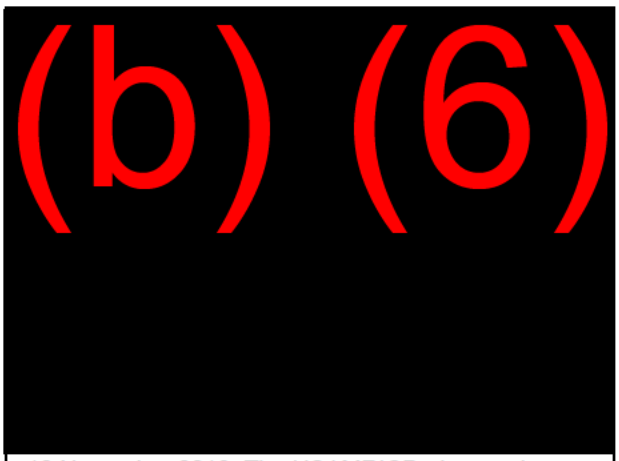
26 August 2014, American Legion National Commander Daniel Dellinger and Medal of Honor recipient Sgt. (b) (6) present USAMRICD SPC (b) (6) with the 2014 American Legion Spirit of Service Award in Charlotte, NC.



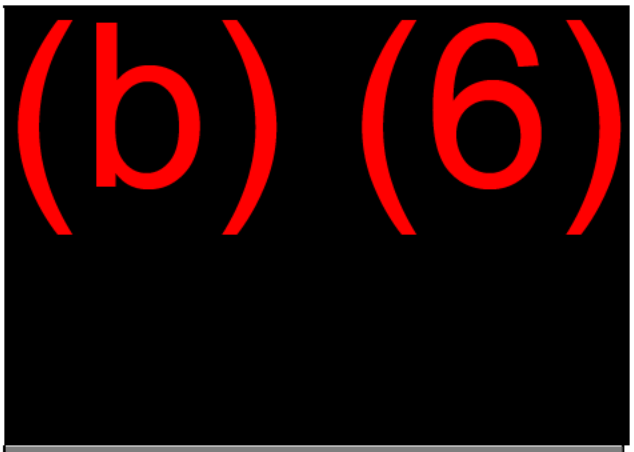
27 May 2014, COL (b) (6), Deputy Commander of USAMRICD, represented the Institute at the charter signing creating a labor-management forum. The signing was held at the headquarters of the US Army Research, Development and Engineering Command, APG North.



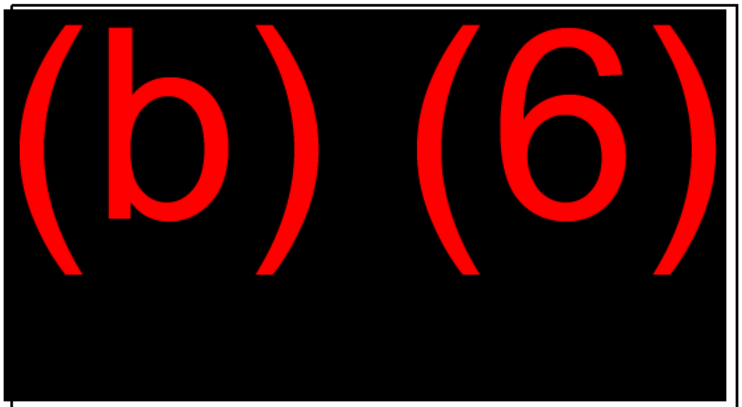
5 June 2014, as part of a professional and leadership development opportunity, Soldiers from USAMRICD and Center for Environmental Health Research toured areas of the White House and had a photo op in front of the East Wing with Bo and Sunny, the first family's pet dogs.



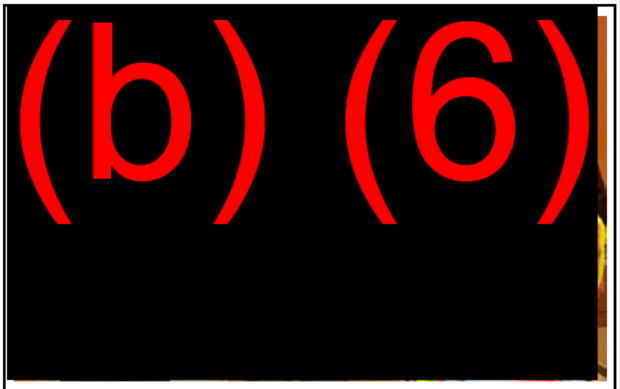
12 November 2013, The USAMRICD observed National Disability Employment Awareness Month with special guest speakers (b) (6) , former Baltimore Ravens player diagnosed with amyotrophic lateral sclerosis in 2007, and his wife, (b) (6)



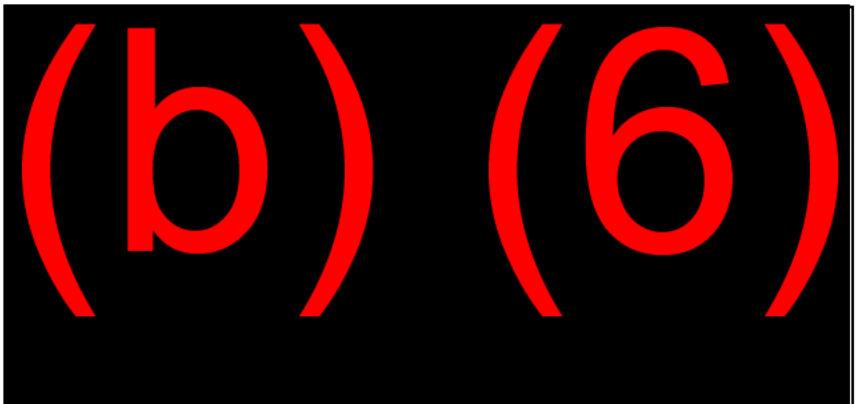
29 May 2014, the installation-wide observance of Asian American Pacific Islander Heritage Month at the Myer Auditorium, organized by the USAMRICD featured guest speaker Secretary of the Maryland Department of Veterans Affairs (b) (6) seen here receiving a commemmorative gift from COL (b) (6)



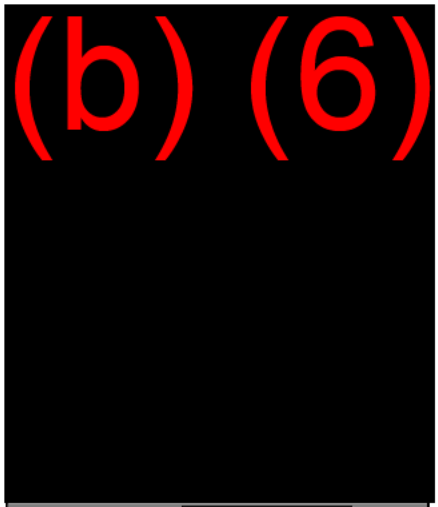
12 February 2014, Representatives of the Swedish Defense Research Agency (FOI) met withleaders and scientists at the USAMRICD to discuss common research interests.



25 September 2014, The Surgeon General of Chile (center) received a tour of the USAMRICD's new facility when he and his entourage visited the Institute.



17 April 2014, a large delegation from the Republic of Korea visited the USAMRICD.



10 April 2014, (b) (6) ,chief of the Army Medical Department Civilian Corps visited for a town hall meeting.

Appendix B – Fiscal Year 2014 Publications

Adler, Michael, Gul, Nizamettin, Eitzen, Edward, Oyler, George, Molles, Brian. Prevention and treatment of botulism. In Molecular Aspects of Botulinum Neurotoxin (ed. KA Foster). Vol. 4. In Current Topics in Neurotoxicity. New York: Springer, pp. 291-342, 2014.

Bhandari, R.K., Manandhar, E., Oda, R.P., Rockwood, Gary A., Logue, B.A. Simultaneous high-performance liquid chromatography-tandem mass spectrometry (HPLC-MS-MS) analysis of cyanide and thiocyanate from swine plasma. Analytical and Bioanalytical Chemistry, 406(3), 727-734, 2014.

Bhandari, R.K., Oda, R.P., Petrikovics, I., Thompson, D.E., Brenner, M., Mahon, S.B., Bebarta, V.S., Rockwood, Gary A., Logue, B.A. Cyanide toxicokinetics: the behavior of cyanide, thiocyanate and 2-amino-2-thiazoline-4-carboxylic acid in multiple animal models. Journal of Analytical Toxicology, 38(4), 218-225, 2014.

Bourne, Andrew R., Mohan, Govini, Stone, M.F., Pham, M.Q., Schultz, C.R., Meyerhoff, J.L., Lumley, Lucille A. Olfactory cues increase avoidance behavior and induce Fos expression in the amygdala, hippocampus and prefrontal cortex of socially defeated mice. Behavioural Brain Research, 256,188-196, 2013.

Chen, Yun, Garcia, Gregory E., Huang, Wei, Constantini, Shlomi. The involvement of secondary neuronal damage in the development of neuropsychiatric disorders following brain insults. Frontiers in Neurology, volume 5, article 22, 1 March 2014.

Chen, J., Pan, H., Chen, C., Wu, W., Iskandar, K., He, J., Piermartiri, T., Jacobowitz, D.M., Yu, Q.S., McDonough, John H., Greig, N.H., Marini, A.M. (-)-phenserine attenuates soman-induced neuropathology. PLoS One, 9(6):e99818. doi: 10.1371/journal.pone.0099818. eCollection 2014, June 23, 2014.

Donelan, K., Romano, C., DesRoches, C., Applebaum, S., Ward, J.R., Schoneboom, Bruce A., Hinshaw, A.S. National surveys of military personnel, nursing students, and the public: drivers of military nursing careers. Military Medicine, 179(5), 565-572, 2014.

Gore, Ariel, Horwitz, Vered, Gutman, Hila, Tveria, Liat, Cohen, Liat, Cohen-Jacob, Orit, Turetz, Joseph, McNutt, Patrick M., Dachir, Shlomit, Kadar, Tamar. Cultivation and characterization of limbal epithelial stem cells on contact lenses with a feeder layer: toward the treatment of limbal stem cell deficiency. Cornea, 33(1), 65-71, 2014.

Graham, John S., Schoneboom, Bruce A. Historical perspective on effects and treatments of sulfur mustard injuries. Chemico-Biological Interactions, 206(3), 512-522, 2013.

Jackson, Randy, Oda, Robert P., Bhandari, Raj K., Mahon, Sari B., Brenner, Matthew, Rockwood, Gary A., Logue, Brian A. Development of a fluorescence-based sensor for rapid diagnosis of cyanide exposure. Analytical Chemistry, 86, 1845-1852, 2014.

Keyser, Brian M., Andres, Devon, Holmes, Wesley, Paradiso, D., Appell, Ashley, Letukas, V.A., Benton, Betty, Clark, Offie E., Gao, X., Ray, P., Anderson, Dana R., Ray, Radharaman. Mustard gas inhalation injury: Therapeutic strategy. International Journal of Toxicology, 33(4), 271-281, 2014.

Lee, Jangwoen, Kim, Jae G., Mahon, Sari B., Mukai, David, Yoon, David, Boss, Gerry R., Patterson, Steven E., Rockwood, Gary, Isom, Gary, Brenner, Matthew. Noninvasive optical cytochrome c oxidase redox state measurements using diffuse optical spectroscopy. Journal of Biomedical Optics, 19(5), 055001, May 2014.

Li, Albert P., Richter, Patricia, Cole, Stephanie, Madren-Whalley, Janna, Oyler, Jonathan, Dorsey, Russell, Salem, Harry. Pulmonary primary cells cocultured in a novel cell culture system, the Integrated Discrete Multiple Cell-Type Coculture System (IdMOC). In Inhalation Toxicology, 3rd edition (ed. H. Salem, S.A. Katz). Enfield, New Hampshire: CRC Press, 327-338, 2014.

Lowery, Colin A., Adler, Michael, Borrell, Andrew, Janda, Kim D. Scorpion toxins for the reversal of BoNT-induced paralysis. Bioorganic & Medicinal Chemistry Letters, 23, 6743-6746, 2013.

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McNutt, Patrick M., Tuznik, Kaylie, Nelson, Marian, Adkins, Angela, Lyman, Megan, Glotfelty, Elliot, Hughes, James, Hamilton, Tracey. Structural, morphological and functional correlates of corneal endothelial toxicity following corneal exposure to sulfur mustard vapor. Investigative Ophthalmology & Visual Science, 54(10), 6735–6744, 2013.

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Peng, L., Adler, Michael, Demogines, A., Borrell, A., Liu, H., Tao, L., Tepp, W.H., Zhang, S.C., Johnson, E.A., Sawyer, S.L., Dong, M. Widespread sequence variations in VAMP1 across vertebrates suggest a potential selective pressure from botulinum neurotoxins. PLoS Pathogens, 10(7), e1004177, 2014 (10 July).

Peng, Xinqi, Perkins, Michael W., Simons, Jannitt B., Witriol, Alicia M., Rodriguez, Ashley M., Benjamin, B.M., Devorak, Jennifer L., Sciuto, Alfred M. Acute pulmonary toxicity following inhalation exposure to aerosolized VX in anesthetized rats. Inhalation Toxicology, 26(7), 371-379, 2014.

Perkins, Michael W., Wong, Benjamin, Rodriguez, Ashley, Devorak, Jennifer L., Alves, Derron A., Murphy, Gleeson, Sciuto, Alfred M. Inhalation toxicity of soman vapor in non-anesthetized rats: a preliminary assessment of inhaled bronchodilator or steroid therapy. Chemico-Biological Interactions, 206(3), 452-461, 2013.

Prager, Eric M., Aroniadou-Anderjaska, Vassiliki, Almeida-Suhett, Camila P., Figueiredo, Taiza H., Apland, James P., Rossetti, Franco, Olsen, Cara H., Braga, Maria F.M. The recovery of acetylcholinesterase activity and the progression of neuropathological and pathophysiological alterations in the rat basolateral amygdala after soman-induced status epilepticus: relation to anxiety-like behavior. Neuropharmacology, 81, 64-74, 2014.

Prager, Eric M., Pidoplichko, Volodymyr I., Aroniadou-Anderjaska, Vassiliki, Apland, James P., Braga, Maria F. Pathophysiological mechanisms underlying increased anxiety after soman exposure: Reduced GABAergic inhibition in the basolateral amygdala. Neurotoxicology, 44, 335-343, 2014.

Schultz, Mark K., Wright, Linnzi K., de Araujo Furtado, M., Stone, Michael F., Moffett, Mark C., Kelley, N.R., Bourne, A.R., Lumeh, W.Z., Schultz, C.S., Schwartz, Julia E., Lumley, Lucille A. Caramiphen edisylate as adjunct to standard therapy attenuates soman-induced seizures and cognitive deficits in rats. Neurotoxicology and Teratology, 44, 89-104, 2014.

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Tsai, Yien Che, Moller, Brian E., Adler, Michael, Oyler, George A. Molecular basis for persistence of botulinum neurotoxin: The role of intracellular protein degradation pathways. In Molecular Aspects of Botulinum Neurotoxin (ed. KA Foster). Vol. 4. In Current Topics in Neurotoxicity. New York: Springer, pp. 191-205, 2014.

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Clarkson, Edward D., Schulz, Susan M., Smith, Kelly H., Schwartz, Julia E., Moffett, Mark C., Lee, Robyn B., Whalley, Christopher E., Lumley, Lucille A. Determination of the 24- and 48-hour median lethal dose (MLD) after cutaneous application of neat EA6030 in unsedated haired and harless guinea pigs with application site occluded and unoccluded. USAMRICD-TR-13-02. US Army Medical Research Institute of Chemical Defense, Aberdeen Proving Ground, Maryland, July 2014.

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Koplovitz, Irwin, Schulz, Susan M., Rousayne, Cassandra, Chandler, Jessica, Smith, Kelly H. Comparative efficacy of medical countermeasure regimens against nerve agents in guinea pigs. USAMRICD-TR-14-04. US Army Medical Research Institute of Chemical Defense, Aberdeen Proving Ground, Maryland, June 2014.

Appendix C – Fiscal Year 2014 Presentations

Apland, James P., Borrell, Andrew C., Russo, Trisha, Glotfelty, Eliot, McNutt, Patrick, Petrali, John, Adler, Michael. Insulin-like growth faactor-1 accelerates recovery from paralysis induced by botulinum neurotoxin A. Interagency Botulism Research Coordinating Committee, Annapolis, Md., 20-23 October 2013. [Poster]

Hubbard, Kyle, Beske, Phillip, McNutt, Patrick. The use of longitudinal deep sequencing to validate stem cell-derived neurons as an in vitro platform for botulinum neurotoxin research: identifying the appropriate time points for biological relevance. Interagency Botulism Research Coordinating Committee, Annapolis, Md., 20-23 October 2013. [Poster]

McNutt, Patrick, Beske, Phillip, Hubbard, Kyle, Lyman, Megan. Synaptic inhibition following BoNT/A intoxication in stem cell-derived central nervous system neurons: shared pathophysiologies with in vivo intoxication. Interagency Botulism Research Coordinating Committee, Annapolis, Md., 20-23 October 2013. [Invited Platform]

diTargiani, Robert C., Boeri, Michael V., Sweeney, Richard E., Soni, Sunil D., Kasten, Shane A., Cerasoli, Douglas M. Characterization of nerve agent hydrolysis using novel analytical methods. DTRA Chemical and Biological Defense Program Enzyme Colloquium, Falls Church, Va., 01-03 October 2013. [Platform]

Cadieux, C. Linn, Kasten, Shane A., Mannion, Joshua, Katz, Francine S., Cerasoli, Douglas M. In vitro characterization of the interaction of novel reactivators with OP-inhibited and uninhibited AChE. DTRA Chemical and Biological Defense Program Enzyme Colloquium, Falls Church, Va., 01-03 October 2013. [Platform]

Cerasoli, Douglas M., Hofstetter, Catherine A., Hodgins, Sean M., Boeri, Michael V., Otto, Tamara C., Kasten, Shane A. Defining the extent of protection afforded against OP nerve agents and pesticides by different catalytic bioscavengers. DTRA Chemical and Biological Defense Program Enzyme Colloquium, Falls Church, Va., 01-03 October 2013. [Platform]

Kasten, Shane A., Kirby, Stephen D., Hofstetter, Catherine A., Nguyen, Dominique L., Boeri, Michael V., Hodgins, Sean M., Otto, Tamara C., diTargiani, Robert C., Cerasoli, Douglas M. DTRA Chemical and Biological Defense Program Enzyme Colloquium, Falls Church, Va., 01-03 October 2013. [Platform]

Mata, David G., Rezk, Peter, Sabnekar, Praveena, Cerasoli, Douglas M., Chilukuri, Nageswararao. DTRA Chemical and Biological Defense Program Enzyme Colloquium, Falls Church, Va., 01-03 October 2013. [Platform]

Devine, Lindsey, Ramirez, Cheryl. Creating inhouse blood values for the African green model. AALAS National Meeting, Baltimore, Md., 27-31 October 2013. [Poster]

Devine, Lindsey. Desensitization in the African green model. AALAS National Meeting, Baltimore, Md., 27-31 October 2013. [Poster]

Apland, James P., Borrell, Andrew C, Murray, Bridget, Glotfelty, Elliot, McNutt, Patrick, Petrali, John, Adler, Michael. The growth factor IGF accelerates recovery from botulinum neurotoxin-induced muscle paralysis and atrophy. Society for Neuroscience, San Diego, California, 9-13 November 2013. [Poster]

Beske, Phillip, Hubbard, Kyle, Gut, Ian, Lyman, Megan, McNutt, Patrick. Network response to intoxication by botulinum neurotoxin in synaptically coupled central nervous system neurons. Society for Neuroscience, San Diego, California, 9-13 November 2013. [Poster]

Bourne, Andrew, Mohan, Giovini, Pham, M., Stone, M.F., Schultz, C., Meyerhoff, J.L., Lumley, Lucille A. Olfactory cures increase avoidance behavior and induce Fos expression in the amygdala, hippocampus and prefrontal cortex of socially defeated mice. Society for Neuroscience, San Diego, California, 9-13 November 2013.[Poster]

Gut, Ian, Beske, Phillip, Hubbard, Kyle, Lyman, Megan, McNutt, Patrick. Cellular and molecular correlates of glutamate--induced excitogenic injury in mouse stem cell-derived neurons. Society for Neuroscience, San Diego, California, 9-13 November 2013. [Poster]

McNutt, Patrick, Beske, Phillip, Lyman, Megan, Hubbard, Kyle, Gut, Ian. Synaptic activity and network behavior in neurons derived from stem cell populations. Society for Neuroscience, San Diego, California, 9-13 November 2013. [Poster]

Furtado, M., Miller, D., Schwartz, Julia, Muse, W.T., Schultz, M.K., Stone, M.F., Yourick, D., Lumley, Lucille A. Treatment with pregnanolone is effective against seizures induced by whole body exposure to sarin, American Epilepsy Society, Washington, D.C., 6-10 December 2013.

Myers, Teri S., Myers, Todd M. A sweet consideration: How could high-sugar diets impact endocrine disruption assays with organophosphates. The SETAC North America Focused Topic Meeting on Endocrine Disruption: Chemical Testing, Risk Assessment Approaches and Implications, Research Triangle Park, NC, 04-06 February 2014.

Andres, Devon, Keyser, Brian, Benton, Betty, Appell, Ashley, Olivera, Dorian, Holmes, Wesley, Paradiso, Danielle, Anderson, Dana, Ray, Radharaman. Store operated calcium entry as a mechanism of phosgene toxicity. Society of Toxicology, Phoenix, Arizona, 23-27 March 2014. [Poster]

Dao, Thuy L., Shih, Tsung-Ming, Kim, Robert K., Braue, Catherine R., Koenig, Jeffrey A., Leuschner, Jessica L., Kan, Robert K. Zebrafish as a novel animal model for chemical warfare nerve agent biomedical research. Society of Toxicology, Phoenix, Arizona, 23-27 March 2014. [Poster]

Holmes, Wesley, Paradiso, Danielle, Koenig, J., Lee, Robyn B., McDonough, John H., Anderson, Dana R. LCt50 determinations of sarin and soman in conscious guinea pigs using a nose-only vapor inhalation model. Society of Toxicology, Phoenix, Arizona, 23-27 March 2014. [Poster]

Kan, Robert K., Leuschner, Jessica L., Kaski, Shane W., Shumway, Lukas J., Braue, Catherine R., Dao, Thuy L. Evaluation of the antihistamine promethazine against acute soman intoxication. Society of Toxicology, Phoenix, Arizona, 23-27 March 2014. [Poster]

Lyman, Megan, Hubbard, Kyle S., Beske, Phillip H., Tuznik, Kaylie M., McNutt, Patrick. Characterization of functionally networked, central nervous system neurons derived from stem cells as an in vitro platform for neurotoxin research. Society of Toxicology, Phoenix, Arizona, 23-27 March 2014. [Poster]

McNutt, Patrick , Beske, Phillip H., Lyman, Megan, Hubbard, Kyle S., Gut, Ian. Perturbation of network balance and synaptic modulation following neurotoxin treatments in stem cell-derived central nervous system neurons: shared pathophysiologies with in vivo intoxication. Society of Toxicology, Phoenix, Arizona, 23-27 March 2014. [Poster]

Smith, Carl D., Miller, S.M., Deeb, T.Z., Silayeva, L., Moss, S.J., McDonough, John H. Soman-induced convulsions change the phosphorylation state of the potassium-chloride cotransporter (KCC2). Society of Toxicology, Phoenix, Arizona, 23-27 March 2014. [Poster]

Tuznik, Kaylie, Nelson, Marian, Adkins, Angela, Lyman, Megan, McNutt, Patrick. Corneal endothelial toxicity following corneal exposure to sulfur mustard vapor: is endothelial loss the pathophysiology responsible for long-term ocular injury? Society of Toxicology, Phoenix, Arizona, 23-27 March 2014. [Poster]

Wright, Linnzi K.M., Miller, D.B., Muse, W.T., Lee, R.B., Emm, E.J., Whalley, C.E., Lumley, Lucille A. Young rats more susceptible to the lethal effects of sarin than adult rats: 24 h LC50 for whole-body (60 min) exposure. Society of Toxicology, Phoenix, Arizona, 23-27 March 2014. [Poster]

Adler, Michael. Effect of peptidomimetic inhibitors on BoNT/A protease activity. 19th Medical Defense Bioscience Review, Hunt Valley, MD, 11 - 15 May 2014. [Invited Platform]

Allen, Andrea R., Hoard-Fruchey, Heidi M., Rothwell, Cristin C., DeFreytas, Margaret R., Hildenberger, Diane, Downey, Jason D., Rockwood, Gary A. Transcriptional analysis of mouse substantia nigra tissue after cyanide exposure. 19th Medical Defense Bioscience Review, Hunt Valley, MD, 11 - 15 May 2014. [Invited Platform]

Andres, Devon K., Keyser, Brian M., Holmes, Wesley W., Paradiso, Danielle, Appell, Ashley, Benton, Betty, Clark Offie E., Hamilton, Tracey A., Kniffin, Denise, Martens, Margaret E., Anderson, Dana R., Ray, Radharaman. Cell death and respiratory toxicity in sulfur mustard inhalation injury in an animal model. 19th Medical Defense Bioscience Review, Hunt Valley, MD, 11 - 15 May 2014. [Invited Platform]

Andres, Devon K., Keyser, Brian M., Benton, Betty J., Melber, Ashley A., Olivera, Dorian S., Holmes, Wesley W., Anderson, Dana R., Ray, Radharaman. Store operated calcium entry as a mechanism of phosgene toxicity. 19th Medical Defense Bioscience Review, Hunt Valley, MD, 11 - 15 May 2014. [Poster]

Apland, James P., Prager, Eric M., Pidoplichko, Volodymyr, Aroniadou-Anderjaska, Vassiliki, Borrell, Andrew C., Levit, Matthew B., Braga, Maria F.M. Pathophysiological mechanisms underlying increased anxiety after soman exposure: Reduced GABAergic inhibition in the basolateral amygdala. 19th Medical Defense Bioscience Review, Hunt Valley, MD, 11 - 15 May 2014. [Poster]

Azeke, John I., Stevenson, Robert S., Railer, Roy F., Deckert, Robin R., Devorak, Jennifer L., Boecker, Joseph D., Lumpkin, Horace L., Doxzon, Bryce F., Graham, John S., Braue, Ernest H. Applying “big data” strategies to characterize cutaneous vesicant injury, wound healing, and treatment efficacy as emergent constructs of clinical, histological, and non-invasive biophysical observations. 19th Medical Defense Bioscience Review, Hunt Valley, MD, 11 - 15 May 2014. [Poster]

Azeke, John I., Stevenson, Robert S., Railer, Roy F., Deckert, Robin R., Devorak, Jennifer L., Boecker, Joseph D., Lumpkin, Horace L., Doxzon, Bryce F., Graham, John S., Braue, Ernest H. Applying “big data” strategies to characterize cutaneous vesicant injury, wound healing, and treatment efficacy as emergent constructs of clinical,

histological, and non-invasive biophysical observations. 19th Medical Defense Bioscience Review, Hunt Valley, MD, 11 - 15 May 2014. [Invited Platform]

Basi, Kelly A., Havens, J., Oyler, B.L., Pennington, M.R. In vitro characterization of drug metabolism and drug-drug interaction. 19th Medical Defense Bioscience Review, Hunt Valley, MD, 11 - 15 May 2014. [Invited Platform]

Beach, Sarah L., Radio, Nicholas M., Shure, Michael, Lehman, John G. III, Ruff, Albert L. Assessment of housekeeping gene expression by high content analysis and other techniques: How do they correlate? 19th Medical Defense Bioscience Review, Hunt Valley, MD, 11 - 15 May 2014. [Poster]

Beske, Phillip H., Bradford, Aaron B., Lyman, Megan E., McNutt, Patrick M. Functional network- and synapse-level responses to Clostridial neurotoxins in stem cell-derived neurons: a next generation cell-based platform with shared pathophysiologies to in vivo intoxication. 19th Medical Defense Bioscience Review, Hunt Valley, MD, 11 - 15 May 2014. [Poster]

Boeri, Michael V., Kasten, Shane A., Cerasoli, Douglas M. Chiral separation of V-type chemical warfare nerve agents via analytical supercritical fluid chromatography. 19th Medical Defense Bioscience Review, Hunt Valley, MD, 11 - 15 May 2014. [Poster]

Bowens, Teresa, Guignet, Michelle A., Irwin, James F., Laitipaya, Kevin, Wegner, Matthew, Johnson, Erik A. IL-1 signaling exacerbates brain injury following seizurogenic exposure to the nerve agent soman (GD) in mice. 19th Medical Defense Bioscience Review, Hunt Valley, MD, 11 - 15 May 2014. [Poster]

Bradford, Aaron, McNutt, Patrick, Beske, Phillip, Lyman, Megan, Hubbard, Kyle, Gut, Ian. Synaptic activity and network behavior in neurons derived from stem cell populations. 19th Medical Defense Bioscience Review, Hunt Valley, MD, 11 - 15 May 2014. [Poster]

Braue, Ernest H. Jr., Doxzon, Bryce F., Lumpkin, Horace L., Azeke, John I. Confocal Raman microspectroscopy. The measurement of VX depth profiles in hairless guinea pig skin and the evaluation of RSDL. 19th Medical Defense Bioscience Review, Hunt Valley, MD, 11 - 15 May 2014. [Invited Platform]

Brown, Stephen M., Stevenson, Robert S., Railer, Roy F., Lumpkin, Horace L., Doxzon, Bryce F., Whitten, Kimberly A., Azeke, John I., Braue, Ernest H. Jr. Development of a mid-dermal thermal injury model in Yucatan miniature pigs. 19th Medical Defense Bioscience Review, Hunt Valley, MD, 11 - 15 May 2014. [Poster]

Cadieux, C. Linn, Wang, Haoyu, Koh, John, Cerasoli, Douglas M., Katz, Francine S. Probing the mechanism of a non-permanently charged, non-oxime reactivator of phosphonylated acetylcholinesterase. 19th Medical Defense Bioscience Review, Hunt Valley, MD, 11 - 15 May 2014. [Invited Platform]

Causey, Robert D., Autrey, Jeff J., McGowan, Kevin J., Cheng, Haibo, Lehman, John, Lakin, Jordan, Ruff, Albert L. Development of an ocular vapor exposure model for chloropicrin and hydrofluoric acid. 19th Medical Defense Bioscience Review, Hunt Valley, MD, 11 - 15 May 2014. [Poster]

Chilukuri, Nageswararao, Myers, Todd M., Mata, David G. Gene-delivery using adenovirus to determine the efficacy of candidate enzymes as chemical warfare nerve agent bioscavengers in mice and non-human primates. 19th Medical Defense Bioscience Review, Hunt Valley, MD, 11 - 15 May 2014. [Invited Platform]

Clarkson, Edward D., Smith, Kelly H., Schulz, Susan M., Chandler, Jessica K., Rousayne, Cassandra L., Kolanko, Christopher. Pupillary light response in guinea pigs and swine exposed to organophosphate agents. 19th Medical Defense Bioscience Review, Hunt Valley, MD, 11 - 15 May 2014. [Poster]

Garcia, Gregory E., Moorad-Doctor, Deborah, Betz, Melissa A. Bioscavenger targeting red blood cells. 19th Medical Defense Bioscience Review, Hunt Valley, MD, 11 - 15 May 2014. [Poster]

diTargiani, Robert C., Hummert, Pamela, Capacio, Benedict R. High-resolution mass spectrometry for the detection of chemical warfare agent adducts on human butyrylcholinesterase and serum albumin. 19th Medical Defense Bioscience Review, Hunt Valley, MD, 11 - 15 May 2014. [Invited Platform]

Downey, Jason D., Allen, Andrea A., DeFreytas, Margaret R., Hildenberger, Diane M., Booker, Lamont, Olivera, Dorian S., Rockwood, Gary A. Development and characterization of an unanesthetized mouse model of cyanide

intoxication by hydrogen cyanide inhalation. 19th Medical Defense Bioscience Review, Hunt Valley, MD, 11 - 15 May 2014. [Invited Platform]

Garcia, Gregory E., Moorad-Doctor, Deborah, Betz, Melissa A. Multimeric bioscavenger complexes. 19th Medical Defense Bioscience Review, Hunt Valley, MD, 11 - 15 May 2014. [Poster]

Garcia, Gregory E., Bhonsle, Jayendra B., McCranor, Bryan, Koh, John. Facilitative transport of reactivators across the blood brain barrier. 19th Medical Defense Bioscience Review, Hunt Valley, MD, 11 - 15 May 2014. [Poster]

Guignet, Michelle A., Johnson, Erik A., Dao, Thuy L., Hamilton, Tracey, Koemeter-Cox, Andrew I., Kan, Robert K. Interleukin-18 expression increases in response to neurovascular damage following soman-induced status epilepticus in rats. 19th Medical Defense Bioscience Review, Hunt Valley, MD, 11 - 15 May 2014. [Poster]

Haggins, Robert L. Jr., Eaton, Erik B. Jr., Varney Timothy R. Development of differentiation induction strategies to generate corneal endothelial cells from mesenchymal stem cells. 19th Medical Defense Bioscience Review, Hunt Valley, MD, 11 - 15 May 2014. [Poster]

Hepperle, Michael The function of ADMET in drug discover. The ADMET Center at MRICD. 19th Medical Defense Bioscience Review, Hunt Valley, MD, 11 - 15 May 2014. [Invited Platform]

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Appendix D

MCMR-CDZ-S 5 June 2014

MEMORANDUM FOR RECORD

SUBJECT: Due-Outs/Comments Noted During the After Action Review Conducted After the Chemical Accident or Incident Response and Assistance Exercise on 22 May 2014

1. The meeting was conducted on 22 May 2014 in the conference room of Bldg E-3100.

2. The following comments/due-outs were noted during the subject meeting:

a. (b) (6) from Public Health Command stated that the quadrant monitoring was the best he has ever seen.

b. Fire and Emergency Services:

(1) They did not learn of the perpetrator until they arrived at the Command Post (CP). They had to wait for the scene to be secure before they could get to the victim and this took a long time.

(2) Once they got to the victim they were ready to transport her to the Clinic within four minutes.

c. Police and Security Guards:

(1) When the police arrived they did not know that the guards were going to be there.

(2) They were not given initial information about a gun being involved. It took an additional six minutes before they were informed of the gun.

(4) Access points were closed within three minutes of notification.

(5) Special Response Team (SRT) responded in seventeen minutes and cleared the building quickly.

(6) There was poor radio communication with SRT because SRT has external mikes on their masks. They need internal mikes instead.

(7) Additional police patrols are needed. They currently only have two patrols.

(8) Two police officers could have possibly been exposed by not wearing proper personal protective equipment (PPE) when apprehending the subject.

(9) If the police had the proper training and equipment, they could clear the building instead of SRT as long as they also have enough police to secure the perimeter.

d. Kirk US Army Health Clinic:

(1) (b) (6) said that they are working well in the trailer.

(2) The paramedics call the clinic when they know an incident has occurred which gives the Clinic extra time to prepare for casualties and that is very helpful.

(3) They feel that everything went well. There was a good transfer of information and that the paramedics did a great job.

(4) In reference to the use of the three ATNAA injectors, (b) (6) stated that you automatically use them if you have any signs of respiratory distress. COL (Ret.) (b) (6) stated that (b) (6) teaches students that if you suspect that you were exposed, use the ATNAA injectors.

e. There was no representation at the meeting from CARA, 20th Support Command (CBRNE); however, they did have a person at the CP and he did a good job coordinating everything. Their emergency response was simulated for this exercise.

f. US Army Medical Research Institute of Chemical Defense (USAMRICD):

(1) (b) (6) stated that we always have primary communication issues. The victim called 911 twice and the 911 operator did not ask the questions from the CAIRA/BIMR Incident Worksheet.

(2) Several personnel stated that two personnel entered and exited the area without vests and they were not challenged by the police or guards.

(3) The first guards who arrived were downwind and were not wearing PPE.

(4) Everyone felt that overall the exercise went very well.

(5) If this had been a real event, the casualty would have suffered from hypothermia due to the delay of Emergency Medical Services (EMS) reaching the casualty.

(6) (b) (6) stated there was no confusion at the CP as to who was in charge. Everything was very unified and very precise.

(7) (b) (6) stated that we are going to work with the receptionist who answers the Chemical Accident or Incident Response and Assistance (CAIRA) line to ensure he provides the information in a timelier manner.

(8) (b) (6) stated that we are going to add the phone numbers for Edgewood Chemical Biological Center personnel to our internal CAIRA flow chart.

(9) (b) (6) stated that the initial response was great. He could tell that they were not just waiting around for the exercise to begin.

(10) (b) (6) asked if this were a real situation is she supposed to lock the vault. (b) (6) stated that the Chemical Surety Material General Provisions say to close the sash

and that we will review the document and decide what , if any, changes should be made (the USAMRICD Security Office needs to participate in this review).

(11) Everyone agrees that it was apparent that the 911 operator was not using the CAIRA/BMIR Incident Worksheet or they would have received the information quicker. (b) (6) (b) (6) will speak with (b) (6) to discuss why the worksheet was not used and why there was so much noise at the 911 center which prevented the operator from hearing (b) (6)

(12) It was also suggested that an evaluator be placed in the 911 center during exercises.

(13) (b) (6) stated that during a real-world event he and/or (b) (6) would have reviewed the security cameras and provided the information to a 911 operator. (b) (6) stated that no one asked our Security Office to review the camera footage to see where the bad guy went. Lieutenant (b) (6) said that reviewing our camera footage would not have made any difference in their response procedures.

(14) (b) (6) is going to contact the Chief, Department of Emergency Services and ask him to put in writing who is going to respond during an event and also how many personnel will respond.

(15) (b) (6) stated that if this had been a real event, the bad guy would have been off post by the time the gates were closed.

(16) (b) (6) stated that he is going to change the Safety Program Book to state that the Command Group will be responsible for notifying MRMC.

g. US Army Medical Command:

(1) (b) (6) stated that we need to be sure to use different players for each live exercise to ensure that all key personnel have participated.

(2) (b) (6) stated that the law enforcement was much better this time as opposed to the previous exercise.

(3) (b) (6) would like for the USAMRICD to practice shelter-in-place and obtaining 100% accountability of all personnel during the next exercise.

(4) (b) (6) suggested that we have two incidents occur simultaneously at the USAMRICD during the next exercise.

(5) (b) (6) asked if the USAMRICD has any plans to install metal detectors to ensure personnel do not enter the buildings with a gun and (b) (6) stated that we do not have necessary funding the purchase them and pay for personnel to man each area where the detectors are located.

(6) LTC (b) (6) said that if there is going to be a delay in initial EMS response, it would be a good idea to have a medical person talk to the casualty on the radio.

h. Comments/questions from Garrison Commander (provided by (b) (6) :

(1) How does the Clinic handle mass casualties? (b) (6) stated that they are not equipped to handle mass casualties.

(2) What are the procedures for foot patrol and searching for bad guys?

(3) The Emergency Operations Center (EOC) needs to have a matrix.

(4) What are the Police procedures for closing the gates?

i. EOC:

(1) (b) (6) stated that personnel should not have to wait 45 minutes for SRT to respond and clear the area. No one would move (i.e., respond to the casualty) until SRT had cleared the area.

(2) (b) (6) stated that he feels the gates should close as soon as the guards are notified of a duress call coming from one of the chemical laboratories and the Police said they are closed at that time. (b) (6) would like a meeting to be scheduled to discuss having the gates close as soon as the duress button is pushed.

(3) (b) (6) wants to know where the duress will go off when the guards are no longer on the gates.

(4) The CAIRA line in the EOC did not work which is why the Garrison Surety Officer telephoned personnel 15 minutes after the incident occurred.

(6) The post went to force protection Delta 27 minutes after the incident occurred.

(7) (b) (6) does not feel that the gates were closed quick enough which would have required them to contact local government officials and police if this were a real world incident.

(8) The EOC did not receive any questions from the Incident Commander so they assumed all was well.

(9) Personnel in the EOC did not know how dangerous the agent was that was taken. (b) (6) stated that the USAMRICD was never asked to provide that information.

(10) (b) (6) stated that the entries into the Web EOC were very informative. There was one issue with someone reporting that two vials were taken which is why she called the USAMRICD to clarify.

(11) (b) (6) reminded everyone of the importance of the initial 911 call.

j. Garrison Safety:

(1) When their office is notified of an event they need a location, not just Edgewood Area or Aberdeen Area.

(2) They need to immediately know if engineering controls were functioning at the time of an incident.

k. Additional comments: As a reminder, you cannot state the casualties' names over the radio or put them on the EOC. However, it was noted that you can say the perpetrators name over the radio and put it on the EOC.

(b) (6)

Surety Specialist

Section 23

Fiscal Year 2014
Annual Historical Report

U.S. Army Center for Environmental Health Research

Introduction:

Under the Command of COL Thomas C. Timmes, the US Army Center for Environmental Health Research (USACEHR) had a break out year for growth and infrastructure development to support the increased mission requirements established in FY13. Ongoing renovation projects totaling over $7M were completed or underway on building 568. These included a basement-level Rodent Vivarium ($3M), an elevator ($1.2M), and new laboratory space ($3.2M) on the second floor to support the Integrative Systems Biology program. The command has a rodent and aquatic vivarium. It also has supporting command, administrative, logistical, and safety sections. The Center is housed in Building 568 on the Fort Detrick post. The USACEHR has three research programs: Environmental Health, Integrative Systems Biology, and Pulmonary Health. An enterprise level Systems Biology Collaboration Center was established this year at USACEHR.

During the year, the Biomarkers Program and the Biomonitoring Program merged under the direction of MAJ (b) (6) and formed the new Environmental Health Program (EHP). This program sustains the USACEHR core competency of environmental toxicants, continued the research of both programs, and added some new efforts. Within the Task Area "Host Response to Environmental Health Hazards," the main research was aimed at identifying biomarkers of organ injury and developing a device for multiplex detection of these biomarkers. New projects were added to include a physiological based, toxicokinetic model of heavy metal intoxication and the utility of the microbiome in assessing toxic exposure. Advanced development of fish biomonitoring and the Environmental Sentinel Biomonitor (ESB) capabilities and a project to assess the toxicity of engineered nanomaterials of military relevance were continued.

The Pulmonary Health Research Program, directed by (b) (6), manages the Defense Medical Research and Development Program (DMRDP), Military Operational Medicine Research Program (Joint Program Committee 5; JPC-5) subtask Biomarkers of Inhalational and Other Exposures (BIOE). Work in this program addressed data gaps in pulmonary injury resulting primarily from deployment to Southwest Asia and was primarily extramural. Research funded through this program at the Institute for Systems Biology, National Jewish Health, Pacific Northwest National Laboratories, and the Brooke Army Medical Center contributed to determining the prevalence and severity of pulmonary disease associated with deployment, a quantitative histopathological assessment method for small airways disease, and candidate biomarkers of pulmonary disease. An intramural project was completed which characterized the toxicity of ambient particular matter from Southwest Asia in rats.

The Systems Biology effort at the USACEHR consisted of two components: Integrative Systems Biology (ISB) and Systems Biology Collaboration Center (SBCC). The ISB program, directed by (b) (6) used integrative research methodologies to address military-relevant health issues including PTSD, coagulopathy, infectious diseases and pain. This research was supported by intramural research but was also highly collaborative, encompassing multi-PI cores that include clinical, imaging, phenotypic and integrative-omics. The SBCC is an enterprise level resource to support the integration of Systems Biology into projects across the US Army Medical Research and Materiel Command (USAMRMC). The SBCC officially began 09 SEP 2014 and was led by Acting Director, (b) (6). The SysBioCube is a data repository and research tool developed through the USAMRMC Systems Biology Enterprise that creates the collaborative infrastructure required for this work. The SysBioCube was developed through collaboration with the ISB and is overseen by the SBCC.

Mission and Vision:

A. MISSION: Develop surveillance capabilities to detect, assess, and prevent health effects from adverse environmental, physiological, and psychological exposures.

B. VISION: Protect the health of Soldiers from environmental and mission-related health threats through innovative science.

Organization and Personnel:

At the end of the year, USACEHR had an end strength of 3 military, 18 civilian, and 25 contractors. The organizational chart is provided in Appendix A. Based on a 2011 manpower study, notice was received that the table of distribution and allowances (TDA) was modified, resulting in an overall loss of four personnel for FY16. This is of particular concern as the manpower analysis was performed prior to the growth of USACEHR by the addition of (b) (6) Integrative Systems Biology group and the increased mission associated with this change. Several key personnel who had extended careers within the government and the USACEHR retired during this year. The result of these retirements is over 150 years of knowledge and service being lost. In addition, the restructured TDA leaves critical vacancies that are likely to reduce the mission effectiveness of USACEHR in the coming years if they cannot be resolved.

A. Retirements

1) (b) (6) retired after 35 years of service from his role as S&T Director and Director of the Biomonitoring Program. He was not replaced, but the TDA slot for the position remains. (b) (6) was appointed as S&T Director, and the Biomonitoring Program was merged with the Biomarkers to form the Environmental Health Program under MAJ (b) (6).

2) (b) (6) retired from her position as Budget Analyst after 37 years of service. She was replaced by (b) (6) and was retained temporarily as a rehired annuitant to assist in the transition.

3) (b) (6) retired after 39 years of service from his primary roles as Chemist with alternate duties as the Information Management Officer, Environmental Officer, and Safety Officer. The chemist position was eliminated on the FY16 TDA, but through the use of VERA/VSIP this position on the TDA was restructured to create an authorization for a DA intern Safety Officer. (b) (6) assumed the role Information Management Officer, and an intern, (b) (6) assumed the Safety and Environmental Officer positions.

4) (b) (6) retired after 38 years of service from her position as Executive Secretary. This position is still vacant but remains on the TDA.

5) MAJ (b) (6) separated from Army service. His position of Deputy Commander was one of the positions eliminated by the TDA restructuring, so (b) (6) was temporarily appointed as Executive Officer to assume the responsibilities of the Deputy Commander. This is a critical vacancy.

B. Notable Promotions

1) (b) (6) was selected for a scientific and professional (ST) position for her work in Systems Biology. Her induction will be in FY15.

2) LTC (P) Thomas Timmes was promoted to the rank of Colonel on 06 JUN 2014.

Statistical data:

Statistical data provided within relevant sections.

Healthcare Delivery:

N/A

Veterinary Services:

Extensive programmatic and physical changes occurred to the USACEHR Institutional Animal Care and Use Committee (IACUC) program in FY14. The traditional aquatic-only animal use program transformed into a rodent

and aquaculture facility. A 1500 square foot rodent vivarium construction project was realized in FY14 (11 APR 2014). (b) (6) replaced MAJ (b) (6) as IACUC chair on 10 MAR 2014. Significant efforts were achieved in preparation for a triennial accreditation visit in October 2014 by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) International. This visit was postponed from FEB 2014 to JUL 2014, then again to October 2014 due to construction of the vivarium. A new 138 page Program Description was generated and submitted to AAALAC International as required for accreditation. In support of this new mission, USACEHR obtained a Controlled Substance Certificate from the US Department of Justice to allow the purchase and use of controlled pharmaceutical drugs. (b) (6) was appointed as the Controlled Substances Custodian.

Institutional Animal Care and Use Committee

A. GENERAL

1) Chairman. MAJ (b) (6) until 10 MAR 2014, replaced by (b) (6).

2) Personnel. 1 DAC. This is an additional duty for (b) (6).

B. MISSION: To establish and document procedures, responsibilities, and policies of the USACEHR in compliance with legal and regulatory requirements for an Institutional Animal Care and Use Program.

C. FOCUS AREAS

1) Organize and participate in formal meetings and inspections of animal care and use facilities.

2) Review all animal care and use protocols submitted to the IACUC for approval.

3) Submit the annual Animal Care and Use Program Report required by Congress.

4) Oversee animal care and use at the laboratory in order to maintain accreditation with AAALAC International as per Department of Defense Instruction 3216.01.

D. SIGNFICANT ACCOMPLISHMENTS

1) Completed Animal Care and Use Review Office (ACURO) Data Call, 2013 AAALAC International Annual Report and FY11 Report to Congress.

2) Convened five IACUC meetings and completed two semi-annual Facility Inspections and Program Reviews.

3) Completed one ACURO Compliance Inspection and one Staff Assistance Visit.

4) Completed annual reviews of three animal use protocols.

5) Initiated oversight of six new animal use protocols and performed four post-approval monitoring observations.

6) The following Memoranda/Policies were updated in FY14:

a. USACEHR Memorandum 70-9, Research and Development Institutional Animal Care and Use Program, 02 JAN 2014.

b. USACEHR Memorandum 70-18, Bldg. 568 USACEHR Rodent and Aquatic Animal Disaster Plan, 10 JUN 14.

c. USACEHR 70-9-4 Animal Care and Use Training Documentation, 19 JUL 2014.

7) Continued Management of the online Animal Care and Use Training Program for:

a. IACUC and USACEHR principal investigators/animal care personnel (CITIprogram.org).

b. A training session on the Animal Disaster Plan (USACEHR Memo 70-18) was completed on 28 AUG 2014 for all USACEHR staff. Additionally, two trainings (Exposure of Research Personnel to Carbon Dioxide during Euthanasia Procedures and Acceptable Means of Euthanasia for Animals at USACEHR) were provided to IACUC members.

8) DoD veterinarian visits, tours, and meetings with personnel from the US Army Medical Research Institute of Infectious Diseases (USAMRIID) and US Army Medical Research Institute of Chemical Defense (USAMRICD) were coordinated through the IACUC.

9) A new IACUC Records Management System was initiated after the FEB 2014 ACURO Compliance Inspection. USAMRICD IACUC staff was contacted for assistance in organizing and generating IACUC records, and best practices were established at USACEHR.

10) Additional program updates occurred in FY14, The occupational health program, veterinary care plan, and DEA Schedule II/III drug pharmacy program were updated to include provisions for the new rodent mission. Membership was changed and new personnel were added to the IACUC to conform to membership and role requirements specified in DoDI 3216.16, AR 40-33

11) The IACUC reported no adverse events or significant deficiencies to AAALACi or ACURO during FY14.

Controlled Substances Custodian.

A. GENERAL

1) Controlled Substances Custodian: (b) (6) .

2) Alternate Controlled Substances Custodian: (b) (6) .

3) Personnel. 2 DAC. This is an additional duty for both (b) (6) .

B. MISSION: To obtain and maintain the Controlled Substance Certificate for USACEHR in order to purchase, dispense, and use controlled substances in the vivarium.

C. FOCUS AREAS

1) Oversee and maintain documents at USACEHR required by the Controlled Substance Registration Certificate. Update as needed.

2) Write and implement SOP for controlled substances.

D. SIGNFICANT ACCOMPLISHMENTS

1) Completed all documentation necessary to obtain a Controlled Substance Certificate from the US Department of Justice and for USACEHR personnel to be able to use controlled substances.

2) Initiated necessary physical security requirements for the use of Controlled Substances at USACEHR (installation of safes, physical security inspection).

3) Arranged for training of USACEHR personnel with USAMRIID.

4) Wrote USACEHR Pharmacy SOP for Controlled Substances.

Training and Education:

USACEHR has supported leader development through numerous training opportunities both for the staff and through efforts to support the community. USACEHR supported the completion of college degrees for three personnel. SGT (b) (6) received a B.S., CPT (b) (6) performed her thesis work at USACEHR to complete an MPH, and (b) (6) received a Ph.D. through the SMART program. (b) (6) was

selected for and began the Army Civilian Training, Education and Development (ACTED) internship program for Safety. USACEHR continued to support multiple facets of the GEMS program at Hood College. In addition, USACEHR maintained a nearly 100% compliance throughout the year for mandatory Army training.

A. SIGNIFICANT TRAINING OBTAINED

1) (b) (6) completed the Foundation Course in the Civilian Education System in OCT 2013.

2) (b) (6) attended a class introducing the NCI high performance computing systems in NOV 2013.

3) SGT (b) (6) met graduation requirements (Thomas Edison State College) to earn his Bachelors of Science and Technology in Clinical Laboratory Science in NOV 2013. His graduation occurred in MAR 2014.

4) (b) (6) completed the Intermediate Medical Acquisition Course at Fort Detrick in DEC 2013.

5) (b) (6) was nominated for the Society of Toxicology's NTSS Student and Postdoctoral Fellow Poster Award in MAR 2014 for her work on the neurotoxic and systemic effects of low-level chlorpyrifos exposure, a project developed in collaboration with (b) (6) at the University of California, Davis.

6) CPT (b) (6), a 72D and former MacArthur Leadership Award winner, interned at USACEHR. CPT (b) (6) completed her University of Maryland School of Public Health, Maryland Institute for Applied Environmental Health Internship for the MPH in Environmental Health Science and defended her thesis, "Prioritization of militarily relevant toxic industrial chemicals by adverse health effects" in APR 2014.

7) (b) (6) attended the three day Leadership and Management Skills course at Aberdeen in APR 2014.

8) (b) (6) completed the Intermediate Medical Acquisition Course at Fort Detrick in APR 2014.

9) (b) (6), a SMART student, successfully defended his Ph.D. dissertation at the University of Maryland Baltimore in APR 2014.

10) (b) (6) attended the Leading & Managing High-Performing Project Teams course on 23-24 APR at USAMRICD.

11) LTC (P) Thomas Timmes and SGT (b) (6) attended the O-6/O-5 Level Command Team Leader Development and Training Session (CTLDTS) at Ft. Sam Houston from 14-17 MAY 2014.

12) (b) (6) was nominated for certification by the American Board of Toxicology in May 2014 and approved in JUN 2014 to sit for the OCT 2014 certifying exam.

13) MAJ (b) (6) completed Supervisory Development Training and Casualty Assistance Officer Training Course in JUN 2014.

14) (b) (6) completed a course, “Advanced Genomics and Genetics Analyses” at the Johns Hopkins University, Krieger School in JUN 2014.

15) (b) (6) completed the distance learning portion of the CES Advanced Course in JUN 2014.

16) (b) (6), MAJ (b) (6), (b) (6) completed training in JUL 2014 on the Wide Area Work Flow (WAWF) to support their roles as CORs in accepting receiving reports and invoices.

17) (b) (6) attended local administrator training for the Strategic Management System and the Balanced Scorecard Framework in JUL 2014.

18) (b) (6) attended the DoD Technology Transfer Training Workshop in Charleston, SC from 14-17 JUL 2014.

19) MAJ (b) (6) completed CLE021 Technology Readiness Assessment, CLE068 Intellectual Property and Data Rights, and CLE045 Introduction to DoD Science and Technology Management JUL 2014.

20) (b) (6) completed ACQ101 Fundamentals of Systems Acquisition Management in AUG 2014

21) MAJ (b) (6) completed SYS101 Fundamentals of Systems Planning, Research, Development and Engineering and Emergency Preparedness Response Course (EPRC) in AUG 2014.

22) (b) (6) completed CLM003 Overview of Acquisition Ethics in SEP 2014.

23) (b) (6) was selected by MEDCOM in SEP 2014 for enrollment in the resident portion of CES Civilian Leader Advanced Course in APR-MAY 2015.

24) (b) (6) completed training requirements to become a COR in SEP 2014.

25) (b) (6) attended the "Healthcare in the Battlefield" training in SEP 2014.

26) MAJ (b) (6) completed ACQ201A Intermediate Systems Acquisition Course, CLE069 Technology Transfer, and CLM014 IPT Management and Leadership in SEP 2014. MAJ (b) (6) has two in-residence courses remaining to complete requirements for S&T Management Level III.

B. SIGNIFICANT TRAINING PROVIDED

1) MAJ (b) (6) was appointed Adjunct Assistant Professor in Preventive Medicine/Biometrics, Uniformed Services University of the Health Sciences (USUHS), F. Edward Herbert School of Medicine effective 23 DEC 2013.

2) (b) (6) led a symposium session at Hood College on 18 FEB 2014 for GEMS instructors on training opportunities in math and computers.

3) COL Thomas C. Timmes attended the Frederick County Higher Education Center Advisory Board meeting on 19 JUN 2014, representing MG Caravalho and Fort Detrick.

4) MAJ (b) (6) facilitated small group discussions in medical genetics and ethics at USUHS on 25 SEP 2014.

5) (b) (6) provided multiple weekly math modules based on stock market “purchases” at the Hood College GEMS program.

6) (b) (6) lead tracks in the training of near-peers in the Environmental Section and teaching the water quality and water contaminants/pollution tracks at the Hood College GEMS program. He also demonstrated the fish Intelligent Automated Biomonitoring System (iABS) for GEMS participants.

7) Three ORISE postdoctoral fellows, (b) (6), were mentored by (b) (6) and MAJ (b) (6).

8) One ORISE post-baccalaureate fellow, (b) (6), was mentored by (b) (6).

Research and Development:

Overview

The USACEHR research and development portfolio is divided into three research programs: Environmental Health, Integrative Systems Biology, and Pulmonary Health. In addition, the Systems Biology Collaboration Center (SBCC) is an USAMRMC Enterprise-level research office to support the advancement of Systems Biology across the

USAMRMC. The work of these groups is supported by the Office of Research and Technology Applications and the Quality Assurance office.

Environmental Health Program

The new Environmental Health Program, headed by MAJ (b) (6), combined the missions and personnel of the Biomarkers and Biomonitoring Programs at USACEHR. The EHP continued to investigate materials of emerging military interest, biomarkers of exposure to toxic industrial chemicals and materials to include engineered nanomaterials, and further developed its capability to conduct systems biology-based approaches for characterizing molecular indicators of host-response to a broad range of environmental insults. Support for the advanced development of fish biomonitoring and the Environmental Sentinel Biomonitor (ESB) capabilities were continued, as the ESB successfully passed user testing and nears Milestone C. The Task Area, Host Response to Environmental Health Hazards, was developed further to include projects that explore the utility of the microbiome in chemical exposure. The main project, which was refocused from pathways of toxicity to biomarkers of adverse health effects in FY13, led to the submission of a provisional patent for 'Articles for the Diagnosis of Liver Fibrosis.' Collaboration with the USAMRMC Biotechnology High Performance Computing Software Applications Institute (BHSAI) was strengthened and expanded into the development of novel absorption, distribution, excretion, toxicity (ADME-T) models. All toxicity biomarker projects were aligned with existing and planned future capabilities (such as the Next Generation Diagnostic System) aimed at assessing chemical exposure and host response, and their relevant concept of operations. In addition, future projects and POMs were refined and developed to focus on top emerging threats, such as environmental health threats related to Megacities.

The EHP program developed a large collaborative project continued efforts to establish a tri-service research program by submitting a proposal to evaluate the utility of the microbiome in exposure assessment. This proposal takes advantage of DMRDP funded for Biomarker efforts under the Military Operational Medicine Research Program (JPC-5). In addition, the EHP began new collaboration with National Institute of Occupational Safety and Health (NIOSH), Engineer Research and Development Center (ERDC), and National Cancer Institute Nanotechnology Characterization Lab (NCI-NCL) funded through the Defense Threat Reduction Agency (DTRA) to develop in silico, predictive and toxicity testing tools to assess threats related to chemical and engineered nanomaterials based on a limited number of physiochemical properties.

A. GENERAL

   1) Program Director. MAJ (b) (6).

   2) Personnel. 5 DACs, 2 military, 3 ORISE, and 4 contractors.

B. MISSION: Protect the Soldier by providing diagnostic and prognostic tools for environmental and occupational health surveillance.

C. FOCUS AREAS

   1) Identify and validate biological markers (biomarkers) of exposures, effects, and susceptibility to environmental hazards, including toxic chemicals and materials and other exposures using genomic, proteomic, and metabolomic technologies.

   2) Develop rapid and cost-effective methods for biomarker discovery using mammalian and non-mammalian experimental model systems (mammalian cell lines, rodents, zebrafish and amphibians).

   3) Develop methods to anchor gene and protein response to environmental stressors and stimuli that in turn will predict adverse outcomes.

   4) Develop methods that leverage existing, bioinformatic- or computational-derived biomarker panels of organ injury/toxicity to assess organ injury/toxicity after chemical exposure.

   5) Determine the utility of the human microbiome in chemical exposure assessment.

6) Improve predictive algorithms of toxicity and biomarker analysis.

7) Develop methods that link physiological based models to 'omics' data.

8) Investigate potential health effects on Soldiers associated with nanomaterials used in Army materiel.

9) Develop in silico, predictive and toxicity testing tools to assess threats related to chemical and engineered nanomaterials based on a limited number of physiochemical properties.

10) Develop toxicity-based approaches to environmental monitoring, such as the ESB.

D. SIGNFICANT ACCOMPLISHMENTS

1) X1Task Area: Host Response to Environmental Hazards

a. Partnered with BHSAI to identify 78 and 244 co-expression clusters and that anchor to classical histopathological evidence of toxicity in liver and kidney, respectively. Results contributed to several submitted and published manuscripts and the development of an in-house gene panel to assess organ toxicity submitted for a patent application in FY15.

b. Collaborated with the Army Corps of Engineers Engineer Research and Development Center in Vicksburg, MS was initiated to capitalize on complementary research capabilities and expertise for the development of biomarkers, zebrafish models, and the analysis of the microbiome.

c. Served as Topic Author for the FY14 Defense Health Program (DHP) phase I Small Business Innovation Research (SBIR) awards. Received four SBIRs to develop tools to multiple types of biomarkers from multiple types of biofluids within one platform. Phase II awards are expected in FY15.

d. Completed collaboration with Naval Research Laboratory to develop a new method to prioritize chemical exposures based on adverse health effects and regional assessment. A final report is expected in FY15.

e. Completed a study of small RNAs in a rat heat stress model, which identified key miRNAs and pathway knowledge that could be useful as injury markers or exploited for therapeutic purposes. A provisional patent application and manuscript is expected in FY15.

f. Completed a large exposure study to collect tissue and biofluids for the analysis of heavy metal toxicity in order to develop candidate biomarkers and a novel ADME-T model of toxicity. A manuscript is expected for both efforts in FY15.

g. Completed a large exposure study to collect microbiome materials from rats exposed to heavy metals in order to develop novel tools and medical concepts and determine the utility of the microbiome in exposure assessment. A manuscript is expected in FY15.

h. Established a research collaboration with the Genomic Center at USAMRIID to support microbiome sequencing for rat studies.

i. Developed a new Defense Health Program (DHP) proposal to expand the studies on microbiome and exposure assessment in order to develop novel tools and medical concepts, bioinformatics pipelines, databases, methods to extract material from exosomes, and isolation of host mucosal cells. A newly funded program is expected in FY15.

j. Continued to serve as the stakeholder on the JASON Chemical Exposure Study, and a presentation on the "Utility of the Microbiome in Exposure Assessment" was presented to the summer meeting.

k. Supported Chem Bio Medical Systems Analysis of Alternatives for the Next Generation Diagnostic System, Increment II, IPR.

2) ESB system

a. Environmental Protection Agency (EPA) Technology Testing and Evaluation Program (TTEP) testing of the ESB system was successfully completed. TTEP testing was the key performance parameter (KPP) for the ESB system. Concurrence from the IPT for successful completion of the KPP was provided.

b. The Army Medical Department (AMEDD) Test Board Customer Assessment of the ESB system was successfully completed at Camp Bullis.

c. Environmental testing of the ESB system was successfully completed at the MRMC Test Methods Branch.

d. Continued improvements and refinements to the ESB sensors based on results from test outcomes was facilitated in preparation for Milestone C scheduled for June 2015.

e. A research collaboration with (b) (6) (City College of New York School of Engineering) was initiated to evaluate her Army Research Office funded project using integrated electric cell-substrate impedance sensing (ECIS) and a quartz crystal microbalance sensor for the detection of toxic chemicals. The sensor will be evaluated to determine if the combination sensor provides improved toxicant sensitivity over ECIS alone.

3) Engineered Nanomaterials (ENM)

a. Initiated a DTRA sponsored research project for the development of in silico and rapid, high throughput tools to predict the toxicity of engineered nanomaterials.

b. Collaborated with the Army Corps of Engineers Engineer Research and Development Center in Vicksburg, MS was initiated to capitalize on complementary research capabilities and expertise for the development of strategic guidance and predictive models for environmental and human health risks of engineered nanomaterial use in Army systems.

c. Renewed an Interagency Agreement with NIOSH to provide methods for exposure assessment and tiered toxicity testing (involving in vitro and in vivo tests and placing nanomaterials into mode of toxic action categories) using a risk-based approach to develop provisional exposure limits and predictive models for human health and toxicity of Army engineered nanomaterials.

4) Coliform Detection

a. Performed market research of potential technologies for the rapid field detection of coliform bacteria in water samples was facilitated with the Air Force Medical Evaluation Support Activity. A final market research report will be finalized in FY15.

5) Biomonitoring

a. The Fort Detrick Fish Biomonitoring Deployment is stored onsite, while upgrades and construction continue at the Fort Detrick Water Treatment Plant.

b. USACEHR continued to support the Aberdeen Proving Grounds (APG) - Old O-Field Deployment and offered technical expertise to the Metropolitan Washington Council of Governments for their system of fish biomonitors.

c. Negotiations with Honeywell Aerospace have been established to acquire the BioMonitor Expert Software source code, since Honeywell has returned the patent license to the Army. Discussions with COBAR Resources, LLC are ongoing as a potential licensee of the biomonitoring intellectual property.

E. SCIENTIFIC PUBLICATIONS

1) Permenter, M.G., W.E. Dennis, T.E. Sutto, D.A. Jackson, J.A. Lewis and J.D. Stallings. 2013. Exposure to cobalt causes transcriptomic and proteomic changes in two rat liver derived cell lines. PLoS One 8(12): e83751.

2) Bunch, K., D. Tinnemore, S. Huff, Z.S. Hoffer, R.O. Burney and J.D. Stallings. 2014. Expression patterns of progesterone receptor membrane components 1 and 2 in endometria from women with and without endometriosis. Reprod Sci 21(2): 190-197.

3) Flood-Nichols, S.K., A.A. Kazanjian, D. Tinnemore, P.R. Gafken, Y. Ogata, P.G. Napolitano, J.D. Stallings and D.L. Ippolito. 2014. Aberrant glycosylation of plasma proteins in severe preeclampsoa promotes monocyte adhesion. Reprod Sci. 21(2):204-14.

4) Hussainzada, N., J.A. Lewis, C.E. Baer, D.L. Ippolito, D.A. Jackson and J.D. Stallings. 2014. Whole adult organism transcriptional profiling of acute metal exposures in male Zebrafish. BMC Pharmacol Toxicol 15(1): 15.

5) Bui-Nguyen, T.M., W.E. Dennis, D.A. Jackson, J.D. Stallings and J.A. Lewis. 2014. Detection of dichlorvos adducts in a hepatocyte cell line. Proteome Research 13(8): 3583-95.

6) Tawa, G.T., M.D.M. AbdulHameed, X. Yu, K. Kumar, D.L. Ippolito, J.A. Lewis, J.D. Stallings and A. Wallqvist. 2014. Characterization of chemically induced liver injuries using gene co-expression modules. PLoS One Sep 16;9(9): e107230.

7) Widder, M.W., L.M. Brennan, E. A. Hanft, M.E. Schrock, R.R. James and W.H. van der Schalie. 2014. Evaluation and refinement of a field-portable drinking water toxicity sensor utilizing electric cell-substrate impedance sensing (ECIS) and a fluidic biochip. J of Appl Tox, Online: 18 September 2014, DOI: 10.1002/jat.3017.

8) Trader, D.E. and W.H. van der Schalie. An Evaluation of the NIDS® ACE™ Test, USACEHR TR-14-01, Defense Technical Information Center, ADA60398730, June 2014.

F. ABSTRACTS

1) Madejczyk, M.S., C.E. Baer, W.E. Dennis, V. Minarchick, S.S. Leonard, D.A. Jackson, J.A. Lewis and J.D. Stallings. 2014. Temporal Changes in Rat Liver Gene Expression after Cadmium and Chromium Exposure. The Toxicologist CD—An Official Journal of the Society of Toxicology, 138: 1297.

2) Lee, Y.S., J.A. Lewis, N. Hussainzada, P.J. Lein, D.A. Jackson and J.D. Stallings. 2014. Neurotoxic effects of repeated exposure to low-dose chlorpyrifos in rats. The Toxicologist CD—An Official Journal of the Society of Toxicology, 138: 1858.

3) Permenter, M.G., D. Kumsher, W.E. Dennis, J.A. Lewis and J.D. Stallings. 2014. Exposure to cobalt, nickel, cadmium, and chromium causes changes in gene expression and protein abundance in a human liver-derived cell line. The Toxicologist CD—An Official Journal of the Society of Toxicology, 138: 1265.

4) Ippolito, D.L., Y.S. Lee, M.S. Madejczyk, M.W. Widder, J.A. Lewis, D.A. Jackson and J.D. Stallings. 2014. Prioritizing military-relevant toxicants and future sensing needs for exposure assessment and adverse health effects. SPIE Sensing Technology + Applications.

5) Lee, Y.S., J.A. Lewis, J.R. Kugelman, M. Sanchez-Lockhart, G.F. Palacios and J.D. Stallings. 2014. Utility of the microbiome in chemical exposure assessment. National Cancer Institute Spring Research Festival.

6) Permenter, M.G., Y.S. Lee, D.L. Ippolito, J.A. Lewis and J.D. Stallings. 2014. Alterations in tissue small RNA after heat stress in conscious rats. Military Health System Research Symposium.

7) Ippolito, D.L., C.E. Baer, W.E. Dennis, J.A. Lewis and J.D. Stallings. 2014. Alteration in circulating metabolites during and after heat stress in the conscious rat: potential biomarkers of exposure and organ-specific injury. Military Health System Research Symposium.

8) Madejczyk, M.S., M.G. Permenter, C.E. Baer, W.E. Dennis, J.A. Lewis and J.D. Stallings. 2014. In vitro and in vivo toxicogenomic evaluation of chromium exposure in the liver. Military Health System Research Symposium..

9) Lee, Y.S., J.A. Lewis, N. Hussainzada, P.J. Lein, D.A. Jackson and J.D. Stallings. 2014. Neurotoxic effects of repeated exposure to low-dose chlorpyrifos in rats. Military Health System Research Symposium.

10) Lee, Y.S., J.A. Lewis, J.R. Kugelman, M. Sanchez-Lockhart, G.F. Palacios and J.D. Stallings. 2014. Utility of the microbiome in chemical exposure assessment. Military Health System Research Symposium.

11) Rakesh, V., J.D. Stallings, B.G. Helwig and L.R. Leon. 2014. Predicting what we can't measure: Heat stress in specific organs. Military Health System Research Symposium.

12) AbdulHameed, M.D.M., G.J. Tawa, K. Kumar, D.L. Ippolito, J.A. Lewis, J.D. Stallings and A. Wallqvist. 2014. Mapping toxicity pathways of liver fibrosis using integrated gene expression and protein-protein interaction network analysis Adverse Outcome Pathways: From Research to Regulation, NIEHS, September 3-5, 2014.

G. SUBMITTED PUBLICATIONS

1) AbdulHameed, M.D.M., G.J. Tawa, K. Kumar, D.L. Ippolito, J.A. Lewis, J.D. Stallings and A. Wallqvist. 2014. Systems level analysis and identification of pathways and networks associated with liver fibrosis. In submission to PLoS One.

2) Rakesh, V., J.D. Stallings and J. Reifman. 2014. A virtual rat for simulating environmental and exertional heat stress. In submission to J Appl Physiol.

3) Stallings, J.D., D.L. Ippolito, V. Rakesh, C.E. Baer, W.E. Dennis, B.G. Helwig, D.A. Jackson, L.R. Leon, J.A. Lewis and J. Reifman. 2014. Patterns of gene expression associated with recovery and injury in heat-stressed rats. In submission to BMC Genomics.

4) Baer, C.E., D.L. Ippolito, N. Hussainzada, J.A. Lewis, D.A. Jackson and J.D. Stallings. 2014. Genome-wide gene expression profiling of acute metal exposures in male Zebrafish. In submission to Genomics Data.

5) Ippolito, D.L., C.E. Baer, W.E. Dennis, J.A. Lewis and J.D. Stallings. 2014. Alteration in circulating metabolites during and after heat stress in the conscious rat: Potential biomarkers of exposure and organ-specific injury. In submission to BMC Physiology.

6) Speir, R.W., J.D. Stallings, J.M. Andrews, M.S. Gelnett, T.C. Brand and S.K. Salgar. 2014. Renoprotective effects of valproic acid and dexamethasone in acute kidney ischemia-reperfusion injury. In submission to PLoS One.

7) Madejczyk, M.S., C.E. Baer, W.E. Dennis, V. Minarchick, S.S. Leonard, D.A. Jackson, J.D. Stallings and J.A. Lewis. 2014. Temporal changes in rat liver gene expression after cadmium and chromium exposure. In submission to PLoS One.

8) Scheff, J.D., J.D. Stallings, J. Reifman and V. Rakesh. 2014. Mathematical Model of the Heat-Shock Response in HeLa Cells. In submission to PLoS Comp Biol.

9) Grieger, K.D., E.S. Money, J.H. Redmon, M.W. Widder, W.H. van der Schalie and S.M. Beaulieu. 2014. A Relative Ranking Approach for Nano-Enabled Applications to Improve Risk-Based Decision Making: A Case Study of Army Materiel Environment, Systems, and Decisions. In submission to Environment Systems and Decisions.

H. SCIENTIFIC PRESENTATIONS

1) Madejczyk, M.S. 2014. Temporal Changes in Rat Liver Gene Expression after Cadmium and Chromium Exposure. Society of Toxicology, Poster Presentation, Phoenix, AZ, 23-27 March 2014.

2) Lee, Y.S. 2014. Neurotoxic effects of repeated exposure to low-dose chlorpyrifos in rats. Society of Toxicology, Poster Presentation, Phoenix, AZ, 23-27 March 2014.

3) Permenter, M.G. 2014. Exposure to cobalt, nickel, cadmium, and chromium causes changes in gene expression and protein abundance in a human liver-derived cell line. Society of Toxicology, Poster Presentation, Phoenix, AZ, 23-27 March 2014.

4) Lewis, J.A. Detection of Dichlorvos Adducts on Proteins from a Liver-derived Cell Line. National Institute of Health, Proteomics Interest Group Seminar Series, Bethesda, MD, 06 March 2014.

5) Stallings, J.D. 2014. Prioritizing military-relevant toxicants and future sensing needs for exposure assessment and adverse health effects. Invited Presentation. Session Co-Chair, Military Medicine II: Physiology and Medicine of Extreme Environments and Spaceflight. SPIE Sensing Technology + Applications.

6) Lee, Y.S., J.A. Lewis, J.R. Kugelman, M. Sanchez-Lockhart, G.F. Palacios and J.D. Stallings. 2014. Utility of the microbiome in chemical exposure assessment. National Cancer Institute Spring Research Festival. Fort Detrick, MD, 5-8 May 2014.

7) Permenter, M.G. 2014. Alterations in tissue small RNA after heat stress in conscious rats. Poster Presentation. Military Health System Research Symposium. Fort Lauderdale, FL, 18-21 August 2014.

8) Ippolito, D.L. 2014. Alteration in circulating metabolites during and after heat stress in the conscious rat: potential biomarkers of exposure and organ-specific injury. Selected as Oral Presentation. Military Health System Research Symposium. Fort Lauderdale, FL, 18-21 August 2014.

9) Madejczyk, M.S. 2014. In vitro and in vivo toxicogenomic evaluation of chromium exposure in the liver. Poster Presentation. Military Health System Research Symposium. Fort Lauderdale, FL, 18-21 August 2014.

10) Lee, Y.S. 2014. Neurotoxic effects of repeated exposure to low-dose chlorpyrifos in rats. Poster Presentation. Military Health System Research Symposium. Fort Lauderdale, FL, 18-21 August 2014.

11) Lee, Y.S. 2014. Utility of the microbiome in chemical exposure assessment. Poster Presentation. Military Health System Research Symposium. Fort Lauderdale, FL, 18-21 August 2014.

12) Rakesh, V. 2014. Predicting what we can't measure: Heat stress in specific organs. Poster Presentation. Military Health System Research Symposium. Fort Lauderdale, FL, 18-21 August 2014.

13) Widder, M.W. 2014. Invited symposium speaker at the IAEAC: Label-Free Biosensing Symposium: Impedance-Based Biosensors for Environmental Applications Symposium at the annual Pittcon Conference and Expo in Chicago, IL, 2-6 March 2014.

14) AbdulHameed, M.D.M. Mapping toxicity pathways of liver fibrosis using integrated gene expression and protein-protein interaction network analysis Adverse Outcome Pathways: From Research to Regulation, NIEHS, Fort Detrick, MD, 3-5 September 2014.

I. KEY BRIEFINGS

1) Stallings, J.D. Biomarkers Program: Task Area: Host Response to Environmental Hazards – X1. US Army Medical Research Institute of Chemical Defense, Internal Seminar Series, Aberdeen Proving Ground, MD, 16 October 2013.

2) Stallings, J.D. Biomarkers Program, Integrated Research Team: Task Area: Host Response to Environmental Hazards – X1. US Army Military Operational Medicine Research Program, Frederick, MD, 26 November 2013.

3) Widder, M.W. Nanomaterials Medical Effects Task Area 11B/Project: Evaluation of the Potential Medical Effects of Nanomaterials in Army Systems. US Army Military Operational Medicine Research Program R&A, Frederick, MD, 13 December 2013.

4) Stallings, J.D. Host response to environmental hazards: Product development strategy, US Army Military Operational Medicine Research Program R&A, Frederick, MD, 13 December 2013.

5) Stallings, J.D. Identification and analysis of metabolomic signatures related to heat injury/stroke-induced organ injury, US Army Military Operational Medicine Research Program R&A, Frederick, MD, 13 December 2013.

6) Ippolito, D.L. X1 Project: Biomarkers of Adverse Health Effects Following Exposure to Industrial Chemicals. US Army Military Operational Medicine Research Program R&A, Frederick, MD, 13 December 2013.

7) Tawa, G. X1 Project: Identification of Gene Module Activation Patterns and Biomarker Indicators Associated with Chemically Induced Organ Injury. US Army Military Operational Medicine Research Program R&A, Frederick, MD, 13 December 2013.

8) Madejczyk, M.S. X1 Project: Toxicogenomics of Metal Exposures. US Army Military Operational Medicine Research Program R&A, Frederick, MD, 13 December 2013.

9) Lee, Y.S. X1 Project: Utility of the Microbiome in Environmental Health Surveillance. US Army Military Operational Medicine Research Program R&A, Frederick, MD, 13 December 2013.

10) Rakesh, V. X1 Project: A Computational Approach to Study Organ-Specific Risks Due to Heat Stress. US Army Military Operational Medicine Research Program R&A, Frederick, MD, 13 December 2013.

11) Stallings, J.D. and S. Muza. Environmental Health and Protection Program Area Overview: 2015 Program Plans and FY17-21 POM UFRs, US Army Military Operational Medicine Research Program IIPT, Frederick, MD, 11-12 March 2014.

12) Stallings, J.D. Task Area: Host Response to Environmental Health Hazards, US Army Military Operational Medicine Research Program IIPT, Frederick, MD, 11-12 March 2014.

13) Lee, Y.S. Utility of the Microbiome in Exposure Assessment. JASON Chemical Study, San Diego, CA, 25 Jun 2014.

14) Widder, M.W., T.C. Timmes and J.D. Stallings. Evaluation of the Potential Medical Effects of Nanomaterials in Army Systems. DoD Nanomaterials Working Group Meeting chaired by Dr. Patricia Underwood, Deputy for Risk Assessment, Office of the Deputy Under Secretary of Defense (Installations & Environment) Science & Technology Directorate, Virtual Meeting, 9 July 2014.

15) Trader, D.E. Intelligent Aquatic Biomonitoring System. Contract Connections: Defense Labs Technology Transfer Workshop, Maryland Department of Business and Economic Development, Linthicum Heights, MD, 15 September 2014.

J. PATENTS

1) U.S. Patent 8,574,603, Hatching Kit for Toxicity Test, Shedd, Tommy R., Widder, Mark W., Hull, E., 5 Nov 2013.

2) Developed a new provisional application to be filed - USSN 62/110,058 (Articles for Diagnosis of Liver Fibrosis) (HJF Ref: HJF-386-15) (F&L Ref: 103783-0178): AbdulHameed, Dr. Mohamed Diwan M. (HMJF); Tawa, Dr. Gregory J. (HMJF); Ippolito, Dr. Danielle L. (CEHR); Lewis, Dr. John A. (CEHR); Wallqvist, Dr. Anders (IPA-TATRC); Stallings, MAJ Jonathan D. (CEHR). Expected FY15.

K. CONFERENCES ATTENDED

1) (b) (6) IAEAC: Label-Free Biosensing Symposium: Impedance-Based Biosensors for Environmental Applications Symposium at the annual Pittcon Conference and Expo in Chicago, IL, 2-6 March 2014.

2) (b) (6) . Society of Toxicology meeting, Phoenix, AZ, 23-27 March 2014.

3) (b) (6) . 2014 Madigan Research Day. Guest Judge. Madigan Army Medical Center, Tacoma WA, 25 April 2014.

4) (b) (6) 2014. Session Co-Chair, Military Medicine II: Physiology and Medicine of Extreme Environments and Spaceflight. SPIE Sensing Technology + Applications. Baltimore, MD, 5-7 May 2014.

5) (b) (6) National Cancer Institute Spring Research Festival. Fort Detrick, MD, 5-8 May 2014.

6) (b) (6) Environmental Health Program, COL Roman Bilynsky, Commander, USAMRICD, Fort Detrick, MD, 19 September 2014.

7) (b) (6) Developing a Biomarker Panel for Organ Injury/Toxicity: Biomarkers of Health Effects Task Area Overview, COL Roman Bilynsky, Commander, USAMRICD, Fort Detrick, MD, 19 September 2014.

8) (b) (6) . Military Health System Research Symposium. Fort Lauderdale, FL, 18-21 August 2014.

9) (b) (6) Adverse Outcome Pathways: From Research to Regulation, NIEHS, September 3-5, 2014.

Pulmonary Health Research Program

The Pulmonary Health Research Program manages the DMRDP Military Operational Medicine Research Program (JPC5) subtask BIOE which builds on research that began under the former USACEHR Biomarkers Program.

While deployed to Southwest Asia, many Soldiers and other service members were exposed to very high levels of naturally occurring fine dust particles in the air. Environmental monitoring by the Army has shown that the particle levels in Iraq and Afghanistan often exceed US Environmental Protection Agency, National Institute for Occupational Safety and Health (NIOSH), and Occupational Safety and Health Administration (OSHA) limits, and military exposure guidelines. In addition to the natural dust, many service members were also exposed to burn pit smoke and to industrial, vehicular, and residential air pollution originating from local communities. While these exposures emerged during Operations Iraqi Freedom/Enduring Freedom/New Dawn (OIF/OEF/OND), they are likely to be pervasive in future conflicts which are expected to concentrate on the urban littoral.

USACEHR has built strong connections to military and non-military federal agencies and academic organizations concerned with airborne hazards by participating in national symposia and convening multidisciplinary, multi-agency working groups to shape the BIOE. The BIOE takes an integrated approach using clinical, epidemiological, and toxicological studies to determine the prevalence and severity of pulmonary disease associated with deployment and to identify biomarkers of pulmonary disease. Current performers are located at the Institute for Systems Biology, National Jewish Health, Pacific Northwest National Laboratories, and the Brooke Army Medical Center.

A. GENERAL

1) Program Director. (b) (6) also serves as Science and Technology Director.

2) Personnel. 1 DAC.

B. MISSION: Determine prevalence and severity of Lung Disease associated with deployment, and identify biomarkers of exposure to hazardous environmental materials and chemicals.

C. FOCUS AREAS

1) Identify, geographical, behavioral, medical, and causative factors related to deployment-associated Lung Disease.

2) Identify biomarkers of exposures related to inhalational and other exposures.

D. SIGNFICANT ACCOMPLISHMENTS

1) Organized a Working Group consisting of tri-service and Department of Veterans Affairs members, to serve as advisers for the FY14-19 DMDRP BIOE subtask. The subtask will provide a multidisciplinary approach to evaluate the causes, diagnosis, and prevalence and severity of respiratory disease associated with deployment, especially to Southwest Asia.

2) Identified and funded the first research projects under this DMDRP subtask, including clinical evaluations of Service members with post-deployment dyspnea, and histopathological analysis of lung specimens from Service Members deployed to Iraq and Afghanistan for possible deployment-related lung disease.

3) Managed a grant to National Jewish Health to develop objective diagnostic tools for small airways disease.

4) Managed a grant to The Institute for Systems Biology which identified a set of candidate miRNA biomarkers for obstructive lung disease in human subjects.

5) Served as COR on two SBIRs for developing algorithms to identify complex biomarkers in large data sets.

6) Served as Moderator and Program Chair for the Military Health Research Symposium session: Human Performance and Occupational Health: Environmental and Occupational Hazards.

7) Initiated and managed a DTRA-funded National Academies of Science study of the applicability of the predictive toxicology approaches developed by regulatory agencies and pharma to acute operational exposures.

8) Initiated an effort to evaluate the potential health effects of engineered nanomaterials in Army materiel.

9) Served as the government liaison to the National Academy of Science's Standing Committee on the Use of Emerging Science for Environmental Health Decisions.

10) Served as an Army liaison to the Biomonitoring and Sensors Working Groups of the federal interagency Working Group on Exposure Science for the 21st Century.

11) Served as USAMRMC liaison to the Health and Environmental Sciences Institute (HESI) Toxicogenomics Technical working committee.

12) Participated in the development and proposal of a multi-generational zebrafish epigenetics study to the HESI Toxicogenomics Working Group.

13) Participated in the development of a NATO human factors Technical Activity Proposal on Health Risk Assessment for Chemical Exposures of Military Interest.

E. SCIENTIFIC PUBLICATIONS

1) Burns, M.B., L. Lackey, M.A. Carpenter, A. Rathore, A.M. Land, B. Leonard, E.W. Refsland, D. Kotandeniya, N. Tretyakova, J.B. Nikas, D. Yee, N.A. Temiz, D.E. Donohue, R. M. McDougle, W.L. Brown, E.K. Law and R.S. Harris. 2013. APOBEC3B is an enzymatic source of mutation in breast cancer. Nature 494:366-370.

2) Cochet AA, Lucero PF, Zacher LL, Morris MJ. 2014 Prevalence of supranormal pulmonary function testing values between a military and non-military cohort. Respiratory Care. 59:749-755.

3) Morris MJ, Oleszewski R, Sterner JB, Allan PF, 2013, Vocal cord dysfunction related to combat deployment. Military Medicine, 178:1208-1212.

4) Morris MJ, Dodson DW, Lucero PF, Haislip GD, Gallup RA, Nicholson KL, Zacher LL. 2014, Study of active duty military for pulmonary disease related to environmental dust exposure (STAMPEDE), American Journal of Respiratory and Critical Care Medicine 1 190:77-84.

F. ABSTRACTS

1) Skabelund A, Morris M. 2013, Baseline symptoms and pulmonary function of military personnel prior to deployment. Chest. 144(4_MeetingAbstracts):480A.

G. SCIENTIFIC PRESENTATIONS

1) Skabelund, AJ, T.B. Zanders; M.J. Morris, Baseline Symptoms and Pulmonary Function of Military Personnel Prior to Deployment, Military Health System Research Symposium, 20 August 2014.

2) Madar, C.A., M.J. Morris, R.A. Harley, T.J. Franks, M. Lewin-Smith, Pathological Diagnoses of Deployed Military Personnel with Pulmonary Disease, Military Health System Research Symposium, 20 August 2014.

H. KEY BRIEFINGS

1) Jackson, David A., Materiel Solutions: Environmental Exposure Measurement, Professional Staff Members, House Armed Services Committee, Washington, DC, 15 November 2013.

2) Jackson, David A., Overview of DHP Deployment Pulmonary Health Research Program, Public Health Subcommittee, Defense Health Board, Fairfax, VA, 5 December 2013.

3) Jackson, David A. Overview of DHP Deployment Pulmonary Health Research Program, USAPHCR-N Environmental Staff, DC, 27 May 2014.

4) Jackson, David A. Overview of DHP Deployment Pulmonary Health Research Program, USACEHR Annual Science Review 24 June 2014.

5) Jackson, David A. Overview of DHP Deployment Pulmonary Health Research Program, Joint VA/DoD Deployment Health Working Group, Washington, DC, 11 September 2014.

6) Jackson, David A. Overview of DHP Deployment Pulmonary Health Research Program, COL Roman Bilynsky, Commander, USAMRICD, Fort Detrick, MD, 19 September 2014.

I. CONFERENCES ATTENDED

1) (b) (6) FutureTox II: In Vitro Data and In Silico Models for Predictive Toxicology, Chapel Hill, NC, 16-17 January 2014

2) (b) (6) Annual Meeting of the American Thoracic Society, San Diego, CA, 18-21 May 2014

3) (b) (6) Military Health System Research Symposium, Fort Lauderdale, FL, 17-21 August 2014.

Integrative Systems Biology Program

The Integrative Systems Biology program focuses on applying integrative approaches to understand the etiology of military-relevant health issues including PTSD, coagulopathy, infectious diseases, and pain. These approaches combine animal studies and human studies, computational simulations, and biologics (i.e., products derived from living organisms) acquired from human samples.

The program uses holistic state-of-the-art, high throughput molecular approaches to characterize molecular events associated with disease progression (stress, infection, coagulopathy, etc.), identify regulation of pathways, and determine key networks to ultimately enable the diagnosis, prediction, therapeutic interventions of illnesses of high relevance to the military.

This ISB program is collaborating with world experts from government, academia, and industry on the Systems Biology Exemplars (SBE) on PTSD and coagulopathy that encompasses multi-PI cores that include, clinical, imaging, phenotypic and integrative-omics and they have characterized panels of signatures for PTSD and an invention disclosure is in preparation

A. GENERAL

1) Program Director. (b) (6)

2) Personnel. 2 DACs and 16 contractors.

B. MISSION

1) Leverage Integrative Systems Biology and Network Biology approaches to comprehend the etiology of and find bench-to-customized solutions for the military-relevant health issues by analyzing, contrasting and integrating disparate data libraries consisting of clinical, pathopsychophysiological information, and multi-omics and phenotypic readouts.

2) Characterize molecular events associated with disease progression (stress, Infection, coagulopathy, etc). Identify regulation of pathways and networks to diagnose and predict course of impending illness and design/identify stage-appropriate diagnostic and therapeutic intervention. Personalized and precision medicine.

C. FOCUS AREAS

1) Extensive work with the multi-core PTSD group using a first cohort of PTSD +/-, volunteers who participated in detailed psychological and physiological testing, and provided biomatrices for discovery of objective measures to diagnose PTSD prevalence. Identified metabolic profiles associated with PTSD. Also, identified epigenomic and genomic changes unique for PTSD individuals.

   a. Sample collection for pre- and post- deployment samples have started to identify the early indicators and pre- and actual symptomatic markers and disease fingerprints for PTSD.

   b. Initiated the Millennium Cohort study related to US Service Members that collect longitudinal pre- and post-deployment data, in this project samples from DoDSR (Department of Defense serum repository) will be assayed for miRNA biomarkers.

2) Initiated a microbiome study to understand the regulation of the microbiome profile in response to traumatic stress exploiting various sources (gut, feces, etc.) using the established animal model simulating aspects of PTSD. This animal model was found to replicates some of the molecular findings from the 52/52 human subjects, such as lipid dysfunction, metabolic disorder, alteration in the circadian rhythm and aspects of cardiac lesions.

3) Work has started on the second consortium, systems biology approaches for the Coagulopathy Exemplar, and the clinical sites have made significant progress at collection of samples related to Acute Coagulopathy of Trauma (ACoTS). Samples are being collected and processed. Candidate genes associated with survivability in a small cohort from the burn patients at the Washington Hospital Center were identified as a part of a hypothesis generating exercise.

4) Furthered the collaborations in new areas and furthered ongoing research utilizing systems biology approaches to solve critical problems related to suicide molecular predictors, differentiating onset of virus infections of military/ biothreat interest, rickettsial infections and the longitudinal implications of infection with virulent *Y. pestis*. The DoD's Space Test Program (STP) selected to continue the initial work, and a plan is under development for a next iteration of test comparing bone regeneration in microgravity versus earth's atmosphere.

5) The SysBioCube is maturing as an integrated platform for disparate data types and is being used by different stakeholders with various research interests. Data analysis and integration pipelines as well as for storage and organization of the massive clinical, pathophysiologic and multi-molecular multi-omic datasets are well established. Connections with other similar efforts have advanced during FY14.

6) Ongoing progress on the SBIR program topic Phase II for two projects related to scaled-up rapid processing of blood samples and their long-term storage at near-ambient conditions for use in global molecular studies of transcriptome, epigenetics and other nucleic acid-based systemic analyses.

D. SIGNFICANT ACCOMPLISHMENTS

1) (b) (6) was selected as the DoD scientist of the quarter for the fourth quarter of fiscal year 2014.

2) (b) (6) was invited by NASA to be a member of the scientific advisory board of the GeneLab NASA initiative.

3) (b) (6) was invited to become an editor for Nature Microgravity Journal.

4) The PTSD Collaborative effort from the Systems Biology Exemplars finished the assessment of the first 52/52 matched (age, gender and ethnicity) male volunteers. The next set of 31/31 is being analyzed for validation. Identified metabolites, genes, proteins and miRNA associated with PTSD.

5) The PTSD mouse model in use to assess gene, metabolite and protein expression as well as the microbiome profile with translational potential.

6) Characterized networks and pathways related to biomolecular species in blood that will be indicative of impending dysregulation in circadian rhythm, metabolic syndrome, cardiomyopathy, renal dysfunction, immune dysregulation, lung disorders, etc.

7) In collaboration with NASA, identified the effect of microgravity on host responses to pathogens using Lipopoplysaccharide.

8) Tools are developed for data mining and data analysis in the SysBioCube. Clinical portal and tissue tracker tools are also developed to help in standardizing the clinical data obtained from the different clinical sites.

9) Prepared the documents needed to submit a disclosure of invention for the diagnostic biomarkers identified for PTSD.

10) Extensively working with the advanced development team on molecular indicators being used to objectively characterize military or veteran personnel as PTSD Yes/No. This has involved scheduled weekly meetings to discuss progress and to engage other professionals who can move the project forward.

11) Worked intensively to setup ancillary studies for applying systems biology approaches to other PTSD studies, such as therapeutic approaches and pre/post deployment of Soldiers. Also, we are part of a new study collecting less “clean” and sharply defined volunteers testing positive for PTSD.

12) In collaboration with the Naval Health Research Center, Deployment Health Research Department, San Diego, CA, we are using the Millennium cohort personnel, the largest prospective health project in military history which characterizes a soldier’s long-term health and psychological well-being throughout their military career and beyond. Soldiers are assessed at least every 3 years; 50% are OIF/OEF, 87% completed recent surveys, 34% are women, 75% are still active military personnel. Archived sera (4 time periods pre/post deployment and at 3 year intervals) are obtained for miRNAseq and some potential epigenetic studies.

13) In collaboration with Mount Sinai School of Medicine, carried out a pilot study to identify biomarkers of suicidality. Results were presented to the American Foundation for Suicide Prevention. The team was invited to submit a full proposal to add more patients.

14) Collaboration with USAMRICD was funded by Biomedical Advanced Research and Development Authority (BARDA) to carry out a systems biology project examining physiological/multi-molecular long-term consequences the low-level exposure to Soman. (b) (6) will carry out the detailed

systems biology studies on animal tissues (Rats, then NHP) exposed by (b) (6) at USAMRICD. The plan will follow the animals over a period of up to a year.

15) Submitted a proposal to study the effect of microgravity on bone regeneration to the NASA research Announcement (NRA) in collaboration with scientists at Indiana University Medical School (IUMS).

16) Submitted a U19 NIH proposal titled “DataCube facilitating storage, sharing, mining and integration of disparate data for the Consortium for Medical Countermeasures Against Radiation (CMCRC)” in collaboration with Indiana University.

17) Submitted a proposal titled “Therapeutic interventions for segmental bone defects” to the CDMRP on collaboration with Indiana University.

18) Published seven peer-reviewed manuscripts. Published, prepared invited oral presentations and presented posters and 20 abstracts at multiple high profile scientific meetings.

E. SCIENTIFIC PUBLICATIONS

1) Laura S. Tenenbaum Margery K. Anderson , Marti Jett, Debra Yourick, *An Innovative Near-Peer Mentoring Model for Undergraduate and Secondary Students: STEM Focus*. Innovative Higher Education, 2014. 39(5): p. 375-385.

2) Megan Linebach, Meghan Murphy, Mark Hiner, Rachel Staab, Nabarun Chakraborthy, Marti Jett and Chanaka Mendis, *Differentiating Gene Expression profiles in Staphylococcal Enterotoxin Band Lipopolysaccharide induced human PBMCs*. Research and Development, 2014. 2.1.

3) Leung KP, D'Arpa.P., Seth AK, Geringer Marti, Jett M, Xu W, Hong SJ, Galiano RD, Chen T, Mustoe TA., *Dermal wound transcriptomic responses to Infection with Pseudomonas aeruginosa versus Klebsiella pneumoniae in a rabbit ear wound model*. BMC Clin Pathol, 2014. 14:20.

4) Lassance-Soares, Roberta M. Subeena Sood, Nabarun Chakraborty, Sunny Jhamnani, Nima Aghili, Hajra Nashin, Rasha Hammamieh, Marti Jett, Stephen Epstein, Mary Susan Burnett *Chronic Stress Impairs Collateral Blood Flow Recovery in Aged Mice*. Journal of Cardiovascular Translational Research, 2014. 7(8): p. 749-755.

5) Ji-Hoon Choa, I.L., Rasha Hammamieh, Kai Wang, David Baxter, Kelsey Scherler, Alton Etheridge, Alena Kulchenko, Aarti Gautam, Seid Muhie, Nabarun Chakraborty, David J. Galas, Marti Jett, and Leroy Hood, *Molecular evidence of stress-induced acute heart injury in a mouse model simulating posttraumatic stress disorder*. PNAS 2014. 111(8).

6) Rasha Hammamieh, Nabarun Chakraborty, Aarti Gautam, Stacy -Ann Miller, Seid Muhie, James meyerhoff, Marti Jett, *Transcriptomic Analysis of the Effects of a Fish Oil Enriched Diet on Murine Brains*. PloS One, 2014. 9(3): p. e90425.

7) Nabarun Chakraborty, Aarti Gautam, Seid Muhie, Stacy-Ann Miller, Marti Jett and Rasha Hammamieh, *An integrated omics analysis: impact of microgravity on host response to lipopolysaccharide in vitro*. BMC Genomics, 2014. 15(659).

F. ABSTRACTS

1) Nabarun Chakraborty, Duncan Donohue , Aarti Gautam, Amirta Cheema, Marti Jett and Rasha Hammamieh, *Microgravity arrests host immunity in vitro: Pan-omics approach*. ISS 2014, 2014.

2) Duncan Donohue, *Opportunities for math and computationally competent students* Third annual NICBR Exploring Careers in a Scientific Environment Symposium (NECSES, 2014. Feb 18, 2014.

3) Duncan Donohue, *Computational Biology Opportunities for Students*. NECS-T Talk, 2014.

4) Seid Muhie, Seshamalini Srinivasan, Nabarun Chakraborty. Aarti Gautam , Marti Jett. Rasha Hammamieh*, Biochemistry and Molecular Biology / Genomics/Transcriptomics in Disease-Time-course*

analysis of gene expression in a mouse model simulating aspects of post-traumatic stress disorder. FASEB J 2014. 28(776.7).

5) Nabarun Chakraborty, Monique Melige, *Effects of omega-3 and omega-6 fatty acids on the ethograms of rodents simulating PTSD-like aspects. Experimental Biology and Medicine*, 2014. vol. 28 no. 1 Supplement 814.7.

6) Seid Muhie , Ruoting Yang, Rasha Hammamieh, Marti Jett *Gene expression alterations in patients with post-traumatic stress disorder*. in FASEB Journal.

7) Allison Hoke,Meskerem Jibitu, Aarti Gautam, Rasha Hammamieh , Marti Jett *Primary screening of siRNA to determine genes involved in vascular leakage (711.3)*. The FASEB Journal, 2014. 28(1 Supplement): p. 711.3.

8) George Dimitrov, Candace Moyler., Aarti Gautam, Raina Kumar, Rasha Hammamieh and Marti Jett, *miRNA expression profile in Non-human primate in response to Yersinia pestis infection*. The FASEB Journal, 2014. 28((1 Supplement), 1138-3.).

9) Aarti Gautam , Bintu Sowe, Duncan Donohue, Raina Kumar, Seid Muhie, Nabarun Chakraborty, Allison Hoke ,Rasha Hammamieh, Marti Jett, *Integrative analysis of microbiome and metabolome in mouse model simulating features of post-traumatic stress disorder*. Faseb Journal, 2014. 28(1 Supplement), 982-1.

10) Duncan Donohue, Stacy-Ann Miller., Ellen Gupta, Routing Yang, Aarti Gautam, Rasha Hammamieh, Marti Jett, *Improving PTSD Biomarkers through Matching PTSD Patients and Controls on Multiple Criteria*. Experimental Biology and Medicine, 2014.

11) Seid Muhie, et al. *Time-course analysis of gene expression in a mouse model simulating aspects of human post-traumatic stress disorder*. in FASEB JOURNAL. 2014.

12) Aarti Gautam, George Dimitrov, Seid Muhie, Rasha Hammamieh, and Marti Jett *Systems biology approach to study host response to Y. pestis*. Gorden Research Conference, 2014.

G. KEY BRIEFINGS

1) (b) (6) , Quarterly Meeting for PTSD and Coagulopathy Exemplars

2) (b) (6) , DoD Neuroscience Working Group (at OASD), December 12, 2013.

3) (b) (6) , DOD Space Experiment Review Board on her proposal to study tissue regeneration in microgravity (SPACE-X7), Crystal City, January 29, 2014.

4) (b) (6) , Neurological Effects after Chemical Nerve Agent Exposures, National Institute of Neurological Disorders and Stroke, February 27, 2014.

5) (b) (6) briefed the AIBS review member on the Systems Biology Exemplar for PTSD, April 28 and 29, 2014.

6) (b) (6) , Integrative analysis of microbiome and metabolome in mouse model simulating features of post-traumatic stress disorder, Experimental Biology, April 2014.

7) (b) (6) . miRNA expression profile in Non-human primate in response to Yersinia pestis infection, Experimental Biology, April 2014.

8) (b) (6) . Effects of omega-3 and omega-6 fatty acids on the ethograms of rodents simulating PTSD-like aspects., Experimental Biology, April 2014.

9) (b) (6) , Overview of the SysBioCub, Trans-Agency Research Consortium for Trauma-Induced Coagulopathy (TACTIC),. May 2014.

10) (b) (6) , American Psychiatric Association (APA), New York, May 3, 2014.

11) (b) (6) mmamieh, multi-omic responses integrated with viral infection of dendritic cells for sets of diverse viruses at DTRA in Aberdeen, May 15, 2014.

12) (b) (6), *Most Compelling Results from the ISS in 2013*. plenary panel 3rd Annual International Space Station Research and Development Conference in Chicago, June 17, 2014.

13) (b) (6), Microgravity Arrests Cellular Metabolism in vitro: a Metabolomics Study, American Society for Gravitational and Space Research in Pasadena, October 2014.

H. CONFERENCES ATTENDED

1) (b) (6) Attended the review meeting at the US Army Criminal Investigation Laboratory in Atlanta, GA., in *These are MURIs to study microbial evolution* sponsored by the Division of Life Sciences at the Army Research Office (ARO).

2) (b) (6) Attended the *Annual Conference of Society of Neuroscience* at the Washington Convention Center, 2014.

3) (b) (6) Attended *beyond the Genome: Cancer genomics* meeting, October 8-10, 2014 at Harvard Medical School Boston, MA, 2014.

4) (b) (6) Attended *Illumina Sequence analysis workshop* in Bethesda, MD, 2014.

5) (b) (6) Attended *Illumina user group meeting* at NIH in Bethesda, MD, 2014.

6) (b) (6), *Acute and chronic metabolomic and liver transcriptomic stress effects in mouse Model with features of post-traumatic stress disorder*, 2014.

7) (b) (6) Attended "*PTSD, the Amygdala and Alcohol Use Disorders*", Satellite Symposium to The Society for Neuroscience 2014 Annual Meeting. Washington, DC, November 14, 2014.

8) (b) (6) Attended *The 3rd Annual Biomedical Informatics Symposium* at Georgetown University, Washington, DC, October 2, 2014.

9) (b) (6) Attended "*Agilent Emerging Omics Research Tour*", Introducing the Hopkins Center for Resources in Integrated Biology. Baltimore, MD, September 24, 2014.

10) (b) (6) Represented USACEHR as a Category Judge and Fair Judge at "*33rd Annual Loudoun County Regional Science & Engineering*". Leesburg, VA, March 20, 2014.

11) (b) (6) Attended "*2014 Mid-Atlantic Genetic Epidemiology and Statistics Conference*". Philadelphia, PA, May 30, 2014.

12) (b) (6) Attended "*The Human Microbiome: Implications for Nutrition and Clinical Practice*". Bethesda, MD, March 28, 2014.

Systems Biology Collaboration Center

The Systems Biology Collaboration Center of the Systems Biology Enterprise officially began 9 Sep 2014 following a decision brief to the CG USAMRMC, MG Caravalho. The SBE was originated in 2009 by a senior leader ((b) (6)) in the Office of the Principal Assistant for Research and Technology (OPART), USAMRMC and developed in coordination with the Director ((b) (6)) and Deputy Director ((b) (6)) of the Integrative Systems Biology (ISB) research program within USACEHR.

A. GENERAL

1) Acting Director: (b) (6).

a. Hired in FY14 Q3 to function as both the SBCC's Acting Director and Chief Data Officer.

2) The proposed staffing structure at the Initial Operational Capability (IOC, FY18) is composed of two civilian FTEs (Full Time Equivalents; Director and Chief Data Officer), three Contract Manpower Equivalents (CMEs for Research Integration and Policy Support, RIPS) and one Military Deputy (O-5 desired). The RIPS team's functions also include training and education. A service contract is proposed for the SysBioCube to support CMEs at the Frederick National Laboratory for Cancer Research (FNLCR), Ft. Detrick. See Appendix B, SBCC Organization Chart.

B. MISSION:

1) Foster and integrate USAMRMC-initiated systems biology collaborative science teams.

2) Facilitate, plan, coordinate, assess, and oversee USAMRMC-wide data and SysBioCube database quality, security, sharing, networking, and analytical resources.

3) Plan, coordinate, and manage the potential expansion to integrate collaborative science and/or data and database utilization with other DoD RDT&E performers.

C. POLICY DOCUMENTS

1) The SysBioCube Data Sharing and Publication Policy, final draft (May 2014; (b) (6)).

2) Began the Command Policy Memorandum 2014-XX, USAMRMC SBCC Coordination of Systems Biology Research and the Sharing of Military Medical Research Data (in staffing process; (b) (6)).

D. KEY BRIEFINGS

1) Systems Biology Collaboration Center Implementation Plan Decision Brief to USAMRMC Commanding General (September 2014; Dr. Glenn, COL Timmes, SBCC staff).

2) Systems Biology OIPT Funds Distribution (CBE) / Program Plan Update: Board of Directors (June 2014; COL Timmes).

3) "Modeling and simulation of the blood platelet storage lesion", 2015.1 Phase I DHP SBIR Topic Review, USAMRMC (July 2014; (b) (6)).

4) "Overview of the Systems Biology Collaboration Center", briefing to Commander, USAMRICD (Sep. 2014; (b) (6)).

5) "SysBioCube", presented to the staff, USACEHR (June 2014, (b) (6)).

E. COMMITTEE RESPONSIBILITIES

1) Federal Interagency Traumatic Brain Injury Resource (FITBIR) three committees (March 2014; (b) (6)):

a. Executive

b. Strategic Vision

c. Policy

2) Planning Committee for the "Systems Biology: the Realities and the Possibilities" Uniformed Services University of Health Sciences (USUHS); Sponsor: Department of Homeland Security (July 2014; (b) (6))

3) Tri-Service Toxicology Consortium, TSTC (July 2014; (b) (6)).

F. SIGNFICANT ACCOMPLISHMENTS

1) Reviewed of the FY15 DoD USAMRMC Broad Agency Announcement (BAA) for Extramural Medical Research for both Army and DHP funding; added a section on submitting Systems Biology data to the SysBioCube; added standard text to the areas of interest statements of Joint Program Committee-7 (JPC-7) and four Program Area Directorates (PADs) (Sep. 2014; (b) (6)).

2) Subject Matter Expert (SME) for the Patient Centered Precision Care (PC2) Digital Biobank's High Performance Team (HPT) meeting sponsored by the Air Force Medical System Support Agency/ Requirements Division (AFMSA/SG5R); hosted by the Johns Hopkins Applied Physics Laboratory (APL) (Sep. 2014; (b) (6)).

3) Planning of oral and poster presentations at the Systems Biology meeting (section 3); designed to educate the audience of administrators, scientists and students. ((b) (6)).

4) Systems Biology Enterprise Operations Manual (in review; March 2014; all SBCC staff).

5) Began drafting charter for the Integrating Integrated Product Team (IIPT) (all SBCC staff)

Office of Research and Technology Applications (ORTA)

A. GENERAL

1) ORTA. (b) (6) .

2) Personnel. 2 DAC. This is an additional duty for (b) (6) . (USAMRMC Invention Evaluation Committee member – (b) (6) [additional duty]).

B. MISSION: Direct the technology transfer function for USACEHR.

C. FOCUS AREAS

1) Review product information sheets on USACEHR's research efforts.

2) Document data/information on USACEHR's Cooperative Research and Development Agreements (CRADAs), royalty and reimbursable money from patentable research products, and patent submissions.

3) Respond to data calls from higher headquarters on ORTA functions.

4) Facilitate the technical transfer of USACEHR research products to the commercial market.

5) Review USAMRMC patent disclosures as a member of the USAMRMC Invention Evaluation Committee (IEC).

D. SIGNFICANT ACCOMPLISHMENTS

1) Provided ORTA metrics to MRMC Technology Transfer Office with USACEHR Business Plan and Quad Chart.

2) Managed 16 active CRADAs (authored or assisted in six new CRADA actions), 22 MOA/MOU (authored or assisted in 11 new MOA actions), and three IAA agreements (one new IAA action).

3) Provided liaison assistance for JAG Review, OPSEC/PAO, Security, and US International Trade Representative Office for all agreements.

4) Attended 18th DoD Technology Transfer Training Workshop with MRMC ORTA, 14-16 JULY 2014, Savannah, GA. USACEHR ORTA provided input on the Army's CRADA policy sculpting in concert with the standing-up of the Defense Health Agency.

5) Attended the Defense Labs Technology Transfer Showcase in Baltimore, MD15 September 2014 via local travel. The importance of travel opportunities is underscored here, since the potential licensee came to this function looking for products. With the ORTA presenting and being present at this function, an Army technology that needs a commercial partner for software upgrades and hardware manufacture will likely be licensed in FY15.

6) Established negotiations with Honeywell Aerospace to get the BioMonitor Expert Software source code back, since Honeywell has given the patent license back to the Army. Discussions on a potential licensee were initiated with COBAR Resources, LLC. regarding the fish biomonitor.

Quality Assurance

A. GENERAL

1) Quality Assurance Coordinator. (b) (6) .

2) Personnel. 1 DAC. This is an additional duty for (b) (6) .

B. MISSION: To plan and implement the USACEHR Quality Assurance Program.

C. FOCUS AREAS

1) Provide administrative support for writing Standard Operating Procedures to research staff. This includes editorial review of new SOPs, and archiving old SOPs.

2) Write, review, and update, as appropriate, administrative procedures for laboratory notebooks, clearance of scientific documents, and the Quality Assurance Program.

3) Initiate biannual review of all active laboratory notebooks and associated binders. Update USACHER notebook register as needed.

4) Review all scientific articles, abstracts, and posters for publication and send to OPSEC and PAO for clearance.

D. SIGNFICANT ACCOMPLISHMENTS

1) Completed the annual review of science protocols (not animal related).

2) Completed the annual review of USACEHR laboratory training records (not animal related).

3) Completed biannual laboratory notebook reviews and oversaw annual inventory of notebooks. The inventory included accounting for all active and retired laboratory notebooks and binders.

4) Assisted in writing and editing of SOPs for AAALAC certification. Ongoing process of organizing and updating USACEHR SOPs with staff.

5) Reviewed documents for clearance: oral presentations (10), poster presentations,(17), manuscripts, journal articles or technical reports (20), and abstracts (32).

Resource Management and Budget:

USACEHR began FY14 with an approved Research Development Test & Evaluation, Army (RDTE,A) direct funding level of $4,460K within projects FH2 and VB4. In addition, we received additional $1,840K RDTE,A, Research Development Test & Evaluation, DHP (RDTE,D) funding of $1,128K, DHP RDTE CSI PTSD funding of $1,383K, DHP-E funding of $4,760K, and DHP Operations and Maintenance (O&M) funding of $179.4K during the year. Reimbursable funding for FY14 totaled $38K. The USACEHR FY15 approved RDTE,A direct funding level is $3,816K within VB4 project. Forecasted funding levels for FY15 are consistent with FY14.

Direct	FY13	FY14
RDTE,A (P6.2/6.3)	$ 4,724,000	$ 6,300,000
DHP O&M (P8.4)	$ 281,900	$ 179,400
RDTE,D (P6.2/P6.3)	$ 473,000	$ 1,128,000
DHP RDTE CSI PTSD	$ 1,367,000	$ 1,383,182
DHP-E	$ 4,501,654	$ 4,760,013
Total Direct	**$11,347,554**	**$13,750,595**

Reimbursable	FY13	FY14
RDTE,A (P6.2)	$ 126,112	$ 37,982

Information Management:

After over 39 years of service to the country, the Information Management Officer, (b) (6) retired. (b) (6) was appointed as his replacement on 25 SEP 2014. The USACEHR IM group manages and provides tier 2 support for over 75 desktops, notebooks, and science workstations. In support of the USACEHR scientific mission, the USACEHR houses a server room with three Windows servers and one Linux server with over 100 TB of storage with tape backup.

A. GENERAL

1) Information Management Officer. (b) (6) until 25 SEP 2014, replaced by (b) (6)

2) Personnel. 1 DAC and 2 contractors. This was an additional duty for (b) (6)

B. MISSION

1) Facilitate the USACEHR's technical needs for advanced scientific computing to support ongoing research programs. Administrate the USACEHR's computing environment to comply with Army security requirements and support daily user tasks and activities over its local area network (LAN).

C. FOCUS AREAS

1) The main focus area is desktop deployment, providing tier 2 user support and maintaining in-house information assurance.

2) Continue to maintain and update the Medical System Inventory Repository (MSIR) with USACEHR's applications and IT initiatives.

3) Maintain USACEHR's Department of Defense (DoD) Information Assurance Certification and Accreditation (DIACAP).

D. SIGNFICANT ACCOMPLISHMENTS

1) Completely replaced network cabling from patch panel to the switch for all active ports in building 568 (> 300 ports).

2) Performed a complete overhaul of USACEHR's Group Policy.

3) Transitioned from static to dynamic IP addressing.

4) Successfully obtained CON's for 6 different pieces of software.

5) Successfully completed a DMLSS audit.

6) Transitioned to DEPO management of enterprise email accounts.

7) Maintained 100% compliance for IA training all year.

8) Installed new DMLSS server and switch.

Operations:

N/A

Modernization:

In addition to the three major renovation projects USACEHR had to modernize the building infrastructure (see Construction below). A variety of building infrastructure and research equipment was modernized.

Facilities and Real Property

A. GENERAL

1) Facilities Manager: (b) (6) , MRMC.

2) Building Coordinator: (b) (6) .

3) Personnel. 2 DAC – (b) (6) is an USAMRMC DAC.

B. MISSION: Ensure a state of the art building and laboratory environment to support USACEHR's mission.

C. FOCUS AREAS

1) Maintain accountability for all government-owned building 568 and real property.

2) Ensure proper functionality of building 568 systems.

3) Develop building 568 as a start of the art research laboratory.

D. SIGNFICANT ACCOMPLISHMENTS

1) Modernization of building 568 infrastructure in junctions with the second floor laboratory project: air handler, high efficiency natural gas boilers, exhaust fans, RO Unit, laboratory vacuum system, and natural gas humidifier.

2) New equipment in junctions with the vivarium project: Lutron programmable lighting system and an additional N+1 laboratory air compressor.

Property Book

A. GENERAL

1) Property Book Officer. (b) (6) .

2) Personnel. 2 DAC maintain property book as an additional duty.

B. MISSION: Ensure all regulations and procedures are followed for government property.

C. FOCUS AREAS: Accountability for all government owned equipment

D. SIGNFICANT ACCOMPLISHMENTS

1) The property book was valued at $5,981,627.98 with a total of 812 pieces of equipment. There were six line items with a unit price greater than $100,000. The number of hand receipts was 11.

2) Replaced outdated undersized autoclave with new unit.

3) Backup well room air compressor was replaced.

4) Additional N+1 laboratory Nitrogen generator was installed.

5) Glassware washer replacement has been awarded.

6) Major Laboratory Equipment Additions:

a. Agilent ICPMS, Acquisition Date: 3/10/2014 Cost: $153,466.19

b. Applied Biosystems Quant Studio, Acquisition Date: 3/10/2014 Cost: $45,984.00

c. Miltenyi Biotec Inc, Pro Separator, Acquisition Date: 8/12/2014 Cost: $46,500.00

Logistics:

Administrative Director

A. GENERAL

1) Administrative Director. (b) (6) .

2) Personnel. 1 military and 5 DACs.

B. FOCUS AREAS

1) Administration.

a. Execute the transition plan that directed movement of the USACEHR staff, aquatic animals, and equipment from laboratories affected by the completed vivarium project into new laboratories.

b. Ensure the administrative aspects of the organization by prioritizing all tasks appropriately and accomplishing tasks, both routine and non-routine, in accordance with schedules and deadlines.

c. Provide timely civilian personnel actions, support managers in recruiting appropriate workforce, assist management in obtaining the appropriate grade structure, and document the required workforce on the TDA.

d. Serve as Management Control Administrator for the USACEHR, ensuring adequate controls for assigned resources are developed and operational so government resources are efficiently and effectively managed.

2) Budget.

a. Provide accurate financial information to assist management in making informed decisions.

b. Monitor fund availability and obligation rates for execution compliance with regulations.

3) Medical Maintenance.

a. Ensure all laboratory equipment scheduled and unscheduled services are performed.

b. Enter all laboratory equipment related data in the Defense Medical Logistics Standard Support (DMLSS) database, ensuring USACEHR equipment accountability and scheduled/unscheduled maintenance functions.

c. Serve as USACEHR's Test Measurement and Diagnostic Equipment (TMDE) Coordinator, ensuring all USACEHR owned TMDE is accurate, calibrated, and repaired in a timely manner.

4) Supply.

a. Maintain a successful credit card program within Army regulations.

b. Monitor the Wide Area Workflow (WAWF) system and the Electronic Document Access (EDA) system to keep interest penalties minimized.

C. SIGNFICANT ACCOMPLISHMENTS

1) Administration.

a. Deployed the Defense Medical Logistics Supply System (DMLSS) as it relates to purchasing.

b. Continued implementation of the General Financial Enterprise Business System (GFEBS) accounting system.

c. Approved all government credit card transactions, validating appropriateness of the charges.

2) Budget.

a. Reduced PY STANFIN ULO's down to 5.

b. Closed FY14 RDT&E, Army funding with a 99% obligation rate.

3) Medical Maintenance.

a. Completed 1087 scheduled services (preventive maintenance, safety inspections, and calibrations) during 2014. Of that total 993 were performed in-house, and 94 were accomplished by contractors.

b. Completed 107 unscheduled services (repairs). Of that total 69 were performed in-house, and 38 were accomplished by contractors.

c. Designed and tested new Zebra Fish breeding chamber.

d. Designed and tested new Zebra Fish recirculation rack using Aquatherm piping.

4) Supply.

a. The Government Purchase Card Program continued to be a success with purchases valued at $1,170,455.65, of which $677,805.02 was obligated to 2014 funds and the remaining $492,650.63 was obligated to 2013 funds.

Health and Environment:

Introduction

After over 39 years of service, the Environmental and Safety Officer for USACEHR, (b) (6), retired at the end of the fiscal year. (b) (6) was selected for the Army Civilian Training, Education and Development (ACTED) internship program and become USACEHR's full-time Safety Officer at the end of the fiscal year. This marks a significant commitment to the importance of health and the environment for USACEHR by creating a full FTE for safety. In addition, USACEHR has made it a goal to incorporate the Army Safety Health Management System (ASHMS) into the USACEHR culture. USACEHR is actively working to become a Star Site and has completed stage 1 certification.

Safety

A. GENERAL

1) Safety Officer. (b) (6) transitioned to (b) (6) at the end of the fiscal year.

2) Personnel. 1 DAC. (b) (6) is currently an ACTED Intern.

B. MISSION: Plan and execute an effective Safety and Occupational Health Program.

C. FOCUS AREAS

1) New laboratory's and employee issues and concerns.

2) Updating USACEHR Health and Safety policies.

3) The close out phases 2 and 3 of the Army Safety Health Management System (ASHMS) to become a STAR site.

D. SIGNFICANT ACCOMPLISHMENTS

1) Passed the organizational inspection program (OIP) safety inspection conducted by USAMRICD personnel without any major negative findings.

2) Passed a Standard Army Safety and Occupational Health Inspection conducted by USACEHR Safety Office with a few housekeeping facility deficiencies that have been corrected.

3) Updated USACEHR Memorandum 385-1, Laboratory Safety and Health Program.

4) Updated USACEHR Memorandum 385-2, Building 568 Evacuation Plan.

5) Updated USACEHR Memorandum 385-7, Safety Awards Program.

6) Updated USACEHR Memorandum 385-6, Accident Investigation and Reporting.

Environmental Management

A. GENERAL

1) Environmental Compliance Officer. (b) (6) transitioned to (b) (6) at the end of the fiscal year.

2) Personnel. 1 DAC -- (b) (6) is currently an ACTED Intern.

B. MISSION: Plan and execute an effective Environmental Management Program.

C. FOCUS AREAS

1) Facility and employee issues and concerns.

2) Supporting Fort Detrick Environmental Program by maintaining our aquatic animal water well production system, which reduces groundwater contamination under USACEHR Building 568.

3) Pumping and treating at least 100,000 gallons of ground water per month at the request of the Maryland Department of the Environmental, in support of Fort Detrick's groundwater cleanup efforts.

D. SIGNFICANT ACCOMPLISHMENTS

1) The USACEHR was inspected one time during 2014 by the Fort Detrick Environmental Management Office with no negative findings or deficiencies.

2) All Fort Detrick Environmental Quality Control Committee meetings were attended by one or more USACEHR personnel.

Construction:

USACEHR had three major construction projects within building 568 during the year. An addition on the west end of the building with an elevator was completed on 31 MAR 2014. This elevator will provide access to three levels of laboratory space plus the attic. The conversion of 1,500 sq ft of the basement vivarium to a new rodent vivarium was completed on 19 MAR 2014, and the ribbon cutting for was held on 11 APR 2015. This newly formatted space contains four husbandry rooms that can each house over 200 rats or 1000 mice, three procedures rooms and a necropsy suite. Finally, 2500 sq ft of office space was converted to a state of the art laboratory to support USACEHR new mission in systems biology.

Facilities Management

A. GENERAL

1) Facilities Manager: (b) (6) , MRMC.

2) Building Coordinator: (b) (6) .

3) Personnel. 2 DAC – 1 Contractor – (b) (6) is an USAMRMC DAC.

B. MISSION: Ensuring all building related repairs and services are performed correctly and in a timely manner.

C. FOCUS AREAS

1) Ensure all service/work orders are submitted and completed in timely manner.

2) Facilitate renovations; attend construction meetings, coordinate all associated work so that it has the least impact possible to ongoing research projects and animals.

3) Provide building access and security for government property.

4) Perform QA inspections for all contracted building services and repairs.

D. SIGNFICANT ACCOMPLISHMENTS

1) Fifty-one (51) maintenance service/work orders were processed.

2) Significant facility renovations and new construction project accomplishments were:

a. Exterior elevator project completed 31 MAR 2014.

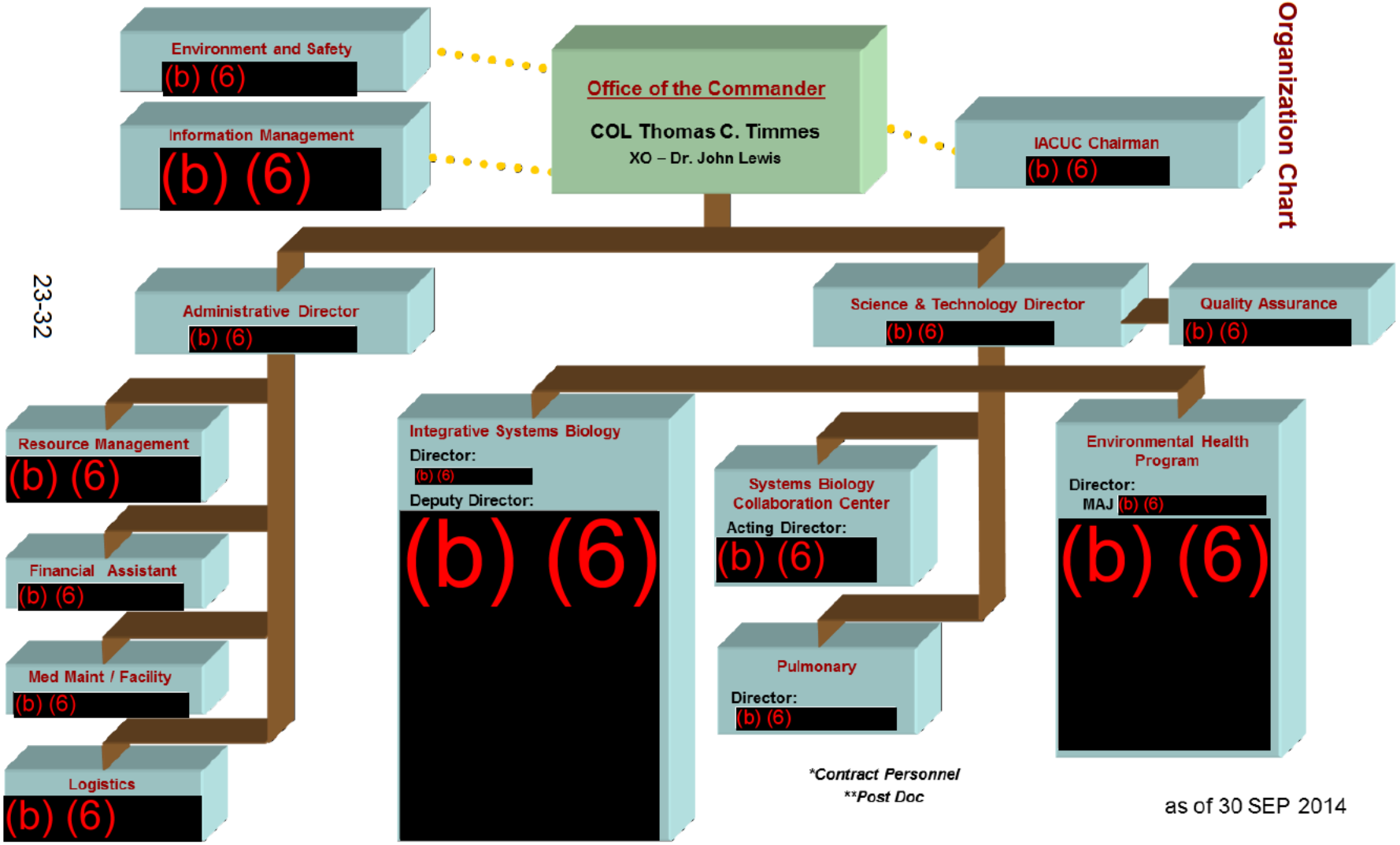
b. New rodent vivarium project completed 19 MAR 2014.

c. Second floor laboratory project near completion.

Other:

N/A

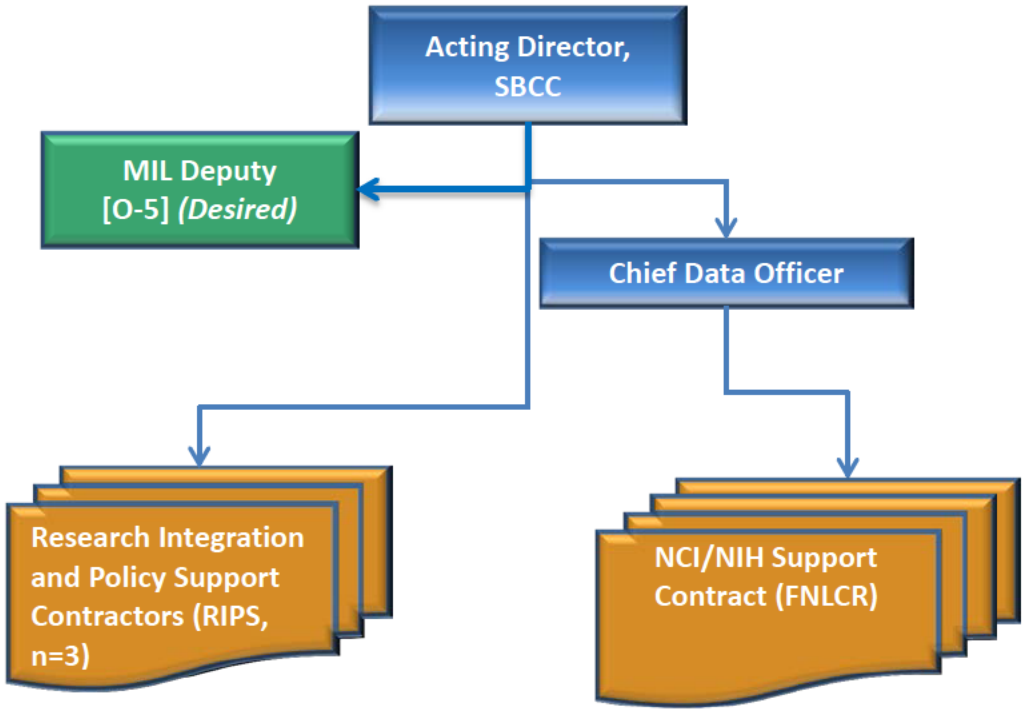
USACEHR Organizational Chart



*Contract Personnel
**Post Doc

as of 30 SEP 2014

Appendix B: SBCC Organization Chart



Section 24

Fiscal Year 2014
Annual Historical Report

U.S. Army Medical Research Institute of Infectious Diseases

Mission

The mission of the US Army Medical Research Institute of Infectious Diseases (USAMRIID) is to provide leading-edge medical capabilities to deter and defend against current and emerging biological threat agents.

USAMRIID's Mission Essential Task List includes the following: 1) Research biological agents to identify promising medical countermeasure (MCM) technologies (drugs, vaccines, diagnostics, and information products) with USAMRIID's internationally recognized subject matter experts and by leveraging collaborations with academia, industry and other government agencies; 2) Test and evaluate MCM to support US Food and Drug Administration licensure of MCM; 3) Rapidly identify biological agents to assist in biological threat assessments, table top exercises and field exercises for the Department of Defense (DoD) and other government agencies; 4) Train and educate the force by providing expert training to military medical providers, civilian first responders and allies to appropriately respond to bioterrorism and biological warfare events; and 5) Maintain safety, security and surety standards for all applicable activities.

USAMRIID plays a key role as the lead military medical biodefense research laboratory for the Defense Threat Reduction Agency's (DTRA) Joint Science and Technology Office for Chemical and Biological Defense and serves as the Joint Program Executive Office for Chemical and Biological Defense's MCM Biosafety Level 4 Good Laboratory Practice test and evaluation capability.

Organization and Personnel

Please see listing of key personnel, strength table and organizational chart that appear at the end of this document.

Statistical Data

USAMRIID published over 70 scientific articles during 2014. A listing of these articles is appended to the end of this document. In addition, USAMRIID scientists present their work to the scientific community both within the United States and internationally. Over 400 posters and scientific presentations were made during 2014.

Health Care Delivery

N/A

Veterinary Services

N/A

Training and Education

USAMRIID and the U.S. Army Medical Research Institute of Chemical Defense (USAMRICD) jointly conduct the Medical Management of Chemical and Biological Casualties Course.

The course is designed for Medical Corps and Nurse Corps officers; physician assistants; Medical Service Corps officers in specialties 67B, C, or E; and other selected medical professionals. Classroom instruction, laboratory, and field exercises prepare graduates to effectively manage casualties of chemical and biological agent exposure.

Classroom discussion includes the history and current threat of chemical and biological agent use, the characteristics of threat agents, the pathophysiology and treatment of agent exposure, and the principles of field management of threat agent casualties.

In the field, attendees practice the principles of personal protection, triage, treatment, and decontamination of chemical casualties. During this exercise, attendees learn the capabilities and limitations of Mission Oriented Protective Posture (MOPP) when treating casualties in a contaminated environment.

USAMRIID - Division Of Medicine - Training & Support Branch - CY2014 Training Data

MCBC/FCBC/HM-CBRNE Courses - conducted in residence

Course Type	Course Location	Start	End	USA	USAF	USN	PHS	Other	FN	Total
FCBC	APG-EA	11/17/14	11/21/14	55	12	7	0	9	0	83
MCBC	APG-EA/Fort Detrick	10/19/14	10/24/14	41	3	12	0	2	3	61
FCBC	APG-EA	9/15/14	9/19/14	26	60	0	2	14	0	102
MCBC	APG-EA/Fort Detrick	8/17/14	8/22/14	32	43	6	0	11	1	93
HM-CBRNE	APG-EA	7/28/14	8/1/14	39	4	1	2	13	2	61
FCBC	APG-EA	6/16/14	6/20/14	48	29	0	1	10	0	88
MCBC	APG-EA/Fort Detrick	5/4/14	5/9/14	76	24	13	0	5	6	124
FCBC	APG-EA	4/14/14	4/18/14	43	14	5	1	9	0	72
MCBC	APG-EA/Fort Detrick	3/16/14	3/21/14	32	18	9	2	11	2	74
FCBC	APG-EA	2/24/14	2/28/14	25	11	1	0	15	2	54
HM-CBRNE	APG-EA	1/27/14	1/31/14	27	1	3	0	8	1	40
										852

Mini MCBC Courses - conducted off-site

Course Type	Course Location/Unit	Start	End	USA	USAF	USN	PHS	Other	FN	Total
MCBC	Ft. Bragg, NC/JSOC	1/21/15	1/22/15	37	3	8	0	2	0	50
MCBC	Ft. Bliss, TX/1st Armored Div	9/24/14	9/25/14	27	0	0	0	11	0	38
MCBC	APG-S/ECBC	8/26/14	8/26/14	0	0	0	0	20	0	20
MCBC	APG-S/ECBC	6/13/14	6/13/14	0	0	0	0	22	0	22
MCBC	APG-S/ECBC	6/3/14	6/3/14	0	0	0	0	140	0	140
MCBC	Ft. Bragg, NC/2nd BDE 82nd Airborne Div	2/5/14	2/6/14	64						64
										334

1,186

USAMRIID's Field Identification of Biological Warfare Agents (FIBWA) program provides foundation training in the complex, specialized tasks required to support both the traditional BW and the broader bio-surveillance (BSV)

mission, which includes bio-terrorist attacks, infectious diseases and food-borne illness missions, in which the Department of Defense (DoD) is involved. FIBWA trains students to set up, maintain, and operate deployable laboratories under field conditions, for both BW and BSV missions. The courses offer training in the most advanced fieldable technologies, along with the background information and concepts of operations (CONOPS) needed to safely perform effective diagnostic or detection missions in austere environments. The FIBWA courses focus on an integrated application of multiple technologies as well as in-depth laboratory knowledge to provide a high-confidence solution. Equipment and technology are integrated with the Joint Program Executive Office for Chemical and Biological Defense (JPEO-CBD). Concepts of Operations and reagents are continually evaluated and transitioned to the field and into the training program to insure that FIBWA training is relevant and on the "Cutting Edge."

The following is a synopsis of the FIBWA programs activities for FY14:

1. Conducted two Field Identification of Bio Warfare Agents courses (ATRRS: 6H-F41/311-F5) resulting in 12 personnel trained. Students for the FIBWA courses include two from the Republic of Korea.

2. Conducted three Field Identification of Bio Warfare Agents Managers courses (ATRRS: 6H-F41/311-F5) resulting in 12 personnel trained.

3. Conducted three Field Identification of Bio Warfare Agents (FIBWA)(RC) courses (ATRRS: 6H-F40/311-F4(RC) resulting in 15 personnel trained from 12 NGB Civil Support Teams across the US and its territories.

4. Developed and conducted a special interest course for the Chemical Biological Incident Response Force, 2nd Marine Expeditionary Force (CBIRF). This course consisted of 80hrs of classroom and laboratory instruction for seven CBIRF personnel, focusing primarily on polymerase chain reaction and sample processing subjects requested by CBIRF. The FIBWA-CBIRF course provided CBIRF personnel a strong foundation in biological agent identification that was lacking prior to attending the course.

5. In response to the Ebola Virus Disease outbreak, FIBWA quickly put into place, an Ebola Qualification Assessment (EQA) testing program for laboratories designated to perform Ebola testing. This required the preparation and assembly of test panels, the distribution of those panels, evaluation of results, and reporting. During FY14, 10 EQA panels were sent to laboratories CONUS and OCONUS.

6. Rapidly developed a training program for personnel deploying in support of the Ebola Virus Disease outbreak in West Africa. The FIBWA-EZ course validated skills required for deploying laboratory personnel, including proper use of personal protective equipment (PPE), critical safety practices, and familiarization with applicable laboratory procedures and instrumentation. The FIBWA-EZ course also provided required training for use of the Ebola Zaire EUA assay. During FY14, 16 personnel were trained for deployment in support of the Ebola response effort.

7. Entered into a 3-9 year support agreement with the USARNORTH Civil Support Training Activity (CSTA) to provide samples for use in the evaluation of National Guard WMD-CSTs. FIBWA began supporting the USARNORTH-CSTA in March of 2014 and provided five sample sets for CST evaluation lanes during the fiscal year. The realistic nature and high quality of the samples provided, offers a level of realism never before seen on the ARNORTH training lanes.

8. FIBWA continued to support the USAMRIID BAIT program, providing samples support and subject matter experts for two, large, multi-agency BAIT exercises. One exercise held at Baltimore's Harbor facility, and a multi-location exercise, at the Groton, CT airport, Groton Submarine Base, and former Connecticut State Hospital. For the Connecticut exercise, FIBWA personnel not only provided sample

material and SME support, but acted as event coordinators and facilitators, for the large, successful, multi-day event.

9. During the 2014 fiscal year FIBWA continued their support of the 1st Area Medical Laboratory (AML) by providing sample material and reach-back support for two 1st AML field problems. In addition, FIBWA personnel traveled with the 1st AML to Ft Indian Town Gap, PA and to Ft Bragg, NC to provide support and to evaluate the 1st AML's capability. The evaluation of the AMLs performance at the Ft Bragg exercise was reported to the 44th Medical Brigade commander, and utilized to assess the 1st AML's readiness to deploy.

Research and Development

A. **Bacteriology:**

1) Conducted the pivotal animal efficacy studies supporting the use of Moxifloxicin Hydrochloride to treat and prevent plague, leading to submission of a Supplemental New Drug Application to the US Food and Drug Administration: FDA decision on plague treatment indication for moxifloxacin by 09 MAY 15

2) Conducted the pivotal animal efficacy studies supporting the use of Moxifloxicin Hydrochloride to treat and prevent anthrax; analysis ongoing.

3) Discovered that Omadacycline was effective in promoting or enhancing survival in animals with anthrax, glanders, or plague.

4) Completed DTRA/BARDA Burkholderia pseudomallei strain panel characterization for animal modeling of glanders and melioidosis.

5) Initiated animal modeling studies to identify the most appropriate NHP model for melioidosis.

6) Identified a potential protective antigen for a subunit tularemia vaccine

7) Discovered a virulence factor of F. tularensis that may represent a novel target for MCM.

B. **Office of Senior Scientist:**

1) Initiated a Phase 2a dose ranging clinical study of a DNA vaccine for hemorrhagic fever with renal syndrome delivered by intramuscular electroporation, in support of the Medical Infectious Diseases Research Program (MIDRP).

2) Completed a Phase 1 clinical study of a DNA vaccine for Venezuelan equine encephalitis virus delivered by intramuscular or intradermal electroporation in support of the JPM-MCS Vaccine program.

3) Evaluated the protective efficacy of DNA vaccines for Ebola, Sudan, Marburg and Ravn viruses delivered by intramuscular electroporation to nonhuman primates.

4) Demonstrated protective efficacy of a combination DNA vaccine for Venezuelan, eastern and western equine encephalitis viruses delivered by intramuscular electroporation against aerosol challenge with any of the three alphaviruses.

5) Collaborated with scientists from Slovenia to test hemorrhagic fever with renal syndrome patient samples for markers of pathogenicity.

C. **Veterinary Medicine:**

1) MOA with USACEHR was signed by the Commanders for USAMRIID to provide laboratory animal medicine veterinary support. Provided support in preparation for their vivarium accreditation site visit and to maintain their animal care and use program fully operational.

2) Assured Institute's Animal Care and Use Program complied with all accreditation requirements and all applicable animal welfare laws and regulations. This allowed research to be conducted and animal care and use support to be provided for all the active research protocols. [VMD supports every single protocol using animals in the Institute].

D. **Molecular and Translational Science:**

1) The Therapeutic Development Center (TDC) was stood up within USAMRIID in order to accelerate medical countermeasure development timelines by applying a biopharmaceutical approach to drug discovery and development.

2) Members of the TDC published 18 manuscripts in peer-reviewed journals describing biodefense-related disease pathophysiology, new drug target identification, and novel therapeutics effective against viral and bacterial select agents and biological toxins.

3) A comprehensive host factor genetic screen identified multiple novel targets necessary for alphavirus and filovirus infection.

4) The TDC successfully executed a screening campaign using AstraZeneca's non-nucleoside antiviral library and identified multiple, highly potent compounds with broad spectrum activity against multiple viruses that cause hemorrhagic fever.

5) Identified 13 novel compounds demonstrating anti-Ebola activity and obtained their structures to enable creation of TDC intellectual property.

6) Created a collaborative alliance between the TDC and Alios BioPharma and identified a lead molecule demonstrating potent anti-Ebola activity to support therapeutic product development.

E. **Division of Medicine:**

1) Initiated a Phase III clinical trial in US troops at Yongsan Garrison, Seoul, Korea! This study will evaluate the efficacy of a new smallpox vaccine (IMVAMUNE) vs the current FDA licensed smallpox vaccine (ACAM2000) in a head-to-head clinical trial of antibody response and adverse events.

2) Published a manuscript showing that the anthrax vaccine adsorbed elicits a strong anamnestic response after a lapse of as many as 7 years. This robust antibody response is not only non-inferior to the response observed in individuals who maintained annual vaccinations but was superior to their response in terms of antibody levels. Of note, the CDC study (published a few months apart) showed similar results out to 3 years and recommend triennial booster vaccinations.

3) Initiated a study to evaluate the longevity of antibody produced in humans by a single smallpox vaccination with the newly FDA approved ACAM2000 vaccinia vaccine (DRYVAX replacement).

F. **Diagnostic Systems:**

1) Performed all laboratory testing required for the DoD to obtain an Emergency Use Authorization (EUA) for regulatory compliant testing of U.S. citizens in the U.S. and West Africa.1. Provided Ebola diagnostic testing support to Liberia and Sierra Leone early in the Ebola outbreak, since March 2014.

2) Continuously provided personnel for direct Ebola diagnostic testing support at the Liberian Institute for Biological Research (LIBR), in Monrovia, Liberia. Support provided since August 2014.

3) Extended Clinical Laboratory Improvement Program (CLIP) certificate to the LIBR laboratory to provide regulatory compliant EUA Ebola diagnostic testing for U.S. citizens and deployed U.S. military personnel in Liberia.

4) Provided all diagnostic training required to perform testing for forward deployed personnel supporting the LIBR lab (3 day Ebola diagnostic training course).

5) Provided National Laboratory reference diagnostic testing for the United States at the outset of the Ebola outbreak when the CDC was under a safety stand down.

6) Provided diagnostic test services to the NIH Special Clinical Studies Unit for U.S. citizens being monitored or treated for Ebola infection (over 200 samples during the course of the outbreak).

7) Completed Competitive Prototype live agent testing for Filoviruses for the Next Generation Diagnostic System program of the JPEO, a subset of this data was used by the DoD to obtain a second emergency use authorization for the Biofire FilmArray system.

8) Produced stock of Ebola Makona, the 2014 West Africa outbreak strain, for the Critical reagents program from a primary clinical isolate. This will be the standard stock for use in medical countermeasure development.

9) Developed Ebola assays for potential diagnostic use on the MagPix system.

G. **Center for Aerobiological Sciences:**

1) An aerosol delivery system has been designed by CAS to study the host responses to aerosolized biothreat agents in an in vitro human tissue model. The system can successfully deliver small aerosol particles to replicate aerosol conditions used in animal studies.

H. **Virology:**

1) Established standard methods to evaluate immune correlates for filovirus vaccines in cynomolgus macaques.

2) Completed multiple studies to evaluate the VRP-GP monovalent vaccines for Ebola Zaire, Sudan Gulu and Marburg Angola in cynomolgus macaques against both parenteral and aerosol lethal challenges.

3) Evaluated the efficacy of a chimpanzee adenovirus 3 (ChAd3)-vectored vaccine to protect against a lethal challenge of Ebola Zaire in cynomolgus macaques

4) Demonstrated the efficacy of ZMapp, a 3 monoclonal antibody cocktail, to rescue cynomolgus macaques infected with a lethal dose of Ebola Zaire once they shows signs of disease, time to treat windows and carrying doses were evaluated.

5) Demonstrated transchromosomal cows can be used to produce polyclonal neutralizing antibodies against viruses of military importance that protect in animal models (published in Science Translational Medicine). This proof-of-concept work is now being used to move an anti-Ebola virus product towards clinical testing.

6) Supported Ebola vaccine development by determining neutralizing antibodies for multiple phase 1 clinical trials using a pseudovirion neutralization assay (two publications in the New England Journal of Medicine). This work has contributed to the rapid development and clinical testing of a candidate Ebola virus vaccine.

7) Initiated Phase 2a clinical trial of hemorrhagic fever with renal syndrome (HFRS) DNA vaccine and began to analyze serum samples using pseudovirion neutralization assay.

8) Completed a VLP-GP Ebola vaccine efficacy study to evaluate efficacy following challenge with lethal 8U and7U Ebola Zaire (Kikwit) virus challenge in cynomolgus macaques.

9) Evaluated efficacy of a triple alphavirus virus-like particle (VLP) vaccine against Inhalation Venezuelan Equine Encephalitis (VEE), Eastern Encephalitis (EEE) and Western Encephalitis (WEE) in a nonhuman primate model to support the JPM-MCS vaccine and therapeutics programs.

10) Continued to develop non-human primate animal models for aerosol alphaviruses (VEE, EEE, and WEE) for evaluation of both vaccines and therapeutics.

Resource Management and Budget

Funding projected in FY 2015: $136,669,357
$50,869,357 – RDT&E, Defense Wide
$1,800,000 – RDT&E, Army
$7,000,000 – RDT&E, DHP
$32,000,000 – O&M, DHP
$5,000,000 – O&M, Army
$40,000,000 – Reimbursable

Funding Received in FY 2014: $170,286,622
$52,722,141 – RDT&E, Defense Wide
$3,194,049 – RDT&E, Army
$36,328,000 – RDT&E, DHP
$33,694,100 – O&M, DHP
$5,085,023 – O&M, Army
$39,263,349 – Reimbursable

Funding received in FY 2013: $131,706,665
$52,283,264 – RDT&E, Defense Wide
$3,351,300 – RDT&E, Army
$13,166,437 – RDT&E, DHP
$24,866,000 – O&M, DHP
$5,197,175 – O&M, Army

$32,842,489 – Reimbursable

Funding received in FY 2012: $129,339,030
$64,905,328 – RDT&E, Defense Wide
$3,626,600 – RDT&E, Army
$2,432,895 – RDT&E, DHP
$30,239,000 – O&M, DHP
$4,419,660 – O&M, Army
$23,715,546 – Reimbursable

Challenges for FY 2014:

The Army mandated General Fund Enterprise Business System (GFEBS) was implemented in July 2012. GFEBs provides better vertical visibility into funds execution, but the system is very labor intensive. In 2014, activity also picked up related to the DoD's financial improvement and audit readiness (FIAR) plan. Increasing requirements related to accounting, time and attendance tracking and related business practices in general will drive up the manpower requirements of the laboratory independent of the research mission.

The organization continues to experience a heightened level of anxiety due to uncertainties regarding funding. While the overall level of funding has remained somewhat stable, the granular distribution of funds remains unclear until very close to the start of any given fiscal year. We have frequently experienced timing issues on the receipt of funds which has caused significant shortfalls in certain areas. Execution of funds in this kind of environment also remains a challenge.

Considerable attention was focused on laboratory infrastructure costs in 2014 by the CBDP community and the CBDP's Program Analysis and Integration Office. The CBDP is examining a path forward for managing and controlling laboratory infrastructure funding. Traditionally, the laboratory has assessed an overhead charge against incoming direct science dollars at the research project level. Lab management made adjustments to the overhead rates as necessary to ensure coverage of all infrastructure costs not supported by other specific programs, such as that provided by O&M. Going forward, the CBDP program may carve off a fixed amount of funding and provide that to the laboratory as infrastructure support.

Information Management

The Information Management Division implemented or supported several Information Technology (IT) projects that helped USAMRIID complete its mission. These projects include: 1) the CAC-enablement of systems residing in BSL/3 and BSL/4 laboratories; 2) establishment of Science & Research Network Enclave; 3) the virtualization of all network server devices; 4) the deployment of blackberry and computing devices for use downrange by Ebola response teams; 5) the establishment of a RIID-Express (SharePoint) site for IT application Development; and 6) site license management of research software.

Information Management spent considerable resources protecting the institute against cyberattacks through the implementation of an incident response plan, lifecycle management and standardization of IT equipment, enforcement of Information Assurance Vulnerability Alert program, implementation of encryption-at-rest, adherence to the Certificate of Networthiness requirement for software, and the Certification & Accreditation of all networked systems.

Information Management worked diligently to ensure the success of multiple systems through the design of the infrastructure for new 8100 facility. These systems include a Building Automation System (with GLP capability), Data Center, Wireless Knowledge Green, Cell Phone Repeater System, Voice-over-IP Telephone System, Building Security System, Science & Research Enclave Network, and conference room Audio/Visual Equipment

From a management standpoint, the Information Management Division began the implementation of a new workforce strategy that will add critical civilian positions to manage each of the core IT departments: Information Management, System Administration, Application Support, and Customer Services. Additionally, future versions of the USAMRIID organization chart will have the Information Management Division assume responsibility for the Library, Visual Information, and Records Management.

Operations

During FY14 the Operations section managed over 610 taskings and 4 FOIA responses, deployed 38 mobile training teams to 18 locations, trained 568 personnel on HQDA mandatory training, managed 442 OCONUS TDY/Leave requests, and coordinated for 189 Soldiers to attend military schools. Overall, the number of taskings increased by 37 percent from the previous fiscal year.

The Operations Section was responsible for deploying 11 teams to Liberia with mission essential equipment in support of building capacity and capability to fight the Ebola Virus Disease in West Africa. They ordered and managed bills of materials in the amount of $552,954.48 for the Liberian Institute for Biomedical Research (LIBR) Lab. Operations conducted pre-deployment briefings to the LIBR Lab teams and ensured they were prepared with a pre-departure checklist and necessary equipment and supplies to deploy.

Operations coordinated transportation of LIBR Lab teams to and from the airport and updated the command team on departure and arrival in and out of theater. They coordinated Field Identification of Biological Warfare Agents (FIBWA) training for 11 LIBR Lab personnel in order to successfully conduct laboratory operations, assay use, and testing of skills in real-world scenarios. They conducted weekly teleconferences with the LIBR Lab teams to identify and discuss issues and synchronization, and supervised the packout of the teams for every rotation, which included special items such as Assays, Reagents, and Qiagen Kits.

Operations also ensured that all team members completed required training and had all required immunizations, passports, DD1610 (Authorization for TDY travel), and visas. They directed and coordinated personal protective equipment (PPE) training for 4,798 Soldiers in support of Operation United Assistance. Operations prepared 38 Mobile Training Teams (MTTs) to travel to 18 training sites CONUS and OCONUS to provide PPE training for deploying troops and MTF staff, and provided the OTSG and USAMRIID Command Group with weekly updates on PPE training. Operations ensured that all MTTs were well-equipped during training by inventorying all training supplies based upon the projected number of personnel to be trained, and briefed the MTT leaders on every mission and the type of training to be conducted.

Modernization

USAMRIID has added and upgraded a number of pieces of equipment bringing into the Institute new technology which will greatly enhance our research capabilities as we move forward into our transition.

Working with the principal investigators and the transition team, commonly used items have been identified in an effort to standardize equipment. This will save money by maximizing the maintenance services performed in-house and minimizing the use of commercial contractors. The Equipment Management Department is actively engaged with the transition team reviewing equipment requirements to identify and recommend other cost savings practices for equipment purchases, as plans continue for transition to the new USAMRIID building.

Logistics

USAMRIID Logistics processed 7906 government purchase card transactions totaling $8,664,783.61. 1094 line items for equipment and services exceeding $3000 were submitted through USAMRAA for processing and contract award. The division managed a Property Book (PB) valued at over $93M encompassing over 11,500 equipment records and 156 hand receipts. PB staff processed over 5,200 property transaction records while conducting and managing other property book actions. Property loss was less than one percent of the total value of the PB. Logistics processed over 1,500 equipment items through the Defense Reutilization Marketing Office (DRMO) valued at over $8.8 million; completed 7,443 equipment scheduled services, unscheduled services and technical inspections, accounting for 11,484 total man-hours; and maintained a 94% completion rate for equipment scheduled services.

Throughout the year, Logistics remained actively engaged with the transition team for the new USAMRIID, developing a transition support plan, a CONOP, and reviewing equipment requirements to identify and recommend cost savings practices for equipment purchases for the new facility. The Logistics staff attended many hours of DCO training in preparation for full implementation of the Defense Medical Logistics Standard Support (DMLSS) system. Full implementation did not occur because DMLSS was unable to process multi-year funds. The Joint Medical Logistics Functional Development Center (JMLFDC) is working on a fix, with an estimated completion date of May 2015.

Construction and Facilities Maintenance

USAMRIID completed 4478 individual preventative maintenance actions valued at $656,883 and 5479 labor hours, and 2745 minor repair actions at a cost of $379,251 and over 10,000 labor hours. Facilities management leveraged an Operations and Maintenance Engineering Enhancement (OMEE) Contract through the US Army Corps of Engineers, Huntsville Center, for certain specialized work to complete 101 additional contract repair actions at a cost of $725,504.The project management section completed nine (9) projects at a total of $6.3M, including a chiller plant replacement which provided 4400 tons of cooling and is located in the new facility, 1458.

Construction of the replacement Steam Sterilization Plant (SSP) reached 100% completion, which is to provide secondary steam sterilization of all biological waste effluent originating from USAMRIID's Biological Safety Level 3 and Level 4 laboratories, with a capacity to process up to 120,000 gallons of liquid waste daily. The plant remains in a non-operational condition pending correction of approximately $3.0M in requirements to bring the plant to code and operability. Once transition to the new plant is completed, the existing SSP will be decommissioned by the US Army Garrison, Fort Detrick. USAMRIID continues to diligently pursue this goal.

Construction of the USAMRIID Replacement Laboratory, Building 8100, continued and recovery from the previous year's fire was ongoing. A new initial occupancy date of June 2016, and final occupancy date of June 2017, was determined.

Health and Environment

N/A

Other

Biological Surety at USAMRIID

The Biological Surety division at USAMRIID successfully managed the Centers for Disease Control and Prevention (CDC) registration of the Institute for work involving Biological Select Agents and Toxins (BSAT). USAMRIID's Select Agent Program enrollment and sustainment in 2014 exceeded 440 individuals approved by the Federal Select Agent Program (FSAP) to have access to BSAT. USAMRIID's Biological Personnel Reliability Program (BPRP) enrollment and sustainment through continuous monitoring exceeded 330 certified individuals in 2014. Biosurety staff submitted about 100 applications for personnel security investigations for USAMRIID employees to meet the requirements of new enrollment/continuous enrollment in the Select Agent Program and BPRP. A Certifying Official (CO) roundtable is held at regular intervals to address issues concerning BPRP. Biosurety staff ensured that individuals approved to access CDC-registered containment laboratories and BSAT storage spaces received the required training to remain in compliance with FSAP, DoD and Army regulations.

Biosurety staff conducted 34 physical inventory audits of the BSAT holdings of CDC-registered principal investigators (PIs) who have been approved to hold BSAT inventories in 2014. Staff continuously monitored BSAT inventory in the Agent Inventory Management System (AIMS) database, and also participated in upgrades to the new DoD BSAT database. Biosurety staff processed documents to obtain CDC/USDA permits/approvals for all BSAT transfers external to the institute and also coordinated these BSAT transfers. All internal BSAT transfers were monitored and facilitated through BSAT chain of custody forms. The Biosurety staff working with CDC-registered PIs and their technical staff also: (1) relabeled BSAT specimens with uniform labels recommended by the Department of Army Inspector General (DAIG) technical inspection team; (2) reviewed over 350 BSAT chain of custody forms and over 90 BSAT destruction documents; (3) identified and destroyed BSAT materials that were no longer needed for current or future scientific investigations; and (4) verified BSAT inventories and wrapped those validated boxes with tamper-evident materials within containment laboratories. The Biosurety Division has made significant progress in 'Centralized BSAT Management.' More than 50% of BSAT stocks are managed by Biosurety at this time. Progress in this area is being made through a BSAT Inventory Management Working Group consisting of Responsible Official, Alternate Responsible Officials, at least one principal investigation from each scientific division, and other technical staff.

On a monthly basis, Biosurety staff also verified individual access to CDC-registered biocontainment laboratories and BSAT storage spaces to ensure that only approved individuals have access to these areas. Closed circuit television (CCTV) covering CDC-registered containment laboratories and BSAT storage spaces was monitored periodically to verify compliance in addition to 24/7 and 365 day-monitoring of CCTV by the Physical Security staff. The Biosurety Division also reported all incidents involving potential BSAT exposures within the CDC/USDA registered containment laboratories and BSAT storage spaces to MRMC and CDC using APHIS/CDC Form-3 in accordance with FSAP, DoD and Army regulations governing BSAT. There were no incidents involving theft or release of BSAT into the environment in 2014. Biosurety Division works closely with Safety and Security Divisions on all aspects of the Select Agent Program, including BSAT management. Members of Biosurety Division are active participants in the Institutional Biosafety Committee (IBC) and USAMRIID Safety Committee.

Since 2013, the Biosurety Division has been conducting reviews of all USAMRIID research proposals and related documents (e.g., progress reports, semi-annual and annual reports) to identify Dual-Use Research of Concern (DURC). In 2014, >350 research documents were reviewed. DURC semi-annual and annual reports were prepared and submitted through the proper channels.

In June 2014, Biosurety Division coordinated the 2-week combined Department of Army Inspector General (DAIG), CDC and U.S. Department of Agriculture (USDA) inspection of all CDC/USDA registered laboratories and storage

spaces containing BSAT materials. During the August-September 2014 period, USAMRIID responded to the White House Directive entitled "Enhancing Biosafety and Biosecurity in the US" by conducting an immediate sweep of USAMRIID laboratories and associated areas to identify unaccounted BSAT and ensure proper registration, safe stewardship, and secure storage and disposal. The Biosurety Division led these efforts, developed procedures to accomplish the necessary tasks to comply with this directive, and submitted the required report through the Command. The Biosurety Division managed the laboratory reports associated with this institute-wide inspection. In December 2014, the Division also coordinated the 8 day CDC/USDA inspection of USAMRIID Biological Safety Level-4 (BSL-4) and Animal Biological Safety Level-4 (ABSL-4) biocontainment laboratories.

Biosurety Division supported the Department of Defense, Defense Transportation Security Administration (DTSA) and the State Department by completing reviews on certain bacterial agents involved in Export Control regulations.

Biosurety staff prepared and submitted the following reports: (1) Biological Weapons Convention (BWC) reports, (2) annual BWC Confidence Building Measures (CBM) report, (3) Schedule-1 Chemical Weapons Convention (CWC) annual and semi-annual reports, and (4) Annual 100% BSAT inventory completion and certification report. The Biosurety Division developed a BSAT movement plan for the new USAMRIID transition team. The group also organized meetings between CDC/USDA inspectors and the transition support team to facilitate timely inspectionS and certification of the new USAMRIID Bldg. 8100.

Scientific Publications 2014

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USAMRIID Key Personnel – FY14 (1 Oct 13 thru 30 Sep 14)

Position	Title	Incumbency
Commander	COL Erin P. Edgar	30 Jul 13 -
Deputy Commander	COL (b) (6)	16 Aug 14 -
	COL (b) (6)	11 Apr 11- 15 Aug 14
Director of Administration	COL (b) (6)	16 Aug 14 -
	COL (b) (6)	15 Dec 11 – 15 Aug 14
Comptroller	MAJ (b) (6)	3 Sep 13 -
Science Director	(b) (6)	7 Sep 14 –
		1 Jul 11 – 6 Sep 14
Science and Professional		22 Apr 08 -
Science and Professional		22 Apr 08 -
Director, Security and Biosurety	LTC (b) (6)	28 May 10 -
Select Agent Management	(b) (6)	1 May 11 -
Safety, Radiation, and Environmental		16 Mar 08 -
Physical Security		12 Jan 14 –
		30 Dec 12 – 11 Jan 14
Aerobiological Sciences	LTC (b) (6)	2 Jan 14 -
	(b) (6)	15 Dec 11 – 1 Jan 14
Bacteriology	(b) (6)	1 Feb 08 -
Molecular and Translational Sciences	MAJ (b) (6)	7 Sep 14 -
	(b) (6)	30 Jan 12 – 6 Sep 14
Virology	(b) (6)	15 Dec 11 -
Diagnostic Systems	(b) (6)	3 Jan 10 -
Medicine	LTC (b) (6)	18 Jun 13 -
Business Plans and Programs	(b) (6)	30 Nov 05 -
Deputy Director, Research Support	LTC (b) (6)	16 Aug 14 -
	COL (b) (6)	22 Jul 13 -
Pathology	LTC (b) (6)	22 Jul 13 -
Veterinary Medicine	COL (b) (6)	1 Aug 11-
Non-Clinical Development	(b) (6)	1 Jan 13-
Budget and Travel		6 May 13 -
Facilities Management		30 Nov 05 -
Human Resources		5 Sep 04 -
Information Services		1 Oct 11 -
Visual Information		13 Sep 09 -
Logistics		20 Sep 04 -
Medical Library		9 Dec 85 -

Personnel Reliability	(b) (6)	2 Jun 13 -
Emergency Management		1 Oct 11 –

Strength Table

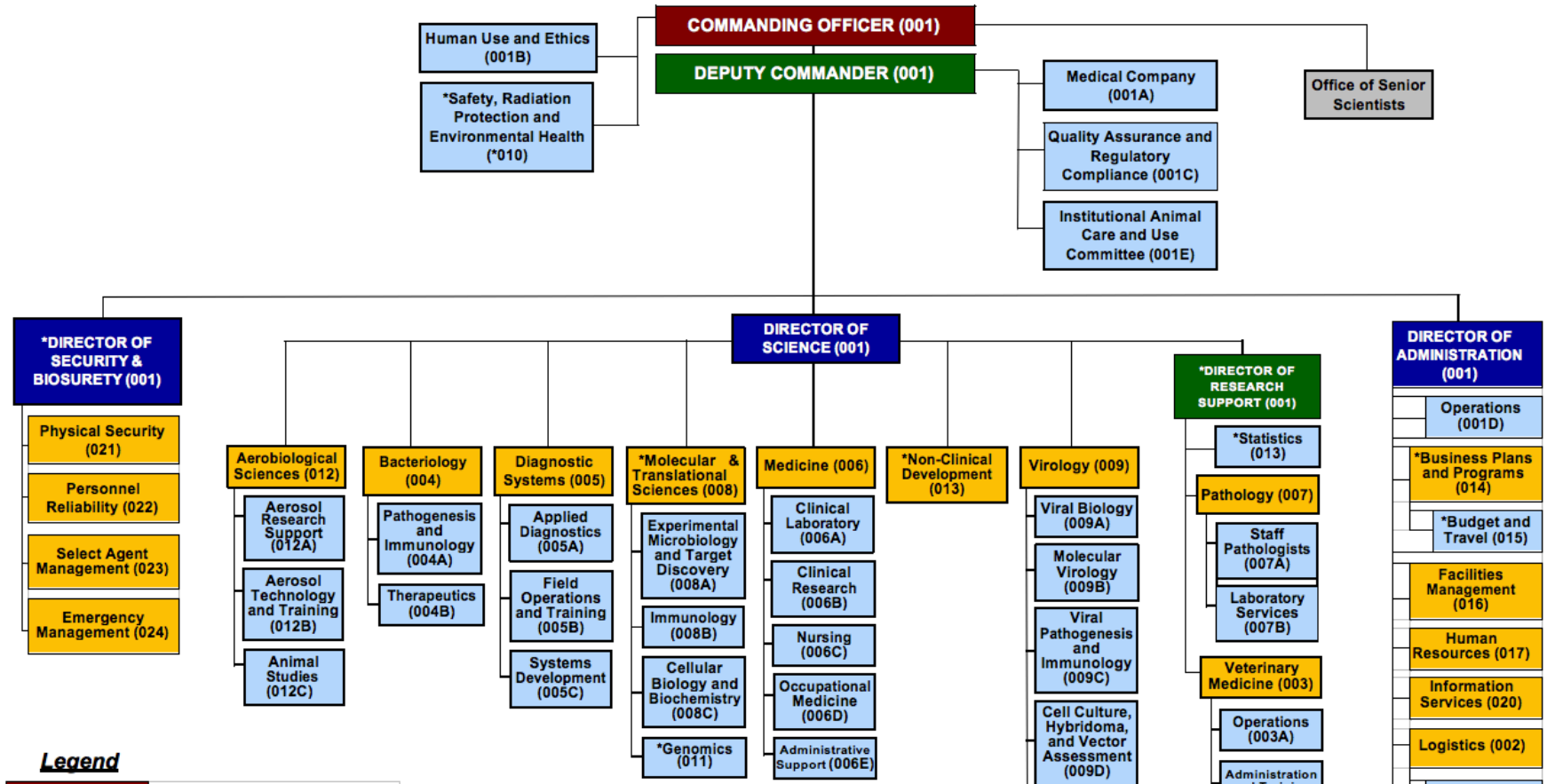
	Oct 13 Actual	Oct 13 Authorized	Oct 14 Actual	Oct 14 Authorized
Military	202	215	206	215
Civilian	306	266	285	266
Contractor	310	78	366	0
Total	**818**	**559**	**857**	**481**

Deployed PROFIS Soldiers

RANK/NAME	SPECIALTY	DEPARTED	RETURNED	DEPLOYING UNIT	PROFIS/MED AUG	BACKFILL
CPT (b) (4) [redacted]	71B	04/18/14	09/16/14	255th PM DET	MED AUG	None

USAMRIID ORGANIZATION STRUCTURE

As of 15 May 2014



Legend

COMMANDER
DEPUTY
DIRECTORATE
Division
Department
Will not be a separate paragraph on the TDA.

*Will be adjusted on TDA during next TDA update.

For Official Use Only

Section 25

Fiscal Year 2014
Annual Historical Report

U.S. Army Research Institute of Environmental Medicine

Mission

The U.S. Army Research Institute of Environmental Medicine (USARIEM) mission is to optimize Warfighter health and performance through medical research.

A. Location and Background Information

1) Located in Natick Massachusetts, USARIEM is internationally recognized as the DoD's premier laboratory for Warfighter health and performance research and focuses on environmental medicine, physiology, physical and cognitive performance, and nutrition research.

2) USARIEM publishes military guidance for operations in heat, cold and high-altitude environments and nutrition for health and performance.

3) In 2014 USARIEM composed a strategic planning team to look at the division structure, mission challenges and build a road map to FY 2020. The following sessions were conducted in 2014:

a. Meetings with senior science and resource management staff were held.

b. An institute-wide Strengths-Weakness-Opportunities-Threats (SWOT) online survey was placed on SharePoint.

c. A brainstorming session with a cross section of civilian, contractor and military staff was conducted.

i) Participants in all of these meetings were asked to help identify our issues, frame our essential competencies and build out possible solutions.

ii) Identified issues were grouped into three categories (Immediate, Near-term and Monitored) and recommendations for consideration were given to the Command and Board of Directors (BOD).

iii) Changes and solutions are expected to be addressed in FY2015.

B. Vision

1) Be recognized by the Department of Defense as the trusted leader in medical research for Warfighter health and performance optimization.

Organization

USARIEM Organization

The Institute is organized into five divisions: Biophysics and Biomedical Modeling, Military Nutrition, Military Performance, Thermal and Mountain Medicine, and Research Support. USARIEM's organization charts show the break down per division.

A. Divisions

1) The Institute is organized into five divisions: Biophysics and Biomedical Modeling, Military Nutrition, Military Performance, Thermal and Mountain Medicine, and Research Support.

a. Biophysics and Biomedical Modeling Division (BBMD)

i) Develops biomedical models and networked physiological sensor systems that enable Soldiers to predict and counter health threats from physical challenges, protective ensembles, non-agent chemical exposure, and extreme environments.

b. Military Nutrition Division (MND)

i) Conducts nutritional research that provides a biomedical science basis for developing new rations, menus, policies and programs to enable Warfighter health-readiness and optimal performance.

c. Military Performance Division (MPD) and Thermal and Mountain Medicine Division (TMMD)

i) In 2014, MPD and TMMD temporarily merged under one division known as Environmental Medicine and Military Performance Division (EMMPD), but each division kept their individual missions listed below.

- MPD
  - Conduct research to enhance the performance (physical, cognitive, behavioral and psychomotor) of military occupational tasks, or to prevent performance decrements due to physical overload, nutritional deprivation, environmental and operational stresses, and musculoskeletal injuries.
- TMMD
  - Conduct research to sustain and enhance performance (physical and cognitive) and minimize medical problems associated with military operations at environmental extremes (heat, cold & high terrestrial altitude). In addition, research supports military materiel developers of clothing, equipment, food and pharmaceuticals.

d. Research Support Division (RSD)

i) Provides administrative support and guidance to the science divisions.

B. Personnel and key changes. In FY14 there were a number of significant changes in key personnel within the organization. The USARIEM Organizational Chart as of 2 Dec 14 (Appendix XX) reflects the current structure while USARIEM Organizational Chart as of 13 Mar 14 shows the structure and leadership that was in place at the start of the fiscal year.

1) Command Team

a. Commander. COL Thomas G. Eccles III, M.D., became the 20th commander of the U.S. Army Research Institute of Environmental Medicine in a June 9 change of command ceremony vice COL Deborah L. Whitmer.

b. Deputy Commander and Executive Officer. In FY14 LTC (b) (6) assumed the Deputy Commander Position vice LTC (b) (4) and MAJ (b) (4) assumed the Executive Officer Position vice MAJ (b) (4).

2) Division Chiefs

a. Military Nutrition Division. In December 2013 (b) (6), Division Chief, Military Nutrition Division retires. (b) (6) was assigned as the Nutrition Chief in (b) (6) place.

b. Military Performance Division. In August 2014 (b) (6), Division Chief, Military Performance Division retired. (b) (6) Division Chief, Thermal and Mountain Medicine, assumed the Military Performance Chief role, temporarily combining TMMD and MPD.

Statistical Data

N/A

Healthcare Delivery

Office of Medical Support and Oversight (OMSO)

Mission

As special staff officer to the USARIEM Command, the Director of OMSO provides expert advice and guidance on health protection for the USARIEM military and civilian population along with the Human Research Volunteer population at Natick Soldier System Center (NSSC). OMSO duties include the planning, development and execution of new medical programs as well as execution of all existing health promotion functional responsibilities. As the source for health promotion programs, OMSO provides sound medical intelligence and guidance for readiness issues, health protection and safety.

A. USARIEM is not a medical treatment facility. Soldiers assigned to NSSC receive medical care from Hanscom Air Force Base, in Bedford, MA. Soldiers' medical and dental records are maintained by the Air Force clinic personnel.

B. After being seen at the Hanscom clinic, Soldiers present any duty limitations/profiles to unit Command. Any notable trends or significant issues involving recurring injuries or profiles are reviewed by OMSO and Command as part of unit health promotion programs. No significant trends or issues have been noted over the past year. In the future, the newly formed Health Promotion Team, established as part of the Ready and Resilient Campaign, will monitor profile trends in relation to other unit programs (physical training, Safety Program, Equal Opportunity, etc.).

Veterinary Services

Veterinary Support and Oversight Branch

Mission

The Veterinary Support and Oversight Branch (VSOB) supports biomedical animal research at USARIEM to sustain and improve Warfighters' health and performance. VSOB provides veterinary support, consultation, research support, investigator training and review of research protocols involving animals. VSOB is responsible for disease detection and surveillance, prevention, diagnosis and treatment, handling and restraint training, use of anesthetics, analgesics and tranquilizers. VSOB provides staff training in the care and use of lab animals, establishes and monitors the occupational health and safety program, monitors for zoonotic diseases and advises for and monitors biohazard control policies and procedures relevant to the animal care and use program. The Attending Veterinarian (AV) oversees and provides training on American Veterinary Medical Association approved methods of euthanasia, surgical and post-surgical care and monitors animals' physical and psychological well-being. The AV oversees the husbandry program, reviews and approves all animal care and use as voting member of Institutional Animal Care and Use Committee (IACUC).

A. Significant Accomplishments in 2014

1) CPT (b) (4)

a. Appointed as member of USARIEM Credentials Committee.

b. Attended 65th AALAS National Meeting, improving knowledge base as Attending Veterinarian at USARIEM and as voting member of the IACUC.

c. Attended 28th Annual Charles River Short Course on Laboratory Animal Science.

d. Provided veterinary support to 326 animals and four active animal research protocols.

e. Procured two new rodent anesthesia machines in excess of $10,000, resulting in better anesthetic procedures for animals and decreasing occupational health risks associated with older, malfunctioning equipment.

2) (b) (6)

a. Served as the alternate attending veterinarian in the absence of the Chief, VSOB.

b. Played an integral role in preparing USARIEM Program Description and VSOB Standard Operating Procedures (SOPs) for 2015 Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) site visit.

c. Served as an alternate voting member of the IACUC in the absence of the AV.

3) SSG (b) (4)

a. Accomplished Assistant Laboratory Animal Technician (ALAT) certification through the American Association for Laboratory Animal Science (AALAS) Technician Certification Program.

b. Attended Army Master Fitness Trainer Course and Army Basic Instructor Course.

c. Served as USARIEM Sexual Harassment / Assault Response and Prevention (SHARP) representative.

d. Played an integral role in preparing USARIEM vivarium for 2015 Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) site visit.

4) SGT (b) (4)

a. Arrived at USARIEM as our new Animal Care Specialist (68T).

b. Played an integral role in preparing USARIEM vivarium for 2015 Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) site visit.

c. Attended Master Driver Course.

d. Participated in 2nd annual Battle Road Memorial March, honoring Massachusetts Soldiers who made the ultimate sacrifice in the service of their country.

e. Served as a Forum Panelist at the 2014 Natick Soldier Systems Center (NSSC) Hispanic Heritage Month Observance.

5) (b) (6)

a. Accomplished Laboratory Animal Technologist (LATg) certification through the American Association for Laboratory Animal Science (AALAS) Technician Certification Program.

b. Attended 28th Annual Charles River Short Course on Laboratory Animal Science.

c. Appointed as the Institute $25,000 credit card holder.

d. Organized a new, hands-on, animal class to enhance the animal use training for IACUC committee members, veterinary staff, and animal users at USARIEM.

e. Conducted training on the proper disposal of Regulated Medical Waste (RMW) for USARIEM personnel.

Training and Education

Military Training and Education

The military detachment was successful on all training endeavors.

A. Training

1) Physical training

a. 100% of unit passed APFT

i) Nine APFT Badges of Excellence

ii) Unit average of 269

2) Warrior training

a. Completed all warrior tasks and battle drills

b. Conducted training on the following ranges:

i) M203

ii) HMMWV Egress Assistance Trainer (HEAT) – Egress Trainer

iii) Survival training

iv) Military Operations in Urban Terrain (MOUT) tactics

v) Land Navigation

3) Mandatory Training

a. Maintained training above 95% for all AR 350-1 training

b. Resiliency

i) Conducted Master Resiliency Training (MRT) course IAW the Ready and Resilient Campaign (R2C)

- One certified Master Resiliency Trainer makes scheduling training difficult

c. SHARP

i) Participated in monthly command team training in order to streamline protocols on the installation as a tenant unit.

d. Safety

i) Quarterly training conducted

- Assisted with two garrison safety days

B. Education

1) Non-Commissioned Officer Education System (NCOES)

a. Warrior Leaders Course

i) Four graduates

ii) Two made Commandant's List

b. Advanced Leader Course (ALC)

i) Four graduates

c. Senior Leader Course (SLC)

i) Two graduates

2) Professional Development programs

a. Officer Professional Development /Non-Commissioned Officer Development

i) Conducted monthly

3) Officer Education System

a. Captain Career Course

i) Four graduates

b. Intermediate Leader Education

i) One graduate

Training and Education

Civilian Training and Education
The Civilian Training Manager was successful in providing the following training endeavors.

A. Training

1) Civilian Awards

2) Helping workforce figure to out IDP (still in the process)

B. Education

1) Civilians who began working at USARIEM after 2006 were required to complete the Foundation Course via distance learning in the Army Learning Management System. All USARIEM civilians have satisfied this requirement.

2) USARIEM personnel were given an opportunity for onsite Acquisitions training. This resulted in many of our CORs and science support staff being level 1 certified.

Research and Development Program

Biophysics and Biomedical Modeling Division (BBMD)

Mission

Development and utilize integrated wearable physiological sensor systems and biomedical models to identify health threats and sustain Warfighter physical performance in extreme training and operational environments.

A. Research topic areas / subprograms**.** BBMD's multi-disciplinary, product-oriented research effort focuses on three main areas:

1) Development and use of real-time physiological monitoring systems.
2) Biophysical assessments of military clothing ensembles.
3) Biomedical modeling and decision aids.
4) Real-time physiological monitoring and health status predictive and estimative algorithm development. Biophysical assessments of existing and next-generation ensembles and equipment are conducted regularly, enabling quantifiable evaluations of items as well as key information for informing safe training guidance, and for modeling applications. BBMD is a leader in modeling and simulation to predict human responses to varied activities, environments, clothing and equipment, and individual variability.

B. Budget. BBMD receives 6.2, 6.3, and 6.4 funding. Division activities are funded primarily by 6.2-6.3 US Army RDT&E core funds with minor reimbursable funding. Significant bioengineering efforts, primarily in collaboration with MIT Lincoln Laboratory, are funded by 6.3-6.4 Defense Health Protection (DHP) monies.

C. Personnel. BBMD internal personnel strength totals 19 individuals: 13 DA civilians, one military enlisted, and five ORISE fellows. This group includes six PhDs, one MD, six Masters and five Bachelor level employees.

D. Projects. BBMD efforts, which align with identified DoD research and capability gaps, include:

1) Incremental development, validation, use, and transition of integrated system of wearable real time physiological status monitoring (RT-PSM) technologies for dismounted operations. This effort is spearheaded by USARIEM scientists and engineers in a collaborative partnership with the Massachusetts Institute of Technology Lincoln Laboratory (MIT LL), a Federally Funded Research Development and Engineering Center (FFRDC). User communities and system integrators include Product Director Soldier Systems Integration (PD SS&I) and Product Manager Soldier Protective Equipment (PdM SPE) within the Program Executive Office Soldier (PEO-Soldier), the USMC Marine Expeditionary Rifle Squad (MERS), and the Army National Guard 95th and 1st Civil Support Teams – Weapons of Mass Destruction. During this FY the BBMD team, in close collaboration with MIT Lincoln Laboratory, conducted numerous field studies, data analysis efforts, and engineering development efforts to improve reliability, accuracy, utility, and acceptability of these integrated systems.
2) Participated in collaborative in-theater research protocol with Marine Expeditionary Rifle Squad (MERS) and MIT Lincoln Laboratory (MIT LL), collecting data using noise dosimetry, doubly labeled water, and physiological monitoring data from 19 Marines test volunteers exposed to harsh acoustic environments and engaged in combat operations in Afghanistan.
3) In support of PEO-Soldier, performed assessments of Army physical fitness uniforms (APFU) and found that the new black APFU t-shirt will impose slightly less thermal burden on Soldiers than the legacy gray Army IPFU t-shirt.
4) Working with the USAF, developed a new method for evaluating performance of winter weather ensembles using manikin tests and modeling approach for prediction of cold weather injuries.
5) Monitored thermal strain in real-time of soldiers performing chemical, biological, radiological, and nuclear (CBRN) training. Demonstrated the usefulness of RT-PSM systems and on-body information display concepts. Observed and documented individual differences in thermal strain levels after walking for approximately 40 min in Level A CRBN personal protective equipment (PPE).
6) Initiated field collection of continuous high-resolution measurements of metabolic cost of soldiers moving over complex terrain. This data will be used to evaluate the validity of existing biomedical models and provide meaningful scientific insights to guide the revision and updating of existing doctrine for foot marches (FM 21-18 Field Manual - Foot Marches).
7) Performed biophysical assessments and tradeoff analyses of existing and prototype body armor configurations, chemical protective clothing, and cold weather ensembles for DoD customers.

E. Major challenges. Protracted decision-making process for non-Governmental conferences, and unrecognized risks of decreased participation in non-Governmental meetings (see: http://www.gao.gov/products/GAO-15-278).

F. Milestones achieved. BBMD established several Technology Program Agreements (TPAs) and Memorandum of Agreements (MoAs) forming complementary and high-quality partnerships to develop meaningful scientific advancements. These advancements have also been further extended into product transition paths via Technology Transition Agreements (TTAs). These formalized TTAs exist primarily among USARIEM, MOMRP, and USAMMDA, with anticipated transitions to broader DoD communities.

1) Current TTAs include:

a. Real-Time Physiological Status Monitoring system (RT-PSM)
b. Mobility Decision Aid (MDA)
c. Core temperature from heart rate prediction algorithm (with a formal transition planned to Program Executive Office Soldier (PEO-Soldier).

2) Pending TTAs include:

a. (b) (4) [redacted]

b. (b) (4) [redacted]

G. See attached appendix (BBMD Research and Development Appendix) for a list of publications, presentations, key briefings, information papers and patents.

Research and Development Program

Military Nutrition Division

Mission

The overarching mission of this program is to conduct nutrition research that provides the biomedical science basis for developing new rations, menus, policies and programs to enable Warfighter health readiness and optimal performance.

A. Research topic areas / subprograms

1) Recovery nutrition (MOMRP Task Area B).
2) Healthy eating (MOMRP Task Area B).
3) Physiological resilience (MOMRP Task Area Q3).
4) Dietary supplement use within the military (DHP JPC-5).

B. Budget. In FY14, the military nutrition research program received $6.9M of research funding from Army RDT&E, Army O&M, and DHP RDT&E fund sources.

C. Personnel. The program was executed using 42 FTEs that include Army civilian, military personnel, contractor supplied personnel, and ORISE fellows.

D. Projects

1) MOMRP Task Area B, Recovery Nutrition. The near term objectives are to assist replenishment during recovery, promote anabolism in muscle and bone, promote resistance to stressors, enhance cognitive function, accelerate recovery from illness/injury, and to determine the influence of body composition on long-term health.

a. Skeletal Muscle Metabolic and Physical Performance Responses to Operational Stress: optimizing recovery nutrition, studied nutritional regulators of muscle recovery. Data collection was completed in FY14 and manuscripts are in preparation.
b. Mechanisms underlying effects of dietary protein on calcium absorption, is using a cell culture model to improve calcium absorption and bone health. Project is on-going.
c. Nutrition Support for Metabolic Recovery, is examining the efficacy of nutritional interventions on local immune response during wound healing. During FY14, experiments were performed to quantify the impact of sleep deprivation on wound healing rate; these data form the basis for effectiveness of the nutritional interventions.
d. Impact of Dietary Protein Level and Weight Loss on Mineral Status in Obese Rats (16320), is identifying factors affecting the absorption of nutrients that contribute to bone structure and function. Project is on-going.
e. An Environmental Intervention in Military Dining Facilities examined the efficacy of labeling plates and trays with the USDA MyPlate image on diet quality during garrison feeding. Data collection was completed in FY14 and papers/reports are being generated.

f. Association between body weight and debilitating health conditions is examining the health implications of Military personnel being overweight. The project is on-going.
g. The Optimal Omega-3 Diet Study is determining the effectiveness of a novel dietary intervention on essential fatty acid status and the physiological impact of increasing the n-3 index. Data collection was completed 1QFY14, data analysis and report generation is underway.
h. Improving Soldier Essential Fatty Acid Status with a Dining Hall Intervention, is determining the cost/benefit of swapping out dining hall foods with ones having low n-6 and high n-3 polyunsaturated fatty acids composition. The project is on-going.
i. An Environmental Intervention in Military Dining Facilities studied the effectiveness of dining hall manipulations on self-selected diet quality. Data collection was completed 3QFY14. Data analysis and report generation are underway.

2) MOMRP Task Area Q3, Physiological Basis of Resilience

a. Changes in Behavioral, Physiological and Nutritional Status during Survive, Evade, Resist, Escape (SERE) School, is investigating how various potential biomarkers change during severe stress relative to cognitive performance and mood state scores.
b. Effects of deployment on nutritional, inflammation, and health status of US Army Special Operations Soldiers, examined changes in nutritional status with deployment. Data collection was completed and report generation is in progress.

3) DHP and extramurally funded efforts

a. Brain Energy and Cognition, studied the impact of multiple days of very low energy intake (independent of food volume) on cognitive function and satiety. Data collection was completed and reports are in preparation.
b. Optimizing vitamin D status during Air Force basic military training: A randomized, double-blind, placebo-controlled trial. This project examined the effectiveness of vitamin D and calcium supplementation on bone architecture and influence of genetic polymorphisms on responsiveness. Data collection was completed during FY14 and data analysis is underway.
c. DHP Dietary Supplement Work. Examines dietary supplement use amongst military members and the factors contributing to their popularity.

E. Major challenges

1) Contracting process became increasingly onerous and processing time delayed acquisition of experimental items.
2) Inability to hire term employees forced reliance on contractor and ORISE fellows to meet manpower needs.

F. Milestones achieved

1) Demonstrated role for higher protein diets in sparing lean body mass during energy deficit in laboratory study.

2) Determined that high protein diets increase intestinal calcium transport and is associated with less bone turnover during energy restriction.
3) Demonstrated that calcium and vitamin D supplementation maintains parathyroid hormone and improves bone density during initial military training.
4) Completed pilot “My Plate” dining intervention at Natick garrison and US Coast Guard Station, Boston, MA.
5) Demonstrated efficacy of suction blister model for assessment of local inflammatory/wound healing response.
6) Established that the n-3 index (a biomarker of tissue fatty acid health status) can be improved to levels similar to what is achieved consuming a Mediterranean diet by dietary substitution of eggs, chicken meat and oils, dressings, sauces, and spreads with lower n-6 and higher n-3 composition.
7) Completed observational assessment of relationship between physiological biomarkers and resilience in US Army Survive, Evade, Resist and Escape (SERE) training.
8) Developed relationship with elite US Army Special Forces unit and collected physiological biomarkers pre/post deployment.
9) Quantified the energy cost of extreme cold weather military field exercise and impact on lean body mass.
10) Identified that military women have a higher use prevalence of DS and multi-vitamins/multi-minerals than males.
11) Demonstrated that dietary supplementation with the catecholamine neurotransmitter precursor tyrosine is able to sustain anger during multiple days of extreme psychological stress.

G. Highlights and Notable Events

1) Published 25 full length peer-reviewed publications (See MND Research and Development Appendix).
2) Staff were invited to speak at several notable events (See MND Research and Development Appendix).

a. (b) (6) presented lecture to the OTSG on role for nutrition in sustaining cognitive performance at Brain Health Consortium, Defense Health Headquarters, Falls Church, VA, April 10-11, 2014.
b. (b) (6), back-briefed MG Ridge and CSM (b) (4) of TRADOC on benefits they have observed in female recruit health provided with iron supplementation and more recently with calcium plus vitamin D supplementation, TRADOC HQ, April 1, 2014.
c. (b) (6) presented “Fundamentals of Vitamin Stabilization for NASA Workshop investigating human travel to Mars,” Houston, Texas, February 10, 2014.
d. (b) (6) presented lecture on iron status and female Warfighters to attendees of the Women in Combat meeting, Uniformed Services University for Health Sciences, Bethesda, MD, August 27, 2014.
e. (b) (6) presented “Iron status and female Warfighters: screening and treatment programs” to the DoD Nutrition Subcommittee, Uniformed Services University for Health Sciences, Bethesda, MD, August 27, 2014.
f. (b) (6) presented “The Ubiquitous Role of Zinc in Health and Disease” at Harvard School of Public Health, Cambridge, MA, February 18, 2014.

3) Customer Service:

a. MND staff are assisting USASOC by evaluating the efficacy of a dining hall intervention USASOC-THOR^3 have implemented to improve Soldier diet quality.
b. (b) (6) participate on the Surgeon General's Performance Triad Nutrition Working Group.
c. (b) (6) represents the DoD on the Federal Working Group for Nutrition.

H. See attached appendix (MND Research and Development Appendix) for a list of publications, presentations, key briefings, information papers and patents.

Research and Development Program

Military Performance Division

Mission

The MPD mission is to develop knowledge and materiel to maximize and sustain warfighter physical and cognitive performance, and prevent, mitigate, and recover from musculoskeletal injury. As of the end of the year, the total personnel for the division was 44 consisting of 11 Federal Civilian Employees, 16 Uniformed Members, and 17 interns, IPAs or contractors. Under the direction of one S&T manager, sixteen principal investigators are responsible for developing and conducting the division's research program. MPD's research program is managed and Army RDT&E funded within the USAMRMC Military Operational Medicine Research Program (MOMRP) portfolio organized into four task areas with a total Army RDT&E FY14 budget of $5.01M. In addition to the Army RDT&E funded projects, three research projects were funded by Defense Health Program grants.

A. Research Program Activities

1) Physiological Mechanisms of Musculoskeletal Injury (MOMRP Task Area S).

a. Research Top Areas / Subprograms

i) Determine the roles of endocrine and intracellular signaling molecules involved in skeletal muscle and bone development, regeneration, and repair utilizing cell-based, animal, and human models for transition to clinical trials.

ii) Identify the ideal bone density and structure that offsets risk of stress fracture.

iii) Utilized the Total Army Injury and Health Outcomes Database (TAIHOD) to identify situations that create unnecessary musculoskeletal risk-hazards, and make recommendations for improvement.

b. Army RDT&E Budget

i) $2.8M

c. Projects

i) Effects of inflammation on sclerostin-mediated bone formation.

ii) Role of p110beta in growth factor-mediated skeletal muscle repair and regeneration.

iii) The cost of Basic Combat Training (BCT) Injuries.

iv) Effect of Increasing Load Carriage Weights on Biomechanics and Metabolic Cost in Marines (extramural performer Naval Health Research Center).

v) Development of a Texterity device for assessment of thumb dexterity.

vi) Psychosocial Adaptation to Upper Extremity Limb Salvage: A Prediction Model.

vii) Effects of muscle temperature and acute-chronic heat stress on skeletal muscle injury susceptibility in humans.

viii) Delineating the Role of Matrix Metalloprotease (MMP) Inhibition on Skeletal Muscle and Bone Function/Remodeling Post-Injury.

ix) A novel marker for diagnosing and potentially preventing skeletal muscle injuries (extramural collaborator: University of Connecticut).

x) Effects of soccer training history on tibial bone strength and mechanical properties during load carriage in females (extramural performer: Ball State University).

xi) Estimating peak skeletal stresses in military relevant cohorts.

d. Milestones Achieved: N/A

e. Highlights and Notable Events

f. Important papers / contributions

i) Henning PC, Scofield DE, Spiering BA, Staab JS, Matheny RW Jr, Smith MA, Bhasin S, Nindl BC. Recovery of endocrine and inflammatory mediators following an extended energy deficit. J Clin Endocrinol Metab. 2014 Mar;99(3):956-64.

ii) Ronald W. Matheny Jr., Melissa A. Riddle-Kottke, Luis A. Leandry, Christine M. Lynch, Mary N. Abdalla, Alyssa V. Geddis, David R. Piper, and Jean J. Zhao. Role of phosphoinositide 3-OH kinase p110β in skeletal myogenesis. 2014 Mol Cell Biol. In Press.

iii) Gong Z, Kennedy O, Sun H, Wu Y, Williams GA, Klein L, Cardoso L, Matheny RW Jr, Hubbard GB, Ikeno Y, Farrar RP, Schaffler MB, Adamo ML, Muzumdar RH, Yakar S. Reductions in serum IGF-I during aging impair healthspan. Aging Cell. 2014 Jun;13(3):408-18.

iv) Hughes JM, Smith MA, Henning PC, Scofield DE, Spiering BA, Staab JS, Hydren JR, Nindl BC, Matheny RW. Bone formation is suppressed with multi-stressor military training. European Journal of Applied Physiology. 2014;114(11):2251-9.

v) Urso ML, Hughes JM. Choosing Your Research Project: Framing the Problem, Research Hypotheses, Predictions. In: ACSM Research Methods. In Press.

vi) Seay JF, Fellin RE, Sauer SG, Frykman PN, Bensel CK. Lower Extremity Biomechanical Changes Associated With Symmetrical Torso Loading During Simulated Marching. Military Medicine 2014 179(1): 85-91.

vii) Seay JF. "Biomechanics of Load Carriage" book chapter in "Mechanobiology and Mechanophysiology of Military-Related Injuries." Submitted.

g. Invited speaking engagements, special guests, awards, patents, special assignments, other recognition

i) 96th Annual meeting of the Endocrine Society, Chicago, IL, June 2014.

ii) American College of Sports Medicine Annual Meeting, Orlando, May 2014.

iii) Military Health System Research Symposium (MHSRS), Ft. Lauderdale, FL, Aug 2014.

iv) ScanCo User's Meeting, Houston, TX, Sep 2014.

v) New England ACSM, Providence, RI, Nov 2014.

vi) World Congress Biomechanics, Boston MA, Jul 2014.

vii) 3rd International Congress on Soldiers' Physical Performance, Boston, MA, Aug 2014

viii) Association of Bone and Joint Surgeons, New York, May 2014.

2) Exploiting Inflammatory Processes to Maximize Skeletal Muscle Repair and Recovery (MOMRP Task Area R)

a. Research Top Areas / Subprograms

i) Identify biochemical, physiological, and genetic markers of pro- and anti- inflammatory events in skeletal muscle and bone using cell, animal, and human models for transition to clinical trials.

ii) Use computational analysis and modeling to elucidate and control molecular mechanisms of the inflammatory and regenerative response to tissue damage. Identify drugs or non-pharmacologic means to address inflammation for transition to clinical trials.

iii) Develop field-forward non-invasive tools capable of supporting decisions for treatment, prognosis, and return to duty following tissue injury for transition to clinical trials.

b. Army RDT&E Budget

i) $773K

ii) $304K (BHSAI)

c. Projects

i) Non-Invasive Optical Detection of Muscular Injury.

ii) Molecular Signatures and Functional Outcomes of the Inflammatory Response following Traumatic Skeletal Muscle Injury.

iii) Tracking Injury Resolution and Tissue Adaptations in Skeletal Muscle of Mice.

iv) A computational model of the inflammatory response to musculoskeletal injury in the mouse.

d. Milestones Achieved

i) Identified type IV collagen (Raman) and cytochrome C (DIR) as markers of tissue damage in live mice.

ii) Developed scorecard with genomic targets to calculate recovery timeline.

iii) Identified Annexin-V, Cofilin A, Cyclophilin A, and Cathepsin S as novel markers of MSI in which levels of these proteins are indicative of injury/recovery status.

iv) Developed and submitted protocol to track injury resolution and tissue adaptations in skeletal muscle of mice.

v) Developed model of inflammatory signaling in immune cells; currently validating model in cultured cells and mice.

e. Highlights and Notable Events

i) Important papers / contributions.

- Maurizio Tomaiuolo, Melissa Kottke, Ronald W. Matheny Jr., Jaques Reifman, Alexander Y. Mitrophanov. Computational modeling reveals signaling sub-networks with distinct functional roles in the regulation of TNF-α production (In review).
- Aguilar CA, Shcherbina A, Ricke D, Pop R, Carrigan CT, Gifford CA, Kottke MA, Meissner A. Integrative Genomics to Profile Lower-Limb Muscle Injury (In review).

ii) Invited speaking engagements, special guests, awards, patents, special assignments, other recognition

- 96th Annual meeting of the Endocrine Society, Chicago, IL, June 2014.
- Military health System Research Symposium (MHSRS), Ft. Lauderdale, FL, Aug 2014.

3) Return-to-Duty Standards and Strategies After Musculoskeletal Injury (MOMRP Task Area P2)

a. Research Top Areas / Subprograms

i) Define the primary conditions responsible for loss of duty time to focus resources in prevention & intervention.

ii) Identify musculoskeletal injury reporting variables impacting injury trends and RTD to develop strategies encouraging early intervention and prevention of further/future injury.

iii) Evaluate current practices (RTD assessments) and associated evidence of efficacy to develop improved guidelines for injury management.

iv) Identify & develop strategies to reduce recovery time following injury and transition to clinical practice.

v) Identify how components of soldier tasks contribute to musculoskeletal injury and develop new prevention guidance.

b. Army RDT&E Budget

i) $1133K

c. Projects

i) Intervention to Reduce Recovery Time and Attrition Among Injured Marines (extramural).

ii) Effect of Increasing Load Carriage Weights on Biomechanics and Metabolic Cost in Marines.

iii) Development of a Texterity device for assessment of thumb dexterity.

iv) The Runners and Injury Longitudinal Study: Injury Recovery supplement (TRAILS_IR) (extramural performer: Wake Forest University).

v) Effects of strength training on musculoskeletal injury rate in female runners: a phase I/II randomized clinical trial (extramural performer: Wake Forest University).

d. Milestones Achieved

i) Data collection underway on Intervention to Reduce Recovery Time and Attrition Among Injured Marines.

ii) Data currently collected on >85% of subjects. Data analysis ongoing.

iii) Collected normative Texterity data on approximately half of total sample (N=550). Additional data collection planned for spring 2015.

e. Highlights and Notable Events

i) Important papers / contributions.

- Seay JF, Fellin RE, Sauer SG, Frykman PN, Bensel CK. Lower Extremity Biomechanical Changes Associated With Symmetrical Torso Loading During Simulated Marching. Military Medicine 2014 179(1): 85-91.
- Seay JF. "Biomechanics of Load Carriage" book chapter in "Mechanobiology and Mechanophysiology of Military-Related Injuries." Submitted.
- Warr, B.J., Fellin, R.E, and Seay, J.F. (2014) A better understanding of barefoot running. Clinical Advisor, *http://www.clinicaladvisor.com/a-better-understanding-of-barefoot-running/article/328384.*
- Warr B.J., Fellin R.E., Frykman P.N., Sauer S.G., Goss D.L., and Seay J.F. (2014) Characterization of Foot Strike Patterns: Lack of an Association with Injuries or Performance in Soldiers. Military Medicine. In press.
- Sih, B.L, Negus, C.H. Physical Training Outcome Predictions with Biomechanics Part I: Army Physical Fitness Test Modeling. Military Medicine. Prepared.
- Negus, C.H., Sih, B.L. Physical Training Outcome Predictions with Biomechanics Part II: Overuse Injury Modeling. Military Medicine. Prepared.

- Invited speaking engagements, special guests, awards, patents, special assignments, other recognition American College of Sports Medicine Annual Meeting, Orlando, May 2014.
- New England ACSM, Providence, RI, Nov 2014.
- World Congress Biomechanics, Boston MA, Jul 2014.
- 3rd International Congress on Soldiers' Physical Performance, Boston, MA, Aug 2014.
- National Strength & Conditioning Association, TSAC Meeting, Orlando, Apr 2015.

4) Operational Exposure Dosimetry for Neurological and Physical Health (MOMRP Task Area F)

a. Research Topic Areas / Subprograms

i) Quantify dose-response relationships to operationally-relevant exposures (specifically permethrin and polycyclic aromatic compounds) in military personnel populations.

ii) Identify pertinent model parameters for assessment of real-time personal dose levels to operationally relevant exposures (such as fuels) among 2-3 high risk jobs.

iii) Identify longer-term neurological and/or physical health trajectories associated with operationally relevant exposures (e.g. permethrin or fuels) during military service.

b. Army RDT&E Budget

i) $973K

ii) $300K – Operational Petroleum Fuel Exposure Dosimetry: At-Risk Occupations (UFR rec'd July 2014)

c. Projects

i) Permethrin Dosimetry in Extreme Environments.

ii) Operational Petroleum Fuel Exposure Dosimetry: At-risk Occupations.

iii) Role of Operational Environmental Exposures to Petroleum-based fuels and neurological and physical health trajectories: A Prospective Cohort Study.

iv) Identify biomarkers for prospective risk assessment of brain health.

v) Examination of Operational Petroleum Fuel Exposure and Neurological Health in Low and High Risk Military Occupational Specialties.

vi) HJF/DHP – Permethrin Exposure Dosimetry: Biomarkers and Modifiable Factors.

vii) VA – Respiratory Health and Deployment to Iraq and Afghanistan.

viii) HJF – ANAM4: Select Psychometric Properties and Administration Procedures / TA C: Analysis of ANAM4TBI Predeployment Assessment Data: USARIEM-OTSG Research Collaborative.

ix) Jet Fuel Exposure and Neurological Health in Military Personnel.

x) Development of a Napthalene Exposure Dosimeter.

xi) Validation of Real-time Dosimeter Technology for Personal Napthalene Exposure to Improve Army Occupational health.

xii) Wearable Dosimeter for Personal Real-Time Assessment of Occupational Chemical Exposures.

d. Milestones Achieved

i) Wrote protocol, received all regulatory approvals to conduct human studies of permethrin dosimetry in extreme environments.

ii) Conducted field data collection Phase II Naphthalene Dosimeter Validation Study, Little Rock AFB.

e. Highlights and Notable Events

i) Important Papers & Contributions

- Proctor S.P, Maule A.L., Heaton K.J., Perry M., Adam G.E., Permethrin exposure from fabric-treated military uniforms under different wear-time scenarios. Journal of Environmental Science and Environmental Epidemiology. 2014; 24: 572-578.
- Rodrigues EG, Smith KW, Maule AL, Sjodin A, Li Z, Romanoff L, Kelsey K, Proctor SP, McClean MD. Urinary metabolite levels and the effect of GST polymorphisms among U.S. Air Force personnel exposed to jet fuel. J Occup Environ Med. 2014; 56(5):465-71.

ii) Invited speaking engagements, special guests, awards, patents, special assignments, other recognition

- (b) (6), April 10-11, 2014, OTSG invitee to Brain Health Consortium.
- (b) (6), Dec 9, 2014- invitee at Joint VA/DoD Epidemiology Summit for Inhalational Hazards in SW Asia.
- (b) (6), Dec 8, 2014- invitee at Joint VA/DoD Airborne Hazards Symposium.
- (b) (6), Co-Principal Proponent (co PI) - VA CSP #595 study: Respiratory Health and Deployment to Iraq and Afghanistan: A Pilot Study.
- (b) (6), Committees/Working Groups:
  - Member, DoD Naphthalene Dosimeter Advisory Group.
  - Executive Committee Member VA-funded CSP #585 study: Gulf War Illness Cohort and Biorepository.
  - Member, VA/DoD Airborne Hazards Analysis and Reporting Working Group.
  - Member, Federal Agency Exposure Science in the 21st Century (ES21) Data Collection and Management Working Group.

5) Defense Health Program Grant (DHP) Development of Military Occupation-Specific Physical Employment Standards, PI: (b) (6) .

a. Research Topic Areas / Subprograms

i) Develop and validate “simple” predictor tests to determine if an individual has the attributes needed to successfully complete critical physically demanding MOS specific tasks.

ii) Following industry standard and best practices, develop legally defensible physical pre-employment predictor tests for previously closed MOSs (11B, 11C, 19D, 19K, 13B, 13F, 12B).

b. DHP RDT&E Budget

i) $1735K

c. Projects

i) Development of Military Occupation-Specific Physical Employment Standards – Phase 1.

ii) Development of Military Occupation-Specific Physical Employment Standards – Phase 2.

iii) Development of Military Occupation-Specific Physical Employment Standards – Phase 3.

iv) Development of Military Occupation-Specific Physical Employment Standards – Phase 4.

d. Milestones Achieved

i) Wrote four project protocols and received all regulatory approvals to conduct human studies.

ii) Conducted data collection at three US Army locations: Ft. Stewart, GA, Ft. Lewis, WA, and Ft. Hood, TX.

iii) Completed phase 1 to conduct the job analysis of the 7 combat MOSs (11B, 11C, 19D, 19K, 13B, 13F, 12B).

iv) Completed phase 2 to assess the test-retest reliability of the task simulations for the 7 combat MOSs (11B, 11C, 19D, 19K, 13B, 13F, 12B).

v) Completed the first iteration of phase 3 to determine the concurrent variability of predictor tests to select Soldiers for the 12B Combat Engineer MOS.

vi) Developed and presented to TRADOC G3/5/7 three validated predictor tests for MOS 12B.

e. Highlights and Notable Events

i) Important Papers & Contributions

- Completed data collection on 408 Army personnel.
- Prepared and submitted to TRADOC G3/5/7 decision paper recommending 3 courses of action for implementing predictive tests for MOS 12B.

ii) Invited speaking engagements, special guests, awards, patents, special assignments, other recognition.

- Numerous 1-4 star briefings of sensitive data.

B. Defense Health Program Grant (DHP) to Henry M. Jackson Foundation, Permethrin Exposure Dosimetry. Biomarkers and Modifiable Factors, PI (b) (6) .

1) Research Topic Areas / Subprograms

a. Address the influence of permethrin exposure from wearing treated uniforms (ACU-Permethrin) on human dose and monitor the potential role of exposure on health and performance for accurate policy guidance regarding potential health risk.

b. Determine the modifiable factors that significantly influence human permethrin dosimetry as a result of wearing the ACU-Permethrin. Specifically, determine whether body weight/body mass index and physical activity patterns influence the absorbed permethrin dose.

2) DHP RDT&E Budget

a. $718.4K

3) Projects

a. Permethrin Exposure Dosimetry: Biomarkers and Modifiable Factors.

4) Milestones Achieved

a. Wrote protocol, received all regulatory approvals to conduct human studies starting summer 2015.

5) Highlights and Notable Events

a. Important Papers & Contributions

i) New Start.

b. Invited speaking engagements, special guests, awards, patents, special assignments, other recognition.

i) New Start.

C. Defense Health Program (DHP) Grant: Multi-Modal Platform for Determining Service Member's Cognitive Readiness in Operational Environments, PI: (b) (6) .

1) Research Topic Areas / Subprograms

a. Multi-Modal Platform for Determining Service Member's cognitive readiness in operational environments.

b. Identifying Biomarkers that Distinguish Post Traumatic Stress Disorder and Mild Traumatic Brain Injury Using Advanced Magnetic Resonance Imaging.

2) DHP RDT&E Budget

a. $300K

3) Projects

a. Multi-Modal Platform for Determining Service Member's cognitive readiness in operational environments.

b. Identifying Biomarkers that Distinguish Post Traumatic Stress Disorder and Mild Traumatic Brain Injury Using Advanced Magnetic Resonance Imaging.

c. Performance.

4) Milestones Achieved

a. Wrote biomarkers protocol, submitted for regulatory reviews.

5) Highlights and Notable Events

a. Important Papers & Contributions

i) Helfer, B.S., Quatieri, T.F., Williamson, J.R., Keyes L., Evans B., Greene, W.N., Vian T., Lacirignola J., Shenk T., Talavage, T., Palmer J., Heaton, K.J.. Articulatory Dynamics and Coordination in Classifying Cognitive Change with Preclinical Mtbi. *Interspeech* September 2014.

b. Invited speaking engagements, special guests, awards, patents, special assignments, other recognition

i) (b) (6) Articulatory dynamics and coordination in classifying cognitive change with preclinical mTBI. Poster presented at the 15th Annual Conference of the International Speech Communication Association, Singapore, 14-18 September 2014.

ii) (b) (6) Voice and ocular dynamics in classifying cognitive change with preclinical mTBI. Poster presented at the 4th Annual Traumatic Brain Injury Conference. Washington DC 16-17 April 2014.

iii) (b) (6) 10-11 April 2014, OTSG invitee to Brain Health Consortium.

D. Congressionally Directed Medical Research Program (CDMRP) Grant: Assessing Reliability and Validity of a Portable Visual Tracking System for Measurement of Attention Performance, PI: (b) (6).

1) Research Topic Areas / Subprogram

a. Validating a Novel Measure of Attention in U.S. Army Personnel.

b. Assessing Reliability and Validity of a Portable Visual Tracking System for Measurement of Attention Performance.

2) CDMRP RDT&E Budget

a. $149K

3) Projects

a. Validating a Novel Measure of Attention in U.S. Army Personnel.

b. Assessing Reliability and Validity of a Portable Visual Tracking System for Measurement of Attention Performance.

4) Milestones Achieved

a. Completed data collection of validation study, and data analysis with Boston University collaborators.

b. Data collection performed on reliability and validity study at Boston University.

5) Highlights and Notable Events

a. Important Papers & Contributions

i) Helfer, B.S., Quatieri, T.F., Williamson, J.R., Keyes L., Evans B., Greene, W.N., Vian T., Lacirignola J., Shenk T., Talavage, T., Palmer J., Heaton, K.J.. Articulatory Dynamics and Coordination in Classifying Cognitive Change with Preclinical Mtbi. *Interspeech* September 2014.

ii) Maruta J, Heaton KJ, Maule AL, Ghajar J. Predictive visual tracking: Specificity in mild traumatic brain injury and sleep-deprivation. Military Medicine. June 2014; 179:619-625.

iii) Heaton KJ, Maule AL, Maruta J, Kryskow EM, Ghajar J. Attention and Visual Tracking Degradation During Acute Sleep Deprivation in a Military Sample. Aviation, Space, and Environmental Medicine. May 2014; 85(5):497-503. DOI: 10.3357/ASEM.3882.2014.

iv) Tong J, Maruta J, Heaton KJ, Maule AL, Ghajar J. Adaptation of visual tracking synchronization after one night of sleep deprivation. Experimental Brain Research. Jan 2014; 232(1):121-131. DOI:10.1007/s00221-013-3725-8.

b. Invited speaking engagements, special guests, awards, patents, special assignments, other recognition

i) (b) (6) [redacted]. Eye tracking measures differentiate fatigue from concussion and recovery. Poster presented at the 10th World Congress on Brain Injury, San Francisco, CA, March 19-23, 2014.

E. Major Challenges:

1) The retirement of the Chief, MPD, July 1, 2014 created very significant challenges.

a. Due to the civilian employee hiring caps, and also due to loss in the prior year of two key MPD scientists that were being trained for management, the MPD was merged with the Thermal and Mountain Medicine Division (TMMD) under one division Chief.

b. The large size (80 personnel), and scope of the combined R&D programs strained effective management. Moreover, several investigators were assigned to be task area managers and needed to be trained up, further straining management and oversight of the division.

2) On a positive note, one MPD DB-03 scientist was selected for promotion to DB-04 by a Factor IV board, and three post-doc fellows were hired as term Federal civilian employees. However, the lack of intramural investigators necessitated outsourcing several projects to extramural performers.

a. New and more complex procurement processes increased the time spent by the research staff to prepare purchase requests and contracts.

b. Obtaining state-of-the-art data acquisition systems to support innovative research projects was hampered and in some cases prohibited due to MEDCOM IT Governance restrictions. Severe limits on attendance and participation in non-DoD conferences impeded developing novel research studies, collaborations with academics, and impaired professional development that has contributed to low morale.

Research and Development

Thermal Mountain Medicine Division

Mission

The TMMD mission is twofold. First the division develops knowledge and materiel to sustain and optimize warfighter performance and minimize medical problems during training and operations in the environmental extremes of heat, cold, high terrestrial altitude and occupational chemical exposure. Second, the division supports military materiel developers (clothing, equipment, food and pharmaceuticals) regarding health hazard assessment of thermal and hypoxic stress. As of the end of the year, the total personnel for the division was 36 consisting of 19 Federal Civilian Employees, five Uniformed Members and 12 interns. Under the direction of one S&T manager, thirteen principal investigators are responsible for developing and conducting the division's research program. TMMD's research program is managed and Army RDT&E funded within the USAMRMC Military Operational Medicine Research Program (MOMRP) portfolio organized into three task areas with a total Army RDT&E FY14 budget of $4.243M. In addition to the Army RDT&E funded projects, a Defense Health Program grant and Office of Naval Research grant funded research projects, and Army materiel developers funded test and evaluation of protective clothing and microclimate cooling systems as part of materiel health hazard assessment.

A. Research Program Activities

1) High Altitude and Cold Weather Operations: Injury and Performance Optimization (MOMRP Task Area T9).

a. Research Topic Areas & Subprograms

i) Validate and refine the USARIEM predictive models of altitude sickness, acclimatization status, and task performance.

ii) Develop a prototype Altitude Readiness Management System decision aid, and automated altitude acclimatization monitor.

iii) Determine if thermoregulatory fatigue increases susceptibility for non-freezing cold injury and hypothermia.

iv) Determine if altitude exposure increases susceptibility for non-freezing cold injury.

v) Identify biomarkers predictive of individual risk for developing altitude sickness.

b. Army RDT&E Budget

i) $1.172M

c. Projects

i) Field Validation of AMS Predictive Models and Development of Acclimatization and Work Performance Models.

ii) Mountain Medicine Database Repository and Predictive Modeling.

iii) Physical load and high altitude: Performance trade-off analyses (TeCD 2.A).

iv) User Test Protocol of the Altitude Readiness Management System (ARMS) Smart Device Software Application.

v) Regulation of circulating microRNA during exercise at low and high altitude: potential biomarkers of individual warfighter performance.

d. Milestones Achieved

i) Developed new predictive model of altitude acclimatization to 4050m, and new predictive model of work performance at altitudes between 2000-4500m. Transitioned to new ARMS app.

ii) Completed development and user testing of new Android-based ARMS mobile software application. Transitioned to USAMMDA PM-MSS.

e. Highlights and Notable Events

i) Important Papers & Contributions

- Kryskow M.A., B.A. Beidleman, C.S. Fulco, and S.R. Muza. Performance during simple and complex military psychomotor tasks at various altitudes. Aviation, Space, and Environmental Medicine 84: 1147-1152, 2013.
- Beidleman, B.A., C.S. Fulco, J.E. Staab, S.P. Andrew, and S.R. Muza. Cycling performance decrement is greater in hypobaric versus normobaric hypoxia. Extreme Physiology and Medicine 3: 8, 2014.
- DePasquale et al., Acute mountain sickness, hypoxia, hypobaria and exercise duration each affect heart rate. International Journal of Sports Medicine (accepted).
- O'Brien, C., J.W. Castellani, and S.R. Muza. Hypobaric hypoxia effects on finger temperature during and after local cold exposure. High Altitude and Biology (submitted).
- Beidleman, B.A., C.S. Fulco, S.P. Andrew, J.E. Staab, and S.R. Muza. Quantitative model of sustained physical task performance at varying altitudes. Journal of Applied Physiology (submitted).
- Contributed altitude and cold sections for ACSM's Guidelines for Exercise Testing and Prescription, 10th Edition.

ii) Invited speaking engagements, special guests, awards, patents, special assignments, other recognition

- Military Health System Research Symposium (MHSRS), Fort Lauderdale, FL, August, 2014.
- "Cold Extreme Environmental Operations: Optimizing Warfighter Performance in Extreme Cold", NATO HFM-255 Workshop, Norwegian Defence Research Organization, Kjeller, Norway, October, 2014.
- 3rd International Congress on Soldiers' Physical Performance, Boston, MA, August, 2014.
- Mountain Warfare Training Center, Jericho, VT, January and May, 2014.
- Arctic Equipment Symposium, Fort Wainwright, AK, Jan., 2014.

2) Hot Weather Operations and Hydration: Injury and Performance Optimization (MOMRP Task Area T10)

a. Research Topic Areas / Subprograms

i) Develop rodent heat stroke models to identify new biomarkers of multi-organ injury.

ii) Evaluate pharmacologic efficacy for mitigation of multi-organ injury in rodent heat stroke models.

iii) Refine hydration assessment sensor(s) prototypes and achieve Advanced Development Milestone A.

iv) Down-select noninvasive hydration assessment sensor(s) technologies.

v) Develop decision aids (matrix) for trade-off analyses of impact of body armor protection and load on aerobic performance capabilities in temperate and hot environments.

vi) Refine design of prototype Arm Immersion Cooling System.

vii) Develop a decision aid software application to provide accurate estimates of soldier hydration needs.

viii) Quantify dehydration effects on neuromuscular function and orthostatic intolerance.

b. Army RDT&E Budget

i) $2553K

c. Projects

i) Effects of dehydration on neuromuscular performance and sympathetic control of cardiovascular function.

ii) Physical load, Body Armor Protection Level (BAPL) and heat stress: Performance trade-off analysis (supports TeCD 2.a).

iii) Molecular level alterations induced by exertional heat stroke.

iv) Multiple hit hypothesis of heat stroke: effects of NSAIDs on multi-organ damage.

v) User Test of the USARIEM Soldier Water Estimation Tool (SWET) Smart Device Application.

vi) GAIA Proteomics study of hydration status (extramural performer).

vii) Study on effects of a rehydration beverage (Enterade) to recover from dehydration.

d. Milestones Achieved

i) Identified novel biomarkers of organ injury and validated point-of-care cTnI test strips for heat stroke severity assessment.

ii) Showed NSAIDs increase heat stroke mortality due to gut hemorrhaging – transition to rat exertional heat stroke model.

iii) Early transition or GAIA proteomics hydration assessment method to Advanced Development (pre-MSB) & signed TTA.

iv) Re-directed Army RDT&E funds to GAIA; original service contract converted to R&D contract.

v) Dehydration studies originally leveraged against HSM have begun & are on-going.

vi) Physical Load, BAPL heat study completed testing of 30 volunteers.

vii) Developed and validated Soldier Water Estimation Tool (SWET) algorithm in collaboration with MIT-Lincoln Laboratory.

viii) Developed SWET Android OS software application and field tested it at US Army Mountain Warfare School.

e. Highlights and Notable Events

i) Important Papers & Contributions

- Stallings et al., *BMC Genomics, 2014;* Ippolito et al., *BMC Physiol., 2014 (USACEHR).*
- 1 Chapter – Leon & Bouchama, *Compr. Physiol., 2014.*
- 1 eBook – Leon, Integrative Systems Physiology eBook series (in clearance).
- Cheuvront and Kenefick, *Comprehensive Physiology, 2014.*
- Cheuvront et al., *Clinical Chemistry and Laboratory Medicine, 2014.*
- Heavens et al., *American Journal of Clinical Nutrition, 2014 (Press Release).**

ii) Invited speaking engagements, special guests, awards, patents, special assignments, other recognition

- CRADA, Research Triangle Institute – leverage NIH funding for metabolomics analysis.
- Experimental Biology (two presentations).
- Military Health System Research Symposium (two presentations).
- University of Florida (one presentation).
- Soldier Water Estimation Tool (SWET) Technology Transition Agreement – USAMMDA PM-MSS.
- SWET user decision aid app transitioned to USAMMDA PM-MSS.

3) Localized Heating to Sustain Hand Dexterity, Thermal Comfort, and Finger Pulse Waves in Cold Warfighters (MOMRP Task Area T15)

a. Research Topic Areas / Subprograms

i) Increase finger blood flow, fine-motor dexterity and thermal comfort by 15% with facial heating during 2-h exposure to 0°C for integration into a microclimate heating prototype by FY2017.

ii) Increase finger blood flow, fine-motor dexterity and thermal comfort by 15% with focused forearm heating during 2-h exposure to 0°C for integration into a microclimate heating prototype by FY2017.

iii) Determine the reliability, reproducibility, and validity of a novel militarily-relevant dexterity assessment instrument during 0°C cold-air exposures by FY2017.

iv) Increase microclimate cooling (MCC) energy efficiency to extend battery life from 4 to 6 hours by integrating patented skin temperature feedback technology into current MCC systems by FY2018.

v) Increase effective surface area contact area of microclimate cooling tubes from 6% to 12% for integration into commercial MCC systems and determine the physical and cognitive performance improvements during exercise in 35°C/70% rh environments by FY2018.

b. Army RDT&E Budget

i) $518K

c. Projects

i) Focused Microclimate Heating to Improve Manual Dexterity.

d. Milestones Achieved

i) Wrote protocol, received all regulatory approvals, and constructed and tested heating devices in preparation for human studies.

e. Highlights and Notable Events

i) Important Papers & Contributions

- Castellani, J.W., R. Demes, T.L. Endrusick, S.N. Cheuvront, and S.J. Montain. Heat removal using microclimate foot cooling: a thermal foot manikin study. Aviation, Space, and Environmental Medicine 85: 445-448, 2014.

ii) Invited speaking engagements, special guests, awards, patents, special assignments, other recognition

- Arctic Equipment Symposium, Fort Wainwright, Alaska, January 2014.

- Cold Extreme Environmental Operations: Optimizing Warfighter Performance in Extreme Cold, NATO HFM-255 Workshop, Norwegian Defence Research Organization, Kjeller, Norway, October 2014.

4) Defense Health Program Grant (DHP), Experimental and Field Validation of Biomarkers and Risk Factors of Heat Injury/Stroke Susceptibility, PI: (b) (6) .

   a. Research Topic Areas / Subprograms

      i) Identify sensitive biomarkers, molecular inflammatory pathways and risk factors of heat injury/stroke susceptibility.

      ii) Delineate the impact of several risk factors on heat injury/stroke susceptibility in hot, humid environments in support of potential Pacific Rim Theater Operations.

      iii) Characterize physiological and cardiovascular responses to multiple environmental stressors.

      iv) Support integration of cardiovascular measurements into medic-based tools (e.g., improved ECG diagnostics) at point-of-contact for improved doctrine, prevention and treatment programs.

   b. DHP RDT&E Budget

      i) $407K

   c. Projects

      i) Identification of Novel Risk Factors that Increase Heat Stroke Susceptibility in Mice (Mus musculus) and Rats (Rattus norvegicus).

   d. Milestones Achieved

      i) Wrote protocol, received all regulatory approvals to conduct animal studies in FY15.

   e. Highlights and Notable Events

      i) New start.

5) Office of Naval Research (ONR) BAA 14-001 Hypoxia Monitoring Alert and Mitigation System, PI: (b) (6) .

   a. Research Topic Areas / Subprograms

      i) HAMS will predict/detect/warn warfighters of impending hypoxic events based on individual physiological, environmental, and cognitive monitoring.

   b. ONR RDT&E Budget

      i) $350K

   c. Projects

      i) Identify appropriate statistical modeling approaches to develop a predictive model of the likely occurrence of acute mountain sickness based on individual physiologic measures.

   d. Milestones Achieved

      i) Developed a preliminary logistic regression model predicting the occurrence of acute mountain sickness (AMS) based on sea level heart rate and altitude heart rate and arterial oxygen saturation during the first hours of altitude exposure.

      ii) Completed a data pull of physiologic and demographic measurements of 500 subjects (40,000 lines of data) from the USARIEM mountain medicine database to develop a time-series model of individual risk of AMS.

      iii) Prepared a preliminary human-studies research protocol for ONR review and FY15 funding.

e. Highlights and Notable Events

i) Invited speaking engagements, special guests, awards, patents, special assignments, other recognition.

- (b) (6) presented preliminary predictive model at the Force Health Protection Pillar, Future Naval Capability Science and Technology Program Review, September 2014.

B. Major Challenges

1) Loss of Federal Civilian employees without replacement is the greatest challenge to sustain the division's research productivity.

a. From the beginning of FY12 to the end of FY14 eight employees retired or terminated their employment and only two new employees were hired.
b. This represents a 36% turnover with a significant loss of institutional history and several key scientific leaders.

2) Additionally, upon the retirement of the Chief, Military Performance Division (MPD) July 1, 2014, TMMD and MPD were merged under one division Chief that strained effective management of the combined division personnel and R&D programs.

a. On a positive note, two TMMD DB-03 scientists were selected for promotion to DB-04 by a Factor IV board. New and more complex procurement processes increased the time spent by the research staff to prepare purchase requests and contracts.
b. Obtaining state-of-the-art data acquisition systems to support innovative research projects was hampered and in some cases prohibited due to MEDCOM IT Governance restrictions. Severe limits on attendance and participation in non-DoD conferences impeded developing novel research studies, collaborations with academics, and impaired professional development that has contributed to low morale.

Resource Management and Budget

A. Personnel

1) The office staff consisted of: (b) (6) (Chief), (b) (6) (Deputy Chief), (b) (6) (Budget Analyst), (b) (6) (Budget Analyst), (b) (6) (Budget Analyst), (b) (6) (Acquisition Management Liaison Officer), and (b) (6) (Contractor Support – GFEBS).

B. Budget Data

1) A three year funding history is shown below in Figure 1. The total budget in FY14 for research and clinical investigations was $34.0 Million. This was a 16% increase in funding over FY13. This reflects the importance and success of the science work being performed by USARIEM.

FIGURE 1: USARIEM Funding

Fiscal Year	RDT&E Funding	O&M Funding	Total Funding
FY12	$27.9M	$1.4M	$29.3M
FY13	$28.6M	$.7M	$29.3M
FY14	$32.7M	$1.3M	$34.0M

Information Management

USARIEM Information Technology (IT) Governance

The purpose of the USARIEM Information Technology (IT) Governance is to ensure that all expenditures related to IT investments supporting USARIEM operational responsibilities are defined, available, maintained, accounted for, distributed and configured in a manner that optimizes the Command's operational capability with best value solutions. The IT requirements review process has been established to provide appropriate validation, prioritization, accountability, visibility and alignment of all USARIEM requirements to include IT assets.

A. USARIEM Commander
    1) All IT requirements will need a final review and approval by the Commander.

B. S6
    1) S6 is assigned the responsibility for IT Governance and oversight of the USARIEM information enterprise to the USARIEM Commander. S6 will outline the primary IT investments and governance processes. S6 serves as the Command's architect, and provides oversight and guidance to ensure compliance with standards for developing, maintaining and implementing sound architectures as a means to ensure information sharing, visibility, assurance and interoperability.

C. S6 Portfolio Manager (PfM)
    1) PfM utilizes the Medical Command's Medical Systems Inventory Repository (MSIR) as the IT portfolio management decision support tool for conducting and maintaining an IT Portfolio of systems.

D. End-user
    1) A user submitting a new IT requirement will validate the requirement through their Division Chief and then submit the requirement to S6. S6 will validate and approve all IT requirements though a review process that identifies the IT solutions interoperability and supportability, ensure compliance with Information Assurance (IA) and Resource Management (RM) requirements.

Requirements Types: User requirements break down into the types shown in Figure #2.

FIGURE 2: Requirements Types

Type	Examples
Hardware	Provision and installation of desktop and laptop computers, printers, scanners, monitors and VTC equipment.
Software*	Addition of software applications not on an Army Approved Product List (APL), followed by a separate request for software installation.
Systems*	Addition of systems (generally involving both hardware and software components) within the USARIEM domain. Typically this would include programs of record needed for operational mission purposes.
Network*	Provision of network access for operational purposes or changes to existing networks.

Infrastructure*	Changes to the infrastructure, generally of a physical nature (additional cable runs, UPS, fiber upgrades)

Figure 2. Types of Requirements (* Requestor may be responsible to fulfill DoD Risk Management Framework (DoDRMF) tasks.)

Operations

A. Continuity of Operations

1) Worked with Natick Soldier Systems Garrison to ensure a smooth transition between worksites.

2) Alternate location has adequate facilities to sustain long term operations.

B. Unit Field Training Exercise (FTX)

1) Detachment FTX conducted at Mount Washington, NH.

a. 40 Soldiers received training.

C. Active Shooter training

D. Garrison events

1) Spring and fall clean-up.

2) Organizational Day support.

3) Health and wellness fair.

4) Installation Change of command/responsibility.

5) Color Guard.

a. 14 Major events – two nationally televised.

Modernization

A. BBMD:

1) Electronic Timing Gates. BBMD began using timing gates, typically used for orienteering, as a means of collecting time-synced and logged data for individual movement during locomotion experimentation.
2) Thermal Sweating Hand**.** BBMD procured a thermal sweating hand, physical model, for assessment of hand-wear. Previous models did not incorporate sweating abilities. This added capability enables better data resolution needed for modeling purposes; importantly in cold predictions.

B. MND:

1) Added 2 Dual EnergyX-ray Absorpiometry systems, state of the art systems for quantifying bone density, fat mass, and non-fat non-bone mass in humans.

2) Upgraded software for the peripheral quantitative tomography (pQCT) 3000, a device that can measure peripheral limb bone architecture.

Construction

USARIEM completed construction of new Medical Warehouse (building 23 at SSC). This 5,600 SQ. FT. air-conditioned and heated warehouse is providing necessary storage accommodation for the USARIEM mission in terms of storing equipment and supplies

1) This construction started in November of 2012 and completed with 30 April 2014.
2) Total cost of project was $1,921,036.14.

Health and Environment

The Office of Medical Support and Oversight (OMSO) personnel have assisted USARIEM as coordinators of the Readiness and Resiliency Campaign (R2C).

A. As part of the Readiness and Resiliency Campaign program, USARIEM has established a Health Promotion Team (HPT).The HPT will provide Unit Leadership a forum to synchronize and monitor standards for a safe, healthy environment for USARIEM Soldiers, civilians and family members. The HPT monitors trends in health metrics and helps determine courses of action. Results are reported to both MRMC R2C coordinators and Natick Soldier System Center's Community Health Performance Counsel.

B. The HPT held their first meeting in March 2015. In accordance with R2C guidance, The HPT will meet monthly from then on. No significant trends have been noted in Health and Environment at present; however, this new group will help supplement and coordinate current unit reporting systems to identify trends before they become problems.

BBMD Research and Development Appendix

1) Publications

a) Brooks K.A., Potter A.W., Carter J.G, & Leal E. Risk of chronic disease and disability in former competitive collegiate athletes. *International Journal of Physical Medicine and Rehabilitation*, 2(1):178, 2014.

b) Gribok A., Rumpler W., Buller M., & Hoyt R. Quantification of uncertainties in respiratory exchange ratio calculations obtained from indirect whole room calorimetry. 3rd International Conference on Recent Advances and Controversies in Measuring Energy Metabolism. Tokyo Japan, 2014.

c) Gribok A., Rumpler W., Hines W., Hoyt R., & Buller M. Subcutaneous Glucose Concentration as a Predictor Variable for Energy Expenditure during Resistance Exercise in Humans. *Proceedings of the Body Sensor Networks Conference,* June 2014. Zurich Switzerland, 2014.

d) Hughes T., Hess A., Simpson J., Young W., Mullen S., & Tharion W. Assessment of two data radio communication systems for real-time physiological status monitoring for Weapons of Mass Destruction-Civil Support Teams (WMD-CSTs). Project Report (PSM-1). Lexington, MA: MIT Lincoln Laboratory and U.S. Army Research Institute of Environmental Medicine, 2014.

e) Laxminarayan S., Buller M.J., Tharion W.J., & Reifman J. Human core temperature prediction for heat-injury. *IEEE Journal of Biomedical and Health Informatics,* (Accepted), 2014.

f) MacLeod T., Rioux T.P., Yokota M., Li P., Corner B.D., & Xu X. Individualized human CAD models: anthropometric morphing and body tissue layering. U.S. Army Research Institute of Environmental Medicine, Natick, MA 01760 USA, Technical Report, T14-6, 2013, ADA#609578, accessible at: www.dtic.mil/dtic/tr/fulltext/u2/a609578.pdf

g) Potter A.W., Gonzalez J.A., Karis A.J., Rioux T.P., Blanchard L.A., & Xu X. Impact of estimating thermal manikin derived wind velocity coefficients on physiological modeling. US Army Research Institute of Environmental Medicine, Natick, MA, 01760, USA, Technical Report, 2014, ADA#607972, accessible at: www.dtic.mil/dtic/tr/fulltext/u2/a607972.pdf

h) Potter A.W., Karis A.J., & Gonzalez J.A. Biophysical characterization and predicted human thermal responses to U.S. Army body armor protection levels (BAPL). U.S. Army Research Institute of Environmental Medicine, Natick, MA 01760 USA, Technical Report, T13-5, 2013, ADA#585406, accessible at: www.dtic.mil/dtic/tr/fulltext/u2/a585406.pdf

i) Riera F., Hoyt R.W., Xu X., Melin B., Regnard J., & Bourdon L. Thermal and metabolic responses of military divers during a 6-hour static dive in cold water. *Aviat Space Environ Med*; 85:509–17, 2014.

j) Tharion W.J., Buller M.J., Clements C.M., Dominguez D., Sampsonis C., Karis A.J., & Potter A.W. Human factors evaluation of the Hidalgo EquivitalTM EQ-02 physiological status monitoring system. U.S. Army Research Institute of Environmental Medicine, Natick, MA 01760 USA, Technical Report, T14-2, 2013, ADA#592523, accessible at: www.dtic.mil/dtic/tr/fulltext/u2/a592523.pdf

k) Tharion W.J., Buller M.J., Potter A.W., Karis A.J., Goetz V., & Hoyt R.W. Acceptability and usability of an ambulatory health monitoring system for use by military personnel. *IIE Transactions on Occupational Ergonomics and Human Factors*, 1(4):203-214, 2013.

l) Tharion W.J., Potter A.W., Duhamel C.M., Karis A.J., Buller M.J., & Hoyt R.W. Real time physiological monitoring while encapsulated in personal protective equipment. *Journal of Sport and Human Performance,* 1(4): 14-22, 2013.

m) Xu X., Rioux T.P., & Potter A.W. Fabric thermal resistance and ensemble thermal resistances are two different concepts. *Journal of Occupational and Environmental Hygiene*, 11(11), D187-188, 2014.

n) Xu X., Allen A., Rioux T., Patel T., Sinha P., Yokota M., & Santee W. Refinement of probability of survival decision aid (PSDA). U.S. Army Research Institute of Environmental Medicine, Natick, MA 01760 USA, Technical Note, TN14-2, 2014, ADA#599590, accessible at: www.dtic.mil/dtic/tr/fulltext/u2/a599590.pdf

o) Xu X., & Tikuisis P. Thermoregulatory modeling for cold stress. Comprehensive Physiology 4: 1057-1081, 2014.

p) Yokota M., Karis A.J., & Tharion W.J. Evaluation of thermal-work strain in law enforcement personnel during chemical, biological, radiological, and nuclear (CBRN) ensembles training. *International Journal of Occupational and Environmental Health*, 20(2): 126-133, 2014.

2) Key Briefings

a) (b) (6) Overview of the Open Body Area Network Personal Physiological Status Monitoring (OBAN-PSM) field study. Key briefing to Maneuver Battle Lab (MBL) and Soldier Division of the Squad as a Foundation of the Decisive Force (SFDF). Presented at the Maneuver Battle Lab, Ft. Benning, GA, 15 April, 2014.

b) (b) (6) . Real-time physiological status monitoring: field study assessments. Key briefing made at the Military Operational Medicine Research Program (MOMRP) Review and Analysis of Task Area H – Human Performance and Load Injury Prevention. U.S. Army Research Institute of Environmental Medicine, Natick, MA January 2014.

c) (b) (6) Squad-Foundation as the Decisive Force (SFSF) Maneuver Fires Integration Exercise: (MFIX) & real-time – physiological status monitoring (RT-PSM) field evaluation. Key briefing to Product Manager Soldier Warrior/Program Executive Office (COL (b) (6)) and Product Director Soldier Systems & Integration/Product Manger Soldier Warrior (LTC (P) (b) (4) and LTC (b) (4) at the U.S. Army Research Institute of Environmental Medicine, 28 March 2014.

d) (b) (6) U.S. Army Research Institute of Environmental Medicine (Overview). Key briefing to Maneuver Battle Lab (MBL) and Soldier Division of the Squad as a Foundation of the Decisive Force (SFDF). Presented at the Maneuver Battle Lab, Ft. Benning, GA, 15 April, 2014.

e) (b) (6) Murder Board brief of the "Assessment of the Open Body Area Network Personal Physiological Status Monitoring (OBAN-PSM) System" protocol. Key briefing made to Maneuver Fires Integration Exercise training leads ((b) (6) from Ft. Benning, GA at the U.S. Army Research Institute of Environmental Medicine, Natick, MA, 13 August 2014.

f) (b) (6) Real-time physiological monitoring of Soldiers encapsulated in chemical-biological clothing, applications for military working dogs. Key briefing made at the USARIEM Working Dog Thermal Workshop. U.S. Army Research Institute of Environmental Medicine, Natick, MA, January, 2014.

3) Presentations

a) (b) (6) Practical Real-Time Assessment of Thermal Work Strain from Measures of Heart Rate for CBRNE Operations. 3rd International Congress on Soldiers' Physical Performance (ICSPP) –Boston, MA, 18-22 August 2014.

b) (b) (6) Performance and Thermal Work Strain Optimization. Workshop Presentation for Health and Performance in Stressing Field Environments. Body Sensor Networks Conference 2014. Zurich Switzerland

c) (b) (6) Thermal impact of US Army body armor protection levels (BAPL). 3rd International Congress on Soldiers' Physical Performance (ICSPP) – Boston, MA, 18-22 August 2014.

d) (b) (6) . Human Factors Assessment of a Physiological Status Monitoring System for CBRNE Operations. 3rd International Congress on Soldiers' Physical Performance (ICSPP) – Accepted abstract, Boston, MA, 18-22 August 2014.

e) (b) (6) Overview of the Open Body Area Network Personal Physiological Status Monitoring (OBAN-PSM) field study. Key briefing to Maneuver Battle Lab (MBL) and Soldier Division of the Squad as a Foundation of the Decisive Force (SFDF). Presented at the Maneuver Battle Lab, Ft. Benning, GA, 15 April, 2-14.

f) (b) (6) Real-time physiological status monitoring: field study assessments. Key briefing made at the Military Operational Medicine Research Program (MOMRP) Review and Analysis of Task Area H – Human Performance and Load Injury Prevention. U.S. Army Research Institute of Environmental Medicine, Natick, MA, January 2014.

g) (b) (6) Squad-Foundation as the Decisive Force (SFSF) Maneuver Fires Integration Exercise: (MFIX) & real-time – physiological status monitoring (RT-PSM) field evaluation. Key briefing to Product Manager Soldier Warrior/Program Executive Office (COL (b) (6)) and Product Director Soldier Systems & Integration/Product Manger Soldier Warrior (LTC (P) (b) (4) and LTC (b) (4) at the U.S. Army Research Institute of Environmental Medicine, 28 March 2014.

h) (b) (6) U.S. Army Research Institute of Environmental Medicine (Overview). Key briefing to Maneuver Battle Lab (MBL) and Soldier Division of the Squad as a Foundation of the Decisive Force (SFDF). Presented at the Maneuver Battle Lab, Ft. Benning, GA, 15 April, 2-14.

i) (b) (6) Murder Board brief of the “Assessment of the Open Body Area Network Personal Physiological Status Monitoring (OBAN-PSM) System” protocol. Key briefing made to Maneuver Fires Integration Exercise training leads (b) (6)) from Ft. Benning, GA at the U.S. Army Research Institute of Environmental Medicine, Natick, MA, 13 August 2014.

j) (b) (6) Real-time physiological monitoring of Soldiers encapsulated in chemical-biological clothing, applications for military working dogs. Key briefing made at the USARIEM Working Dog Thermal Workshop. U.S. Army Research Institute of Environmental Medicine, Natick, MA, January, 2014.

k) (b) (6) Signal Processing for Exercise Dosimetry. 3rd International Congress on Soldiers' Physical Performance (ICSPP) – Accepted abstract, Boston, MA, 18-22 August 2014.

4) Information Papers: None submitted

5) Patents

a) (b) (6) (Dec 2013). Estimation of Human Core Body Temperature Based on Heart Rate and Method. US Patent Application # 14/107,920

b) (b) (6) (2014) Adaptive Physiological Strain Index a Universal Index of Thermal Work Strain. RIEM 14-19. Approved by MRMC IP Committee for Provisional Patent Application.

MND Research and Development Appendix

Publications

1) Austin, K.G., McGraw, S.M., and Lieberman, H.R. Multivitamin and protein supplement use is associated with positive mood states and health behaviors in US military and Coast Guard personnel. Journal of Clinical Psychopharmacology, 34(5):595-601, 2014.

2) Bukhari, A.S., Roberts, S.B., Young A.J., McGraw S.M., Dallal, G.E., and Krupa, D.S. Pilot study to determine interest of adult civilian dependents of active duty military personnel in participation in a weight control program. Military Medicine*, 179: 254-259, 2014.* http://publications.amsus.org/doi/pdf/10.7205/MILMED-D-13-00321

3) Carbone J.W., Pasiakos S.M., Vislocky, L.M., Anderson J.M., and Rodriguez, N.R. Effects of short-term energy deficit on muscle protein breakdown and intramuscular proteolysis in normal-weight young adults. Applied Physiology Nutritional Metabolism*. 39: 1–9, 2014. dx.doi.org/10.1139/apnm-2013-0433* http://www.nrcresearchpress.com/doi/abs/10.1139/apnm-2013-0433

4) Carbone J.W., Margolis L.M., McClung J.P., Cao J.J., Murphy N.E., Sauter E.R., Combs G.F. Jr, Young A.J., Pasiakos S.M. Effects of energy deficit, dietary protein, and feeding on intracellular regulators of skeletal muscle proteolysis. FASEB Journal. 2013;27(Dec):5104-11, 2013. doi: 10.1096/fj.13-239228. Epub 2013 Aug 21

5) Castellani J.W., Demes R., Endrusick T.L., Cheuvront S.N. and Montain S.J., Heat Removal using microclimate foot cooling: A Thermal Foot Manikin Study. Aviation, Space, and Environmental Medicine 84(April): 445-448, 2014*.* DOI: 10.3357/ASEM.3781.2014

6) Fallowfield, J.L., Delves S.K., Hill, N.E., Cobley R., Brown P., Lanham-new S.A., Frost, G., Brett, S.J., Murphy, K.G., Montain, S.J., Nicholson, C., Stacey, M., Ardley, C., Shaw, A., Bentley, C., Wilson, D.R. and Allsopp A.J. Energy expenditure, nutritional status, body composition and physical fitness of Royal Marines during a 6-month operational deployment in Afghanistan. British Journal of Nutrition*, 9: 1–9, 2014. doi:10.1017/S0007114514001524* http://www.researchgate.net/publication/263779429_Energy_expenditure_nutritional_status_body_composition_and_physical_fitness_of_Royal_Marines_during_a_6-month_operational_deployment_in_Afghanistan

7) Farina, E.K., Austin, K.G., and Lieberman, H.R. Concomitant Dietary Supplement and Prescription Medication Use is Prevalent among United States Adults with Doctor-Informed Medical Conditions. Journal of the Academy of Nutrition and Dietetics 114(11):1784-90, 2014. e2. doi: 10.1016/j.jand.2014.01.016.

8) Gaffney-Stomberg, E., Cao, J.J., Lin, G.G., Wulff, C.R, Murphy, N.E., Young, A.J., McClung, J.P. and Pasiakos, S.M. Dietary protein level and source differentially affect bone metabolism, strength, and intestinal calcium transporter expression during ad libitum and food-restricted conditions in male rats.. Journal of Nutrition, 144: 821-829, 2014. doi: 10.3945/jn.113.188532.

9) Gaffney-Stomberg, E., Lutz, L.J., Rood, J.C., Cable, S.J., Pasiakos, S.M, Young, A.J., and McClung, J.P., Calcium and vitamin D supplementation maintains parathyroid hormone and improves bone density during initial military training: A randomized, double-blind, placebo controlled trial. Bone *68: 46–56, 2014.* http://dx.doi.org/10.1016/j.bone.2014.08.002

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Presentations

1) February 18, 2014, (b) (6), "The Ubiquitous Role of Zinc in Health and Disease." Harvard School of Public Health, Cambridge, MA

2) April 14, 2014, (b) (6), Protein Supplementation for Warfighters, SMR-CP Injury Prevention / Human Performance Optimization Educational Seminar.

3) April 26-30, 2014, (b) (6), "Longitudinal trends of dietary supplement use by US Army Soldiers differ from the US civilian population," Experimental Biology, San Diego, CA.

4) April 26-30, 2014, (b) (6), "A calcium and vitamin D fortified food product improves bone adaptation during military training," Experimental Biology, San Diego, CA.

5) April 26-30, 2014, (b) (6), "Carbohydrate energy replacement attenuates protein turnover and promotes nitrogen retention during acute periods of increased metabolic demand," Experimental Biology, San Diego, CA.

6) April 26-30, 2014 (b) (6), "Optimization of Calcium and Vitamin D Status During Initial Military Training: a Randomized, Double Blind, Placebo-Controlled Trial," Experimental Biology, San Diego, CA.

7) April 26-30, 2014, (b) (6), "Effects of a 7 day military training exercise on whole-body protein turnover: an observation of military specific protein requirements," Experimental Biology, San Diego, CA.

8) April 26-30, 2014, (b) (6), "Low Dietary Zinc inhibits Skeletal Muscle Remodeling Following Blast Injury," Experimental Biology, San Diego, CA.

9) April 26-30, 2014, Dr. Tracey J. Smith, "A Suction Blister Model Reliably Assesses Skin Barrier Restoration and Immune Response," Experimental Biology; San Diego, CA.

10) May 11-15, 2014, MAJ (b) (6), "Phytonutrients: Novel Tools to Enhance Physiological Detoxification of Aviation Fuel Chemicals," Aerospace Medical Association, San Diego, CA.

11) June 21-24, 2014, (b) (6), "Pilot study of absorption of Omega-3 fats from food matrices before and after storage," Institute of Food Technologists, New Orleans, LA.

12) August 19, 2014, (b) (6), "Iron status and initial military training: Experiences within the U.S. Army and Israeli Defense Force," 3rd International Congress on Soldier Physical Performance, Boston, MA

13) August 20, 2014, (b) (6), "Meeting the Energy Demands of Warfighters in Austere Environments: the United States Perspective," 3rd International Congress on Soldier Physical Performance, Boston, MA

14) September 29, 2014, (b) (6), "Encouraging healthy food choices with an environmental intervention in military dining facilities," Soldier Medical Readiness Campaign Educational Seminar, Online Presentation

15) September 29, 2014, (b) (6), "Iron Nutrition for Women in Combat Arms," Uniformed Services University for Health Science, Bethesda, MD.

Briefing(s)

1) November 13, 2013, (b) (6), "Military Nutrition Division Orientation" Combat Feeding Research and Engineering Program, NSRDEC, NSSC, Natick, MA

2) February 10, 2014, (b) (6), Invited speaker for NASA Fundamentals of Vitamin Stabilization Workgroup, NSBRI headquarters, Rice University, Houston, Texas

3) February 10, 2014, (b) (6), Task Area I presentation at WRAIR: Nutritional Interventions to Increase Resilience to Blast Injury, Fort. Detrick, Frederick, MD.

4) March 10, 2014, (b) (6), "Physiological Health Program Overview", at MOMRP IIPT, Fort. Detrick, Frederick, MD.

5) March 10, 2014, (b) (6), "Task Area B FY15 Plan", Fort. Detrick, Frederick, MD.

6) March 19, 2014, Military Nutrition Division hosted representatives from Defence Research and Development Canada, USARIEM, Natick, MA

7) April 10-11, 2014, (b) (6), "Nutrition and Brain Health", Brain Health Consortium, Defense Health Headquarters, Falls Church, VA

8) April 24, 2014, (b) (6) presented Military Nutrition Division Overview brief to MG Michael Shields, Commanding General, US Army Alaska, USARIEM, Natick, MA

9) May 2, 2014, (b) (6), "Women in Combat – "Nutrition," Uniformed Services University for Health Science, Bethesda, MD

10) May 22, 2014 Dr. (b) (6) presented Military Nutrition Division Overview brief to BG (b) (6), Commanding General, Natick Soldier Systems Center, USARIEM, Natick, MA

11) August 27, 2014, (b) (6), "Iron status and female Warfighters: screening and treatment programs" DoD Nutrition Subcommittee, Uniformed Services University for Health Science, Bethesda, MD.

Information Papers

1) February 19, 2014, Vitamin D and Health, Military Nutrition Division

1) March 6, 2014, Nutritional Support for Missions with Long Flight Schedules, Military Nutrition Division

2) December 9, 2014, THOR^3 DFAC Study, Military Nutrition Division

Patents

None issued

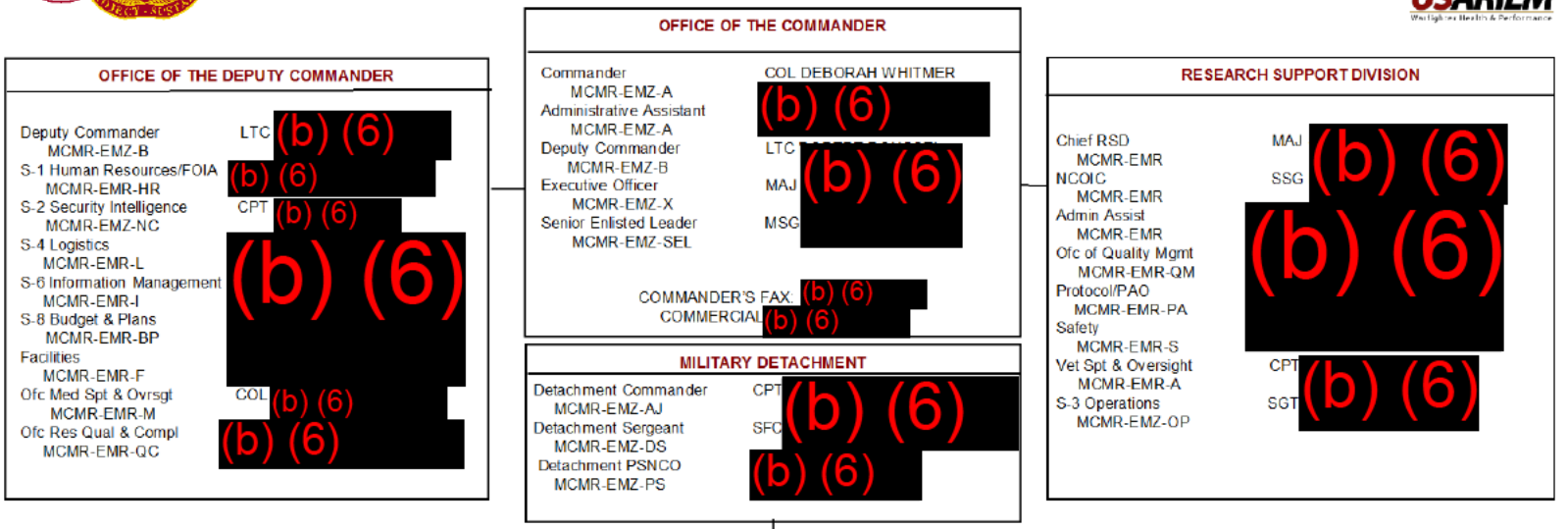
OTHER

Podcast on nutritional treatment of traumatic brain injury - episode is available at http://pmandrpodcast.libsyn.com/nutritional-treatment-after-traumatic-brain-injury and on iTunes, at https://itunes.apple.com/us/podcast/the-pm-r-podcast/id747449886?mt=2

DEPARTMENT OF THE ARMY

U.S. ARMY RESEARCH INSTITUTE OF ENVIRONMENTAL MEDICINE

NATICK, MASSACHUSETTS 01760-5007
COMMERCIAL TELEPHONE (508) 233-XXXX DSN 256-XXXX FAX XXX-5298 WEBSITE: www.usariem.army.mil



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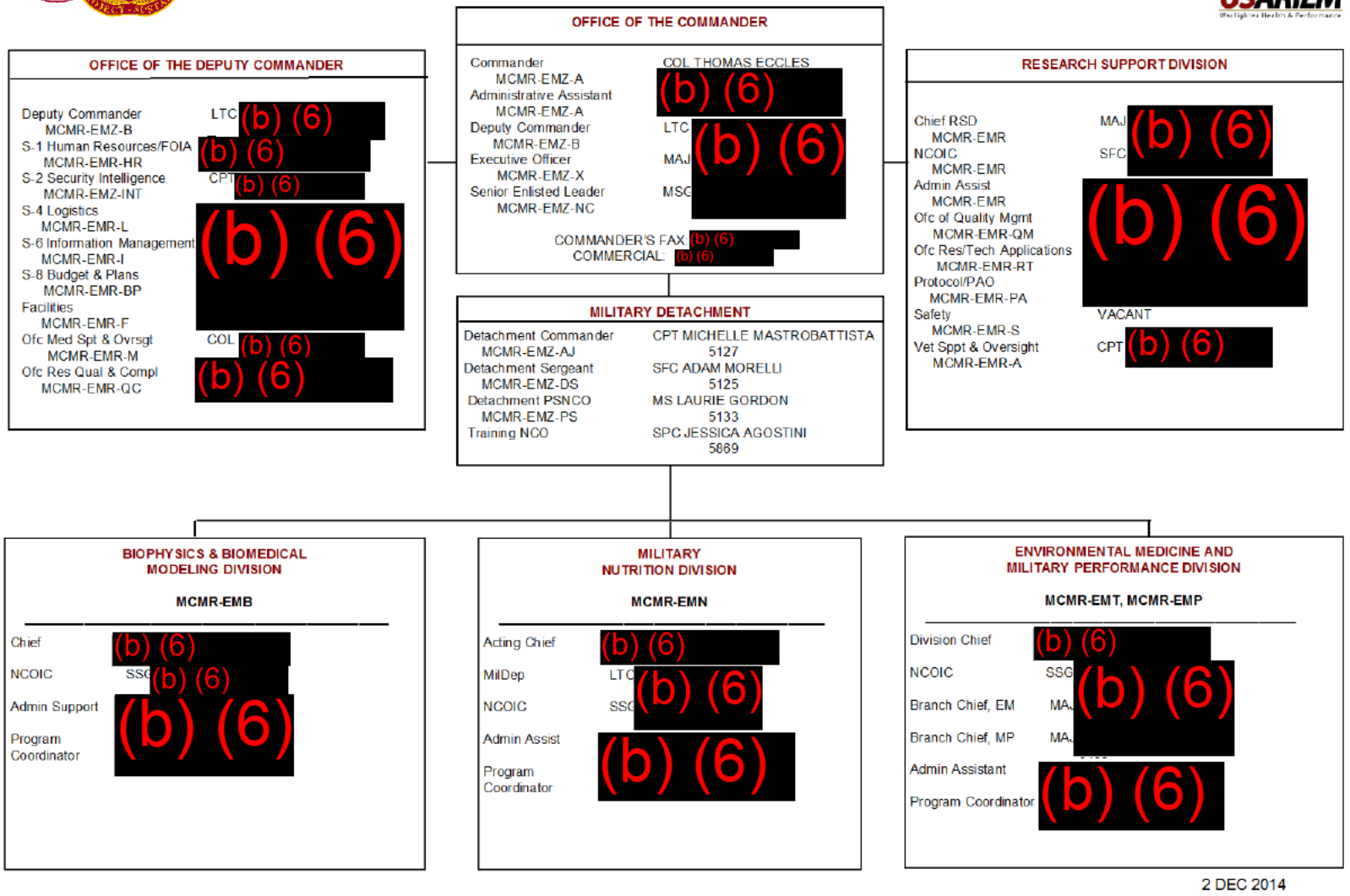

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Section 26

Fiscal Year 2014
Annual Historical Report

The Walter Reed Army Institute of Research

Mission.

Ensure the health and readiness of the Warfighter by anticipating, mitigating, and/or eliminating future threats to the force by executing strategic and relevant biomedical research, education, and consultation on military infectious disease, psychiatry and neuroscience.

Vision.

We are the premier Department of Defense biomedical research enterprise solving global health threats to the Warfighter.

The Walter Reed Army Institute of Research (WRAIR) is the largest and most diverse, as well as the oldest, subordinate laboratory of the U.S. Army Medical Research and Materiel Command (USAMRMC). WRAIR is also the largest biomedical research laboratory within the Department of Defense (DoD) and the oldest public health and preventive medicine Institute in the United States. As the DoD's lead agency for infectious disease research and a crucial source of research support for medical product development, WRAIR is transitioning to the Center for Infectious Disease Research and Center for Psychiatry and Neuroscience.

WRAIR's resources include a state-of-the art laboratory facility in Maryland that was dedicated in September 2001 to Senator Daniel K. Inouye, as well as laboratory and clinical facilities in Asia, Africa, and Europe. WRAIR's greatest resources are the dedicated scientists, technicians, and support personnel who make up the core of the WRAIR today. Currently, WRAIR consists of fourteen research divisions and twelve support divisions in association with the Maryland headquarters, as well as a total of five research detachments, two within the United States and three overseas laboratories.

The WRAIR is the DoD's premier biomedical research facility which focuses on the health and medical readiness of U.S. military personnel while supporting global health efforts. The WRAIR fulfills its mission by conducting innovative basic and applied biomedical research and development of technologies to: prevent, diagnose, and treat infectious diseases; treat combat casualties; and prevent and minimize operational stress and health hazards.

WRAIR specializes in biomedical research in the scientific and engineering disciplines of microbiology, parasitology, virology, biochemistry, immunology, molecular and systems biology, entomology, pathology, neuroscience and neurotrauma, psychiatry and behavioral biology, veterinary studies, pilot bioproduction, clinical testing, vaccine development, therapeutics discovery, blood product development, and preventive medicine. The staff is roughly 30% each military, civilian and contract staff, equally divided between scientific and support personnel. Important organizational components of the WRAIR are the special field activities in Thailand, Kenya, and Germany. Research and support functions at the overseas labs are closely coordinated with efforts at the main facility near Washington, D.C.

WRAIR primarily works at the applied research and pre-development level, but the Institute is also intimately involved in product development with the United States Army Medical Material Development Agency (USAMMDA), Fort Detrick, Maryland. By chairing or serving on scientific steering committees, WRAIR scientists provide the technical guidance required for rational development of its technology-based products. Indeed, many products are developed and tested at the WRAIR Special Field Activities.

WRAIR's efforts are not limited to research; WRAIR was originally founded in 1893 as the U.S. Army Medical School. It continues to be a center of learning through the military preventive medicine residency, a veterinary medicine training program, the National Research Council Associates program, clinical pharmacology fellowship and science, technology, engineering and mathematics (STEM) programs for middle to graduate school participants. Hundreds of fellows and students take part in WRAIR research annually and some return to or continue in research endeavors within or associated with the WRAIR.

WRAIR's Special Foreign Activities

The WRAIR is a complex organization consisting of the main laboratory located at the Forest Glen Annex, Silver Spring, Maryland, as well as a set of three Overseas Operations. The Special Foreign Activities (SFAs) including the U.S. Army Medical Component - Armed Forces Research Institute of Medical Sciences (USAMC-AFRIMS) in Bangkok, Thailand, the U.S. Army Medical Research Unit - Europe (USAMRU-E) in Sembach, Germany, and the U.S. Army Medical Research Unit - Kenya (USAMRU-K) in Nairobi, Kenya. In this document is the first report from the new SFA called the U.S. Army Medical Research Unit – Georgia in Tbilisi, Georgia. USAMRU-K also supports other field units in subSaharan Africa while USAMC-AFRIMS includes field sites elsewhere in Southeast Asia.

Personnel

During FY 2014, WRAIR, including all detachments, employed 1984 military, civilian and contract personnel. Of these, 1041 personnel were assigned to WRAIR's CONUS facilities at Building 503 and the Forest Glen Annex. An additional 369 were employed at the USAMC-AFRIMS, 10 at USAMRU-E, 556 at USAMRU-K and 8 at USAMRU-G. A total of 270 were military, 309 were federal civilians, 1306 were contractors/special foreign-service nationals and 99 occupied fellowships, internships and IPAs.

Headquarters Staff:

Commander, WRAIR	COL Steven E Braverman
Deputy Commander, WRAIR	COL (b) (6)
Executive Officer	COL (b) (6)
Senior Scientific Professional (ST)	Dr Frank Tortella
Director, Overseas Operations	LTC (b) (6)
Sergeant Major	SGM (b) (6)
Headquarters Company Commander	CPT (b) (6)
Science Director	(b) (6)
Director, Science Educ. & Strat. Comm.	(b) (6)
IACUC Office	(b) (6)

Special Foreign Activities:

Commander, USAMC-AFRIMS	COL William Geesey
Commander, USAMRU-E	LTC Jeffrey Thomas
Commander, USAMRU-K	COL Thomas M. Logan
Director, USAMRU-G	LTC (b) (6)

Center for Military Infectious Diseases Research:

Branch Director, Bacterial Diseases	COL (b) (6)
Branch Director, Entomology	CDR (b) (6)
Branch Director, Experimental Therapeutics	LTC (b) (6)
Branch Director, Malaria Vaccine Development	LTC (b) (6)
Branch Director, Preventive Medicine	COL (b) (6)
Branch Director, Translational Medicine	COL (b) (6)
Branch Director, Military HIV Research Program	COL (b) (6)
Branch Director, Veterinary Medicine	LTC (b) (6)
Branch Director, Viral Diseases	LTC (b) (6)

Center for Military Psychiatry and Neuroscience

Center Director	COL (b) (6)
Branch Director, Military Psychiatry	LTC (b) (6)
Branch Director, Behavioral Biology	(b) (6)
Branch Director, Brain Injury Neuroprotection and Neurorestoration	(b) (6)
Branch Director, Blast-induced Brain Injury	(b) (6)

Directors/Support Services Chiefs:

Director, Human Resources (Civilian)	(b) (6)
Director, Human Resources (Military)	Vacant
Director, Human Subjects Protection	(b) (6)
Director, Information Management	MAJ (b) (6)
Director, Logistics	LTC (b) (6)
Director, Operations and Security	(b) (6)
Director, Resource Management	MAJ (b) (6)

Teaching, Mentoring and Professional Development Programs

A. **Medical and Science, Technology, Engineering and Mathematics (STEM) Education Programs (Managed by SESC):** WRAIR scientists mentor students in paid research internships for middle school through high school and may also mentor college students in internships through graduate school. They serve a highly diverse student population, with more than 50% minority representation in any year, across programs. These internships include the WRAIR-developed Gains in the Education of Mathematics and Science (GEMS) program for students in middle to high school (now an Army-wide program), with 485 participants in 2014; the Science and Engineering Apprentice Program (SEAP) program for juniors and seniors in high school, with 10 participants in 2014; and the College Qualified Leaders (CQL) program for undergraduate and graduate-level students, with more than 80 participants in 2014. In the GEMS program, students are taught in teaching laboratories by near-peer mentors (college students in the CQL program) in Beginning, Intermediate and Advanced GEMS programs. Near-peer mentors also act as much needed and effective role models for the GEMS participants. Oak Ridge Institute of Science Education (ORISE) fellows also participate at WRAIR with mentors requesting their support. These fellowships include undergraduate through post-baccalaureate and post-doctoral positions. In addition, WRAIR has participants from retired federal staff in the ORISE **Knowledge Preservation Program.**

B. **The National Research Council (NRC)'s Post-Doctoral Associateship Program (Managed by SESC):** Managed by the Office of Science Education and Strategic Communications, the National Academy of Sciences Research Associateship Program (NAS RAP) allows for the participation of postdoctoral and experienced senior scientists at WRAIR as guest researchers. The NRC reviews and recommends, as appropriate, outstanding scientists to the WRAIR. Applicants are chosen by WRAIR staff to participate in their laboratories on research problems that both interest the scientists and fit the research priorities of WRAIR.

WRAIR SUPPORT DIVISIONS
Information Management Division

Purpose

A. Provide:
   1) A reliable communications network
   2) Streamlined process for system/application network access
   3) Provide a more positive end user experience
   4) Work toward an accredited OCONUS .ORG network environment.
   5) A collaborative research environment.

Organization/Personnel/Statistics

A. DoD Civilians - 20, 6 vacancies; Military - 2, no vacancies; Contractors - 19 from 4 vendors. Military CIO/Director of IMD deployed Jan 2014 returning Oct 2014.

B. Statistical Data:
   1) Department of Medical and Audio Visual Services (DMAVS): In calendar year 2013-2014 DMAVS completed 696 work orders, 3751.15 man-hours. Calendar year 2014-2015 DMAVS completed 785 work orders, 4890.25 man-hours.
   2) Library: Performed 226 online literature searches; created the WRAIR database (Index of Publications) with 296 publications; have 384 borrowers' records; total number of database queries was 35,854; total number of viewed or downloaded full text articles/pages, abstracts, citations was 35,966; staff provided over 3,000 references (short and long) in person or virtually; staff provided 1,456 interlibrary loans to WRAIR and MRMC patrons; staff filled 1,080 requests from other libraries.
   3) Department of Applications Services: Environmental Monitoring requirements increased from 650 channels to approximately 900 channels; which has increased the workload by roughly 28 percent.
   4) Department of Network Operations: N/A
   5) Department of Information Assurance: Army Records Manager conducted 52 record coordinators site assistant visits and 1 division director site assistant visit. A total of 29 record boxes were archived at the National Archives (NARA) in Suitland, MD.

C. Training and Education: Information Management Division (IMD) had instructors conduct Certified Ethical Hacker (CEH) and Certified Information Systems Security Professional (CISSP) training on-site at WRAIR. These two courses were attended by six IMD personnel, one AFRIMS person, and one person from an outside DoD entity. For the six IMD personnel the cost savings realized from training on-site was $5,300 in TDY costs and approximately 480 man hours equating to $20,683.20.

   1) Department of Medical and Audio Visual Services (DMAVS): Fort Eustis DMAVS subject matter expert came to WRAIR in Jun 2014 and conducted Visual Information Ordering Site (VIOS) refresher training for assigned staff.
   2) Library: All library staff attended the MEDCOM Webinar.
   3) Department of Applications Services: N/A
   4) Department of Network Operations: N/A
   5) Department of Information Assurance: N/A

D. Resource Management and Budget:
   1) Department of Medical and Audio Visual Services: N/A
   2) Library

3) Department of Applications Services: Environmental Monitoring systems' original contract, a base plus four optional years was budgeted and approved for $358,587.00 in August of 2013 based on the history of past requirements. However, due to the recent incidents within the command which resulted in substantial financial and scientific loss, the command revamped its Temperature Sensitive Medical Products (TSMP) program which resulted in a change in standard of monitoring requirements designed to protect the interest of science. This requirement resulted in the addition of two hundred sixteen unplanned additions in FY14. We were forced to use funding allocated for future optional years of the contract to fulfill the mission requirement and will therefore require additional funding to maintain the system.
4) Department of Network Operations: Funding of lifecycle replacement efforts allowed Information Management Division (IMD) to perform the first network infrastructure refresh since 2007. IMD is now performing a 5 year lifecycle management plan for all network infrastructures.
5) Department of Information Assurance: N/A

E. Information Management*:*
1) Department of Medical and Audio Visual Services: N/A
2) Library: Purchased and implemented a link resolver (SFX) by Ex Libris with two other products we use. Implemented newest version (9.2) of Voyager which also serves for other MRMC library.
3) Department of Applications Services: N/A
4) Department of Network Operations: IMD deployed a pilot medical device enclave. This pilot allowed medical devices to be secured on the network for the first time in WRAIR history. The pilot identified potentially significant manpower resource restraints if implemented across WRAIR. IMD is developing a manpower plan to address these weaknesses.
5) Department of Information Assurance: N/A

F. Modernization:
1) Department of Medical and Audio Visual Services: N/A
2) Library: Purchased and moved data to new virtual server, which serves for USARIID (MRMC) library. Identified hard copy journals that were available electronically in a perpetual access format and purchased electronic files for the entire MRMC command (Wiley over 51 titles). Upgraded 9 public/shared computers for efficiency/life cycle management.
3) Department of Applications Services: Environmental monitoring system has undergone significant changes to enhance mission support. During this time we have customized the system to support the WRAIR/NMRC mission. We requested input from the customer and implemented changes to the front end of the system to better accommodate the end user if allowed by 21CFR Part II. Performed upgrade of the actual application server. Moved the database to an independent virtual server which increased the performance of the system.
4) Department of Network Operations: IMD performed a complete core and access level network infrastructure refresh. This allowed WRAIR to begin upgrading its network connections to 10 GB/s. IMD additionally performed an upgrade of its data storage system. This upgrade will fulfill IMD data storage requirements for 3 years. Additionally, IMD performed a VTC upgrade for Room 1W81 in building 503. This upgrade replaced the previous end of life VTC system.
5) Department of Information Assurance: N/A

H. Other:
1) Department of Medical and Audio Visual Services (DMAVS): DMAVS assets did support the NATICK Soldier center with high speed motion imagery as well as still imagery support this past year in support of ongoing blast protection mission. DMAVS also supported the Army Safety center with high speed imagery support in the production of 2 different Public service Announcements dealing with motorcycle safety and handgun safety.
2) Library
3) Department of Applications Services: N/A
4) Department of Network Operations: N/A

5) Department of Information Assurance: N/A

Resource Management

Organization and Personnel

Director: MAJ (b) (6)

Staff: One Army Officer, ten Department of the Army civilians, and eight support contractor personnel. The office was informally broken down into the DRM,Financial Reporting, Manpower and Management, Overseas and Reimbursable Budget and Direct CONUS Budget divisions. The financial manager and de facto deputy was (b) (6) .

A. **Mission**

1) Operational manager of WRAIR's fiscal and manpower resources and related business practices. The DRM represents the Commander in exercising directional authority over the management and control of total WRAIR resources.
2) Provides executive-level insight, guidance, assistance, and direction for financial management issues.
3) Serves as the Command's integration hub, providing the resource management system and framework for sound and timely business and program decisions.
4) Directs and supervises the Headquarters (HQ) resource management support functions, consisting of manpower documentation, Indirect Cost allocation, and Defense Travel System.
5) Responsible for issuing funds, recommending fiscal policy, monitoring execution of all WRAIR funds, and preparing fund utilization reports.
6) Provides the WRAIR staff and Science Branch Directors with technical advice on budget cycle and execution matters, budget analysis, and obligation and disbursement rate performance.
7) Principal staff advisor to the Commander on all fiscal matters.
8) Reports to the Chief of Staff.

FIGURE 1 : WRAIR Research Funding

Funding Type	FY13	FY14
DEF HEALTH PGM 01302F2D## - 1831	10,548,618.15	31,217,526.00
REIM DEF HEALTH PGM 01302J1A## - 1881	1,368,341.71	21,942.97
DEF HEALTH PGM 01302J1D## - 1881	36,405,000.00	46,517,736.28
DEF HEALTH PGM 0130602D## - 18N1	2,021,810.78	4,368,882.35
DTRA 04002U2D## - 2601	499,000.00	772,724.00
Global HIV/AIDS Init 103022XDXX - 18E1	3,229,292.11	
DHP, PEPFAR-Child 10312Q5D## - 18Q1	62,549,214.00	12,084,920.00
Global Health/Child 10317AXDXX - 18L1	26,190,063.95	1,655,444.56
O & M, ARMY 202010D##	392,012.05	404,598.80
OMA 1yr Direct Supp 202011D12		
REIM RDT&E, 204020A##	38,473,191.56	66,597,076.76

RDT&E, A 204020D##	74,962,518.50	55,617,706.37
Total	256,639,062.81	219,258,558.09

B. **Significant Accomplishments**

1) Managed 11 single and multiple year appropriations worth approximately $220M - each with its own unique management requirements.
2) Participated in the "Budget Task Force" that changed the overhead model to a 1.11 multiplier plus a seat tax.
3) Separated the Special Foreign Activities (SFA) G&A accounts from the WRAIR – Forest Glen account. This resulted in lowering their overhead rates from 39% to 16% in USAMRU-K and 21% in AFRIMS.
4) Developed a new spend plan request methodology that resulted in funding coming in earlier in the year in FY15
5) Chartered and stood up a new version of the Resource Process Management Committee
6) Manpower and Management division moved from Human Resources to Resource Management

Human Subjects Protection Branch (HSPB)

Mission

The mission of the HSPB is to maintain practices consistent with moral, ethical and legal standards, and assure appropriate review and approval of human research activities. The HSPB Director serves as advisor to the Commander for human subjects protection and is responsible for support of the WRAIR Institutional Review Board (IRB), development of human subjects research policies/procedures, and management of the approval process for all research involving human subjects for the WRAIR and detachments (in-country and international). The HSPB and IRB conduct site assistance visits (SAV), as needed, and provide information and access to HSP education programs for investigators, IRB members, IRB staff, and collaborators involved in conducting or supporting human subjects research. Additionally, the HSPB recommends guidance and policy to the United States Army Medical Research and Materiel Command (USAMRMC).

Organization and Personnel

Director (b) (6), M.S., CIP, CCRA, CIM
Administrative Officer: (b) (6)
Deputy Director: (b) (6), BSN, RN, CIP, CCRA, CCRC (Separated September 2014)

Office Staff Members (Alphabetically):
(b) (6), M.A., CIP, CCRP, Human Subjects Protection Scientist (Separated December 2013; *Reassignment back to WRAIR March 2015 as Deputy Director*)

(b) (6), Administrative Assistant (CRM Contractor) (Separated December 2013)

(b) (6), M.P.H., CCRP, Human Subjects Protection Scientist (CRM Contractor) (Effective January 2014)

(b) (6), M.P.H., CCRP, Human Subjects Protection Scientist

(b) (6), M.P.H., CIM, CCRP, Human Subjects Protection Scientist

(b) (6), M.S., CIP, CCRP, Database & Information Manager (CRM Contractor)

(b) (6), M.P.H., Human Subjects Protection Scientist (Separated December 2014)

(b) (6), M.S.W., IRB Coordinator (Separated August 2014)

(b) (6), M.A., RAC, CIM, Human Subjects Protection Scientist

IRB Key Staff Members:
COL (b) (6), MC, IRB Chair (Effective January 2014)
(b) (6), Vice Chair, Volunteer Emeritus Program
(b) (6), COL (Retired), MC, Civilian Consultant (Effective July 2014)
(b) (6), Civilian Consultant
(b) (6) Civilian Consultant

Vacancies included:

IRB Coordinator (DB-0601-II)
Human Subjects Protection Scientist (DB-0601-III)
Post Approval Compliance Monitor, Clinical RM, New Hiring action
Administrative Assistant, Clinical RM

Statistical Data:

Monthly reports are sent to the WRAIR Commander and detachment Commanders to demonstrate status of protocol actions. Additionally, routine metrics on protocol actions are kept and provided to the WRAIR Commander and IRB Members.

Training and Education:

WRAIR HSPB Staff and IRB Members were not permitted to travel due to financial restrictions from January 2012 through this reporting period. The below represents free, on-line, and/or local opportunities that were an attempt to stay current with regard to regulatory requirements and ethics. SAVs were not permitted to the OCONUS detachments which could have a negative impact on WRAIR's HRPP.

A. 23 October 2013: HSPB and Good Clinical Practice - USAMDAA
B. 30 October 2013: CIP-DCO Education Session: "Pediatric Research: Regulatory Requirements and Best Practices" - USAMRMC
C. 6 November 2013: CIP-DCO Education Session: "Research Misconduct" - USAMRMC
D. 7 November 2013: Mediation Refresher Training
E. 13 November 2013: EEO Counselor Refresher Training
F. 20 November 2014: "Biobanking: When Issues with Tissues Come a Knockin' - OHRP
G. 8 January 2014: CIP-DCO Education Session: "Human Subjects Research and Exemption Determinations" - USAMRMC
H. 22 January 2014: Webinar: "The Data Sharing Process in Human Subjects Research" – Army Medicine
I. 24-25 February 2014: National Cancer Policy Forum Workshop: "Contemporary Issues in Human Subjects Protection" - Institute of Medicine
J. 5 March 2014: CIP-DCO Education Session: "Neuroethics: Beyond the Boundaries of Bioethics" - USAMRMC
K. 2-3 April 2014: Conference: Human Subjects Protection: An IRB Perspective" – including the following sessions: How IRBs Assess the Risk of Research Study; Readability of Informed Consent; Research with Vulnerable Subjects; Payment, Undue Inducement; Coercion Applying the US Regulations, Including Informed Consent Internationally; Research Using the Internet; Investigators Responsibility to Provide Research Results - NIAID, NIH
L. 24-25 April 2014: Society of Clinical Research Associates Conference (SoCRA) entitled, "Protecting Human Research Participants – Legal, ethical and Practical Considerations" - Baltimore, MD

M. 8 May 2014: Internet Research Webinar
N. 24 July 2014: Webinar: "Guidance on Reporting Incidents to OHRP" – NIH
O. Special Act of Service Award – WRAIR HRPP Assessment from 9-13 June 2014 – Ference, Soderberg, Holland, Mighty, Rule, Slade, Sun, Walker
P. Department of Army "Achievement Medal for Civilian Service" Award for work ethic and service to WRAIR from 4 February 2007 to 13 December 2013 (Cancel)
Q. February 2014 - Selected to participate in the "I Save Lives Program" – Mighty and Soderberg

WRAIR Human Subjects Protection (HSP) Training /Presentations Conducted

A. 10 December 2013 - Provided training to Retrovirology, Clinical Operations Office regarding the completion of continuing review reports for protocols reviewed by the WRAIR IRB.
B. 9 September 2014: "Ethical Considerations When Developing/Managing Human Research Protocols" – by (b) (6) – WRAIR
C. In-services for individual departments or branches.

Research and Development:

The HSPB has been understaffed for its mandate. With the Ebola outbreak, many resources were re-prioritized for this effort, putting other projects in queue. A backlog from the understaffing and priority projects is still being managed at the time of this report.

Resource Management and Budget:

The HSPB Budget for FY14 was approximately $2.5 million to account for nine civilians, two contractors, travel, copier maintenance, computer upgrades and supplies. Travel was basically restricted during this fiscal year, the only exception was HSPB's support of an IRB training session given to Mongolian Investigators and IRB members (see below) in September 2014 for two staff members. This was funded by GEIS. Since travel was restricted, many staff members were unable to obtain continuing education credits needed to keep certifications.

Information Management:

(b) (6) continues to support the specialized Access database that houses all human subjects research protocols. Additionally, WRAIR uses IRBNet for membership document sharing. (b) (6) also supports the WRAIR by serving on different DoD selection committees for an enterprise-wide system for IRB management. She supplies monthly data to the Commander and contributes metrics to the Balanced Score Card SMS.

Operations:

The WRAIR HRPP received its triennial assessment from the Army Human Research Protections Office (AHRPO) between April and July 2014. The WRAIR's DoD Assurance was renewed and minor findings were addressed. This assessment requires the full-time support of the employees of HSPB and thus, backlog was created due to this visit as well.

The HSPB provided support to the Ebola outbreak in the review of several Ebola vaccine studies and the support provided by Kenya in virus identification/reference lab.

19-25 September 2014 - Provided support to the IRB 101 Course in Ulaanbaatar, Mongolia, from 22-24 September 2014, by presenting a talk "Challenges of International Research." The IRB 101 course was led by MAJ (b) (6), AFRIMS Epidemiology and Disease Surveillance Department and Human Subjects Protection Office, in coordination with the Mongolia National Center for Communicable Diseases. Presenter support was also provided by (b) (6) and the regional ethical review board capacity building organization (Forum for Ethical Review Committees in the Asian and Western Pacific Region (FERCAP). As per the AFRIMS team, the course and

study coordination were resounding successes; building upon/ strengthening local ethical review capacity, ethical research understanding, and relationships between and among WRAIR, AFRIMS, MAF, and the Mongolian NCCD/MOH. ((b) (6)

Accomplishments/Notes for the Record

A. HRPP Assessment (June 2014)
B. Recruitment actions: IRB Coordinator DB-0601-II (vice Slade); Human Subjects Protection Scientist, DB-0601-III (vice (b) (6)) and Human Subjects Protection Scientist, DB-0601-II (vice (b) (6))
C. Co-Conducted SHARP Training for HSPB staff on 18 June and 24 June 2013 ((b) (6)
D. Assisted the Director in writing the office Army Manpower Report and the Annual AHRPO report ((b) (6))
E. Annual WRAIR Cadaver Report to MRMC ORP HRPO for year 2012, January 2013 ((b) (6))
F. Presented training to the IRB on the revised SOP 619 Safety Reporting for Clinical Trials ((b) (6)
G. Additional studies were monitored for regulatory compliance (both routine and directed) in 2014.
H. The HSPB continues to assist the WRAIR Office of the Science Director (WOSD) with triaging of protocols prior to scientific review.
I. Assisted in finalizing several SOP's for HSPB
J. Created a database for the Scientific Review Committee
K. Provided custom queries for data calls for several special requests at HSPB
L. SOP In-Services occurred for Investigators, HSPB Staff, and the IRB.
M. Division-level training on lifecycle actions, current requirements, and updates continued in 2013.
N. Members of the HSPB continue to serve on the U.S. Army Research Institute (ARI) IRB, Safety Committee, and Agreements Review Committee. ((b) (6))
O. HSPB continued to support the WRAIR Association. ((b) (6))

Certifications Maintained

A. Clinical Research Professional (CCRP) certification obtained through the Society of Clinical Research Professionals (SoCRA), Certified through:
1 April 2015 ((b) (6))
B. Certified IRB Professional (CIP) credentials ((b) (6))
C. Association of Clinical Research Professionals certifications as Certified Clinical Research Coordinator (CCRC) ((b) (6))
D. Certified Clinical Research Associate (CCRA) ((b) (6))
E. Basic Life Support Course Recertification ((b) (6))

BEHAVIORAL BIOLOGY BRANCH

MILITARY PSYCHIATRY BRANCH

Mission

Provide knowledge and interventions to improve psychological functioning and resilience, reduce the impact of mental disorders, and enhance the readiness and performance of Soldiers and Leaders, and the well-being of Families.

Leadership, Organization and Personnel

Branch Chief: COL (b) (6)
Deputy Branch Chief: (b) (6)
NCOIC: SGT (b) (6)
Survey Production and Data Manager: (b) (6)
Adm. Assistant: (b) (6)
Principal Investigators: MAJ (b) (6), CPT (b) (6), CPT (b) (6), CPT (b) (6)
Staff: SPC (b) (6), PFC (b) (6), PV2 (b) (6)

Major Research and Development Projects by Branch Task Area

A. Task Area WX – Optimizing Behavioral Health Services and Return to Duty Decisions

1) PTSD Practitioner Registry: Researchers from Military Psychiatry, along with personnel at the New England Research Institute (NERI) and the VA health system have been working together to develop and launch a PTSD Practitioner Registry. One of the most difficult aspects of clinical treatment is bridging the practice-research gap; the concept of a practice registry has been used in other healthcare settings (e.g., The Community Physicians Network; The HIV Medical Association) although there is no such centralized network of military mental health clinicians. Recent findings indicate that although most clinicians report using evidence-based practices (EBP), actual adherence to the specific regimens is much less consistent across providers (Wilk et al, 2013). The PTSD Practitioner Registry will address current training needs by: (1) providing in-depth, longitudinal data on factors influencing clinicians' adoption and utilization of evidence-based practices (EBPs) and clinical practice guidelines (CPGs) in the DoD, VA, and community; (2) providing an interactive, web-based dissemination resource and support mechanism for clinicians to access EBP/best practice information, online training resources, and other practice-relevant materials; (3) evaluating in a prospective study the potential benefits and outcomes associated with exchange participation prior to large-scale implementation of the Registry across systems. Specific benefits for providers include providing personalized feedback, including

comparison to aggregated practice patterns, and providing an interactive resource of current EBPs to facilitate adoption. This project was funded through a grant from the Congressionally Directed Medical Research Program.

B. Task Area W1- Enhancing Warfighter Psychological Resilience

1) Social Fitness Training Study: This study is a longitudinal effort to assess the effectiveness of training to enhance social fitness at the platoon level for post-deployment behavioral health and resilience. This study is being conducted among Soldiers from the California Army National Guard who recently returned from a deployment to Operation Enduring Freedom in Afghanistan. Data collections, which occur at four different time points, have continued with all study units over the past year. The last data collection is scheduled during the summer of 2015.

2) Operation United Assistance – Ebola Study: The Military Psychiatry Branch assisted units deploying to Liberia in support of Operation United Assistance (OUA). Operation United Assistance was launched by US Army Africa to support U.S. Agency for International Development (USAID) efforts to contain the spread of the Ebola Virus/Disease outbreak in conjunction with the Governments of Liberia, Sierra Leone and Guinea. Military Psychiatry staff were tasked with providing information about unit behavioral health status and Soldier pre-deployment concerns to the leadership of deploying units. Qualitative data were collected in September which informed the development of surveys that were administered in October to deploying Soldiers at Ft. Bliss,TX. Soldiers were asked questions regarding resilience, stressors, physical and mental health information, and concerns about their forthcoming deployment. Results were briefed to senior leadership. WRAIR's Research Transition Office used these findings to develop training material that has since been included in the health threat brief provided by the Public Health Command. Follow-up data collections with units supporting OUA are scheduled to occur in 2015 during deployment and again when units return.

3) Branch Addresses Changes to the Diagnostic and Statistical Manual of Mental Disorders: Due to the pending publication of an updated edition of the Diagnostic and Statistical Manual of Mental Disorders (from DSM-IV-TR to DSM-5), branch researchers conducted a study to better understand how the new post-traumatic stress disorder (PTSD) definition in the DMS-5 would affect research, policy, and clinical application regarding the diagnosis. Soldiers were administered surveys containing both DSM-IV-TR and DSM-5 scale versions and results suggest that the DSM-5 PTSD criteria is equivalent to the DSM-IV-TR PTSD criteria in prevalence rates, but the DSM-5 symptom criteria do not seem to improve upon the DSM-IV-TR PTSD criteria. Furthermore, 30% of Soldiers who met criteria under DSM-IV-TR criteria did not meet DSM-5 criteria. The implication of this research includes how this discrepancy might influence clinical work and policy. In this transition, the population of service members and veterans with PTSD who no longer meet the DSM-5 criteria are particularly vulnerable which also warrants attention.

4) Study Conducted to Evaluate Chronic Pain and Opioid Use in Soldiers: The Military Psychiatry Branch researchers conducted a study regarding chronic pain and prescription opioid use among Soldiers after deploying to Afghanistan or Iraq. Results indicated that 44% of Soldiers reported being in pain for at least three months and 15% had used opioids during the past month. This research has exposed a

large unmet need for assessment, management, and treatment of chronic pain and related opioid use and misuse in military personnel after combat deployments.

5) Creation of the Walter Reed Functional Impairment Scale: The Walter Reed Functional Impairment Scale was created to assess functional impairment in the military and other occupational groups consisting of active, healthy workers, including those routinely exposed to stressful traumatic events as part of their occupation. The scale can be used to assess whether Soldiers and others exhibiting functional impairment are ready to return to work. This 14-item scale includes four domains (physical, occupational, social, and personal) and exhibited excellent psychometric properties. Pending future research, it is promising that The Walter Reed Functional Impairment Scale will be useful for occupational groups (such as police and fire fighters) beyond the military as well.

C. Task Area W1A – Novel Strategies to Reduce Aggression and Enhance Behavioral Health

1) Establishment of the Neurocognitive Assessment and Intervention Lab (NAIL): The Military Psychiatry branch established a Neurocognitive Assessment and Intervention Lab (NAIL) in 2014 to conduct to determine the neurocognitive processes underlying risk and resilience to stressful events. Branch researchers have established collaborations with investigators from Tel Aviv University and the University of Notre Dame as the program is being stood up. Program research efforts include both laboratory and field based studies. Preliminary data collections looking at neurocognitive correlates of stress-related symptoms were conducted with the California Air National Guard. Early results suggest that deployment-related changes in attention are predictive of behavioral health symptoms. Additionally, staff have been collaborating with colleagues at Tel Aviv University to identify a neurocognitive model of anger. This model will be extended in 2015 through collaboration with the University of Notre Dame to specifically examine neurocognitive links between stress and aggression. Measures of attention bias and emotional working memory have also been embedded in a recently completed study of chronic sleep restriction; data analysis is underway. A pilot study of an attention bias modification protocol designed to improve behavioral health will be conducted in the summer of 2015.

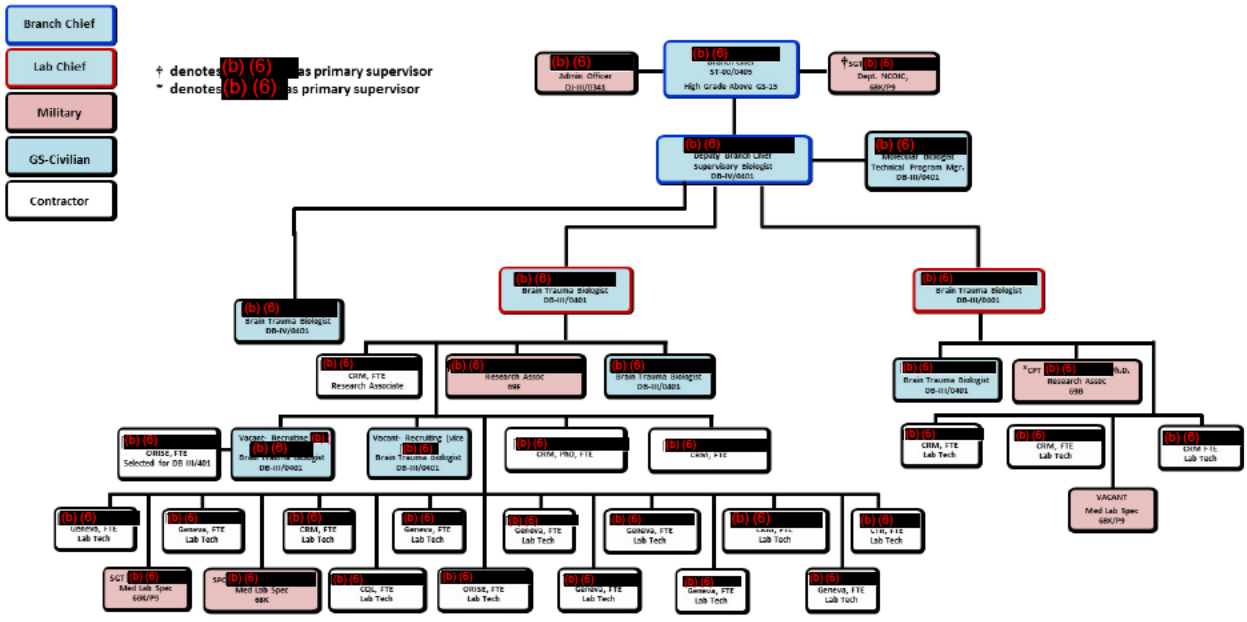
BRAIN TRAUMA NEUROPROTECTION AND NEURORESTORATION BRANCH

BTNN Branch Mission

Conduct preclinical research aimed at furthering our knowledge of the pathophysiology of mild-severe TBI, specifically the penetrating "ballistic-type" TBI and closed head impact concussion, across the spectrum of acute – chronic post-injury periods. Study novel strategies to diagnose (i.e. biomarkers) and/or treat TBI in a military centric environment. Overarching goals: 1) Discover TBI specific protein biomarkers capable of diagnosing and monitoring TBI 2) Discover a neuroprotection therapeutic applicable to acute (in-theatre) and chronic treatment of TBI. The Department utilizes a multidisciplinary neurobiology, neurobehavioral and neuropharmacology research platform to study cellular and molecular mechanisms of neuronal damage, neurofunctional impairments, and novel biomedical and therapeutic strategies.

Branch Organization and Personnel

Branch Chief and CCCRP Program Manager: (b) (6) ST, Ph.D.
Deputy Branch Chief: (b) (6)
Technical Program Manager: (b) (6)
Head, Molecular Biology Research Unit: (b) (6)
Head, In Vivo Research Unit: (b) (6)
Administrative Officer: (b) (6)
Additional Personnel (please see BTNN wireframe below)



A. **Primary Research Projects Major Accomplishments**:

1) Neuroprotection/Anti-Siezure Drug Therapy Projects

a) Completed final monotherapy assessments of the neuroprotection drugs (5 total) and the seizure protection drugs (7) for the 3 year DHP (Defense Health Protection) Combination Therapy grant.
b) Completed the first anti-seizure combination therapy study and initiated the first combination therapy experiments for neuroprotection in PBBI for the DHP Combination Therapy grant.
c) Completed drugs 5, 6 and 7 for the 5 year for the Operation Brain Trauma Treatment Grant, a consortium of five academic and industry partners to examine TBI treatments in various animal models of TBI.

2) Selective Brain Cooling Project

a) Initiated studies of a selective brain cooling therapy in a model of polytrauma and PBBI injury.
b) Initiated discussion with Advanced Development Representatives at USAMMDA to strategize entry into the Decision Gate process.

3) Stem Cell/Neuro-Regeneration Project

a) Completed comprehensive histopathological analysis of intracerebroventricular (i.c.v.) Amnion-derived Cellular Cytokine Suspension (ACCS) delivery in the PBBI model.
b) Demonstrated that ACCS significantly attenuates PBBI-induced neutrophil infiltration at 1 week post-injury and microglial reactivity at 2 weeks post-injury.
c) Noted that i.c.v. ACCS significantly reduces silver staining pathology in the corpus callosum at 2 weeks post-injury; these results demonstrate ACCS's strong capability to modulate neuro-inflammatory responses and neurodegeneration.
d) Demonstrated that continuous i.c.v. infusion of ACCS (1) results in significant improvement in motor function following PBBI; (2) protects against PBBI-induced neuropathology as evidenced by reductions in lesion volume, axonal degeneration and neuroinflammation.

4) mTBI/Concussion Model Development Project

a) Established new core capabilities for expansion in mTBI/concussion, neuroplasticity and polytrauma studies: including - Microdialysis, UPLC/HPLC and Seahorse (automated oxytherm) System (for mitochondrial functional assay) labs.
b) Identified metabolic and biochemical alterations that reflected increased susceptibility to repeated concussive impact.
c) Established sensitivity of additional neurofunctional tests (i.e. revised neurological severity scale (NSS-R) and righting reflex) to single and repeated concussion.
d) Added elevated plus maze and light dark box for testing anxiety-like behaviors in the mTBI/concussion model.
e) Increased sensitivity of rotarod and water maze testing measures to detect motor and cognitive deficits in the mTBI/concussion model.
f) Demonstrated that single and repeated concussion lead to neurological impairments associated with increased expression of GFAP in CSF and serum in the mTBI/concussion model.
g) Initiated the advanced development of the new WRAIR model of mild concussive TBI (a closed head, projectile concussive injury) to include acute, sub-acute and chronic recovery time points and repeated concussions.

5) Molecular/Biomarkers Project

a) Established a dedicated real-time EEG video monitoring rodent sleep lab to examine sleep parameters in experimental TBI.
b) Demonstrated initial proof-of-concept to identify changes in microRNA in brain tissue and serum following a PBBI and used the established Systems Biology approach to depict pathway analysis following the microRNA changes.
c) Characterized changes in Tau protein expression and cleavage during the acute and subacute periods following PBBI to determine if these neurodegenerative factors can be used as markers of therapeutic efficacy.
d) Demonstrated that there are substantial decreases in full length Tau protein and increases pathogenic Tau fragments that start acutely after injury and continue through 7 days post-PBBI and which can be used to evaluate potential neurotherapeutic efficacy
e) Determined changes in several protein biomarkers (including GFAP, GFAP-BDPs, α-II spectrin, spectrin break down products (SBDPs), and ubiqutin carboxy-terminal hydrolase L-1 (UCH-L1) in tissues and serum during the sub-acute period after PBBI and demonstrated GFAP response is a potential marker of therapeutic efficacy.

B. **Advanced Development Major Accomplishments**:

1) Laboratory Assay for TBI (LATBI) Project:

a) Completed enrollment for the multi-site pivotal trial in 2000 mild, moderate and severe TBI subjects (conducted with Banyan Biomarkers).
b) LATBI Project: Milestone B Decision Gate completed.
c) LATBI Project: Continued negotiations with Abbott laboratory for the i-STAT® Development and Assay Integration.
d) Initiated negotiations with Future Diagnostics to develop an optimized IVD Assay with mouse monoclonal antibodies for GFAP and UCH-L1 biomarkers.
e) Submitted SOW to DoD to fully fund assay development testing on the Philips Minicare POC platform and completed the feasibility testing on the alternate point of care device, Phillips Minicare Platform.

2) Drug Therapy for Traumatic Brain Injury (DTTBI) Project

a) Continued patient recruitment under approved EFIC for cohort 3 (200 moderate-severe TBI male and female subjects) of the Phase II TBI drug therapy clinical trial; Moderate to Severe TBI Clinical Study Randomized 2:1 drug to placebo, 3 cohort sequential dose-escalation.
b) Started enrollment for a Phase 2a A Randomized, Double-Blind, Placebo-Controlled Study of the Safety and Efficacy of NNZ-2566 in the Acute Treatment of Adults with Mild Traumatic Brain Injury at FT Bragg.
c) Formed a working group to discuss the selection of endpoints that can be used to define success criteria for the study, “A Randomized, Double-Blind, Placebo-Controlled Study of the Safety and Efficacy of NNZ-2566 in the Acute Treatment of Adults With mTBI” in order to support a Phase III study.
d) Submitted Technology Transition Agreement (TTA) to establish a collaborative relationship between the Combat Casualty Research Area Directorate and the Neurotrauma and Psychological Health Project Management Office for the transition of: Drug Treatment of Traumatic Brain Injury (DTTBI).

3) Noninvasive Diagnostic Device for TBI Project

a) Prepared documents to present the non-invasive devices (DANA, Brainscope, Infrascanner, Neurokinetics) to the Milestone Decision Authority for recommendation into the Decision Gate process.

b) Submitted an Inter-Service Agreement between USAMMA and USUHS to evaluate the test-retest inter-reliability of devices submitted for evaluation.

4) Intrathoracic Pressure Regulation Therapy (IRPT) Project

a) Prepared documents to present the IRPT device to the Milestone Decision Authority for recommendation into the Decision Gate process.

C. **Other Research and Development Major Accomplishments**:

1) Agreements:

a) Initiated new CRADA with Neuren Pharmaceuticals and NNZ-2591.
b) Initiated CRADA collaborations with PresSura Neuro for therapeutics with neuroprotective properties and seizure protection.

2) Information Productivity:

a) Submitted 3 extramural research proposals: 1 awarded (OBTT-extended studies, 1 pending final review (OCBTT for chronic studies, 1 not selected for award (CENC in collaboration with Boston University)
b) Submitted 3 new core proposals (Therapeutic Strategies for Concussion, Resuscitation Strategies for TBI/Polytrauma and PET/Concussion studies in collaboration with USHUS). Received 1.7, 1.5 and 1.6 AIBS scores respectively.
c) 8 new intramural Core Program proposals were submitted, reviewed and selected for funding beginning FY'14
d) Published 13 Peer-reviewed manuscripts and 29 abstracts

Blast-Induced Neuotrauma Branch

Mission

Conduct basic and applied research on militarily relevant closed-head injury resulting from exposure to blast(s), including studies of blast(s) accompanied by polytrauma and hemorrhage. Validate and standardize experimental blast exposure conditions and assessments of outcomes across multiple modalities, including cognitive and neurological function and visual, auditory, and vestibular processing. Define the biomechanical and neurobiological underpinnings of blast TBI and the contributions of operational & environmental stressors and nutritional deficiencies to bTBI severity and Warfighter vulnerabilities to blast exposure. Discover, evaluate and advance therapies or doctrinal changes that would improve survival and functional outcomes following these injuries.

Veterinary Services

Inter-institutional transportation of experimental animals by the Veterinary Services Program, WRAIR, has been instrumental to success of ongoing collaborative projects.

Research and Development

Personnel
(b) (6) Ph.D. (DB-IV, Branch Chief); (b) (6) (DE-IV); (b) (6) Ph.D. (CRM); (b) (6), M.D. (Geneva); (b) (6), Ph.D. (Geneva); (b) (6) M.D. (CRM); (b) (6) (Geneva); (b) (6) (CRM); (b) (6) (CRM); (b) (6) (Geneva); (b) (6) (CRM); (b) (6) (CRM); (b) (6) (YSCOA); (b) (6) (CRM); (b) (6) (CRM); (b) (6) (CRM); SGT (b) (6).

Special Events
Visited B. Braun Melsungen to review collaborative research investigating the effects of an intravenously infused lipid emulsion formulation containing highly enriched ω3-fatty acid triglycerides and medium chain triglycerides (MCT) on blast-induced traumatic brain injury (bTBI) and to plan a pre-pre-IND meeting with the FDA (17-18 March 2014, Melsungen, Germany).

Hosted Dr. (LTC) (b) (6) from the Department of Neurosurgery, Military Hospital, Hamburg, Germany to establish the groundwork for a collaborative blast traumatic brain injury project supported by the German Defense Ministry (28 April-1 May 2014).

Participated in a three day International State-of-the-Science Meeting on the Biomedical Basis for Mild Traumatic Brain Injury (mTBI) Environmental Sensor Threshold Values (4-6 November 2014, McLean VA).

Accomplishments

(b) (6) and (b) (6). Patent application entitled, ***Diagnosis and Treatment of Tauopathy and Chronic Traumatic Encephalopathy***. This application claims priority from U.S. Provisional Application Serial No. 61/997,050 filed on April 15, 2014.

(b) (6) (Principal Investigator) –The research proposal "Assessment and Treatment of Blast-Induced Auditory and Vestibular Injuries" was selected for funding as a Clinical Rehabilitative Medicine Research Program (CRMRP) Neurosensory Research Award within the Defense Health Program/Defense Medical Research Development Program. Co-Is are (b) (6) and (b) (6) of WRAIR and (b) (6), and (b) (6) of the National Institute on Deafness and Other Communication Disorders.

(b) (6) (Principal Investigator) - The research proposal “Elucidation of Inflammation Processes Exacerbating Neuronal Cell Damage to the Retina and Brain Visual Centers, as a Quest for Therapeutic Drug Targets, in a Rat Model of Blast Over Pressure Wave Exposure” was selected for funding as a CDMRP Clinical and Rehabilitative Medicine Research Program (CRMRP) Vision Research Program - Hypothesis Development Award. Co-Is are (b)(6) of WRAIR and (b) (6) and (b) (6) of Carnegie Mellon University.

Demonstrated the age-dependent variations in the pathology of blast-induced traumatic brain injury and molecular changes directing DNA damage repair and regulation of cell proliferation.

Determined the neurobehavioral, pathological and biochemical effects of single blast exposure, weight drop insult and the combination blast/weight drop injuries in rat TBI models.

Established functional outcome assessments to evaluate blast-induced disruptions of visual, auditory, and vestibular function in rodent injury models.

Determined that several drugs derived from metabolites of polyunsaturated fatty acids, known to be pro-resolving mediators of inflammation, are surprisingly not efficacious at healing blast-induced injuries to the retina and brain.

Established that an intravenously administered omega-3 fatty acid emulsion is efficacious as a blast TBI countermeasure when administered post-blast.

Systematically evaluated the contribution of head acceleration to TBI resulting from blast overpressure.

Using extremely high resolution diffusion tensor imaging, with collaborators at Duke University School of Medicine quantified appreciable microstructural white matter injury after repetitive blast exposures, importantly illustrating that primary blast sensitizes the brain to subsequent insults.

Demonstrated that phosphorylation of Tau protein occurs significantly at serine 396 after blast exposure and was proposed as a mechanism of Alzheimer’s-like pathology observed in TBI victims.

Evaluated the efficacy of intravenous administration of anti-LPA antibodies for protection against blast-induced TBI.

Modernization

A state-of-the-art Advanced Blast Simulator (ABS) was installed and utilized and provides high fidelity blast simulations that are critical to mission research objectives.

RESEARCH TRANSITION OFFICE (RTO)

Research Transition Office

Mission

Ensure that psychological health and resilience products delivered to Soldiers, Families, and DA Civilians have an evidence base and are implemented as intended by developing or transitioning evidence-based modules and evaluating internally and externally developed products.

Leadership, Organization and Personnel

Branch Chief: LTC (b) (6) (Jan-Aug), LCDR (b) (6) (Sept-Dec)
Program Officer: (b) (6)
Principal Investigators: (b) (6)
Master Trainers: 1SG (ret) (b) (6), MSG (ret) (b) (6), SSG (ret) (b) (6)
Staff: (b) (6)

Major Research and Development Projects

A. Completed the Resilience Training for BCT Pilot at Ft Benning, GA
B. Conducted MRT Day 9 Sustainment training at various training sites until May 2014 – Last location to transition to 3.0 was Ft Jackson.
C. Developed training material for and completed the MRT 3.0 train-up of MRT PIs and APIs, transitioning away from Day 9, Sustainment training in the MRT Course
D. Updated MRT Facilitator portion of Sustainment training
E. Updated and piloted all 3 Soldier Deployment Cycle Resilience Training (DCRT) modules with Soldiers and Performance Experts.
F. Updated 2 Spouse DCRT modules and piloted with Performance Experts.
G. Developed training material for and trained DCRT workshops designed to prepare MRT-PE to train MRT's in the DCRT material.
H. Responded to 3 requests for DCRT training delivered directly to deploying/returning Soldiers.
I. Updated the enlisted, warrant officer, and officer institutional resilience training modules.
J. Completed MRT Medical curriculum development and three pilots.
K. Trained a contractor to replace a GS employee as TDC course developer.
L. Developed first draft of slides related to mental well-being for deployments for the Ebola virus disease that are currently a part of the medical threat brief provided by the Public Health Command.

Fiscal Year 14 Publications

Deployment Cycle Resilience Training Manual
This training manual helps Master Resilience Performance Experts to train company-level Master Resilience Trainers who, in turn, train Soldiers from within their own unit on resilience skills specifically related to the deployment cycle. There are five modules: Pre-Deployment for Soldiers, Pre-Deployment for Spouses, Post-Deployment (Reintegration) for Soldiers Post-Deployment (Reintegration for Spouses), and Post-Deployment (3-6 months) for Soldiers.

Master Resilience Trainer-Medical Manual
This training manual helps Master Resilience Trainers (MRTs) that serve in military treatment facilities learn how to teach a two-hour module to health care staff to help with specific concerns such as burnout and compassion fatigue. It also helps MRTs to learn how to use medical examples with the basic mandatory fourteen resilience skills taught annually.

Basic Combat Training Resilience Manual and Manual of Applied Performance Skills
This training manual helps drill sergeants learn how to teach resilience skills that will help recruits build their resilience during the red phase of basic training. The Manual of Applied Performance Skills is a booklet provided to Soldiers that accompanies the modules they learn that has information and exercises to reinforce the skills they have learned.

U.S. Military HIV Research Program (MHRP)

Mission

The U.S. Military HIV Research Program (MHRP) will protect the U.S. Military from HIV and improve global health by conducting research to develop an HIV vaccine, reduce new infections and find a cure.

Division Organization and Personnel

Division Director — COL (b) (6)
Principal Deputy — COL (b) (6)
Deputy Director, Operations — (b) (6)
Acting Senior Admin Officer
Ch. Dept. of Lab Diagnostics and Monitoring
Ch. Laboratory of Vaccine Immunology
Ch. Dept. of Epidemiology And Threat Assessment
Ch. Dept. of Global Health Programs
Ch. Dept. of Department of Adjuvant & Antigen Research

Research and Development

A. Clinical Research

1) Results from the first Ebola vaccine clinical trial in Africa revealed a vaccine candidate produces the same immune response seen in the United States in an African setting. Importantly, this vaccine candidate is a precursor to candidates currently being tested at our site in Uganda and in West Africa.
2) HDRL conducted Vesicular Somatitis Virus (VSV) viremia/viral shedding screen for WRAIR, NIH, and US sites for Ebola VSV Clinical Trials; conducting testing to support down selection of VSV dosage for pending African trials. COL (b) (6) was heavily involved in the design of the WRAIR study, data interpretation, and communication of the study in a high impact medical journal.
3) MHRP, a Clinical Trials Unit for NIH HIV/AIDS Clinical Trials Networks, was selected to participate in follow-up vaccine studies related to RV144 in Mozambique and Tanzania. These trials will begin in 2015.
4) Johnson & Johnson has selected MUWRP in Uganda as a site for the planned HIV-V-A004 HIV Vaccine trial. A004 is a phase II study of an HIV candidate vaccine for prevention using Ad26 prime with MVA and protein boost. A0004 is the critical path study to down-select for a final regimen to advance to efficacy testing. In addition to contributing sites and collaboratively designing the study and development plans, MHRP provides the MVA to be tested in A004.
5) MHRP's large, long-term cohort study at multiple African sites called the African Cohort Study (AFRICOS) has enrolled 1,200 volunteers. This study is evaluating HIV prevention, care and treatment services it supports through local facilities, funded by the U.S. President's Emergency Plan for AIDS Relief (PEPFAR). A critical component of the study is the collection of data regarding co-infections such as malaria and tuberculosis. TB/HIV co-infection rates are especially high in Kenya and Tanzania, two countries where MHRP conducts research with local partners.
6) MHRP began a new cohort study, RV363, to assess the incidence of HIV and the willingness of adults to participate in future HIV vaccine trials in Maputo Mozambique.
7) MHRP began a new cohort study (TRUST study) RV368 in high-risk populations in Nigeria in collaboration with the Institute of Human Virology (IHV) and Johns Hopkins University.
8) MHRP began RV393, a cohort study to assess incidence of HIV infection, retention rate and willingness of adults to participate in future HIV vaccine trials in Western Kenya.

9) The Walter Reed Project HIV Program in Kericho Kenya continued to participate in HIV Therapeutic studies as part of the NIH-funded AIDS Clinical Trial Group.
10) MHRP continued its unprecedented study of acute HIV infected volunteers, RV217, at its sites in East Africa and Thailand and has recorded more than 100 cases of acute infection. This study, called the Early Capture HIV Cohort Study (ECHO) is a multi-site research study to follow a group of high-risk volunteers to gather information on acute HIV infections and collect blood and mucosal samples.
11) MHRP continued its acute infections collaborations with SEARCH in Bangkok Thailand at the Thai Red Cross, called RV254, which has enrolled more than 200 volunteers most of whom were then enrolled in a study where they immediately received ART. Patients treated early in acute infection showed similar characteristics to 'elite' HIV controllers.
12) MHRP developed several protocols for treatment interruptions studies in its two acute infections cohorts (RV254 and RV217). These protocols are undergoing review in Thailand and Africa, and are planned to start in 2015.
13) MHRP is collaborating on a new vaccine study in January 2014 to evaluate the safety and immunogenicity of two boost immunizations with MVA CMDR, a viral vectored HIV vaccine developed by MHRP and DAIDS scientists. The study involves healthy volunteers who previously received DCVax-001 plus poly ICLC within the last three years. This project is a collaboration with the Laboratory of Cellular Physiology and Immunology at Rockefeller University, where the study is taking place.

B. RV144 Related Clinical (Thailand)

1) An HIV immunogenicity study in Thailand, RV306, is using the RV144 vaccine regimen to compare additional vaccine boosts and gather more immunogenicity data in 360 new volunteers. This study is providing more intensive and comprehensive characterization of the innate, cell-mediated and humoral immune responses than possible within RV144.
2) An MHRP-led vaccine trial RV305, the first post-RV144 vaccine clinical trial conducted in Thailand, was completed and initial results were presented at AIDS Vaccine. Researchers have identified the most effective boosts and found that late boosts in this study, given six years after initial vaccination, are producing some surprising and promising immune responses with developing neutralizing antibodies.
3) Signed MOU with Ministries of Public Health and Science and Technology supports continuation of long-term partnership with Thai government; secures resources for vaccine development and study execution in country that has been key partner.
4) Basic and translational science fueled by samples generated from MHRP studies RV144, 305, and 306 has provided a basis for analysis of HIV vaccine studies. Collaborations have focused and fundamentally changed how HIV vaccines are selected and evaluated and refocused attention on protein based products.

C. Science/Pre-clinical

1) Two studies in the 19 March 2014 issue of *Science Translational Medicine* shed new light on the antibodies that appear to have played a role in decreasing the risk of HIV infection in the RV144 HIV vaccine trial. The results provide a better understanding of the immune response a vaccine may need to elicit in order to provide protection from HIV.
2) In a study published October 2013 in the journal *Cell*, a scientific team has shown that bioinformatically optimized HIV vaccine antigens known as “mosaic” antigens might be useful in the design of a global HIV vaccine.
3) A research team led by investigators at Beth Israel Deaconess Medical Center (BIDMC) in collaboration with MHRP demonstrated that the viral reservoir is established extremely early after simian immunodeficiency virus (SIV) infection of rhesus monkeys and before the virus can be detected in the blood. The findings appeared online on July 20 in the journal *Nature*.
4) At the HIV Research for Prevention Conference (R4P) in 2014, MHRP researchers gave nine oral

presentations and eight poster presentations, in addition to two pre-conference symposium presentations. Research associated with the RV144 trial dominated the conference, and results were presented on the RV144 vaccine regimen safety in a trial in South Africa which showed it was safe and immunogenic.

5) MHRP had a major presence at the annual Conference on Retroviruses and Opportunistic Infections (CROI) in March, with ten posters and four oral presentations.
6) (b) (6) gave plenary address at the 2014 AIDS Conference in Australia around cure research, and several MHRP scientists presented posters.

D. Soldier Health

1) Identified the primary HIV infection attribution category in the Army for the first time since repeal of Don't Ask Don't Tell, which defines a very specific population most at risk for HIV that can now be provided with targeted preventive intervention activities.
2) Conducted medical economic analysis of a MHRP Hepatitis C infection (HCV) seroprevalence study of more than 17,000 recently deployed US military personnel which demonstrated that HCV screening of all applicants for military service will result in a net cost savings to the DoD in treatment cost avoided.
3) Tasked with conducting HIV DA Force Test Mission, May 2014.
4) HDRL Director served as DOD Prosecution Expert Witness/Dx Consultant for 3 (2 Air Force; 1 Army) aggravated sexual assault courts marital cases; all cases resulted prosecution of Defendant.
5) MHRP investigators completed all phases of data collection for a sexual behavior and sexually transmitted infection risk survey of U.S. Navy personnel. The deployment phase of the study included data collection while underway and the survey included more than 2,000 Sailors on 11 U.S. warships. These data will generate knowledge products that identify specific targets for preventive intervention and will inform policy force health policy development, and adaptation of existing evidence-based best practices preventive interventions for use in U.S. military personnel.
6) MHRP's Department of Epidemiology & Threat Assessment and study team members from Fort Carson completed adaptation of existing evidence based HIV/STI interventions for use in military Service member and beneficiary populations. Evaluation of these intervention knowledge products was initiated in a focus group setting involving Soldier study volunteers at Fort Carson.
7) HIV Diagnostic and Reference Laboratory (HDRL) continued to conduct more than 1 million HIV-1 screening tests per year from personnel within the Army's active, reserve, and National Guard units, and from individuals applying for Army service.

E. President's Emergency Plan for AIDS Relief (PEPFAR)

1) Under the President's Emergency Plan for AIDS Relief (PEPFAR), MHRP sites in Nigeria, Kenya, Uganda, and Tanzania continued to make a profound impact. Since 2004, more than 250,000 patients have been enrolled on antiretroviral therapy and more than one million have received HIV counseling and testing.
2) Through a combination of active duty US military, DAC, contractors and predominantly local in-country hires, WRAIR works with host country national public, private, mission and military hospital staff as well as community and faith based organizations to support a comprehensive program along a continuum of care model (facility to community). Developed sites are in:

    a) Kenya: South Rift Valley, Kombewa District and with the Kenya Defense Forces
    b) Nigeria: Nigerian Ministry of Defence
    c) Tanzania: Southern Highlands (Mbeya, Rukwa and Ruvuma Regions) and the Tanzania Peoples Defense Forces
    d) Uganda: Kayunga and Mukono Districts

3) Achievements in PEFAR-funded Care and Treatment as of September 2014:

a) Helped support **1,016** facilities in the provision of HIV treatment
b) Currently **189,641** patients are on Anti-Retroviral Therapy (ART)
c) Counseled and tested more than **1.4 M** women, of which more than **107,009** have received ARTs
d) Supported the provision of medical male circumcision to more than **204,807** males between the ages of 13 to 60 years old in last four years.

Resource Management and Budget

MHRP funding is diversified, with a large portion coming from the President's Emergency Plan for AIDS Relief (PEPFAR). Funding for that program, along with DAIDS, has fluctuated over the last three years and CSI funding decreased in 2014. Funding is shown below in millions for the last three years.

FUNDING TYPE	FY14	FY13	FY12
PEPFAR	62.50	46.20	87.26
MIDRP POM	16.09	16	16.19
DAIDS	16.80	37.42	17.22
CSI	7.00	16.00	16.00
ADV DEV POM	4.45	5.52	6.20
P8 (DR. PEEL)	7.02	6.43	5.74
CTU	1.70	1.51	1.61
OTHER	1.31	4.17	2.94
Total Funding	116.87	133.25	153.16

Operations

MHRP underwent a strategic planning process during FY2014. The new strategic plan is attached in the appendix.

Military Malaria Research Program (MMRP)

Mission:
The mission of MMRP is to develop new vaccines and prophylactic or therapeutic drugs to prevent infection and minimize disease due to malaria and other diseases with significant impact on military readiness and operations. We maintain a robust expert capacity in basic and applied research necessary to transition candidate drugs and vaccines to advanced clinical testing in endemic areas. We train military physicians in Clinical Pharmacology and provide expert consultation in infectious diseases, malaria, parasitology, clinical pharmacology, vaccinology, and clinical trials to the AMEDD and the U.S. Army.

Organization and Personnel
(see Appendix #, Organizational Chart): The MMRP was established in August 2013, combining the Experimental Therapeutics and Malaria Vaccine Branches under the same leadership. The merging of these two branches leveraged capabilities, scientific capacity, and personnel to meet increasingly complex mission requirements. No changes in personnel or organizational structure occurred in FY14.

1) Program Director: COL (b) (6)
    a. As Director, COL (b) (6) provides oversight to two branches, Experimental Therapeutics (ET) which is dedicated to malaria and infectious diseases drug development and the Malaria Vaccine Branch (MVB).
    b. NCOIC: SFC (b) (6)
2) Experimental Therapeutic Branch Director, COL (b) (6)
3) Malaria Vaccine Branch Director, LTC (b) (6)

Statistical data:
Overall, for FY14 there were 33 publications (14 for Experimental Therapeutic Branch and 19 for Malaria Vaccine Branch). Five patents were either filed or granted. Further information is provided in the appendices of each branch description below.

Healthcare Delivery:
N/A

Veterinary Services:
N/A

Training and Education:
MMRP is dedicated to the professional development of our soldiers, staff scientists, and contractors as evidenced by the accomplishments listed from our subordinate branches and sections below. Several of our enlisted soldiers have been selected for Officer Candidate School, the Army Physician Assistant training program, and/or completed their baccalaureate education in FY14.

Research and Development:
Major accomplishments for FY14 were highlighted by the identification of a new lead candidate drug for the treatment and prevention of malaria. This was the first novel drug class identified for human clinical trials in over 15 years at the WRAIR. In FY14, we saw a significant improvement in vaccine efficacy targeting the circumsporozoite protein by modification of the dose and schedule of RTS,S, a lead malaria vaccine candidate co-developed by the WRAIR and GSK, that has launched further field testing in Africa in FY15-16. The Program also has had a

significant impact in basic, translational, and clinical science as evidenced by the publication and patent records as above and further details provided in sections below.

Resource Management:

In FY14, MMRP received a total allocation of Army RDT&E (6.1-6.3) of $13,555K ($8,617K for ET, and $4,938 for MVB). In addition $1,300K of Advanced Development funding (Army RDT&E 6.4), $857K of DHP RDT&E, and $3,833K in Congressional Special Interest (CSI) funds were received, for a total of $19,545K.

EXPERIMENTAL THERAPEUTICS BRANCH

Mission:

The mission of the WRAIR Branch of Experimental Therapeutics is to discover and develop new pharmaceutical agents to protect military members from death, disease, and injury. We are the nation's primary developer of new drugs to prevent and/or treat malaria and leishmaniasis. The Branch engages in drug discovery, drug efficacy and mechanism evaluation, and formal preclinical and clinical development. Our Branch contributed to Graduate Medical Education via the Clinical Pharmacology Fellowship, the only fellowship of its kind in the DoD. We additionally maintained a national and international resource with a College of American Pathology (CAP) accredited Leishmania Diagnostic Laboratory (LDL).

The Branch of Experimental Therapeutics is the United States Government's only "bench to bedside" drug company. The Branch carries out state of the art research in every stage of drug discovery and development. The program literally begins with a concept of a useful drug and carries that idea through to a FDA approved product. We screen putative antimalarial compounds *in vitro* for potency, toxicity, solubility, permeability and metabolic stability. We also evaluate the phenotypic profiles of relevant metabolic enzymes (CYP450s, MAO, FMOs), and assess the enzyme kinetics of these enzymes, and identify metabolites as needed. Animal testing in mice and non-human primates follows the *in vitro* work on promising drug leads. This includes drug formulation leading to requisite pharmacokinetic, pharmacodynamic and toxicity testing needed for advancing a compound into human trials which are also a Branch function. During the entire drug discovery/development process, target structural parameters are utilized to optimize the efficacy of the end product by the iterative application of rational drug design technologies. The unique biomedical infrastructure includes:

- Identification of new targets for anti-malarial drugs.
- Discovery of new drugs for prevention and/or treatment of malaria.
- Drug design to optimize structure-activity relationships, minimize liabilities, and exploit antimalarial drug properties.
- Chemical synthesis laboratories capable of synthesis and characterization of novel chemical matter
- Preclinical and clinical studies with antimalarial drugs.
- Isolation of malaria clinical specimens for determination of drug sensitivity, phenotype, and genotype.
- Graduate Medical Education: Clinical Pharmacology Fellowship.
- Nuclear Magnetic Resonance Laboratory
- Mass Spectrometry Laboratory
- Operate the Leishmania Diagnostics Laboratory, the only College of American Pathologists (CAP) - certified and Clinical Laboratory Improvement (CLIP) - accredited laboratory of its type in the world for the diagnosis of leishmania in the DoD and all U.S. citizens.
- Integrated chemistry and biology information systems
- One of the world's largest chemical inventories of antimalarial compounds and one of the world's largest collections of biological data on antimalarial compounds

Organization and Personnel

1) Director: COL (b) (6), PhD, PMP
2) Deputy Director: LTC (b) (6), PhD, MT (ASCP)
3) NCOIC: SSG (b) (6)
4) Administrative Officers: (b) (6)

Statistical Data:

Publications: 14 Patents: 1 Budget: $$13,178K

Healthcare Delivery:

N/A

Veterinary Services:

N/A

Training and Education:

The Experimental Therapeutics Branch hosts the Clinical Pharmacology Fellowship, a unique training program in Clinical Pharmacology open to MD and PhD officers to provide training in clinical pharmacology.

Research and Development:

In 2014, Experimental Therapeutics finished optimization and final selection of candidate compounds to advance to clinical development based on a substituted triazine scaffold for the prophylaxis and treatment of malaria. Clinical development will begin in 2015 and advance through Phase 2A efficacy studies here at the WRAIR. Follow-on development after Phase 2A will be directed by the US Army Medical Materiel Development Agency (USAMMDA) to licensure.

Resource Management:

Army RDT&E: $8,617K, Adv Dev: $1,300K, DHP: $857K, CSI: $1,833K

Department of Drug Discovery

Mission:

Plan, coordinate, and execute basic and advanced research into the appropriate testing methods to evaluate compounds that inhibit, combat or otherwise treat specific biological threats to the warfighter. Perform *in vitro* and *in vivo* preclinical studies on the activity, efficacy, toxicity, potency, pharmacokinetics, and pharmacodynamics of candidate antiparasitic drugs.

Organization and Personnel:

A. **Department Office**
   1) Chief, Department of Drug Discovery: LTC (b) (6), DVM, PhD (replaced LTC (b) (6) in October 2013)
   2) NCOIC: SGT (b) (6) / SGT (b) (6)
   3) Project Manager: (b) (6)
   4) Senior Scientist: (b) (6)

B. **In Vivo Systems**

1) Chief: CPT (b) (6)
2) (b) (6) (Civilian) (b) (6), PhD (Contractor), (b) (6) (Contractor), (b) (6) (Contractor), SPC (b) (6), SPC (b) (6) (Contractor), (b) (6) (Contractor), (b) (6) (Contractor), (b) (6) (Contractor), (b) (6) (Contractor)

C. **Leishmania Diagnostic Laboratory**
1) Chief: Vacant
2) (b) (6) (Civilian), (b) (6) (Contractor), (b) (6) (Contractor)

D. **In Vitro Laboratories**
1) Chief: (b) (6) (Civilian)
2) (b) (6) (Contractor), (b) (6) (Contractor), SPC (b) (6), SPC (b) (6) SPC (b) (6) (Contractor), SPC (b) (6) (Contractor)

Statistical data

A. 12 funded research projects, totaling $4 Million in funding in FY14
B. 11 peer-reviewed publications, 4 conference presentations (oral and poster)
C. 6620 chemical compounds tested in vitro assays
D. 331 chemical compounds tested in animal models

Healthcare Delivery:

N/A

Veterinary Services:

Mouse Hepatitis Virus infection in the WRAIR vivarium resulted in depopulation and discontinued all animal research for over six weeks during this FY.

Training and Education

A. Key personnel attended the Combating Antibiotic Resistance Symposium in Boston.
B. All Military Officers and Civilian employees continue to work toward DAWIA Certification in Science and Technology Management.

Research and Development:

A. **Q0300_12_WR_CS In vitro testing of antiparasitic drugs for potency and toxicity**

In vitro testing for malaria for FY14 encompassed support for testing novel chemical entities and screening new compounds from the Experimental Therapeutics Chemical Repository. In vitro testing has been conducted to advance lead scaffold series (triazines, 8AQs, pyrimidinyl guanidines, aminoquinoline analogues) and to discover new antimalarial compounds with potency but not toxicity. In vitro testing assays performed in FY14 include: SYBR Green malaria potency assay, malaria liver stage development assay, cytotoxicity assay, induction of resistance assays, combination therapy assays, and identification and resistance determination of malaria species isolates.

In Vitro Potency: There were 1,904 compounds tested in the SYBR Green malaria potency assay which comprises IC50 determinations for 3 parasite strains (D6, C235, and W2). This translates into 19,627 replicate assays performed. Compound potency prescreens in D6, done in duplicate at two different concentrations (10000 and 1000 ng/ml) resulted in 480 actual compounds tested and 1920 replicate assays.

Specialty Parasitololgy: In addition, 7 parasites were assessed to profile their antimalarial resistance. Standard antimalarial compounds tested include: Arteether, Artemether, Atovaquone, Dihydroartemisinin, Artesunate, Artelinic acid, Artemisinin, Mefloquine, Proguanil, Primaquine,

Tafenoquine, and Chloroquine. The specialty parasitology lab also supported training conducted by the Tropical Medicine Course on parasite identification by microscopy.

In Vitro Cytotoxicity: 1,432 compounds were tested for in vitro cytotoxicity against the HepG2 cell line, and 50 compounds were tested against the RAW macrophage cell line. Also, in FY14, 376 compounds were tested for inhibition of malaria liver stage activity.

Vector Dissection: As part of the support provided by the in vitro staff to in vivo liver stage testing, mosquitoes were dissected to recover 91,000,000 sporozoites needed for in vivo testing (27,000,000) and in vitro testing (64,000,000).

Resistance Studies: Induction of resistance studies were initiated for profile compounds from the triazine and pyrimidinyl guanidine projects. Thus far, no induction of resistance has been noted after the compounds were under pressure for 14 months. Combination studies with standard antimalarial drugs are planned to see if novel drug synergies can be elucidated.

B. **Q0297_12_WR_CS Using bioluminescent in vivo imaging screening (IVIS) of luciferase-expressing parasites to determine specific activity of novel antiparasitic drugs.**

This mouse model allows direct evaluation of liver stage (causal) prophylactic activity. Selected oral causal prophylaxis compounds and non-hemolytic toxicity 8-aminoquinoline analogs, next generation 8-aminoquinoline (8-AQ_NH) derivatives, and other selected antimalarial drugs including triazines have been developed as potentially the next prophylactic drugs to prevent malaria in deployed Soldiers. We conducted studies using validated liver-stage models in the male C57BL/6 albino, C57BL/6 black, transgenic C57BL/6 mice with knockouts in 2D6 and 2D6 knockouts with the human 2D6 gene knocked-in and female C3H mice following inoculation intravenously with P. berghei sporozoites. These models were successfully executed and the mice have been used in a number of studies to evaluate the causal prophylactic effects of putative antimalarial drugs. Identification and development of 94 drugs with 198 dose levels (causally active antimalarials) have been evaluated using our In Vivo Imaging System assay (IVIS) this year. Testing of novel prophylactic drugs is not only ongoing to determine their potential as efficacious malaria prophylaxis drugs, but also to determine methods of enhancing the PK/PD properties of these compounds. Selected compounds with acceptable minimal curative dose (MCD) and PK/PD values will be planned for further development and down-selection of further lead candidates.

The animal assays that support the CYP2D6 study testing primaquine metabolic activation was conducted using this core proposal. The CYP2D activation has also been shown to be necessary for PQ efficacy against the liver stage of *P. berghei* in mice (Pybus, *et al.*,2013) by assessing liver stage efficacy in CYP2D knockout mice. In addition, our team has demonstrated that other 8AQ compounds in late stage studies such as tafenoquine (Phase III) and NPC-1161B (pre-IND) also require CYP2D activation for liver stage efficacy.(Marcsisin, *et al.*,2014)

The animal studies in support of the biology of ortho-quinones were conducted as part of this proposal. Ortho-quinone (OQ) was compared to tafenoquine (the parent compound) to determine if it was the active metabolite. Using multiple doses (up to 20-fold the ED100 of TQ), the efficacy was assessed against liver schizonts of P. berghei.

No liver stage efficacy or liver stage suppression was observed. We conclude from these data that the OQ is not an active metabolite of TQ. Recall that PK data with PQ in the 2DKO implicate the 5OH metabolism pathway. Thus, the active species must be prior to the formation of the OQ, in the C5 oxidized metabolic pathway.

The insight resulting from the 2D knockout mice experiments has enabled the development of a rational plan to design molecules to circumvent the physiological need for CYP 2D metabolic activation of 8AQs.

The IVIS model was also utilized to determine the efficacy of decoquinate when dosed IM in various formulations and vehicles. The efficacy of IM DQ is well beyond 6 weeks in this rodent model after a single IM injection against P. berghei.

The Thompson Test model was added as an amendment to the IACUC protocol that supports this proposal allowing us the capability to conduct experiments to determine the blood schizonticidal activity of chemical compounds. All compounds in the triazine scaffold were assessed in this model under the support of the Triazine Research Proposal and subsidized by this core proposal. Unfunded efforts to identify novel compounds were also supported under this proposal to ensure new compounds are continuously feeding the drug discovery efforts.

C. **PQ0299_12_WR_CS Evaluations of pharmacokinetics of selected novel antiparasitics in rodents**

In FY14, PK studies were conducted on a total of 61 compounds performed at 67 dose levels and different formulations following single intravenous, intramuscular, and/or intragastric administrations. A wide variety of drug scaffolds were tested including triazines, decoquinate formulations, acridones, 4-aminoquinolines, and 8-aminoquinolines, WinNonlin was utilized to assess the raw data from all PK studies conducted at the WRAIR and at AFRIMS. The purpose of PK studies of antimalarial drugs is to guide chemical synthesis, efficacy and toxicity studies in the same animal species for selecting superior PK property candidate in further development.

D. **Q0298_12_WR_CS Evaluations of acute and subacute toxicities (pre-GLP) of selected novel antiparasitic drugs in rodents.**

We have developed and validated pre-GLP acute and subacute toxicity models in male ICR mice following single and multiple administrations of compounds. During FY14, 8AQ compounds and multiple decoquinate (DQ) formulations were assessed for toxicity. The DQ formulations were assessed for systemic as well as local toxicity at the sight of injection.

E. **Q0296_12_WR_CS Screen and assess new antimalarial compounds for blood schizonticidal activity, causal prophylaxis or radical cure in the Plasmodium berghei- mouse blood and exoerythrocytic malaria models; and Plasmodium cynomolgi-Rhesus monkey relapsing malaria model (AFRIMS).**

The P. cynomolgi-Rhesus monkey model is the only model to assess antihypnozoite activity in animals. During FY14, there was one large experiments conducted on the P. cynomolgi-Rhesus monkey relapsing model. These experiments examined the prophylactic activity of triazine compounds dosed on a weekly schedule. This model has been an invaluable tool for assessing prophylactic antimalarials dosed weekly due to the 4 relapses the monkeys will experience throughout the 100 day study period. This poses a continual parasitic challenge to prophylactic drugs dosed weekly, as the relapses from the hypnozoites in the liver constitute repeated infections that occur on a regular basis at a consistent interval.

ET chose to discontinue the use of the murine blood schizonticidal model at AFRIMS due to economic and schedule constraints. The model was validated and incorporated into the IVIS protocol at the WRAIR.

F. **Q0294_12_WR Drug Evaluation in the Human-Aotus Plasmodium falciparum/P. vivax model (contract W81XWH-07-C-0044).**

This model is the only model to evaluate drugs against the main human parasites (P. falciparum and P. vivax) in vivo to which WRAIR has access through an existing contract. No experiments were conducted in the Aotus model because of internal concerns regarding the execution of the experimental design. Current efforts are underway to establish a humanized mouse model that will be run in Experimental Therapeutics. If the humanized mouse model can be validated and used in conjunction with testing conducted at AFRIMS using ex-vivo samples, this contract may be completely unnecessary after FY15.

G. **Cutaneous Leishmania Drug Discovery**

The cutaneous leishmania drug discovery and development effort was downgraded to a tech-watch program. Two grants were obtained in the spring of FY14 from the Congressionally Directed Medical Research Program. One grant is a collaborative grant with Anacor Pharmaceuticals to explore promising new oxyboryl compounds with demonstrated efficacy against cutaneous leishmania, and a second grant is collaboration with (b) (6) of Ohio State University to investigate the efficacy of a novel combination of compounds: an arylimidamide combined with azoles such as fluconazole. Work will begin on these two projects in early 2015. Other projects or collaborations in FY14 included the University of Virginia, Anacor compounds, a chochleate study, testing in vitro hits from the CIS9000 collection, and pharmaceutical compounds such as moxifloxicin and clorpropamide.

Other funding was obtained include a Commercial Testing Agreement with Sanofi Aventis to test novel topical creams in our in vivo test systems and with DNDi to conduct in vitro and in vivo testing for their compounds

H. **Q0230_11_WR *In vivo* screening of compounds for lead identification and development of anti Leishmanial drugs.**

Due to budget and quality reasons, in vivo screening of compounds was moved from the University of Miami to WRAIR. Mouse lesion suppression, mouse lesion cure, and hamster lesion cure assays are now being performed using In Vivo Imaging which provides more data on parasite load that cannot be obtained through traditional lesion cure assays. The workload was significantly reduced to focus on compounds that were the most worthy of in vivo testing.

A total of 91 compounds were testing during the FY. Of those, 61 compounds were in the mouse lesion suppression model, 10 in the mouse leson cure model, PK samples were collected on 8 compounds, and 12 compounds were tested for acute toxicity.

L. guyanensis and L. panamensis were successfully transfected with the luciferase gene. ET now has three Leishmania species, both old and new world, for use in animal models. All three have been validated in the BALB/c and Golden Syrian Hamster models.

I. **Q0301_12_WR In vitro Amastigote-Macrophage Leishmania Testing**

During FY14, 447 compounds were tested for potency against amastigote-macrophages of different Leishmania species. This constitutes 5,712 replicate IC50 determinations. Also, 1,152 compounds were pre-screened for activity against L. major leishmania amastigote-macrophages. This constitutes 4,608 prescreen replicate assays. Also, 184 compound were tested for potency in the promastigote alamar blue IC50 assay with constitutes 836 replicates.

Additionally, six species of Leishmania were successfully transfected with the firefly fuciferase gene for use in in vitro assays (L. guyanensis, L. panamensis, L. tropica, L. donovani, L. infantum, L. mexicana). Prior to FY14, only L. major was available for testing using luciferase expression.

J. **Leishmania Diagnostic Laboratory**

The Leishmania Diagnostic Laboratory (LDL) is the only laboratory of its type in the world accredited by both the College of American Pathologists (CAP) and the Clinical Laboratory Improvement Program Office (CLIPO). The mission of this laboratory is to provide diagnosis of leishmania for patients in the DoD and to all U.S. citizens. The College of American Pathologists (CAP) is an accreditation organization for laboratories under the Clinical Laboratory Improvement Amendments of 1992 (CLIA), and the Clinical Laboratory Improvement Program Office (CLIPO) implements the CLIA within DOD.

The transition process to move the LDL to the Military HIV Research Program under Dr. Sheila Peel began in FY14. It is anticipated that the transfer of all capabilities will be completed no later than 4QFY15. The LDL will be included in the largest CAP diagnostic laboratory within the DoD with this action.

K. **Q0381_14_WR Long-acting, injectable formulation of decoquinate for malaria prophylaxis**

Decoquinate (DQ) was formulated in various vehicles and particle sizes to determine the efficacy of DQ when dosed IM in mice. Oily IM-DQ suspension had a superior pharmacokinetics profile and longer prophylactic efficacy than the Tween-80/Saline formulation of DQ, but demonstrated inflammation in muscle tissues at injection sites. DQ micro-particle formulation had a prolonged prophylactic activity (8 weeks). DQ nano-particle formulation was a quick release formulation and the prophylactic effect was shorter (2-3 weeks).

All selected FDA approved vehicles showed mild damage at the injection sites in addition to the reaction from the DQ particles which also induced a mild inflammation. Emulsion alone and DQ in emulsion showed the lowest injury at IM injection sites.

In FY15, ET will investigate the possibility of implant technology to offset the inflammation noted at the injection site.

Resource Management and Budget

1) ARMY RDT&E funds: $3,746 K
2) DHP RDT&E funds: $0 K
3) Reimbursable funds: $190 K
4) Expenses
5) Contracts: $2,065 K
6) Civilian Salaries: $614 K
7) Other (supplies, software, etc): $350K

Modernization:

1) A second In Vivo Imaging System (IVIS) was added to the laboratory to support experiments to identify compounds that are function as more than blood schizonticidal agents and to support the cutaneous leishmanial experiments.

Department of Drug Development

Mission:

Plan, coordinate, and execute basic and advanced research into the design, synthesis and development of novel chemical entities to inhibit, combat or otherwise treat specific biological threats to the warfighter. Perform *in vitro* and *in vivo* preclinical studies on the absorption, distribution, metabolism, excretion, and toxicology of candidate antiparasitic drugs.

Organization and Personnel:

A. **Department Office**
   1) Chief, Department of Drug Development: CPT (b) (6), PhD (replaced by MAJ (b) (6), PhD, September 2014)
   2) NCOIC: SGT (b) (6)
   3) Project Manager: (b) (6)

B. **Medicinal Chemistry Section**
   1) Chief: vacant
   2) (b) (6), PhD (Civilian), (b) (6), PhD, PMP (Civilian), (b) (6), PhD (Contractor)

C. **Synthetic Chemistry Section**
   1) Chief: CPT (b) (6), PhD
   2) SPC (b) (6) MS (Contractor), (b) (6), PhD (Contractor), (b) (6), PhD (Contractor), (b) (6), PhD (Contractor), SPC (b) (6) MS (Contractor), (b) (6), PhD (Contractor), (b) (6), PhD (Contractor), CPT (b) (6), PhD.

D. **Drug Metabolism and Disposition (DMD) Section**
   1) Chief: CPT (b) (6), PhD
   2) (b) (6), MD (Contractor), (b) (6) (Contractor), SPC (b) (6) (Contractor), (b) (6) (Contractor), (b) (6), PhD (Contractor), (b) (6), MS (Contractor)

Statistical data

A. 8 funded research projects, totaling $5 Million in funding in FY14
B. 11 peer-reviewed publications (including one patent), 8 conference presentations (oral and poster)
C. 561 new chemical compounds synthesized in 8 chemical series
D. 6,069 assays run in DMD section

Healthcare Delivery:

N/A

Veterinary Services:

N/A

Training and Education

A. MAJ (b) (6) achieved Level 3 DAWIA Certification in Program Management
B. All Military Officers and Civilian employees continue to work toward DAWIA Certification in Science and Technology Management.

Research and Development:

A. **Triazines**
   The triazine program nominated a preliminary candidate, WR 909388.

Milestone: Full Patent Application (034047.059WO1) was submitted on 13MAR2014. Published: PCT Int. Appl. (2014), WO 2014159993 A1

The initial candidate WR150008, weekly prophylactic in Rhesus relapsing monkey model (65 mgs, *q.w.*) and curative in the rhesus blood stage model (31 mpk x 7 days) was dropped due to cardio toxicity (hERG IC50 = 600 nM). Due to a short synthetic sequence, the hypothesis driven analog design effort was quickly implemented and the analogs were assessed in the well-defined testing strategy. The strategy was based on literature precedent and project SAR to identify a number of analogs that minimized the hERG liability, maintained efficacy but with improved plasma half-lives.

The back-up candidate was WR 823701: Pf blood stage (3 resistant strains) all IC50s <150 ng/mL; modified Thompson test 5/5 cures @80 mg/kg x 3 days; 3/5 cures @40 mg/kg x 3 days; mouse PK (single dose 80 mg/kg): t1/2 6.7hrs and a Cmax of >1.0uM; prophylactic in Rhesus (65 mg/kg/week); 2/2 monkeys protected from clinical signs of malaria; Rhesus treatment model (31.7 mg/kg/day X 7 days); and most importantly 0% inhibition @33 uM in the hERG assay.

Although WR 823701 was prophylactic in the rhesus prophylaxis model showing no clinical signs of malaria, parasites were observed between weekly doses both at 65 mpk *q.w.* (PO) and 100 mpk *q.w.*(PO). The current hypothesis: the same results will be observed with mefloquine weekly dosing in rhesus (to be tested in 2015).
Third generation targeted longer half-life triazines that could prevent clinical signs of malaria, any parasite breakthroughs and possible with doses less frequently than weekly. The triazine mouse in vivo efficacy and PK appears to scale consistently with the observed rhesus in vivo efficacy and PK. Therefore the main focus was to identify analogs with a half-life in mice >7 hours, equipotent and as safe as WR 701.

For 2014, new analog synthesis is winding down and scale-up work for more advanced studies was more prevalent.

CHEMISTRY. Over ~300 novel triazine analogs were synthesized in 2014 with >45 analogs requiring initial scale up synthesis (200-1000 mgs) and EIGHT compounds prepared on large scale (7-10 grams) for the rhesus monkey studies.

IN VITRO. Of the newly synthesized compounds tested in the hERG assay 75% were <50% inhibition @10uM; *P. falciparum* blood stage assays 135/260 analogs were potent (IC50 <150 ng/mL against *P. falciparum* D6, W2, C235). The low percentage of actives represents follow up on higher risk SAR areas to complete the rational drug designs.

IN VIVO (mouse). 45 new compounds were assessed in the modified Thompson test at 80 mg/kg x 3 days: 21 produced cures, 17 suppressed parasitemia (>2x vehicle control) and no toxicity was observed for any dose groups. Sixteen compounds were dosed lower in the modified Thompson test at 40 mg/kg x 3 days: 6 produced cures and 4 suppressed parasitemia (>2x vehicle control). To support these mouse studies and NHP studies 16 compounds required mouse PK analysis.

IN VIVO (Rhesus). Of the compounds specifically designed, SEVEN new compounds (616, 621, 647, 667, 380, 388, 390) met all down selection criteria and possessed comparable activity and safety to WR701, but with a plasma half-life in mice >7hrs (4/7 new analogs possess an mouse plasma half-life of 18-26hrs). The compounds were dosed as before PO, 65 mpk, *q.w.* @ days [-7, 0, 7, 14, 21, 28] and ultimately following blood parasite counts during the experiment out to day 95. Of the 7 analogs tested in the NHP study: 4 compounds produced 2/2 prophylaxis results (no clinical signs of malaria in NHP) and 2 compounds produced 1/2 prophylaxis results. Compound dosing was completed on Day

28, of the 4 compounds with 2/2 prophylaxis results, three compounds did not reach parasitemia levels greater than 5000 parasites before the end of the experiment (>95 days). The three analogs (WR647, WR388, WR390) all demonstrated a monkey plasma half-life of >20 hours.

A preliminary pre-clinical candidate has been selected from these three analogs (WR647, WR388, WR390). WR388 has the highest Rhesus plasma Cmax (903 ng/mL, compared to 623 ng/mL (WR390), and 662 ng/ml (WR647)); greatest Rhesus exposure (42 ug*hr/mL, compared to 31 ug*hr/mL for both WR390 and WR647) and demonstrated the lowest parasite count on Day 14 (77K) compared to WR647 (167K) and WR390 (130K).
NOTE: Typically in the rhesus study the first relapse in the vehicle control animals is the highest parasitemia seen between days 10-12. In the treated animals the first relapse has the highest parasite count on Day14; therefore this parasite count could be used to predict how rapidly the parasites are being killed by the test drug (i.e. lower numbers of parasites with the same doses of different drugs infers higher kill rates).

Pre-clinical candidate WR388 will next be assessed for genotoxicity (Ames test), general in vivo toxicity (IVT) in 14-day and 28-day rodent testing, CYP inhibition and in vivo micronucleus (if required).

B. **8-aminoquinolines**

Through collaborative work with the Malaria Vaccine Branch, Experimental Therapeutics discovered that primaquine, an 8-aminoquinoline (8AQ), requires metabolic activation by cytochrome P450 2D6 (CYP2D6) in order to be efficacious against relapsing malaria from *p. vivax* in humans.([b) (6) , *et al.*,2013). This CYP2D activation has also been shown to be necessary for PQ efficacy against the liver stage of *P. berghei* in mice ([b) (6) , *et al.*,2013) by assessing liver stage efficacy in CYP2D knockout mice. In addition, our team has demonstrated that other 8AQ compounds in late stage studies such as tafenoquine (Phase III) and NPC-1161B (pre-IND) also require CYP2D activation for liver stage efficacy.([b) (6) , *et al.*,2014)

Although the mechanism of liver stage efficacy and anti-hypnozoite activity remains uncertain, it is likely that efficacy of 8AQ compounds is mediated via oxidative stress resulting from redox cycling of one or more reactive 2D6 metabolite(s). Specifically, current data continue to support the hypothesis that 2D6 mediated C5 oxidation of primaquine is important to the efficacy of the class. Redox cycling of a 5,8 quinone imine has been proposed as the basis of the *hemolytic toxicity* of primaquine,([b) (6) ,1992) however, recent pharmacokinetic data in both wild-type and CYP 2D mice recently gathered at WRAIR strongly suggest that the C5-OH-8AQ/5,8-quinone-imine metabolic pair is critical for the *efficacy* of primaquine. While it has been difficult to confirm this redox cycling pair as the active species due to their instability and transient residence time *in vivo*, we have found supportive evidence that a 5,6 ortho-quinone, which arises from an irreversible hydrolysis of the 6-methoxy group on the 5,8 quinone-imine, can serve as a marker of the 5-hydroxy metabolic pathway.

In order to study the biology of these ortho-quinones in vivo, we synthesized these compounds on larger scale from the parent 5-O-benzyl 8-aminoquinoline. Hydrogenation of the N-Boc protected-5-OBn 8AQ (WR251855) revealed that the resulting 5-hydroxyl derivative, 1, was highly unstable to air resulting in oxidation to the Boc protected ortho-quinone (OQ), WR910489. This ortho-quinone was deprotected with phosphoric acid to give the phosphate salt of WR910512 as a stable orange solid. The stability data suggest these ortho-quinones are lower energy downstream oxidation products of the unstable 5-hydroxy-8AQs. Although the kinetics of 5-OH-PQ to PQ 5,6-ortho-quinone conversion have not yet been rigorously quantified, this conversion happens in a matter of hours when exposed to air.

We dosed tafenoquine and monitored the levels of WR910512 in plasma and liver in both wild type and CYP2DKO mice to examine the possible involvement of 8AQ ortho-quinones in liver stage efficacy or hemolytic toxicity. When tafenoquine was dosed in CYP2DKO mice and the 5,6-ortho-quinone (WR910512) levels were analyzed, there were significantly lower levels of the WR910512 in 2DKO mice compared to wild type.

Knowing the ortho-quinone (WR910512) levels when dosing tafenoquine, we modeled the dose-proportional levels of WR910512 for the ED100 dose of TQ (3mpk) to estimate the ortho-quinone levels in the liver attained at the ED100 dose in mice. The liver levels of WR910512 estimated at the efficacious dose of TQ were critical in assessing the biological significance of WR
910512. WR910512 was then dosed directly in mice to understand if the liver levels of WR910512 obtained with an efficacious dose of TQ are achievable with direct dosing of WR910512.
The exposure achieved in the 0 to 48h timeframe critical for liver stage from direct dosing of 30 mpk of WR910512 is 9894hr*ng/mL, which is higher exposure than the exposure of WR910512 liver levels released from TQ at the ED100.

We subsequently dosed WR910512 directly in the IVIS model at 30 and 60 mpk (10-fold and 20 fold over the TQ ED100*. No liver stage efficacy or liver stage suppression was observed*. We conclude from these data that WR910512 is not an active metabolite of TQ. Recall that PK data with PQ in the 2DKO implicate the 5OH metabolism pathway. Thus, the active species must be prior to the formation of WR910512, in the C5 oxidized metabolic pathway. Additionally, WR910512 did not show any hemolytic toxicity in the NOD SCID hemolysis model up to 120 mpk.

The insight resulting from the 2D knockout mice experiments has enabled the development of a rational plan to design molecules to circumvent the physiological need for CYP 2D metabolic activation of 8AQs.

C. **Pyrimidinylguanidines**

The pyrimidinylguanidine (PG) series transitioned from hit to lead to lead optimization in 2014. This program is leveraging CDMRP funding (FY12 $: CRADA with Geneva in place. Funding schedule: Year One- EFT done quarterly starting 9/30/13: $301,712.00; Year Two: $287,244.00; Year 3: $293,087.00. Additionally the program received $460K in UFR MIDRP FY13 funding. This UFR funding was used to help purchase a replacement NMR for analog characterization and an IVIS for in vivo testing.

Significant progress has been made in terms of enabling synthetic routes to open compound design options for targeted SAR exploration that were not available at the commencement of the PG project. Two complementary methods were developed that allow for R1 modification while keeping the R1 amine constant. The SAR is fairly steep since small changes to the 3,4-dicloro group have a significant impact on antimalarial potency. Relative to 147759, removal of 1 chloro substituent at the 3 position [WR911089] or removal of the 4 chloro group [WR911085] reduces potency in the D6 strain. In addition, a cross resistant profile in these mono chloro analogs as well, since the IC50s in resistant strains lose potency to a greater degree.

KEY RESEARCH ACCOMPLISHMENTS: PGs

- A novel expansion of the Buchwald–Hartwig coupling has been developed on a pyrimidine scaffold.
- Pyrimidinylguanidines that have been previously tested in human clinical trials have been assessed in the in vivo Thompson mouse model and the IIVIS model providing target baseline activities in these models.

- An adaptation of the AFRIMS prophylactic mode of the Thompson Mouse model has been established wherein pyrimidinylguanidines compounds show prophylactic activity when dosed up to 3 days prior to sporozoite challenge.
- Pyrimidinylguanidines have been designed and synthesized which have a lipE >4 and a hERG IC50 > 1uM.

Several synthetic routes to diverse analog chemical space in the pyrimidinylguanidine chemical class have been established and executed to broaden the SAR of this promising chemical class of potential prophylactic antimalarial agents. The initial work has shown that although the SAR is relatively tight, proof of concept has been reached for a PG with a lipE >4 with diminished hERG binding of greater than1uM. The superior biological profile of WR147759 appears to be related to this branched alky piperidine moiety at R1. Future work will continue to test this hypothesis with rationally designed analogs attempting to exploit the beneficial effect of this group while building on the progress of modifications which reduce hERG binding.

D. **4-Amidinoquinolines and 9-Amidinobenzonaphthyridines**

During 2014, medicinal chemistry efforts were focused mainly on design, synthesis and assessment of phenyl derivatives [R_1= Ph. 4-Cl-Ph, or 3-pyridyl] of 4-amidinoquinoline and 9-amidinobenzonaphthyridine (ABN) to research for compounds with optimal efficacy and better therapeutic index.

4-Arylamidinquinoline derivatives [II, R_1 = Phenyl, p-chlorophenyl, 3-pyridyl]:

Ten new pheny/pyridinylamidinoquinoline compounds were prepared, including 3 phenyl (WR909730, WR910376, and WR910383), one p-chlorophenyl (WR10415), 3 pyridyl (WR910429, WR910444, and WR910445), and 3 bis-alkyl derivatives (WR910369, WR910377, and WR910386). Among the new phenyl derivatives, compound WR910415 is the most active (IC50: D6 = 1.07, W2: 1.5 ng/ml) and least CQ cross-resistant index (W2/D6 = 1.4). Compounds with mono-alkyl side chain are much more active than those with bis-alkyl side chain. Replacement of the phenyl ring of WR909730 (D6: 0.71, W2: 2.84 ng/ml) with a 3-pyridyl ring gave WR910429 (D6: 13.6 and W2: 79 ng/ml) with 15 fold decrease in activity. On the contrary, compounds with bis- alkyl side chains are much more stable metabolically (HLM and MLM > 60 min.) than those with mon- alkyl side chains. Although QT prolongation has been a concerned toxicity for chloroquine uses, the new series showed weak in vitro hERG % inhibitory activity. Overall, the phenyl derivatives are much more active than the corresponding methyl and isopropyl analogs of 4-amidinoquinoline antimalarial prepared during the FY13, but are less stable metabolically.

9-Amidinobenzonaphthyridine Derivatives [III, R_1 = CH_3-, Isopropyl, Phenyl, p-chlorophenyl, 3-pyridyl]:

Fifteen new ABN compounds were prepared and assessed during the period, including three methyl [III, R_1 = -Me: WR909677, WR909371, and WR909445], four isopropyl [R_1= -isopropyl: WR910171, WR910292, WR910224, and WR910190], six aryl [R_1 = Ph, 4-ClPh, and 3-pyridyl: WR909890, WR909777, WR909830, WR910402, WR910397, and WR910499] and two bis-alkyl side chain analogs (WR909678 and WR909831). All new analogs showed potent in vitro inhibitory activities against both chloroquine (CQ) sensitive (D6) and CQ resistant (W2 and C235) strains, with IC50 of D6 = <12 ng/ml. Like 4-amidinoquinolines, isopropyl and aryl derivatives of ABN (IC50 < 1 ng/) are 5 to 10 fold more potent than methyl analogs against *Plasmodium falciparum* clones. However, except bis-alkylated compounds WR910190, WR909678, and WR909831 (t1/2 > 60 min), methyl and isopropyl ABN derivatives are much less stable metabolically than that of 4-amidionquinoline analogs. Like 4-amidinoquinolines, 9-ABN generally showed weak activity in % hERG inhibitory test with IC50 > 10 □M.

Antimalarial Activity in Thompson Test:

Six ABN compounds were assessed for antimalarial in Thompson test at dose of 120 and 60 mpk x 3 by oral administration. Methyl analogs WR909677, WR909371, and WR909445 showed moderate activity in the test, prolonging the life span of mice from 7.4 days for the untreated control to 22 and 24.5 days for group treat with WR909677 and WR909445, respectively. Compound WR909371 showed only marginal activity with average life span of 15 days. However, phenyl analog (WR909890, WR909830, and WR909831) showed 4/5 or 5/5 cures at 60 and 120 mpk x 3.

PK study of Compounds W909831 and WR826809

Compounds W909831 and WR826809 were selected for PK studies (Table 1), because of their high efficacy, low toxicity and metabolic stability. Data indicated both compounds were well absorbed and have long plasma half-life. Especially, the plasma half-life of WR909831 is almost 50 hours which qualifies it for a weekly dosing prophylaxis candidate.

% hERG inhibition:

During the reporting period, 10 of the new compounds were submitted for assessment for % hERG inhibitory activity. The results are shown in Table 2. Eight out of 10 compounds showed IC50 >/= 10 uM as compared with quinidine = 0.82 [illegible] and chloroquine

Summary:

In summary, good progress was made during the reporting period. The results of SAR studies have provided sufficient information to guide our future directions in medicinal chemistry efforts to down select ideal candidates for further development.

E. **CIS9000 Screening Effort**

All CIS9000 compounds have been pre-screened at two concentrations, and IC50s are 50% complete for active compounds.

The metrics for CIS9000 compounds tested for FY14:
-Prescreen Actual # Compounds - 480
-Prescreen # Replicates - 1920
-IC50 Actual # Compounds - 105
-IC50 # Replicates - 840

F. **Quinoline Esters (more soluble, decoquinate analogs)**

We have modified our original hypotheses: less lipophilic compounds will have improved water solubility to include design of new less lipophilic analogs with more 3 dimensional steric bulk to block potential intermolecular pi-stacking. The project continued understaffed with 0.5 chemistry support; however, 8 new analogs were synthesized, 2 of 8 which are considered potent against D6, W2, C235 IC50s <250 ng/mL; both had C2B IC50s <250 ng/mL (strain resistant to Atovaquone). We continue to pay close attention to the cross-resistance toward C2B. This particular strain is highly resistant to Atovaquone (>5000x) which targets the electron transfer chain (ETC) of the mitochondria (bc1 complex). The quinolines also target the ETC, however, results published this year concerning the genetics of the bc1 complex provided proof that although some cross-resistance with Atovaquone is shared, quinolines bind specifically to a different region of the complex.
One of the new, potent, analogs (WR909960) will be scaled up for an in vivo modified Thompson assay.

The overall strategy of the project has been to design and synthesize more soluble analogs of decoquinate (DQ) to improve the in vivo efficacy. Of the 39 new designed analogs that were assessed in the solubility assay: 9 compounds were no better than DQ (solubility <10 uM); 3 were between 10-200uM; 25 analogs were between 200-400uM and 2 >400uM.

G. **Drug Metabolism and Disposition (Q0302_12_WR_CS)**

The Drug Metabolism and Disposition Section of Experimental Therapeutics conducted the flowing analyses in support of ET's anti-parasitic drug development efforts in FY14:

- Metabolic stability: assayed 534 compounds.
- MDCK Permeability: assayed 543 compounds.
- Purity: assayed 1933 compounds.
- Pharmacokinetic analysis: assayed 3029 unique samples.
- Drug-Drug Interactions: assayed 13 compounds.
- Stability: assayed 17 compounds.

The Drug Metabolism and Disposition Section analyses have contributed to the further development of four novel chemical series with internal efforts and in collaboration with four external organizations.

In FY2014, the Drug Metabolism and Disposition Section has also conducted in house quality control measures by participating the World Wide Anti-malarial Resistance Networks laboratory assessment.

The efforts of the Drug Metabolism and Disposition Section have been presented in two scientific abstracts and four papers published in high impact peer reviewed journals.

H. **Hit to lead (Q0282_12_WR)**

MIDRP proposal transitioned into the Synthesis Core Service while maintaining the original intent of the proposal. The Synthesis Core provided the necessary organic chemistry support for proposal (Q0282_12_WR). This was accomplished by the production of 561 chemical compounds evaluated for their drugable properties and anti-malarial activity. These compounds represent eight different chemical series, which includes large scale synthesis of highly purified material up to 10 grams for NHP (AFIRMS) study (8 compounds) and up to 2 grams for mice studies (21 compounds). The compounds were iteratively designed and over 90% of the 561 compound are novel, with no prior published examples containing the same molecular structure. External collaborations provided 48 individual chemical compounds for the analysis of their in vitro anti-malarial properties and the results were represented at 3 scientific conferences. The Synthesis Core hired two additional contracted chemists. Requested 76 chemicals from the Fisher Repository saving the department over ~$10K worth of supply money and reducing the storage requirements of the Repository. Obtained contracts for outside vendors to conduct the Ames assay on three chemical series and synthesis sub-contracts worth over $~356K. The Synthesis Core QA/QC 5 NMR samples analyzed for collaboration with the Defense Advanced Research Projects Agency (DARPA), Texas A&M, the WRAIR Biological Production Facility (BPF), and ET for a Surviving Blood Loss program to improve Tactical Combat Casualty Care during prolonged evacuations.

I. **Cutaneous leishmaniasis drug discovery**

As Leishmania research has moved from active status to tech base status, current efforts for leishmania research are focused on minimal research to maintain existing competencies for leishmania *in vitro* and *in vivo* assays. Two partner proposals involving Experimental Therapeutics were accepted by the Peer Reviewed Congressionally Directed Medical Research Program in FY14. One proposal is a partner proposal with (b) (6) from OSU, and the second proposal is a partner project with Anacor Pharmaceuticals. Work begins on these projects in early FY15.

J. **Accomplishments in clinical development**

The Next Generation Malaria Drugs (NGMD) IPT was chartered by the Milestone Decision Authority in FY14. A Materiel Development Decision (MDD) briefing to the MDA was successfully conducted in April 2013, formally transition the program into the Materiel Solution Analysis phase of the Acquisition lifecycle.

1) Resource Management and Budget:
   a. ARMY RDT&E funds: $4,698 K
   b. DHP RDT&E funds: $50 K
   c. Reimbursable funds: $247 K
   d. Expenses
      i. Contracts: $4,427 K
      ii. Civilian Salaries: $398 K
      iii. Other (supplies, software, etc): $416K

1) Modernization:
   a. Nuclear magnetic resonance (NMR) equipment and facility upgrade – Two new, state-of-the-art NMR spectrometers (400 and 600 MHz) were ordered in FY14 to replace existing, aging, and obsolete NMR instrumentation. The NMR laboratory facility (room 2E18) is being remodeled to accommodate both new NMR spectrometers, freeing up room 2E13 for other instrumentation and laboratory needs.

Chemical Repository and Informatics

Mission:

Acquire, integrate, and maintain chemical and biological information and maintain the chemical repository. Develop systems for the diffusion of maintained information. Support drug discovery and pre-clinical development. Manage the extramural contract support program.

Organization and Personnel:

A. **Compound repository operations**
   1) Three full time contract personnel
   2) Project Manager: (b) (6)
B. **Laboratory Information Management System (LIMS)**
   1) Customer Success Manger (b) (6) replaced by (b) (6) .
C. **CRI Office**
   1) Chief: MAJ (b) (6)
   2) Knowledge Manager/System Admin: (b) (6)

Statistical data

A. Shipped 3,070 samples in 700 packages
B. 1,134 new samples added to inventory
C. 7,295 labels applied to storage and shipping containers
D. 40 active registered system users

Training and Education

A. Representation from CRI office and Repository staff at CoreLIMS user group meeting.
B. Continuing education for (b) (6) : Managing Oracle on Linux and NIST/FISMA IA compliance.

Research and Development:
N/A

Resource Management and Budget (See Figure 1):
A. MIDRP Core funding proposal Q0384_14: ~$670k/FY (approved for funding thru FY18)
B. MIDRP core funding proposal Q0430_15: ~$600k/FY (approved for funding thru FY17)
C. Expenses
    1) LIMS contract: ~$215k/OY; 1 OY remaining.
    2) LIMS enhancement contract: $100k (complete)
    3) Repository contract: ~$700k/OY, 3 OY remaining.
    4) SMMRS TO 95: ~$150k/OY
    5) Civilian Chief, CRI: New hire in progress. Estimated ~$190k/yr

Information Management:
Describe deployment of new information systems and strengths and shortcomings of existing information systems that were identified during the previous year. Identify significant internal changes to information policy implemented during the previous fiscal year along with the reasons for those changes. If external information management policy affected the operational capability of the organization, identify the policy, impact, and solutions developed.

A. CoreLIMS v4.2 DIACAP package initiated through WRAIR IMD
B. CoreLIMS v4.2 CON application initiated through WRAIR IMD
C. Transitioned from CoreLIMS v3.9 to CoreLIMS v4.2 providing significant enhancements to end users.
    1) Customizable dashboards to allow quick and easy access to sample status, workflow progress, data trends and other timely information.
    2) Project Management tools provide semi-autonomous movement of samples through ETs gated tier testing paradigm greatly reducing manual data manipulation requirements.

Operations:
N/A

Modernization:
A. Purchased installed and configured new server hardware providing greater capacity, speed and reliability to the system.
    1) Utilization of a cold backup strategy uses matched systems to provide rapid recovery of the production system in the event of catastrophic hardware failure.
        a. Each server equipped with Dell PowerEdge 420, 4 x 1 TB Hard Drives (2.5”-SATA-300), 2 x 1 500GB Hard Drives, 1 x 1 Xeon E5-2407/2.2 GHz processor + additional 1 x 1 Xeon E5-2407 processor, 40 GB memory (base 1 x 8GB RAM + 4 x 8GB RAM additional)

FIGURE 1 : CRI Budget for FY14-FY18

($ in $1000's)	FY14	FY15	FY16	FY17	FY18
Income					
Q0384_14_WR_CS_OC	$ 650	$ 670	$ 690	$ 710	$ 730
Q0430_15_WR_CS_OC	$ -	$ 587	$ 598	$ 610	$ -
Q0295_12	$ 911				
Total Income	$ 1,561	$ 1,257	$ 1,288	$ 1,320	$ 730
Expenses					
Chief (DJ-04)	$ -	$ 85	$ 190	$ 190	$ 190
Lindita (CRM)	$ 150	$ 160	$ 165	$ 170	$ 175
FBS (14-C-0055)	$ 692	$ 712	$ 733	$ 755	$ 777
LIMS (11-P-0476)	$ 350	$ 216	$ 216	$ 250	$ 250
WRAIR OH	$ 90	$ 125	$ 129	$ 132	$ 73
Seat Tax	$ 65	$ 65	$ 65	$ 65	$ 65
Civ Salary	$ 186				
Civ Salary	$ 212				
Total Expenses	$ 1,745	$ 1,363	$ 1,498	$ 1,562	$ 1,530
Delta	$ (184)	$ (106)	$ (210)	$ (242)	$ (800)

DEPT OF CLINICAL PHARMACOLOGY AND CLINICAL PHARMACOLOGY FELLOWSHIP

Mission:

Train physician and PhD fellows to become competent in the field of clinical and applied pharmacology. This includes completion of a research project, as well as instruction and experience with staff in rational therapeutics in the clinic, pharmacokinetics, pharmacodynamics, medical toxicology, pharmacogenomics, and drug discovery and development with a focus on translational medicine and regulatory sciences. The department also leads teams to identify health-related solutions for US soldiers, in support of the Combatant Commands (COCOMS), and to support global health and security. Achieve FDA approval of new products when needed. Provide the Command and the US Government with drug development expertise.

Personnel:

A. Department Chief: MAJ (b) (6), MD
B. Fellowship Coordinator: (b) (6)
C. Fellows: MAJ (b) (6), MD, MAJ (b) (6), MAJ (b) (6), MD, and MAJ (b) (6), PhD

Malaria Vaccine Branch

Mission Statement:

MVB is the only DoD laboratory that conducts product-oriented basic and translational research leading to the fielding of highly effective malaria vaccines against both *P. falciparum* and *P. vivax* malaria. MVB sustains an active program to evaluate new antigens and delivery systems and to identify correlates of protection. With proven "bench-to-bedside" expertise in malaria vaccine development, MVB manages a robust portfolio comprised of internal (DoD) and external vaccine candidates. MVB is positioned to engage the global malaria vaccine community to exploit and advance malaria vaccine candidates. An effective vaccine against malaria ensures the Warfighter operational readiness and offers durable and cost-effective protection against infection.

Organization and Personnel

A. Director: LTC (b) (6) , PhD
B. Deputy Director: LTC (b) (6) , PhD
C. NCOIC: SSG (b) (6)
D. Administrative Officer: (b) (6)

Statistical Data:

Publications: 19 Patents: 4 Budget: $ 4937.5k

Department of Plasmodium vivax Malaria-Dr Anjali Yadava

The mission of the Department of *Vivax* malaria Vaccine Development is to develop a vaccine that would prevent malaria caused by *Plasmodium vivax* which is the most widely prevalent malaria globally and is also the major cause of malaria in U.S. troops.

A. Purified multiple Plasmodium vivax Circumsporozoite Protein (CSP) recombinant proteins to assess as vaccine candidates.
B. Performed immunogenicity studies in mice to compare vaccine candidates. Assessed immune responses to the full length protein, as well as its subunits.
C. Established transgenic *P. berghei-P. vivax*$_{(repeat)}$ parasites challenge model via bite model in mice.
D. Tested efficacy of recombinant proteins in mice using transgenic parasites.
E. Developed a panel of monoclonal antibodies against the N-term, C-term and repeat region of *P. vivax* CSP.
F. U.S. Patent No. 8,697,856, Awarded 15 April, 2014. Plasmodium Vivax Hybrid Circumsporozoite Protein & Vaccine, Anjali Yadava and Christian F. Ockenhouse.
G. Published manuscript in Public Library of Science PLoS Neglected Tropical Diseases describing protective efficacy of vaccine in an Aotus challenge model and its correlation to antibodies.

Department of Molecular Engineering-(b) (6)

The major focus of the laboratory's research is the development of a malaria vaccine based on the use of a self-assembling protein nanoparticle (SAPN) formulated with a liposomal monophospholipid A (L(MPLA)) based adjuvant. The P. falciparum parasite protein in the vaccine is the circumsporozoite protein (CSP) found on the sporozoite. The SAPN displays on its surface the CSP central repeat peptide epitope (NANP) and the C-terminal region known as alpha-TSR (aTSR) whose conformation is critical for presentation of correct protective epitopes.

A The development of a new construct that contains the PfCSP-aTSR domain as well as six NANP repeats. The final SAPN protein product was given designator FMP-014.

1) Showed that we could express this protein in high amounts in bacteria and purify it with a high final yield.

2) Processes were scalable and transferable to a GMP suite.

B. Analysis of the immune response induced in mice to the product FMP-014 showed production of high titer antibodies against both NANP and the TSR regions

1) Greater than 80% of the antibodies to the TSR region were directed against conformational epitopes as demonstrated by loss of antibody recognition following reduction of a synthetic peptide, p16, known to have the correct TSR folding as demonstrated by specific mAb binding.

C. Showed that the immune response to the FMP-014 administered in L(MPLA) adjuvant was able to protect 100% of the immunized mice against an otherwise lethal challenge of a transgenic mouse malaria parasite expressing the human malaria parasite CSP.

1) The antibodies proved to have high avidity after two doses of vaccine.

2) The ratio of Ig subtypes indicated both a TH1 and TH2 response (cellular as well as humoral) which are suspected to be required for protection in humans.

Flow Cytometry Center-(b) (6)

The Flow Cytometry Center (FCC) provides support to the USMMVP through standardized and optimized protocols evaluating cellular responses induced by vaccines using different platforms. This effort has led to development of common methods of data analyses and presentation. The FCC provides flow cytometry access to investigators within the USMMVP and outside divisions at WRAIR and NMRC such that they can utilize state of the art equipment without the up front and continuing costs of procuring and properly maintaining the equipment. Additionally, FCC staff stands ready to assist investigators in the development and design of methodologies to perform CMI testing of their pre-clinical and clinical samples.

A. Maintained two BD FACSCalibur (4-color) and two state of the art BD LSRII (10–color and 17-color) flow cytometers, two automated cell counters, one Acumen eX3 microplate cytometer, one AID EliSpot Analyzer, one MESO QuickPlex SQ 120 and two work stations designated for flow cytometry data analysis using specialized software.

B. Continued to optimize novel SOPs to be used by the lab to assess expression of CD3, CD4, CD8, and memory T cell markers, including CD45 RA, CD45 RO, and CD27, in addition to the intracellular expression of cytokines such as IFN-γ, IL-2 and TNF-α. In addition, actively developing and optimizing panels for the detection of different T-cell subsets, such as Regulatory T-cells and Follicular Helper T-cells.

C. Continued support of pre-clinical trials by USMMVP investigators as well as those from other Divisions/Branches in WRAIR to include the Division of Viral Diseases, the Division of Bacterial and Rickettsial Diseases, and Wound Infection Division by assisting in the development of panels characterizing cell populations customized for investigator interest. Assessed the immunogenicity of candidate human malaria vaccines.

D. The FCC also supported the preparation of peripheral blood mononuclear cells for the VSV-based Ebola vaccine that was evaluated in the Clinical Trials center) and preparing for the cellular analysis of clinical studies (PfSPZ, IMRAS) that are funded through Advanced Medical Development and a Joint Warfighter Fund (Navy). The FCC developed analysis panel for T cell characterization of vaccine-induced mouse immune responses in peripheral blood and tissues

E. The FCC developed a functional assay for the assessment of biological activity of anti-CSP specific antibodies to capture the ability of the antibody to mediate binding of the malaria parasite to phagocytic cells (scavengers) and thus achieve neutralization. The assay was selected by PATH/MVI to be assessed for its predictive value in vaccine evaluation and these pilot samples will be completed in FY15.

F. Maintained a basic operator training course to ensure basic competence with all equipment available in the FCC. Provided instrument training, technical support, and guidance on assay design and analysis for 10+ novel users of the FCC.

G. Screened donors for use as a biological assay control and identified the proper control that will allow the bridging of experimental results over several studies. Screened non-human primate samples for immune correlates using Flow Cytometry and the Mesoscale Platform.

H. The team completed the development of novel panels for the characterization of follicular T helper cells as well as panels that characterize vaccine-induced B cells. The immunologist in the FCC is increasingly getting involved in consulting other PIs of the USMMVP in regards to planning immunization experiments and the subsequent immunological analysis.

Department of Molecular Parasitology-(b) (6)

Develop and evaluate malaria blood stage vaccines derived from the *P. falciparum* MSP1-42 sequence. Develop and evaluate malaria pre-erythrocytic vaccines derived from the P. falciparum CelTOS sequence. Evaluate novel expression, delivery systems and adjuvant formulations to improve induction of protective humoral and cellular immune responses. Continue to develop and optimize assays for the quantification of antibody responses, antibody fine specificities, avidities and evaluate in vitro functional antibody activities against the parasite, i.e. blood stage invasion/growth inhibition, sporozoite motility assays and inhibition of sporozoite invasion (ISI), and inhibition of sporozoite invasion and development (ILSDA). Evaluate cellular immune responses using standard methods such as ELISpot, ICS and other readout methods.

A. FMP012 (PfCelTOS malaria vaccine candidate) formulated with GSK's AS01B adjuvant clinical development activities. Providing guidance, documents and reports preparation and review for submission to SRC, IRB, QC stability and testing reports for product submission in a new IND document for FDA.

B. Evaluated protection and humoral and cellular responses of PfCelTOS formulated with GSK AS01B adjuvant system. Based on these studies, progression of this formulation to clinical investigation.

C. Established research collaboration with (b) (6) and (b) (6) to evaluate the self-assembling polypeptide nanoparticle (SAPN) for delivery of CelTOS and MSP1 antigens. Several particles were developed and evaluated for immunogenicity in mice.

D. Presented final report for 1st year funded ILIR project and awarded 2nd year funding under the WRAIR ILIR program for project entitled "Mechanistic characterization of the complement receptor 2 derived peptide p28 as potent adjuvant for vaccines".

E. Evaluated the goat expressed MSP1-42 recombinant protein expressed from transgenic goats developed by rEVO in the WRAIR established P. berghei transgenic (PfMSP1-19) blood stage challenge model. Results suggest that eukaryotic expressed protein is immunogenic. Results were reported to USAID. Further work is suspended for the time being while other projects are priorities.

F. Performed passive transfer of IgG isolated from humans and rabbits immunized with Chimp adenovirus and MVA expressing MSP1-42 antigens and blood stage challenge with P. berghei (PfMSP1-19) parasites in mice. Materials were obtained from University of Oxford under a CRADA. These additional human and rabbit immune samples were being tested in this model to 'validate' the murine blood stage challenge model.

G. Completed antibody fine specificity analysis of post 3rd sera by ELISA from FMP012 (PfCelTOS)/GLA-SE clinical trial. Antibody fine specificities will be used to map immune responses to CelTOS and to determine if we can more specifically define antibody and T cell dependent correlates of protection from preclinical and clinical trials.

H. Developed recombinant protein for P. vivax CelTOS; using optimized codon usage with codon harmonization algorithm. Purified protein to homogeneity for the purpose of crystallization and to evaluate cross reactive immune responses induced by PfCelTOS based vaccine platforms.

I. CRADAs/MTAs and status of efforts
   1) Established CRADA-MTA with (b) (6) ; PATH MVI for providing recombinant CelTOS antigen for development of human monoclonal antibodies for use as therapeutics against infection
   2) Established CRADA-MTA with (b) (6) ; PhageVax for codon harmonization of malaria antigen sequences for expression on bacteriophage head for use as a particle-based malaria vaccine.
   3) Established CRADA-MTA with (b) (6) ; Oxford University for codon harmonization of malaria vaccine candidate PfRIPR.
   4) Established MTA with Professor Kwaku Poku Asante at the Kintampo Health Research Center, Ghana for recombinant protein PfCelTOS and GST-MSP1$_{19}$ for seroepidemiological studies.

J. US Patents submitted or issued
   1) Patent application filed by Army, US Patent issued: 25 June 2013, US Patent # 8,470,560, Titled "CR-2 binding peptide P28 as molecular adjuvant for DNA vaccines", Inventors: (b) (6) (WRAIR-MVB); (b) (6) (WRAIR MVB) and (b) (6)
   2) Patent application filed by JHU, US Patent issued: 6 August 2013, US Patent # 8,501,926, Titled "Malaria Vaccine; Pfs48-45 transmission blocking antigen", Inventors: (b) (6) (WRAIR-MVB) and (b) (6)
   3) Patent application filed by GSK, US Patent application: 61/919268, Title: "Novel Malaria Vaccines", Inventors: (b) (6) .

Clinical and Field Trials-(b) (6) , MD

MVB has been a global leader in developing, manufacturing, and clinical testing of malaria vaccines. The Clinical and Field Trials section has evaluated numerous candidate malaria vaccines and various novel vaccine delivery platforms in clinical trials. The Clinical and Field Trial section has a long track record for the safe execution of malaria vaccine trials, experienced clinical staff, and access full service complement of ancillary and immunology laboratory capabilities to facilitate the collection and analysis of the highest quality clinical data. In summary, this

section conducts clinical trials testing the safety, immunogenicity, and efficacy of candidate malaria vaccines in humans.

Clinical Trials

A. Prepared FMP012 (PfCelTOS malaria vaccine candidate) formulated with GSK's AS01B adjuvant clinical protocol for submission to scientific review committee and WRAIR institutional review board (IRB) for review and approval
B. Assisted the product Sponsor (OTSG) with preparation and submission of the FMP012/AS01B Investigator's Brochure and submission of investigational new drug (IND) application to Food and Drug Administration (FDA)
C. Executed the clinical trial entitled "Phase 1 Clinical Trial with Controlled Human Malaria Infection (CHMI) Open-label Dose Safety, Reactogenicity, Immunogenicity, and Efficacy of the Vaccine Candidate Plasmodium falciparum Malaria Protein (FMP012), Administered Intramuscularly with AS01B Adjuvant system in Healthy Malaria-Naïve Adults"
D. Participated in ongoing clinical trial activities for the clinical trial entitled "Efficacy, safety and immunogenicity study of GSK Biologicals' candidate malaria vaccine 257049 in the sporozoite challenge model in healthy malaria-naïve adults"
E. Assisted in clinical activities for testing the safety, immunogenicity, and efficacy of candidate dengue virus, Ebola virus, and anthrax vaccines in humans.

Clinical Trials Agreements

A. Supervised the establishment of a Clinical Trials Agreement with GSK Biologicals' and USAID for the execution of the clinical trial testing PfCelTOS/AS01B (WRAIR#2113).

Subject Safety

A. Served as the objective research monitor or as a safety monitoring committee Chair/member overseeing clinical safety in subjects administered investigational products by the US Government as well as non-Governmental organizations under the following protocols
    a. Phase I study of the safety, reactogenicity, and immunogenicity of Sm-TSP-2/Alhydrogel® for intestinal schistosomiasis in healthy adults
    b. A Phase 1 study of the safety and immunogenicity of plant-derived Pfs25 VLP-FhCMB malaria transmission blocking vaccine in healthy adults
    c. A Phase 2a randomized, double-blind, dose-optimizing study to evaluate the immunogenicity of Hantaan/Puumala Virus DNA vaccine for prevention of HFRS administered to healthy adult volunteers using the TDS-IM electroporation
    d. A Phase 1, randomized, open-label, single-center, study of the TDENV-PIV and LAV Dengue vaccine platforms as part of a heterologous prime-boost strategy (Day 0, 28 versus Day 0, 180 vaccination schedule) in healthy adults in a non-endemic region

Malaria Diagnostics-CPT (b) (6)

The Department of Malaria Diagnostics has two mission critical objectives to support the development of an effective malaria vaccine in support of the warfighter. Objective one: provide real-time molecular diagnostic support during malaria vaccine clinical trials conducted at WRAIR and NMRC. This is accomplished by detecting single parasite genomic DNA from minute amount of blood samples using Polymerase Chain Reaction (PCR) from human volunteers participating in clinical trials. This data provides supplementary information for the clinician when volunteers are presenting symptoms and microscopy results are inconclusive. Objective two: develop a 2nd

generation NYVAC-based malaria vaccine. Our vaccine formulation consists of over three times the amount of pre-erythrocytic, blood-stage, and transmission blocking antigens compared to the 1st generation vaccine. Empirical evidence is demonstrating the 2nd generation vaccine is producing significantly more *P. falciparum* protein for a longer period of time compared to the 1st generation vaccine at the new proposed site of immunization – human skin cells.

A. Secured over $500K of funding for reagents, equipment, and salaries to continue supporting malaria vaccine clinical trials.
B. Have provided molecular diagnostic support for 3 ARMY and 2 NAVY malaria vaccine clinical trials.
C. Secured over $500K of funding for the development of the 2nd generation NYVAC-based malaria vaccine.
D. Completed the MTA between Sanofi Pasteur and WRAIR to use NYVAC as a 2nd generation malaria vaccine.
E. Cloned 26 *Plasmodium falciparum* (strain 3D7) pre-erythrocytic, blood-stage, and transmission blocking genes into shuttle plasmids all constructed and generated at WRAIR.
F. To date, we have generated 10 recombinant NYVAC viruses expressing *P. falciparum* genes.
G. Performed growth kinetics and protein expression experiments in two primary human skin cells to determine virus viability and protein production at the proposed site of immunization.

Department of Structural Vaccinology-[redacted]

The mission of the laboratory of Structural Vaccinology is to elucidate the structural, immunological and functional correlates of humoral immunity using sera from humans, Rhesus and mice vaccinated with either CSP or AMA1 vaccine. We then apply this knowledge to design vaccines that will be cost effective and broadly effective against a diverse group of parasites. In that regard we developed processes for the cGMP production of vaccines against both blood and liver stages of malaria and are currently developing multi-antigen vaccines based on soluble proteins, particles and viral vectors.

A. Studying the immunological correlates of immunity for the GSK's RTS,S and WRAIR's soluble CSP vaccine in mice and Rhesus. A Rhesus trial was completed in 2014 where we compared the immunogenicity of the RTS,S vaccine against soluble CSP adjuvanted with AS01B. Remarkably the soluble CSP showed similar immunogenicity to the RTS,S vaccine and additionally it showed broadening of antibody responses to regions of CSP not included in RTS,S. This has led us to propose the vialing of the WRAIR CSP vaccine. We also obtained the RTS,S vaccine for evaluation in the transgenic mouse parasite *P. berghei* challenge model. We have developed a model for rapid down-selection of human vaccines in mice. In order to validate this model we collaborated with GSK and tested the RTS,S vaccine in this model. The study was a success as high levels of protective antibodies were induced by RTS,S. We are now conducting detailed immunological studies on these sera as benchmark criteria for future vaccines.

B. Evaluation of a multivalent AMA1 vaccine (Quadvax) in the Rhesus model**.** While a monovalent AMA1 vaccine was not very effective in the field, we showed that a multivalent form of AMA1 vaccine containing the four diverse allelic proteins can overcome the antigenic diversity of AMA1 in the rabbit model (Dutta et al. PLOS Pathogens 2013). We are now collaborating with GSK to test Quadvax+AS01B vaccine in the Rhesus monkey model. This trial is currently underway.

C. cGMP vialing and release tests for the WRAIR CSP vaccine. Following the results of the Rhesus trial where the WRAIR CSP showed excellent immunogenicity and epitope broadening, we developed bioproduction

records for the vialing of this vaccine. Release tests for the WRAIR CSP fermentation, protein bulk and final container were performed. We are now testing adjuvants from various partners as access to AS01B may not be granted by GSK. Among alternative adjuvants we are working with the WRAIR Retrovirology group and the Infectious Disease Research Institute (Seattle).

D. Development of a prime boost vaccine (Army-Navy collaborative project). The Navy group has that a AMA1+CSP vaccine delivered via DNA prime and Ad5 boost approach successfully protected 4/15 individuals. Despite protection, no significant antibody responses were observed in the vaccinees. We collaborated with the Navy group to conduct mouse immunogenicity studies with the AMA+CSP vaccine where the DNA-Ad approach was combined with the protein boost. We showed that certain combinations of DNA-Ad-Protein were clearly superior and no competition between CSP and AMA1 antibody responses was observed in the multi-antigen combination groups. We are now proposing to replicate these leads with the next generation of Gorilla Adeno-vectors being developed by the Navy.

Department of Cellular Immunology-(b) (6)

The Department of Cellular Immunology has two mission goals. The primary goal is to identify and validate novel Plasmodium liver-stage (LS) antigens as potential vaccine candidates to be used either solo or in combination with *Plasmodium falciparum* circumsporozoite protein or with RTS,S. As a commitment to the constantly evolving new approaches in vaccine development and application, we have been conducting pre-clinical studies in mice by testing the newly identified pre-erythrocytic or LS vaccine antigens as DNA vaccines either solo or in combination with prime and boost approaches using several different platforms for the purpose to achieve sterile and lasting immunity.

The second mission goal of our research efforts is to identify and characterize correlates of protective immunity induced by Plasmodium pre-erythrocytic antigens that are used in a various anti-malarial vaccine strategies. Identification of cellular correlates will not only lead to improved strategies towards vaccine development, but it will contribute to our understanding of the various immunologic mechanisms involved in the reduction of Plasmodium parasite burden as well as elimination of malaria, one of the deadliest infectious diseases. Our experimental approaches have been based on the wealth of evidence from previously conducted studies that antigen-specific CD4+ T cells as well as CD8+ T cells that secrete inflammatory-type cytokines play an important role in protective immunity.

A. As a result of the primary effort we have finalized down-selection of 8 out of 30 LS antigens that, as DNA vaccines, showed reduction in liver parasite burden in several different inbred mouse strains, including Balb/c, C57Bl/6, and CB6F1 (Balb/c x C57Bl/6) mice as well as CD1 mice, an outbred mouse strain, infected with *Plasmodium berghei* and *Plasmodium yoelii*.

B. Initiated protection studies with LS antigens aimed at inducing sterile protection.

   1) Using *P.* yoelii circumsporozoite protein (CSP) DNA in combination with Adeno 5 expressing *P.yoelii* CSP for a prime:boost vaccination strategy, we demonstrated that approximately 50% of CD1 mice have been protected against experimental *P. berghei* sporozoite challenge.

   2) Using P. yoelii CSP-DNA followed by Adeno 5 expressing P. yoelii CSP for a prime:boost vaccination strategy, we demonstrated that approximately 40% of CD1 mice have been protected against experimental *P. yoelii* sporozoite challenge.

   3) Using *E. coli*- or baculovirus-expressed *P. yoelii* LS proteins in a prime:boost strategy with Adeno 5 expressing corresponding *P. yoelii* LS antigens, we observed approximately 20% protection in Balb/c mice.

C. Initiated expression of *P. berghei* LS protein antigens in the E.coli expression system. These reagents will be used as vaccines in combination with Adeno 5 virus and as reagents to test for immune responses.

D. Initiated expression of *P. berghei* LS antigens in the Adenovirus 5 system to be used in prime:boost approach with either *P. berghei* DNA LS antigens or *P. berghei* LS protein antigens.

E. Evaluated kinetics of Kb-17 tetramer-positive IFN-□†CD8 T cell responses following *P.berghei* RAS immunization. Kb-17 peptide corresponds to *P.berghei* a novel LS antigen that reduces liver parasite burden. Interestingly, Kb-17-specific CD8 T cells are induced in *P. berghei* RAS immunized mice and they persist during long-term protective immunity and are recalled upon sporozoite re-challenge.

F. Evaluated Papaya Mosaic Virus (PapMV) as an immunomodulator and as an adjuvant.

1) Initiated studies to test the concentration and kinetics of PapMV as an adjuvant for the induction of

a. *P. berghei* CSP-specific Ab responses

b. *P. berghei* CSP-specific CD8 T cell responses

c. Protective immunity in the *P. berghei* protection model

G. For studies of immune responses as correlates of protective immunity in humans protected against experimental P. falciparum sporozoite challenge, we have been collaborating with colleagues from NMRC in an effort to evaluate T cell responses specific for *P. falciparum* novel LS antigens in subjects exposed to *P. falciparum* RAS (the BMGF-sponsored IMRAS project).

H. CRADAs/MTAs/RCA

1) Renewed RCA between NIH LMVI and our laboratory for the continuation of collaboration involving LS antigens as potential vaccine candidates.

2) Established CRADA-MTA with (b) (6), Folia Biotechnology, Quebec, CA to collaborate on the application of the Papaya Mosaic Virus system as an immunomodulator and possibly adjuvant for the induction of CD8 T cell responses with *P. berghei* LS antigens.

3) Extended CRADA with (b) (6) from the University of Miami, Coral Gables, FL, to study gp96 HSP as an adjuvant for *P. berghei* LS antigens.

4) Renewed CRADA agreement with MVI to include Kymab and Atreca to the HPATIC Consortium.

Malaria Serology Laboratory-LTC (b) (6), PhD

WRAIR's International Reference Center for Malaria Serology, also known as the Malaria Serology Laboratory (MSL), supports the U.S. Military Malaria Vaccine Program (USMMVP) by testing malaria vaccine clinical trial samples and pre-clinical samples to assess vaccine potency and immunogenicity. The MSL develops high quality, reproducible Enzyme-Linked Immunosorbent Assays (ELISA) using antigens from both *P. falciparum* and *P. vivax*. The laboratory works closely with the Program for Appropriate Technologies in Health-Malaria Vaccine Initiative (PATH-MVI) and the U.S. Agency for International Development (USAID) to increase the repertoire of assays in order to further characterize antibody from samples obtained testing novel vaccine candidates. The MSL remains the only international serology reference center for malaria vaccine studies conducted both within and outside the U.S. Military.

A. The Malaria Serology Lab (MSL) completed over 13,000 ELISA, IFA, and Avidity index assays, some 2.5 times increase over last year's workload. The total included 1550 limit setting assays that are essential for establishing acceptable quality control (QC) limits for each antigen, and completed 393 operator competencies which are essential components of the QA/QC program at the MSL that qualifies the laboratory as Clinical Good Laboratory Practice (CGLP). This designation has emphasized the role that this

highly regulated laboratory plays in deciphering the humoral correlates of immunity as more researchers are converging in elaborate and targeted clinical trials to develop an efficacious Malaria vaccine.

B. Prepared and submitted a new 2015 budget that reflects the increased demand for ELISA analysis by lab sponsors/customers which resulted in increased reimbursable funding by 65% over 2014 funding.

C. Optimized and deployed the multiplex Luminex assay platform with a capability to test the IgG subtype titers for three *P. falciparum* antigens, namely, CSP, Pf16, and NANP repeats. This is quite a powerful tool that allows investigators to probe the immune response down to the IgG subtype (IgG1 through IgG4) implicated in conferring immune protection.

D. Successfully completed the upgrade to the FreezerPro Enterprise software for electronic sample inventory. All data from the legacy software was successfully migrated to the new software, which gives our team a greater capacity to manage and archive the large volume of samples compiled over the years. This upgrade will also facilitate the secure transfer of clinical trial samples from WRAIR Clinical Trials Center (CTC) or from other customers to the serology lab.

E. Optimized and implemented several ELISA assays, in particular, a new CSP repeat (NANP) ELISA and Avidity Index (AI) assays were optimized and used to analyze samples from the RTS,S Delayed Fractional Dose (DFD) study (MAL071).

F. Exercised Option year 3 of the service contract that supports the MSL with contract staff. This unique arrangement where all contract staff for a mission-critical laboratory, like the MSL, probably needs strategic rethinking and must be reviewed carefully to ensure continued service to the Malaria Vaccine development community at the WRAIR and NMRC in particular, and for the global Malaria community in general. For example, in 2014 this lab had 100% personnel turnover rate due to attrition of contract employees. The only government position overseeing the operations of the lab is the Chief of the Laboratory which was held for the last 10 years by active duty service members.

Malaria Parasite Culture-LTC (b) (6) , PhD

This is a core service developed for the maintenance of *P. falciparum* parasites in culture. The laboratory supports WRAIR and NMRC projects by providing malaria parasites for basic research and applied research projects. Listed are several key efforts that have been supported in FY 2014.

A. *P. falciparum* synchronized culture parasites were used to measure serum samples for parasite growth inhibitory activity (Angov Lab).

B. *P. falciparum* isolates were adapted to culture and used to identify cross reactive growth inhibitory activities for new chimeric AMA1 molecules and combination vaccine approaches

C. New *P. falciparum* isolates were culture adapted, expanded, and stored for future use vaccine development assays and human challenge

D. New *P. falciparum* isolate was culture adapted and expanded to produce a new GMP candidate seed lot for 3D7 strain for future human challenge.

E. *P. falciparum* isolates were expanded and provided to entomology for evaluation of infectivity and use in the human challenge model

F. *P. falciparum* parasites were cultured and provided to NMRC scientists for development of humanized mAbs from humanized mouse models

G. A research technician from USMMVP lab was trained on malaria parasite culture

H. *P. falciparum* parasite DNA was used for the development of sensitive PCR detection methods for use in malaria diagnostics (NMRC/WRAIR). This effort supported the USAMMDA Milestone B diagnosis platform for malaria detection

I. Malaria parasites were provided to partners to teach military medical providers and medical students how to diagnose malaria.

Bacterial Diseases Branch 2014 Annual Report

Vision:

The preeminent United States Army bacterial threat surveillance and research branch, seamlessly partnering with fellow DoD, Federal, commercial, and academic entities, providing the greatest return on investment in support of Soldier and world health.

Mission:

We conduct basic and applied research leading to knowledge and products that will protect the force from the threat of bacterial diseases. Our team of expert scientists and clinicians provides state of the art bacterial disease surveillance, prevention, diagnosis, and treatment for the United States Army and the DoD.

Personnel

Director: COL (b) (6) (military)
NCOIC: SFC (b) (6) (military)
Admin Officer: (b) (6) (civilian)

Emerging Bacterial Infections

Personnel

A. (b) (6) (civilian), Chief
B. MAJ (b) (6) (military), Deputy Chief
C. Bacteriophage
    1) (b) (6) (contractor)
    2) (b) (6) (contractor)
    3) (b) (6) (contractor)
D. Overseas Diagnostics
    1) (b) (6) (contractor)
    2) SGT (b) (6) (military)
    3) (b) (6) (contractor)
E. Genotyping & Molecular Epidemiology
    1) (b) (6) (contractor)
    2) (b) (6) (contractor)
    3) (b) (6) (contractor)

Accomplishments

A. In collaboration with AmpliPhi Corporation, EBI scientists selected a therapeutic bacteriophage cocktail for phase 1 trials that has 99% activity against military and global isolates of methicillin-resistant *Staphylococcus aureus* (MRSA).

B. In a multi-year collaborative project with three Kazakh research institutes and the University of Florida, EBI scientists determined the genetic subtypes of 454 *Brucella* species isolates of human and livestock origin for combined analysis of genetic and spatial-temporal patterns of brucellosis transmission in Southern Kazakhstan.

C. In an effort to develop candidate bacteriophage therapeutics for *Shigella* species, EBI scientists:

   1) Discovered and characterized 36 new bacteriophages that are lytic for *Shigella* species.

   2) Formulated a phage cocktail containing some of these that was active against 100% of *Shigella sonnei* and 97.4% of *Shigella flexneri* clinical isolates from Southeast Asia, as determined in a collaboration with AFRIMS.

D. In collaboration with the Eliava Institute of Georgia, a unique host range variant of the Sb-1 therapeutic bacteriophage was selected and characterized that is active against 92% of MRSA strains.

E. Department Chief (b) (6) continued to serve as the Science Director for U.S. Army Medical Research Unit - Georgia (USAMRU-G) throughout 2014 with the dual missions of establishing a coherent collaborative research program in Georgia for USAMRU-G and the new mission to stand up laboratory operations in the USAMRU-G laboratory in the Lugar Center in Tbilisi, Georgia. (b) (6) established and led the USAMRU-G Science Team, a multidisciplinary team of WRAIR scientists, Local National contractor scientists in the WRAIR-USAMRIID Clinical Research Unit, and USAMRIID scientists in continuing collaborative research and establishing new collaborative research in Georgia and the region. The department provided multiple scientists including its Deputy Chief MAJ (b) (6), overseas diagnostics team, and PIs to serve as part of the USAMRU-G Science Team effort. In 2014 (b) (6) continued to coordinate a continuous presence of WRAIR and USAMRIID scientists in the USAMRU-G laboratory (in addition to the Local National contractor presence) by TDY rotations as directed by the WRAIR command until the arrival of the first permanent US personnel in August 2014.

Live Attenuated Shigella Vaccines

Personnel

A. (b) (6) (civilian), Chief

B. (b) (6) (contractor), Product Evaluation Manager

C. Vaccine Development

   1) (b) (6) (contractor)

   2) (b) (6) (contractor)

   3) (b) (6) (contractor)

   4) (b) (6) (contractor)

   5) (b) (6) (contractor)

Accomplishments

A. Phase 1 clinical trial of a 1st-generation *S. sonnei* vaccine candidate (WRSS1) in Bangladeshi adults and children completed.

B. Phase 1 clinical trial of two 2nd-generation *S. sonnei* vaccine candidates (WRSs2 and WRSs3) in US adults completed.

C. Pre-clinical characterization of cGMP lots of two *S. flexneri* 2a vaccine candidates (2nd component of a *Shigella* trivalent vaccine) nearly complete.

D. Pre-clinical characterization of a cGMP *S. sonnei* human challenge strain completed.

E. Construction of *S. flexneri* 3a vaccine candidates (3rd component of a *Shigella* trivalent vaccine) completed and ready for cGMP manufacture.

Multidrug-Resistant Organism Repository & Surveillance Network

Personnel

A. COL (b) (6) (military), Chief

B. MAJ (b) (6) (military), Deputy

1) (b) (6) (civilian)

C. Laboratory Operations

1) (b) (6) (civilian)

2) CPT (b) (6) (military)

Accomplishments

A. Achieved POM funding: $7M this year, $5-6M for the out years.
B. Became key element in national response plan to Antimicrobial Resistance.
C. Wrote 10 publications in high impact peer reviewed journals.
D. Presented 15 poster or podium forum abstracts.
E. Produced 5 outbreak/MRSN reports.
F. Responded to 5 requests for outbreak investigation support.
G. Achieved CAP - re-accreditation, receiving only 1 minor/900 evaluated items. “One of the best labs” that senior inspectors have reviewed.

Subunit Enteric Vaccines and Immunology

Personnel

A. (b) (6) (civilian), Chief

B. Fermentation
1) SPC (b) (6) (military)
2) SPC (b) (6) (military)

C. Biochemistry
1) (b) (6) (contractor)
2) (b) (6) (civilian)

D. Immunology
1) (b) (6) (contractor)

2) (b) (6) (contractor)
3) (b) (6) (contractor)

E. Pathology: LTC (b) (6) (military)

F. Administrative support: (b) (6) (contractor)

Personnel Achievements

A. GLP toxicology, pyrogenicity and general safety tests to support for Phase 1 testing of intranasal *Shigella* vaccine.
B. Successful pre-IND meeting for Phase 1 testing of intranasal *Shigella* vaccine.
C. Preparation for IND submission for Phase 1 testing of intranasal *Shigella* vaccine.
D. Manufacture of cGMP LPS isolated from mutant *Shigella* strain with lower endotoxin activity for downstream use in parenteral *Shigella* vaccine formulations.

Bench

A. Generation of detoxified Invaplex formulations and completion of *in vitro* and *in vivo* testing.
B. Generation of multiple ETEC antigens for distribution to research community through CRADA partners DMID and PATH-EVI.
C. Expanded recto colitis challenge model to include *S. sonnei.*
D. Demonstrated efficacy of Invaplex vaccine delivered intranasally or parenterally in *Shigella* guinea pig rectocolitis model.

Wound Infections

Government Personnel

A. MAJ (b) (6) (military), Chief
B. SGT (b) (6) (military), NCOIC
C. Animal Support
   1) MAJ (b) (6) (military)
   2) PFC (b) (6) (military)
D. Structural Biology
   1) (b) (6) (civilian)
   2) SPC (b) (6) (military)
E. Diagnostics
   1) SGT (b) (6) (military)
   2) SPC (b) (6) (military)
F. Wound Biology
   1) CPT (b) (6) (military)
   2) (b) (6) (civilian)

Accomplishments

A. (b) (6) have brokered several external collaborations and earned grants.

B. MAJ (b) (6) and CPT (b) (6) (Level I) have completed USARMY Acquisition training.

C. CPT (b) (6) and (b) (6) were awarded $519K over three years for a novel research study on bacterial antagonism in war wounds.

D. MAJ (b) (6) selected to become a section chief in ET.

E. The staff has been very flexible in moving labs and planning for the lab repairs.

F. (b) (6) started a Master's program.

G. MAJ (b) (6) and CPT (b) (6) recently oversaw the completion of the first formal Memorandum of Understanding between WRAIR WID and multiple NMRC Directorates. This MOU provides a well-defined legal framework to pursue novel research together, supplementing each other's capabilities and leveraging each other's resources to decrease cost, increase efficiency and serve as a model for other inter-service research groups working towards similar goals and from the same funding sources.

H. CPT (b) (6) took over as IPT chair for 2 major advanced development efforts, totaling $280M, to develop and forward medical diagnostic solutions to the warfighter. She also renewed her MLS certification by continuing to educate herself on the latest trends and technologies in clinical laboratory science, ensuring that she is able to apply a clinical perspective to ongoing research here at WRAIR. She was instrumental in two separate inter-service research endeavors: one to pursue medevac flight approval for medical maggots with the USAF and another on several wound infection projects with NMRC.

I. CPT (b) (6) directed the instruction of over 120 students in the WRAIR tropical medicine course, most of whom provide direct support to Soldiers in the field. They were also both instrumental in aiding the dept. in the acquisition of over $100K of capital equipment for use in cutting edge research. (b) (6) also performed a study on sample collection systems that was presented at the ASM General Meeting.

J. (b) (6) contributed to the WID by managing a research laboratory that has moved not just once, but twice. Her hard work and scientific acumen directly contributed in the award of $519K in funding for an ongoing original research project, which prior to this had gone unfunded for several years. She authored a poster at the ASM General Meeting which was also submitted to peer reviewed journals.

K. MAJ (b) (6) collaborated with LTs (b) (6), as well as with (b) (6), all of NMRC, to edit and revise an animal protocol in support of the Navy's Acute Care Cover for Severely Injured Limbs (ACCSIL) project. We recently obtained WRAIR/NMRC IACUC approval for this protocol, and will soon begin animal studies that will compare a number of novel therapeutics to the current standard of care.

L. (b) (6) has started her IDP. Collaborated with extramural scientists (GMU and others) and has initiated Acquisitions training. Continues to receive significant RAD 1 MIDRP funding ($250k).

M. Patents: Provisional Docket No. WRAIR 14-27: (b) (6) . “Monoclonal antibodies to Treat Infections Caused by Gram Negative, ESKAPE Pathogens”

VIRAL DISEASES BRANCH

Mission

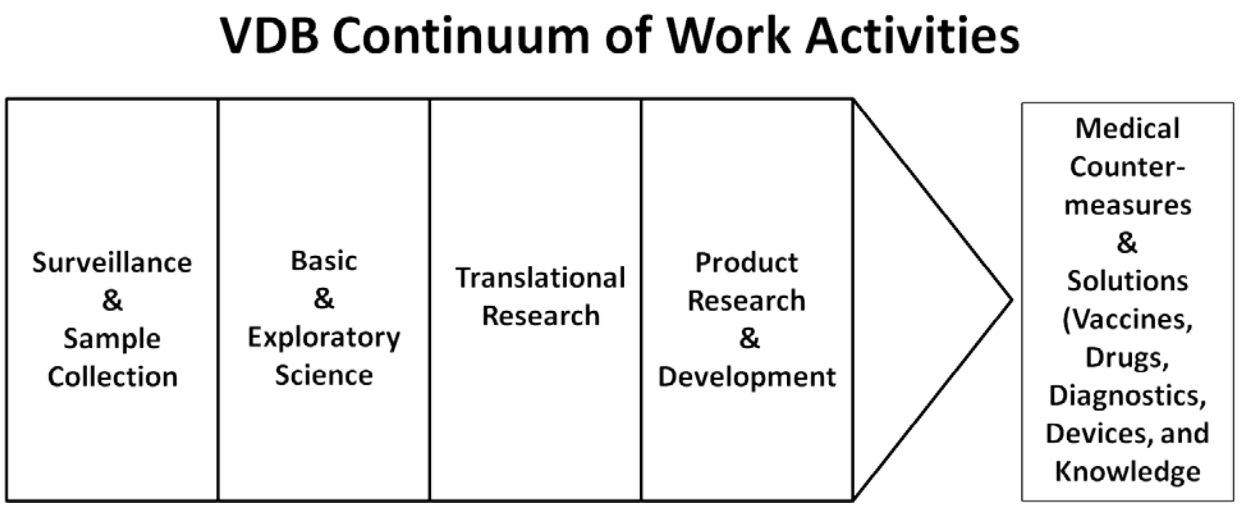
We are the Viral Diseases Branch.

We protect and sustain the health of the US military through the conduct of high quality, strategic, and mission-relevant infectious diseases research with a focus on viral diseases. We carry out our mission by developing and testing therapeutic and preventive drugs and vaccines, supporting global infectious diseases surveillance, completing detailed pathogen and disease description, and educating and training the next generation of world class scientists and research support personnel.

The Viral Diseases Branch is committed to developing the products which protect the men and women who protect our Nation.

The VDB organizes their mission efforts based on a contemporary understanding of the viral diseases threatening U.S. military personnel both domestically and abroad. Dengue, influenza, adenovirus, rabies, chikungunya, Japanese encephalitis, and Yellow fever virus infections constitute a large portion of the active research portfolio. Infectious disease syndromes caused by existing, emerging, or re-emerging viral pathogens, not otherwise identified, is also of interest to the VDB.

The VDB develops capabilities to prevent or treat identified viral threats by working along a scientific continuum including epidemiologic disease surveillance and biologic sample collection, basic and exploratory science, translational research, and product research and development (figure below). The intent is to license (as applicable) and field medical countermeasure capabilities designed to eliminate or mitigate viral disease threats in the most safe, expeditious, cost effective, and high quality manner possible.

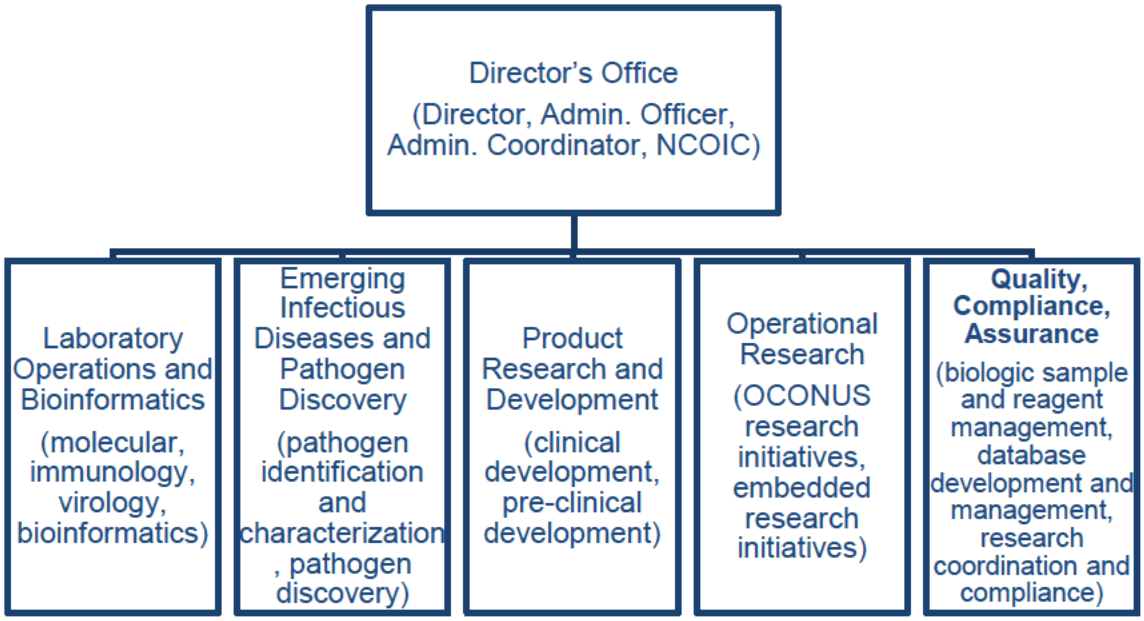


Organization and Personnel

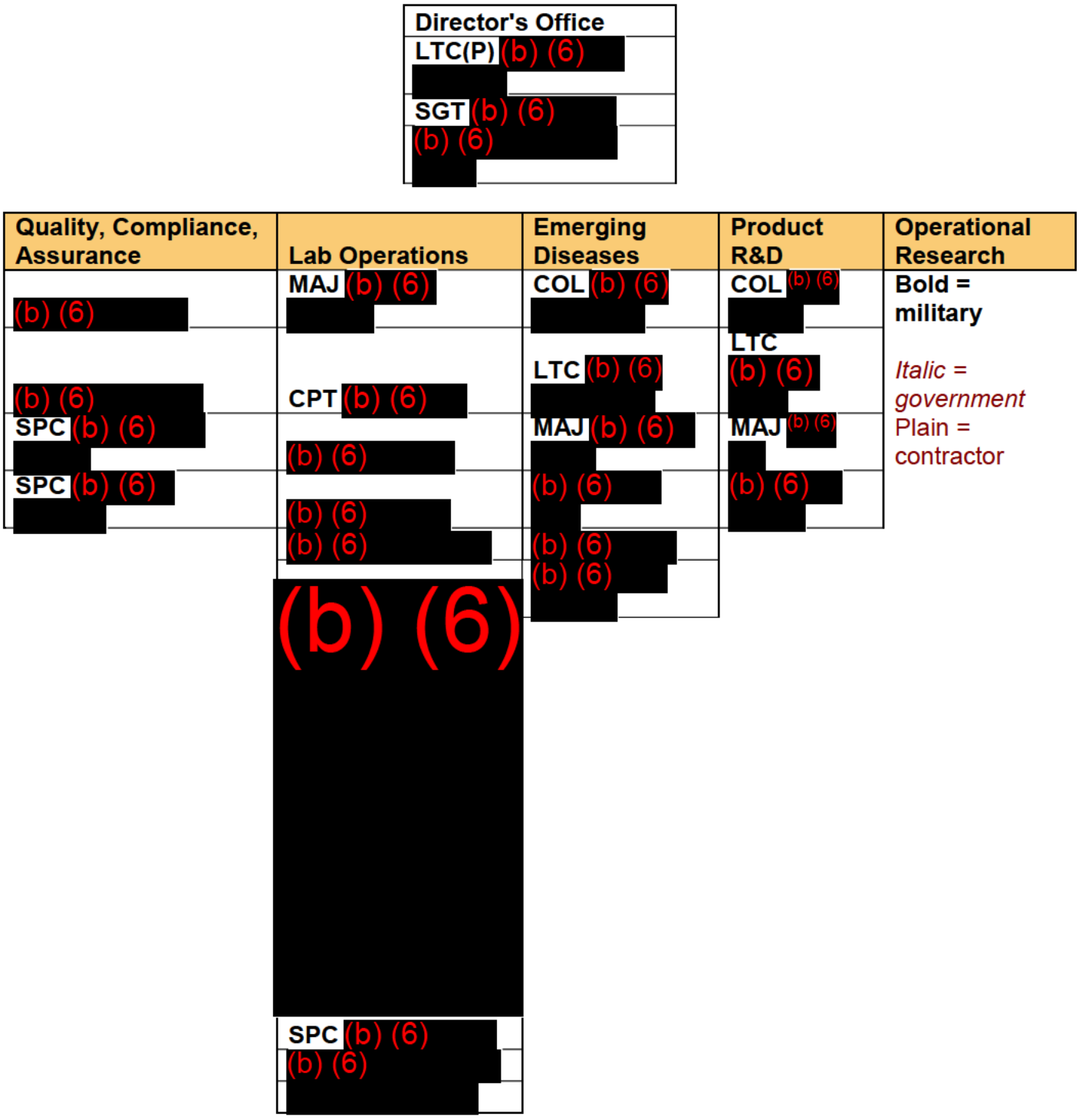
The Viral Disease Branch underwent significant leadership changes during 2014. Initially led by MAJ (b) (6), COL (b) (6) returned from deployment in March and resumed his position as Branch Director until June when he moved to the WRAIR Deputy Commander for Operations position. COL (b) (6) filled in the Branch Director position until COL (b) (6) returned from a TDY assignment to the Command and General Staff Officer's Course and has been Branch Director since September. MAJ (b) (6) has continued to serve as Deputy Director, providing continuity of leadership and scientific direction.

Other changes in personnel include the arrivals of civilian (b) (6) (investigator) and contractor (b) (6) (project manager). CPT (b) (6) and MAJ (b) (6) deployed to and returned from Kuwait during the year.

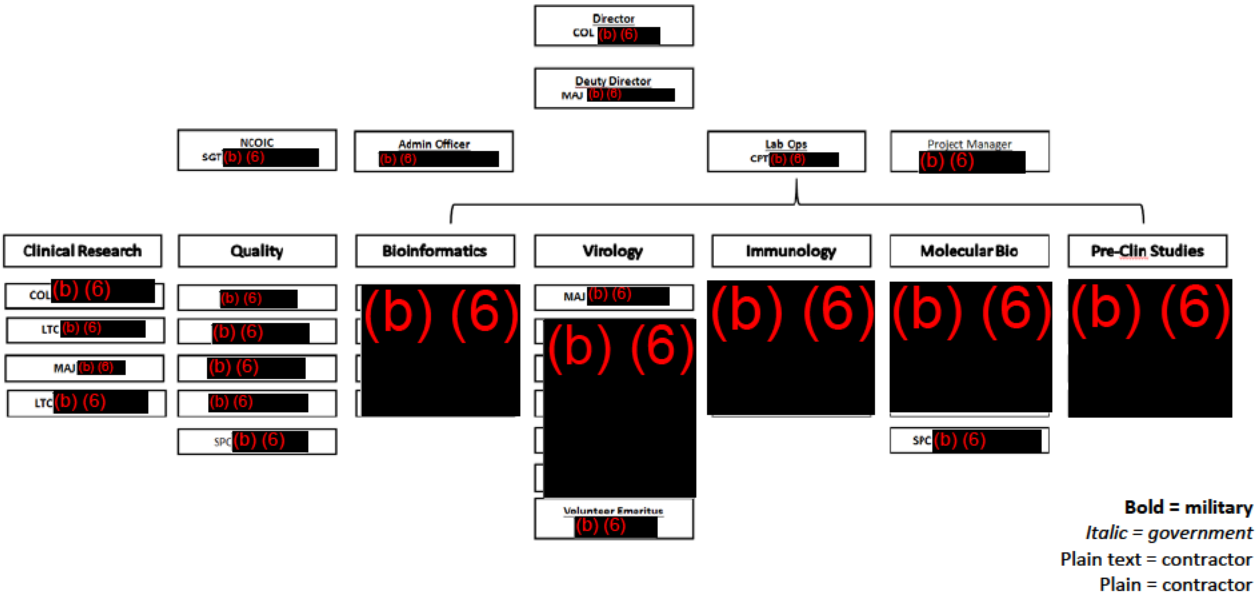
Programmatic Organizational Diagram as of January 2014:



Viral Diseases Branch – Functional Organizational Chart as of January 2014



Organizational Diagram as of December 2014:



Training and Education

Training Conducted

A. A. Operational Clinical Infectious Disease (OCID) Course – This course was developed to provide medics and healthcare providers of deploying units with a focused update on infectious diseases of geographic significance. VDB clinicians presented lectures for the OCID course at the following locations and dates. This course was developed by COL (b) (6) during his time as Branch Director and, with his move to the DCO position, is now managed out of WRAIR Headquarters.
   1) Fort Lewis, February 2014 (COL (b) (6), MAJ (b) (6))
   2) Fort Riley, February 2014 (COL (b) (6), LTC (b) (6))
   3) Fort Carson, March 2014 (LTC (b) (6))
   4) Eglin Air Force Base, April 2014 (COL (b) (6))
   5) Fort Stewart, September 2014 (LTC (b) (6))

B. A Comparative Genomic Analysis Workshop was conducted by the VDB Bioinformatics group in December for two scientists based at the U.S. Army Medical Research Unit – Georgia (USAMRU-G) in December 2014.

C. (b) (6) also provided instruction on next generation sequencing at the Workshop on Genomics in Cesky Krumlov, Czech Republic in January 2014.

Training Attended

A. VDB soldiers/contractors/employees took part on the following training venues:
   1) COL (b) (6): Command and General Staff Officer's Course, Fort Lee, Va., May-August.
   2) LTC (b) (6): Tropical Medicine Certification Course, Philadelphia, November 1-2.
   3) LTC (b) (6): Intermediate Medical Acquisitions Course.

Research and Development

Research Projects

Studies are conducted within each pillar of the VDB continuum of work activities. Major projects conducted in 2014 are listed below.

A. Surveillance and Sample Collection

1) GEIS surveillance of acute respiratory disease in select populations

a. Purpose: identification and characterization of influenza-like illness pathogens in embassy employees from 36 locations worldwide

b. Progress: >500 samples processed for pathogen identification

c. Budget: $500K (GEIS)

d. Personnel: MAJ (b) (6), MAJ (b) (6)

2) Pathogen-Discovery

a. Purpose: Central resource for NGS for human and environmental specimens

b. Progress: >1000 samples sequenced

c. Budget: $500K (GEIS)

d. Personnel: MAJ (b) (6), (b) (6)

3) Sequencing

a. Purpose: to sequence known pathogens (ie, influenza, dengue) for phylogenetic analysis

b. Progress: on-going data collection

c. Budget: $500K (GEIS)

d. Personnel: MAJ (b) (6), CPT (b) (6)

4) NGS for infectious diseases diagnostics development

a. Purpose: To develop protocols to NGS as a clinical diagnostic tool.

b. Progress: Project complete; will expand on this in 2015 through a CRADA with Illumina.

c. Budget: $100K (MIDRP)

d. Personnel: (b) (6)

5) Dengue quasi-species dynamics during infection and in vitro transmission cycling

a. Purpose: Examine the development of dengue quasi-species over the course of natural and in vitro infection.

b. Progress: Laboratory models developed and source sera identified.

c. Budget: $400K (ILIR)

d. Personnel: (b) (6)

6) Upper respiratory metagenomics

a. Purpose: In anticipation of future studies of respiratory health in deployed populations, this study seeks to:

i) Collect data on the composition and stability of the upper airway microbiome in a stable garrison population;

ii) Determine the effect of occupation, work location, tobacco use and flu vaccination on the upper airway microbiome.

b. Progress: 63 individuals were enrolled and specimens collected through the second of four planned quarters.

c. Budget: $100K (MILVAX)

d. Personnel: LTC (b) (6), COL (b) (6), COL (b) (6)

B. Basic and Exploratory Science

1) FcGamma receptor

a. Purpose: develop a candidate marker for immune protection.

b. Progress: assay complete for DENV-2; assay development for other serotypes on-going.

c. Budget: $295K (MIDRP, ILIR, GSK)

d. Personnel: (b) (6)

C. Translational Research

1) DENV3 human challenge model virus derivation

a. Purpose: Develop strain of DENV-3 for use as a challenge strain in human studies.

b. Progress: Study complete.

c. Budget: $130K (Advanced Development)

d. Personnel: (b) (6)

2) Improving the DENV rhesus infection model

a. Purpose: to develop an improved model of dengue infection in non-human primates

b. Progress: delays in animal procurement have pushed this study to FY2015

c. Budget: $850K (GSK)

d. Personnel: MAJ (b) (6)

D. Product Research and Development

1) DPIV-001

a. Purpose: Phase 1 study of a purified inactivated dengue vaccine in healthy volunteers.

b. Progress: The study was amended to administer a booster dose and collect additional samples by plasmapheresis.

c. Budget: (CRADA with GSK)

d. Personnel: MAJ (b) (6) LTC (b) (6)

2) ADVP-003

a. Purpose: Clinical trial compare different heterologous prime-boost schedules using purified inactivated and live attenuated dengue vaccines

b. Progress: Clinical trial protocol was drawn up and approved, screening and enrollment begun; first group received first vaccination

c. Budget: $1.97M (MIDRP)

d. Personnel: LTC (b) (6), MAJ (b) (6), COL (b) (6)

3) Dengue Human Infection Model

a. Purpose: to clinically evaluate an attenuated strain of DENV-1 in a human challenge.

b. Progress: protocol development, contracting support, site development (SUNY-Upstate)

c. Budget: (Ad Dev)

d. Personnel: LTC (b) (6), COL (b) (6), MAJ (b) (6), MAJ (b) (6), (b) (6)

4) Serologic testing of MV-CHIKV vaccine

a. Purpose: to assess the immune response of human volunteers in a phase 1 clinical trial of a measles-vectored chikungunya virus vaccine

b. Progress: Study completed, reported and published.

c. Budget: $80K (CRADA with Themis Biosciences GmbH)

d. Personnel: (b) (6)

5) DPIV-002

a. Purpose: to assess the performance of the WRAIR/GSK purified inactivated dengue vaccine in an endemic population.

b. Progress: Vaccination (at the University of Puerto Rico) completed, volunteers now in follow-up phase.

c. Budget: (GSK CRADA; MIDRP)

d. Personnel: MAJ (b) (6)

6) CYD 56

a. Purpose: to assess the performance of the Sanofi-Pasteur yellow-fever vectored-dengue vaccine when co-administered with other flavivrus vaccines.

b. Progress: Vaccination of volunteers (at SUNY-Upstate medical center) completed, volunteers now in follow-up phase.

c. Budget: $665K (Ad Dev)

d. Personnel: MAJ (b) (6)

7) DENVAX

a. Purpose: to compare intradermal versus intramuscular administration of the Takeda tetravalent dengue vaccine.

b. Progress: Clinical phase complete. Laboratory assessment of cell-mediated immunity on-going.

c. Budget: $800K (MILVAX)

d. Personnel: (b) (6)

e. Major challenges: Monitors from Takeda found several irregularities in the conduct of the study; FDA inspection completed in June 2014 and provided corrective actions which were taken by the SUNY PI.

8) RABVAX

a. Purpose: to compare intradermal versus intramuscular administration of the licensed Novartis rabies vaccine.

b. Progress: protocol drafted and IRB-approved

c. Budget: $1.4M (MILVAX)

d. Personnel: COL (b) (6)

9) MALRAB

a. Purpose: to determine the effect of concomitant malaria prophylaxis on immune response to rabies post-exposure prophylaxis

b. Progress: preliminary trial design completed

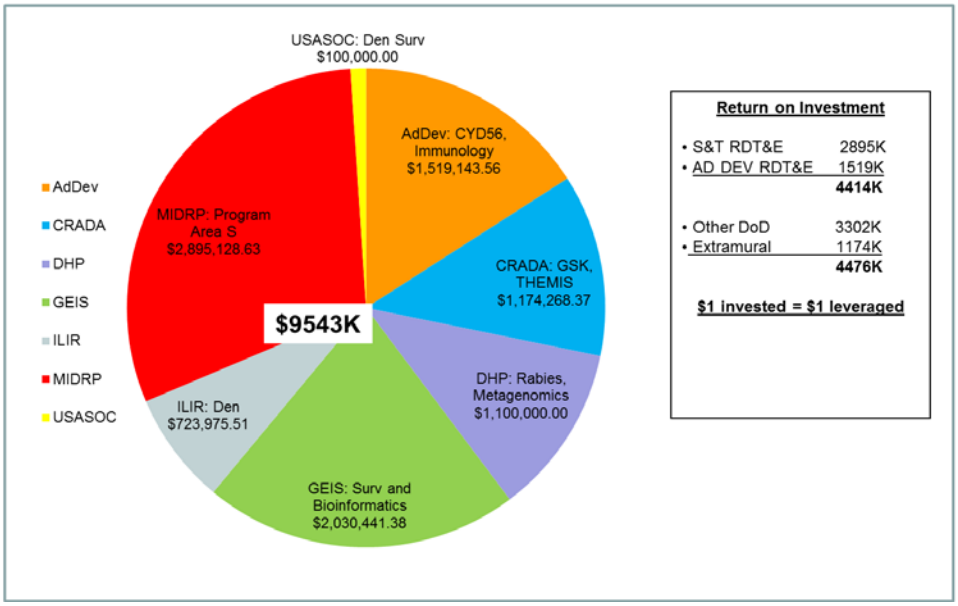
c. Budget: $800K (MILVAX)

d. Personnel: COL (b) (6)

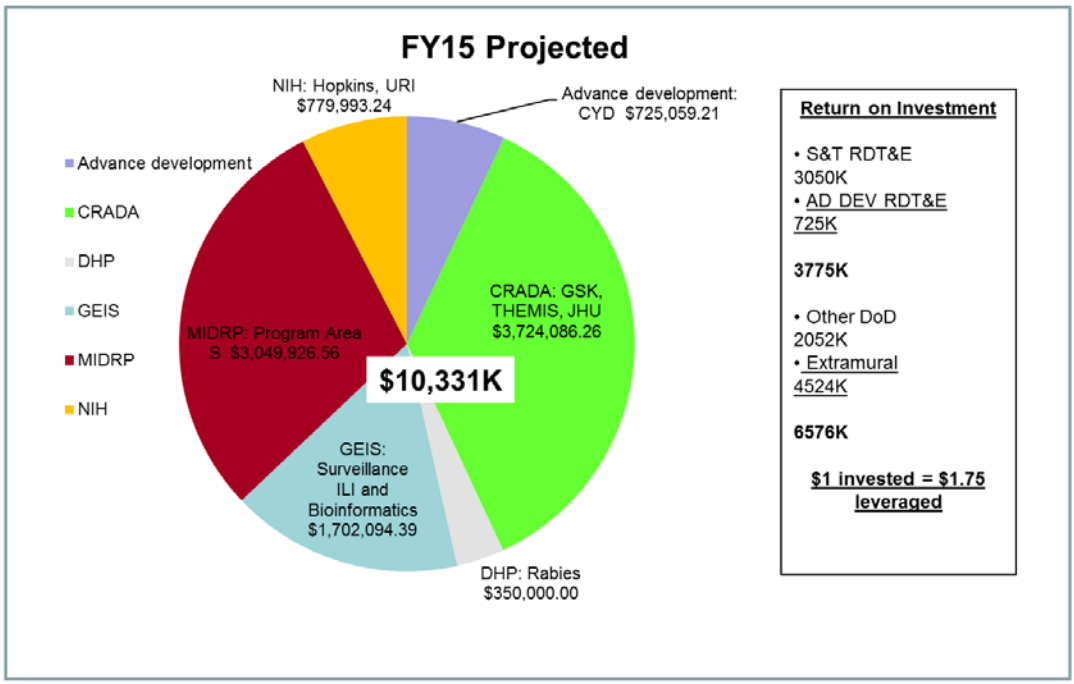
Resource Management and Budget

The following pie charts show VDB funding by source for FY2014 and FY2015.

Distribution of FY 2014 funds



Distribution of FY 2015 funds



Modernization

Modernization of Equipment

The following pieces of equipment were obtained in 2014 as part of an on-going effort to maintain

A. Illumina MiSeq
B. Eppendorf Epimotion 5070 automated pipetting workstation system
C. Qiagen QIAcube robotic workstation for automated purification of DNA, RNA, or proteins.
D. BD Science FACSAria Fusion, a multi-color flow cytometer with integrated biosafety cabinet.

Modernization of Tools for Bioinformatic Analyses

A. VDB Bioinformatics group continued development of a pathogen discovery informatics pipeline, completing version 4.0 in 2014. Versions 4.1 and 4.2 will have expanded capabilities and flexibilities and are slated for release in late 2015.
B. VDB Bioinformatics group finished development of a pipeline to process next generation sequencing data from several different platforms and do high throughput viral genome construction and quality control.

ENTOMOLOGY BRANCH

Preventive Medicine Branch

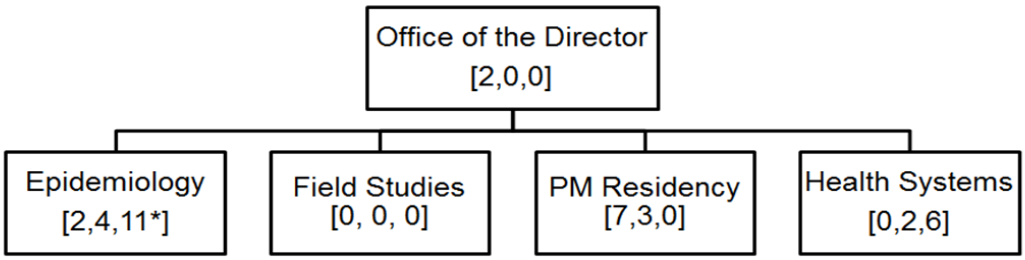
Mission

To provide epidemiologic and public health research support to Department of Defense (DoD) units worldwide, on infectious diseases, chronic diseases, non-battle injuries, and public health aspects of humanitarian assistance. To provide assistance in the design and conduct of other militarily-relevant medical investigations. To provide research support in the development of evidence-based DoD medical standards for accession, retention, and disability discharge through the Accession Medical Standards Analysis & Research Activity. To conduct graduate medical education in preventive medicine in partnership with the US Army Public Health Command and the National Capital Consortium. To provide support to the Defense Threat Reduction Agency's Cooperative Biological Engagement Program, in the development and implementation of national disease reporting systems for select pathogens.

Organization

In addition to the Office of the Director, the Preventive Medicine Branch (PMB) consists of the Departments of Epidemiology, Field Studies, and Health Systems, and the General Preventive Medicine Residency Program.

The PMB functional organizational chart as of September 2014 follows. [Assigned staff: Military, Civilian, Contractor; *Professional Services Contract Staff (Not DoD CTRs)]



Personnel

Office of the Director

A. Director — COL (b) (6), DO, MPH

B. NCOIC — SGT (b) (6)

Department of Field Studies

Among TDA slots in Field Studies (FS) only the PM Officer has been filled periodically, and in recent years workload attributed to this slot has been exclusively in support of Experimental Therapeutics and Military Malaria Research Program (MMRP) protocols. Following a MEDCOM manpower study in 2012 when all FS positions were vacant, in lieu of either re-justifying or losing the 60C authorization, during FY 2014 this slot was functionally realigned to the MMRP, pursuant to FY 2015 TDA realignment.

A. Chief — LTC (b) (6), MD, MPH

Department of Epidemiology

Mission

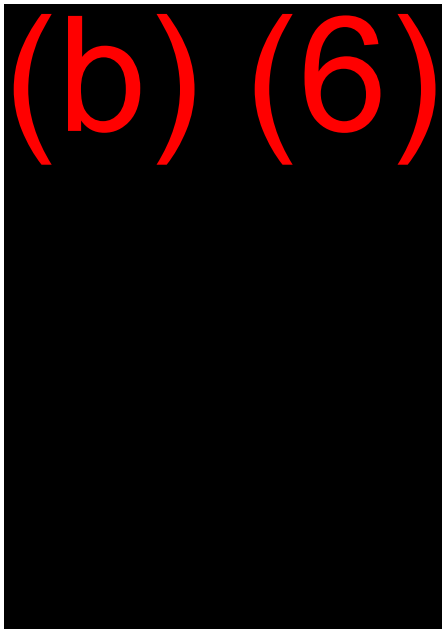
Support evidence-based DoD medical standards through the Accession Medical Standards Analysis Research Activity (AMSARA), and develop collaborations to conduct epidemiologic research using unique military resources to benefit the health of military and civilian populations.

Organization

During FY 2014 MAJ (b) (6) succeeded COL (b) (6), MD, MPH as Department Chief. Based on available personnel and workload changes, and in response to a 2012 MEDCOM manpower study proposed reduction in authorized slots, we elected to lose the Chief, AMSARA authorization in favor of the Department Chief assuming this role.

Personnel

A. Chief — MAJ (b) (6), MD, MPH
B. Senior Epidemiologist
C. Senior Statistician
D. Health Science Officer
E. ATG Program Manager
F. ATG Principal Public Health Analyst
G. ATG Statistician
H. ATG Public Health Analyst
I. ATG Public Health Analyst
J. ATG Public Health Analyst
K. ATG Public Health Analyst
L. ATG Public Health Analyst
M. ATG Public Health Analyst
N. ATG Data Manager



Research and Development

A. WRAIR Protocol #2023: Attrition, Morbidity and Disability Among Military Personnel: Analysis of Existing Databases

1) Purpose: To evaluate the impact of and research priorities for military medical standards and screening procedures, by quantifying the burden associated with various medical conditions and service-related outcomes, including medical disqualifications for enlistment, accession and deployment medical waivers, discharges due to conditions existing prior to service or disability, early discharge (attrition) from service, and deployment readiness

2) Progress: 2 manuscripts in progress, 9 requests for information (RFIs) completed, 4 Accessions Medical Standards Working Group (AMSWG) meetings attended, AMSARA Annual Report in progress, passed audit by AHRPO

3) Budget: $676K (DHP)

4) Personnel: MAJ (b) (6) [redacted]

B. WRAIR Protocol #2023.01: Disability Evaluations among U.S. Military Personnel

1) Purpose: To evaluate the DoD Disability Evaluation System in an effort to support the DoD Medical Personnel Executive Steering Committee in its mission to establish military accession, deployment, and retention/disability medical standards and develop policy based on evidence-based information

2) Progress: 8 manuscripts in progress, 2 publications, 3 RFIs completed, Disability Annual Report completed.

3) Budget: $450K (AMAP)

4) Personnel: MAJ (b) (6) [redacted]

C. WRAIR Protocol #2023.02: Evaluation of non-cognitive personality tests as predictors of morbidity and attrition in U.S. Military applicants and accessions

1) Purpose: To evaluate the utility of the non-cognitive temperament tests, AIM and TAPAS, as predictors and potential screens for morbidity, specifically mental disorder diagnoses, and attrition from military service

2) Progress: 3 manuscripts in progress, awaiting data for FY 2011-present

3) Budget: Included in core protocol #2023

4) Personnel: MAJ (b) (6) [redacted]

D. WRAIR Protocol #2023.03: Accession and Service-Related Risk Factors for Suicide, Suicide Attempt and Ideation among U.S. Marines from 2001-2012 (collaboration with the U.S. Marine Corps Behavioral Health Program)

1) Purpose: Evaluate associations of suicides, suicide attempts and ideation with selected demographic, accession, and service-related factors, including deployment, length of service and military occupation

2) Progress: Analysis in progress, presented twice at the USMC Marine & Family Programs Division, Behavioral Health Branch Research Summits for study update; final report due March 2015

3) Budget: $215.6K (from USMC)

4) Personnel: MAJ (b) (6) [redacted]

E. WRAIR Protocol #2023.04: Assessment of Recruit Motivation and Strength (ARMS)

1) Purpose: To evaluate the attrition, morbidity, health care utilization, deployment, disability in ARMS study subjects

2) Progress: 4 manuscripts in progress, 1 publication

3) Budget: included in core protocol #2023

4) Personnel: MAJ (b) (6)

F. WRAIR Protocol #1068 (pilot): The Association of New Onset Schizophrenia and Bipolar Disorder with Selected Infectious Agents, Genetic Markers, and Inflammation in U.S. Military Personnel from 1992-2001

1) Purpose: To further explore the relationship between schizophrenia and bipolar disorder and antibody seropositivity to Human Herpes Viruses (HSV-1, HSV-2, CMV, EBV, HHV-6, VZV) and other organisms not yet specified, as well as markers of immune response, that may be associated with schizophrenia or bipolar disorder

2) Progress: Analysis complete, revisiting results for comparisons

3) Budget: $280K

4) Personnel: Dr. (b) (6) MAJ (b) (6)

G. WRAIR Protocol #1272: A Nested Case-Control Study of New Onset Schizophrenia and Toxoplasma gondii and other infectious Agents, Genetic Markers, and Inflammation in U.S. Military Personnel from 1992-2005

1) Purpose: To further explore associations between infectious agents, including Toxoplasma gondii, polymorphisms in cytokines and other immune response genes, and other markers of immune response and schizophrenia

2) Progress: Laboratory testing and data analysis in progress, 3 manuscripts in progress, 2 presentations at local meetings

3) Budget: Included with protocol #1068 above

4) Personnel: (b) (6), MAJ (b) (6)

H. WRAIR Protocol #1452: A Nested Case-Control Study of Bipolar Disorder, Selected Infectious Agents, Genetic Markers, and Inflammation in U.S. Military Personnel from 1992-2005

1) Purpose: To continue exploration of infectious agents sero-prevalence and potential associations between infectious agents, including *Toxoplasma gondii,* polymorphisms in cytokines, markers of immune response and the risk of development of bipolar disorder

2) Progress: Laboratory testing continues, Analysis and manuscript in progress

3) Budget: Included with protocol #1068 above

4) Personnel: (b) (6), MAJ (b) (6)

I. WRAIR Protocol #1859: A Nested Case-Control Study of Schizophrenia Immune Markers in U.S. Military Personnel from 2006-2010

1) Purpose: To explore if there are specific antibodies produced in patients before and during a clinical presentation of schizophrenia and if they can be used as serologic markers for the disease, and address these questions by screening serum samples from schizophrenia patients and matched controls against the peptoid and peptoid-like compound library with approximately 1,000,000 compounds to assess for peptoid-antibody ligands with high specificity for the disease

2) Progress: Laboratory analysis in progress at the OPKO laboratory, passed audit by AHRPO

3) Budget: $110K, no cost extension

4) Personnel: (b) (6), MAJ (b) (6)

J. WRAIR Protocol #1932: A Nested Case-Control study of Gene Environmental Interactions Contributing to Schizophrenia in Individuals in the U.S. Military Population

1) Purpose: To further explore associations between infectious agents, including *Toxoplasma gondii,* food antigens, biomarkers of immune response, genetic polymorphisms, and the risk of schizophrenia

2) Progress: Protocol #1932A, feasibility is completed

3) Budget: Estimated $129,360

4) Personnel: (b) (6), MAJ (b) (6)

K. WRAIR Protocol #2140: A Nested Case-Control Study of New-Onset Schizophrenia and Infectious Agents, Inflammation, and Serum Biomarkers in U.S. Military Personnel from 2006-2013

1) Purpose: To explore associations between schizophrenia and common infectious agents (including Herpes family viruses and *Toxoplasma gondii*), food antigens (including casein and gliadin), and biomoarkers associated with immune response

2) Progress: Protocol is approved, pending initiation of study

3) Budget: $140.5K

4) Personnel: (b) (6), MAJ (b) (6)

L. WRAIR Protocol #1397: DNA Extraction and Whole Genome Amplification

1) Purpose: Determine feasibility of DNA amplification for studies of vitamin D genotyping

2) Progress: DNA can be successfully extracted from DoD Serum Repository using archived samples of 0.5ml volume; next steps are to incorporate SNP analyses in future studies

3) Budget: TBD

4) Personnel: (b) (6)

M. WRAIR Protocol #2045: Prediagnostic markers of immune activation and viral infection and risk of non-Hodgkin lymphoma --Continuance of former WRAIR #1325

1) Purpose: Determine whether B cell cytokine and cytokine-like molecules and vaccination history are associated with risk of subtypes of NHL

2) Progress: Data analysis is fully underway; preliminary results show a decreased risk of NHL with number of prior vaccinations; B cell activation markers are positively associated with risk

3) Budget: prior CRADA

4) Personnel: (b) (6)

N. WRAIR Protocol #2096 (Pending): Serologic Biomarkers and the Risk of Multiple Sclerosis in Active-Duty Service Members

1) Purpose: Determine whether EBV and vitamin D are associated with risk of MS.

2) Progress: Awaiting WRAIR scientific approval; USUHS has approved all documents
3) Budget: TBD
4) Personnel: (b) (6)

Other

A. Serve as IRB member ((b) (6)) and IACUC reviewer ((b) (6)) in support of WRAIR
B. Faculty, WRAIR, Preventive Medicine Residency Program ((b) (6))
C. Supervised two SEAP/CQL students ((b) (6)

SHARED SERVICES FOR THE CENTERS FOR MILITARY RESEARCH

VETERINARY SERVICES PROGRAM

MISSION STATEMENT:

Provide relevant, professional, world class veterinary service support that enables WRAIR/NMRC investigators success in their endeavor to create, develop, deliver and sustain medical capabilities for the Warfighter.

Veterinary Medicine

The Department procured, housed and provided veterinary care to approximately 20,584 animals for FY14. Animals are maintained to the highest industry standards, with a focus on preventive medicine, excellent veterinary medical care, a robust quality assurance/quality control program and an effective environmental enrichment program for all animals, representing twelve different species. Animals are housed in two separate buildings in a 155,000 square foot vivarium; 511 primarily houses non-human primates (NHP) and other large animals, 503 primarily houses rodents and other small mammals. The Division supports the Institutional Animal Care and Use Committee (IACUC) in reporting requirements for all animal-based research for both the WRAIR and NMRC. This includes Congressional requests, Inspector General Reports, annual DOD reports, MRMC requests for information, United States Department of Agriculture (USDA) reports, Office of Laboratory Animal Welfare (OLAW) assurance reports, and accreditation requirements from the Association for the Assessment and Accreditation of Laboratory Animal Care International (AAALAC). In addition to managing and providing medical/surgical care to the research animal colony, veterinary officers actively participate as investigators and co-investigators in animal-based research, conduct DOD Laboratory Animal Techniques and Handling Workshops (for investigators, research support staff, veterinary staff and animal care personnel) and participate in the Army Laboratory Animal Medicine Residency Training Program.

Pathology

The Department provides collaborative pathology expertise to support both WRAIR and NMRC studies on diseases of defined military importance through the study of lesion morphology at the gross, cellular, and subcellular levels, and the interpretation of attending clinical chemistry, and immunologic perturbations. Support studies in the pathogenesis of relevant endemic infectious disease conditions and military psychiatry and neuroscience, and development and assessment of vaccine candidates, prophylactic agents and diagnostic methods for such conditions. Provide central laboratory services for hematology, clinical chemistry, bacteriology, necropsy, histology, immunohistochemistry, scanning electron microscopy, and transmission electron microscopy. Provide diagnostic pathology support to ensure the health of the Institute's diverse laboratory animal colony. Instruct Department and Institute professional and technical staff in basic and advanced pathology techniques and maintain technical proficiency.

DIRECTOR'S OFFICE, VETERINARY SERVICES PROGRAM:

Personnel assigned: Five personnel consisting of three military VCOs, one military 68T, and one DJ-3 civilian administrative officer.

NMRC personnel has one VCO assigned to support the VSP.

The Director's office is responsible for overseeing the daily activities and functions of the entire Veterinary Services Program.

A. **Large Animal Medicine Branch (LAMB)**

LAMB has the primary responsibility for protocol support, in processing, health maintenance, housing, and quarantine of non-human primates and large animals housed at WRAIR/NMRC, which includes swine, sheep, cats, ferrets and a snake. LAMB also conducts DOD Laboratory Animal Workshops for multiple species designed to train Institutional Animal Care and Use Committee (IACUC) personnel, technicians, and investigators on proper handling techniques, biosafety and husbandry for laboratory animals at WRAIR/NMRC.

1) Personnel assigned: Nine personnel consisting of two military VCOs, and five military 68Ts, and two SoBran contract technicians.
2) Notable Trends: N/A
3) Significant Issues: The VSP imaging capability has been improved with the purchase of a new, upgraded radiograph machine, enabling the Veterinary Services Program to better diagnose, and treat animals appropriately.
4) Innovations: In order to better utilize our valuable NHP assets among DOD labs, we have established an effective communication system with RIID to allow WRAIR NHPs to be used there after they have become tier three.

B. **Small Animal Medicine Branch (SAMB)**

SAMB is responsible for providing animal protocol support and general veterinary care for all animals and animal studies conducted in Building 503, which includes mice, rats, guinea pigs, hamsters and rabbits. SAMB provides guidance and consultation to investigators and technicians of animal use protocols, and supervision for all veterinary care within Building 503. They also conduct training in rodent handling and husbandry, basic and advanced surgical techniques, and euthanasia.

1) Personnel Assigned: Nine personnel consisting of two military VCOs, five military 68Ts and one SoBran contract technician.
2) Notable Trends: Between SAMB and LAMB they conducted approximately 82 animal care and use workshops that supported 174 investigators and technicians from the WRAIR/NMRC Divisions, Directorates and Programs during FY 14. This is a 28% increase in workshops compared to the previous year. This training is designed to meet requirements mandated by the Animal Welfare Act that require personnel working with laboratory animals be qualified to do so. The workshops, which include didactic and practical instruction in humane handling and sampling techniques, are provided: for rodents, rabbits, dogs, swine, snakes, ferrets and non-human primates. Other workshop topics include lectures on operating room sterile techniques, aseptic technique for rodent-survival surgery, anesthesia and working safely with NHPs.
3) Significant Issues: Swift and effective response mitigated adverse effects of the MHV disease outbreak, saving more than 2,000 research animals and $1.2M of research.
    a. Mice Hepatitis Virus outbreak in the vivarium
    b. Streamlining animal rounds procedures enabled the branch to meet the demands for technical protocol support; while improving animal health and welfare.
4) Innovations: N/A

C. **Resources and Operations Branch (ROB)**

ROB manages the logistical and fiscal operations for the Veterinary Services Program to include: ordering animals for the WRAIR/NMRC; animal husbandry; animal transportation; maintains Army and Navy credit card and orders all division supplies and equipment; procured animals; manages the Program's annual budget of over $5,000,000; manages the RHC hand receipt; coordinates and provides technical oversight of facility projects; work order requests; manages the Program's controlled substance.

1) Personnel assigned: Thirty-seven personnel are assigned to the ROB: One DJ-3 civilian Branch Chief; two military personnel consisting of one E-6 and one E-4; *one Navy research program coordinator; thirty SoBran husbandry contract staff: one Lovelace Animal Management Software Integration Specialist; and two budget personnel under the Destiny Management contract.

2) Notable Trends: A new five-year contract was awarded to SoBran for animal care, husbandry, and pathology support. This contract included a veterinarian and two additional pathology technicians to support the VSP mission.
3) Significant Issues: The Navy Research program Coordinator retired 31 December 2014 and will not be replaced.
4) Innovations: The Datatron system was installed in the building 511 animal rooms, feed cooler, and vaccine refrigerator. This system provides a log of validated temperature and humidity data as well as notification to designated staff when room environment exceeds a pre-designated set point.

D. **Veterinary Surgery Branch (VSB)**

VSB has direct responsibility for experimental surgery procedures performed on resident species in the Institute. They conduct the DOD Aseptic Techniques training workshop and provide hands-on surgical training to ensure that all investigators and technicians perform surgeries in the course of their protocols IAW regulations, policies and guidelines. They assist Investigators in the planning of surgical procedures and provide logistical and technical support as needed. They provide oversight for all surgeries to ensure proper recovery and post-operative care.

1) Personnel Assigned: Personnel assigned: Nine personnel consisting of two VCOs, three 91Ds, two 68Ts, and two contract technicians.
2) Notable Trends: N/A
3) Significant Issues: N/A
4) Innovations: The Innovian system - implemented use of electronic data collection system, which automatically charts patient parameters and allows seamless transfer of
5) patient data to browser equipped workstations. This technology improves
6) patient monitoring and archiving of critical research data.

E. **Comparative Pathology Branch**

This Branch provides support in anatomic pathology for research performed on endemic infectious diseases relevant to the military community as well as military undersea medicine, neuroscience, and neurotrauma. To collaborate in research projects initiated by WRAIR and NMRC Institute divisions, and provide consultations in the area of comparative pathology. To provide central laboratory services in the areas of necropsy and histology in support of WRAIR and NMRC research projects and the laboratory animal colony. To train personnel in the specialized techniques employed in the areas of anatomic pathology.

1) Personnel Assigned**:** The Comparative Pathology Branch is organized into two sections: Necropsy and Histology. The Branch is comprised of a Branch Chief, who is a Veterinary Corps Officer and board-certified pathologist (64D), a Branch NCOIC who is an animal care technician (68T), five military medical laboratory technicians (68K), and one general schedule (GS) civilian.

   Notable Trends: The Comparative Pathology Branch has increased personnel and expanded equipment resources to more effectively meet mission demands and to provide consistent customer service. The Branch leadership has improved communications with customers to better coordinate research efforts, including giving presentations to each research division at the WRAIR, by detailing available pathology services for their use.

   Innovations: The use of a new computer database (Filemaker Pro) has enabled more accurate tracking of pathology materials and workload reporting along with improved pathology reports (including ability to add digital images) generated for principal investigator use.

   Significant Issues: Future storage requirements for pathology materials archiving (formalin-fixed tissues, paraffin-embedded blocks, and slides) will need to be addressed. The Joint Pathology Center will no longer store pathology materials in its repository. In addition, the current room in Building 511 utilized for more recent formalin-fixed tissue archival storage

(1S33) was not constructed for this use (inadequate ventilation). Therefore, Comparative Pathology Branch leadership has undertaken planning to meet this future need.

F. **Diagnostic Pathology Branch**

This Branch provides central laboratory services in the areas of hematology, clinical chemistry, microbiology, ultrastructural and immunopathologic diagnostic support for the DOD medical research mission to the WRAIR/Research/NMRC. The Branch provides research and technical support to investigators, conducts independent and collaborative research in pathogenesis of infectious diseases of military importance and wound casualty research.

1) Personnel Assigned: The Branch is under the direction of the Branch Chief who is a Veterinary Corps Officer and board-certified pathologist (64D). The Clinical Pathology section is comprised of a general schedule (GS) microbiologist. One military medical laboratory technician (68K) provides support to both the Clinical Pathology and Immunohistochemistry sections. The Ultrastructural section employs a general schedule (GS) research biologist. One contractor (CTR) provides clinical pathology, immunohistochemistry, and imaging support in the Diagnostic Pathology Branch.
2) Notable Trends: There has been increased interest by Institute researchers in the use of confocal microscopy to enhance their study findings and results for publications and posters.
3) Innovations: A new confocal microscope is now available for Institute researcher use. The confocal microscope provides innovative and modern imaging capabilities to include reconstruction of three-dimensional structures from obtained images and fluorescent double-labeling of cellular structures of interest.

TRANSLATIONAL MEDICINE BRANCH

MISSION

The Translational Medicine Branch at WRAIR serves as a centralized resource for regulatory compliant activities including clinical trials, product development, and manufacturing. The branch further serves as a bridge and coordinator of collaborative interaction between product sponsors and licensing bodies. The branch led by COL (b) (6), and is comprised of three departments; the Department of Clinical Trials, managed by MAJ (b) (6) the Pilot Bioproduction Facility managed by (b) (6), and the Department of Regulatory Affairs.

GOVERNMENT PERSONNEL

COL (b) (6), Military
LTC (b) (6), Military
SGT (b) (6), Military
(b) (6), GS Civilian

DEPARTMENT OF CLINICAL TRIALS (UWD-C)

DEPARTMENT MISSION

The WRAIR Clinical Trials Unit is the Army's center of excellence for clinical trials, conducting Phase I, Phase II and Phase III multi-center human studies to the highest ethical and safety parameters exceeding Good Clinical Practices standards in support of MRMC's mission to develop effective and safe vaccines, drugs and devices for the warfighter.

GOVERNMENT PERSONNEL

MAJ (b) (6), Military
CPT (b) (6) Military
PVT (b) (6) Military

The Department of Clinical Trials (CTC) is led and managed by MAJ (b) (6), CTC Chief. The Department consists of 19 personnel (4 military, 15 contractors). (b) (6) is the supervisory clinical research coordinator (CRC) and assists in all facets of management for contracted employees (Clinical Research Coordinators, informatics, phlebotomy, recruiting, QA, and admin) and clinical research. (b) (6) is the supervisor for quality assessment of clinical trials activities within the department.

ACCOMPLISHMENTS

- During this time period, 2 FDA regulated critical studies were completed and 8 were initiated to support the development of effective products to protect the warfighter and advance global health. Product development was initiated to treat multiple types of malaria, Ebola, Dengue, Anthrax, Hantavirus, and multiple forms of bacterial diarrheal diseases. In addition, studies involving HIV and blood research were conducted throughout the fiscal year in support of the Army's HIV effort. Further, the development of several new studies commenced to include novel vaccines against Hantavirus, Malaria, Dengue, and Shigella as well as a new class of antibacterial products which were co-developed and planned with stakeholders involving bacteriophage.
- CTC personnel authored or co-authored 4 manuscripts published in peer-reviewed literature. These studies, were acknowledged in 2 additional papers, and contributed to 1 poster and podium presentations at national meetings during FY14. The team is preparing 3 or more presentations with accompanying publications in FY15.

DEPARTMENT PILOT BIOPRODUCTION FACILITY (UWD-B)

DEPARTMENT MISSION

WRAIR's Bioproduction facility's mission is to conduct and support research, development, production, and testing of vaccines for human use in the protection of global health and the warfighter. The Pilot Bioproduction Facility, located at Forest Glen, Silver Spring, Maryland, is a multi-use facility designed and operated for the production of vaccines in compliance with current Good Manufacturing Practices (cGMP) regulations. Adhering to cGMP standards in manufacturing ensures that products developed in the facility will be safe, potent, and reproducible. Vaccines manufactured in the Bioproduction facility protect soldiers against diseases encountered in areas of deployment. These include vaccines to prevent shigellosis and other diarrheal infections, dengue, malaria, meningitis, and HIV. The PBF remains flexible in its ability to develop and manufacture new and emerging infectious disease threats.

GOVERNMENT PERSONNEL

(b) (6), GS Civilian
(b) (6), GS Civilian

ACCOMPLISHMENTS

GMP vaccines prepared to bulk or final container included:
DENV-3 human challenge (1 lot)
DENV-4 human challenge (1 lot)
Malaria 3D7 sporozoites (for mosquito feeding and human challenge, 1 lot)
Malaria CS vaccine (1 lot)
Malaria vaccine (NIH) 2 lots
Rotavirus vaccine antigen P8 (PATH) 1 lot
Rotavirus vaccine antigen P6 (PATH) 1 lot
Rotavirus vaccine antigen P4 (PATH) 1 lot
Typhoid conjugated vaccine (Matrivax) 1 lot
ETEC adhesion (1 lot)
Shigella subunit vaccine (1 lot)
EPA conjugant (NIH) 1 lot
Various fills:
Liposomes (for Retrovirology) 1 lot
Alum (PATH) 1 lot
Diluent fill (EMEM for human challenge studies) 1 lot
DENV DNA vaccine (Navy) 1 lot
Not listed above are 8 cell banks (seeds), 7 fermentations, and 8 purifications that were used for production of final bulk lots.

COLLABORATORS

NIH Malaria Vaccine Development Unit (IAA)
WRAIR/NMRC (shigella)
WRAIR Retro (fill validation and liposome fill)
WRAIR Malaria
PATH Vaccine Solutions (CRADA)
GlaxoSmithKline (CRADA)
Matrivax (CRADA)
Biologics Resources (CRADA)
Fraunhofer (CRADA)
NIAID Ebola (IAA)
USAMRIID (fill validation for future ricin fill)

DEPARTMENT REGULATORY AFFAIRS (UWD-R)

The Department of Regulatory Affairs provides regulatory guidance and promotes compliance for all product development activities. Professional regulatory services ensure that development plans will meet FDA standards and that submissions (Clinical Protocols, IND applications, Investigator's Brochures, Clinical study reports) are complete in order to accelerate the development process. The regulatory affairs team includes a regulatory affairs scientist, biostatistician, database manager, medical writer and an archivist who work closely with the Department of Clinical Trials and Pilot Bioproduction Facility within the Translational Medicine Branch. This group also serves other WRAIR divisions within the enterprise as development partners in addition to bilateral and multilateral stakeholders and sponsors for OTSG-sponsored products for the warfighter. The Department of Regulatory Affairs provides education and training for the development of clinical researchers and statistical support for protocols submitted to the Institutional Review Board (IRB) and the Institutional Animal Care and Use Committee (IACUC).

GOVERNMENT PERSONNEL

(b) (6), GS Civilian

ACCOMPLISHMENTS

- Provided all regulatory support for the US Military Malaria Vaccine Program – coordinating regulated activities for programs partnered among WRAIR, NMRC, and USAMMDA, as well as corporate partners and external funders. In 2014 these efforts entailed:
  - 45 formal submissions to FDA in support of numerous products, the malaria challenge model, and the Pilot BioProduction Facility
  - Full Regulatory support for the Malaria Vaccine Integrated Project Team including 2 active trials, 3 trials in safety follow up, and 3 new products in the pre-clinical and manufacturing phase
  - Submission of 1 new IND (CELTOS2) as well as conduct of a successful pre-IND meeting (NavOx)
  - Coordination, negotiation, and review of budget agreements, CRADAs and CTAs for several new programs
  - Direct communication with USAMMDA personnel, the FDA, and the Sponsor's representative at the MRMC level

ADDITIONAL ACCOMPLISHMENTS INCLUDE

- Ongoing consultation with the FDA, implementation of improved practices in production of malaria-infected mosquitos for human challenge studies
- Regulatory support for the Bacteriophage development program (novel treatment for antibiotic resistant infections)
- FDA-compliant database management in support of 4 regulated clinical trials conducted in the CTC
- Medical writing support for 4 clinical development programs
- Statistical support to WRAIR investigators, the WRAIR IRB, the WRAIR IACUC, and NMRC investigators
- Coordination and advising on records retention and archiving for 6 departments at WRAIR
- Support to WRAIR's Department of Human Subjects Protection for DoD regulatory audits
- Provided review and content to 2 new WRAIR SOPs to improve compliance for regulated document storage
- Oversight of new archiving facility in building 50

UNITED STATES ARMY MEDICAL COMPONENT
ARMED FORCES RESEARCH INSTITUTE OF THE MEDICAL SCIENCES
(USAMC-AFRIMS)

Mission:

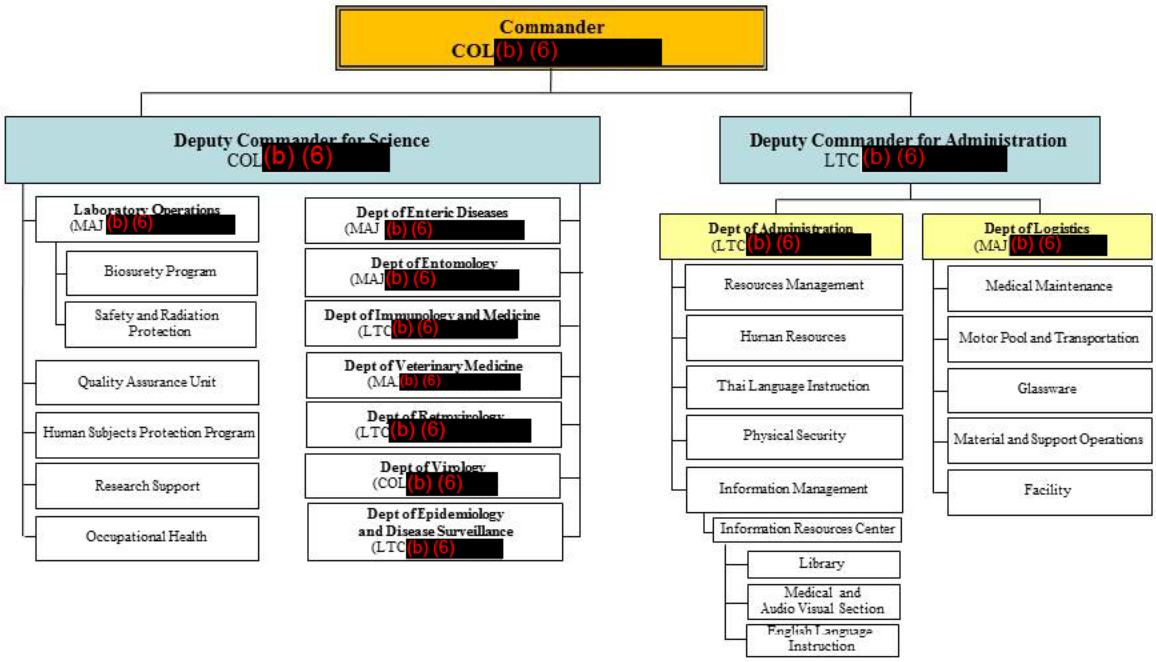
The USAMC-AFRIMS is the U.S. Army Medical Component of a Royal Thai Army-U.S. Army joint command on the grounds of the Phramongkutklao Army Medical Center in Bangkok, Thailand. The current Commander of the U.S. Component is COL (b) (6), MS. The Institute is one of five U.S. Army and Navy overseas medical research labs and is a Special Foreign Activity of the Walter Reed Army Institute of Research (WRAIR) located in Washington, DC, which is subordinate command of the U.S. Army Medical Research and Materiel Command (USAMRMC), headquartered in Ft. Detrick, Maryland.

The mission of the USAMC-AFRIMS is medical research, disease surveillance, and develop-ment and evaluation of medical products for militarily important infectious diseases. These products are generally drugs or vaccines, but may be diagnostic tests or specialized knowledge. The USAMC-AFRIMS is an agency within the U.S. Embassy Mission and the Commander is a member of the Country Team. The diseases focused on by the Institute are public health problems in Thailand and the region, and thus are areas of common interest with the host country. These diseases include malaria, HIV/AIDS, dengue fever, hepatitis, and diarrheal diseases. The USAMC-AFRIMS Commander and staff also serve as subject matter experts for PACOM on medical issues and tropical disease threats in Thailand and other countries in Southeast Asia.

Organization and Supervisory Personnel:

Colonel (b) (6) has been in command since 27 July 2012. Joining the command in July 2012 were Lieutenant Colonel (b) (6), Deputy Commander for Administration, and Colonel (b) (6) Deputy Commander for Science. Staffing during the year included 29 active duty Army personnel, 2 General Schedule (GS), 111 Foreign Service Nationals (FSN), 224 Cooperative Agreement (CA) employees, and 85 contractors. Operational funding for 2014 was approximately $23.5 million. The Command occupies approximately 159,383.58 ft^2 of floor space in seven administrative and research buildings in Bangkok, and has fixed field sites in Thailand, Cambodia, Nepal, and the Philippines.

U.S. ARMY MEDICAL COMPONENT
ARMED FORCES RESEARCH INSTITUTE OF MEDICAL SCIENCES



Training and Education:

- AFRIMS DMLSS/CITRIX Training, Jun 14
- Animal Biosafety Level-3 (ABSL-3) Hazard Training/Primary Hazard Training, Mar 15
- Annual Safety and Occupational Health Training, Oct 13, Jun, Jul, Aug 14
- Annual Occupational Health, Safety and Biosurety Training to Cambodian staff, Oct 13
- Basic Life Support Training, May 14
- Biohazardous Waste Management, May 14Biological Clock, 15 Aug 14
- Cold Chain Management Awareness Course (CCM) Training, Oct 13
- CRR Lapse, May 14
- Database Demonstration, Jun 14
- DCO Responsibilities Review, Jul, Sep 14
- DMLSS Class, May 14
- Effective Use of Biological Safety Cabinet and Certification Overview Workshop: Myths and Facts, Jan 14
- Endothelial-based Biomarkers and Interventions for Life-threatening Infection, May 14
- Essential OHS Topic for Supervisors Training, Jun, Aug 14

- Ethylene Oxide Sterilizer Operation and Maintenance, Apr 14
- External Competency Assessment by WHO for 12 Malaria Microscopists
- Fire Fighting Training, Dec 13
- General GEIS Brief, May 14
- GLP Archivist Training, Jul 14GLP Basics for Medical Maintenance Supervisor, Jul 14
- GLP Basics Review, Mar and Apr 14
- GLP Refresher, Dec, 13, Mar and Jun 14
- GLP Refresher: Problem Solving Quiz, Jan 14
- IBM SPSS 22 Class: Quick Illustration, Mar 14
- IBM SPSS 22 Class: Essential, Mar 14
- Intermediate Medical Acquisition Course (IMAC), Oct 13
- J Club: Enterohemorrhagic E.coli, Jul 14
- J club: Evolution of the Influenza A Virus and Vaccine Development, Jun 14
- J Club: EBOLA Virus, Why is it Deadly:, Sep 14
- J Club: Hepatitis C Virus: The Silent Killer, Jun 14
- J Club: The Legend of Diarrheagenic Escherichia coli EP: 1 ETEC and Its CFS, May 14
- J Club: Development of a Loop-mediated Isothermal Amplification Assay for Detection of Cronobacter spp. (Enterobacter sakazaki), Mar 14
- J Club: Environmental Determinants of Transformation Efficiency in Helicobacter Pylori, Jan 14
- J Club: Multiplex PCR and Plasmidome-Analysis of Beta-Lactamase Gene, Feb 14
- J Club: Noroviruses 101, Jan 14
- J Club: Rota Virus: A Third World Country Infection, May 14
- J Club: The Genesis of Superbugs, Feb 14
- Laboratory Animal Occupational Health Questionnaire, Feb 14
- Laps in CRR Approval, May 14
- Military Malaria Research Program, Mar and Apr 14
- Nasopharyngeal Swab, Placement of Feeding Tube Intra-Tracheal, Placement of ET Tube, Apr 14
- Next Generating Sequencing Approaches to the Study of Malaria, Aug 14
- Occupational Health and Safety Program , and Communication, Mar 14
- Occupational Health and Safety for Visitors/New Employees, Oct, Nov 13, Jan, Feb, Mar, Apr 14
- Occupational Health and Safety Training for KAVRU, May 14
- Occupational Health SOPs Training for ECHO, May 14
- Occupational Health TB Screening and Surveillance, Feb 14
- PMK-AFRIMS Research Collaborative Discussion: Dengue – What Clinicians and Scientists Should Know, Feb, May 14
- PMK-AFRIMS Research Collaborative Discussion, Microbial Pathogenesis, Oct 13
- Primary Hazard Training (Guidelines for Prevention of Herpes Virus Simiae (B Virus) Infection in Monkey Handlers, ABSL-3 Hazard Training
- Protocol WRAIR 1877 Training
- Protocol WRAIR #1949, “Production of Malaria Parasites for Malaria Research” Version 4.5/dated 22 October 2013
- Protocol WRAIR #1949, “Production of Malaria Parasites for Malaria Research” Version 4.4/dated 18 March 2013
- Requirement for Document Amendment, Oct 13
- Respirator Fit Test, Mar, May, Jun, Jul 14

- SSP Informed Consent Process, Nov 13
- Statistical Tools and Resources Update & Quick Review on IBM SPSS Statistics Version 22, Jan 14
- Temperature Sensitive Medical Products (TSMP) Training, Nov 13
- Statistical Tools and Resources Update & Quick Review on IBM SPSS Statistics Version 22, Jan 14
- Temperature Sensitive Medical Products (TSMP) Training, Nov 13
- The Humane Care and Use of Lab Animals, Mar 14
- Transport of Biomedical Material (TBM) Course, Apr, May 14
- Upgrade Intelligence Temperature Monitoring and Alarm System Software Training Class, Nov, Feb 14
- Weapons of Mass Destruction Preparedness, Aug 14

Resource Management and Budget:

During FY 14, RM provided financial oversight of AFRIMS's overall operating budget. This included an Army/DOD Research, Development, Test and Evaluation (RDT&E) program of $5.6 million; Defense Health Program (DHP), including O&M and RDT&E of $11.3 million and the Biosurety Engagement Program (BEP) of $1.6 million in FY 12. The reimbursable program totaled $5 million.

Resource Management staff prepared and conducted FY 13/14 status of funds updates for the Commander and Branch Chiefs to provide awareness on the financial health of the organization. The Division provided expert advice and recommendations to Division Chiefs for budget actions, determining the amount and timing of fund allocation reprogramming actions. Reports were distributed on the obligation and disbursement rates and the uncommitted balances. The organization closed the fiscal year with an obligation rate above 99%.

Resource Management staff prepared and presented to the Commander the FY 14 G&A Budget Implementation Plan. The approved course of action provided the Commander with an up-front, conservative financial analysis and projection on funding so that he could make critical decisions at the start of FY 14 instead of waiting until the end of the year to determine if he could fund time sensitive, critical initiatives.

Resource Management Division staff worked with Division Chiefs and Administrative Officers to prepare, consolidate, and submit the FY 15 Command Budget Estimate with the Commander's Impact Letter to WRAIR by the required suspense date.

The Resource Management Division developed and executed the implementation plan for the new accounting/financial system (General Fund Enterprise Business System – GFEBS) as well as the single charge card acquisition process.

Information Management:

The Information Management Division (IMD) at AFRIMS performs information technological, library, medical audio visual and language services to AFRIMS personnel. It does this with a staff of one (1) U.S. Military, one (1) G.S. Civilian, seven (7) Foreign Service Nationals, and six (6) Cooperative agreement local nationals.

A. Information Systems

1) Top Level Architecture

a. Many changes occurred to the AFRIMS Top Level Architecture.

i) De-militarized Zones (DMZ)

- Added two DMZs. One for the support network and one for externally facing web devices.

- Both systems use a high availability firewall to ensure continual protection

ii) Intrusion Detection System (IDS)

- Added an IDS to provide protection against threats and issues by monitoring the outbound connection from AFRIMS

iii) Virtualized Private Network (VPN)

- With the latest technology firewalls, AFRIMS implemented the capability to allow for user systems to use a VPN to connect to the AFRIMS domain from external networks, securely.

iv) Removal of Internet Service Providers (ISP)

- Removed at least 3 Internet service providers from connecting to the AFRIMS network, bringing it down to two.
- One is a 20 mbps download and 20 mbps upload connection with static IP addresses for AFRIMS main network. The other is a 40 mbps download and 5 mbps upload with a few static IP addresses that is used primarily for AFRIMS Wifi, VOIP and failover for the primary line.

b. These system changes occurred over at least three visits by WRAIR's overseas network engineer who assisted and guided AFRIMS in the purchase and implementation of these systems.

2) Vulnerability Scanner

a. Implemented a Beyond Eye Retina Scanner that performs vulnerability scans per the latest Common Vulnerability and Exposures (CVE). This translates to the Department of Defense Information Assurance Vulnerability Alerts (IAVA), which assists in AFRIMS deployment and protection of network assets.

b. Due to a change in contract, MEDCOM is moving towards an Assurance Compliance Assessment Solution (ACAS). Due to potential contractual issues, AFRIMS cannot deploy the same system and so renewed the Beyond Eye Retina license to maintain this capability.

3) Help Desk Operations

a. AFRIMS.org deployed Spiceworks All-in-one inventory and helpdesk management solution in FY14Q2. This system has assisted in the tracking of knowledge base articles, inventory items to include software changes, hard disk utilization and more, as well as, communicate tickets with users and maintain the repository of previously completed tickets.

b. This system has quickly brought AFRIMS into the 21st century allowing for prioritization of tasks and more information readily at our fingertips.

B. Policy Changes

1) Acceptable Use Policies (AUP)

a. Added a General User AUP, Privileged User AUP, and a Wifi AUP for signature and responsibility compliance.

b. These AUPs are in line with WRAIR's and USAMRMC's Acceptable Use Policies.

2) Incident Response Plan

a. Submitted and received approval for the AFRIMS Incident Response Plan detailing how and when Incidents should be responded to.

b. The IRP has been used several times and after action reports are generated to incorporate changes into the next iteration.

3) Vulnerability Management SOP

a. Completed an internal vulnerability management SOP for AFRIMS helpdesk on how to patch systems, what software is utilized and how the reporting should be conducted.

b. This SOP satisfies many requirements for certification and accreditation.

4) Risk Management Framework (RMF)

a. This policy went into effect May 2014 and has large impacts to the future of systems DoD wide. The biggest requirement change is the transition to a risk based approach on system approvals.

b. Since RMF replaces Department of Defense Information Assurance Certification and Accreditation Process (DIACAP), all new certifications and authorities to operate need to meet the new standard.

c. The last staff assistance visit was based upon DIACAP and so a translation from the old to the new is being conducted to ensure meeting of the old and the new requirements.

C. Organizational

3) Added GS Civilian IT Specialist

a. Needed to perform on-site functions and support for the .MIL network.

b. Required to provide Department of Defense expertise in security to current Thai IMD Staff

4) Removed “Freezerworks Administrator” position from contract

a. Although a function that may be needed in the future, the time and resources needed to provide an enterprise laboratory sample system was not in the forecasted 24-36 months due to staff assistance visit findings and priorities.

b. Attempts to adapt duties to current needs were unsuccessful for current employee and so AFRIMS IMD requested removal of position from contract

5) Added ‘Systems Administrator’ position to staff

a. Position was approved by AFRIMS Personnel Budget Advisory Committee

b. Position was advertised, but pool of applicants has been low and has not been filled

c. Position is needed to perform backups, event log checks and alternative contact for system outages

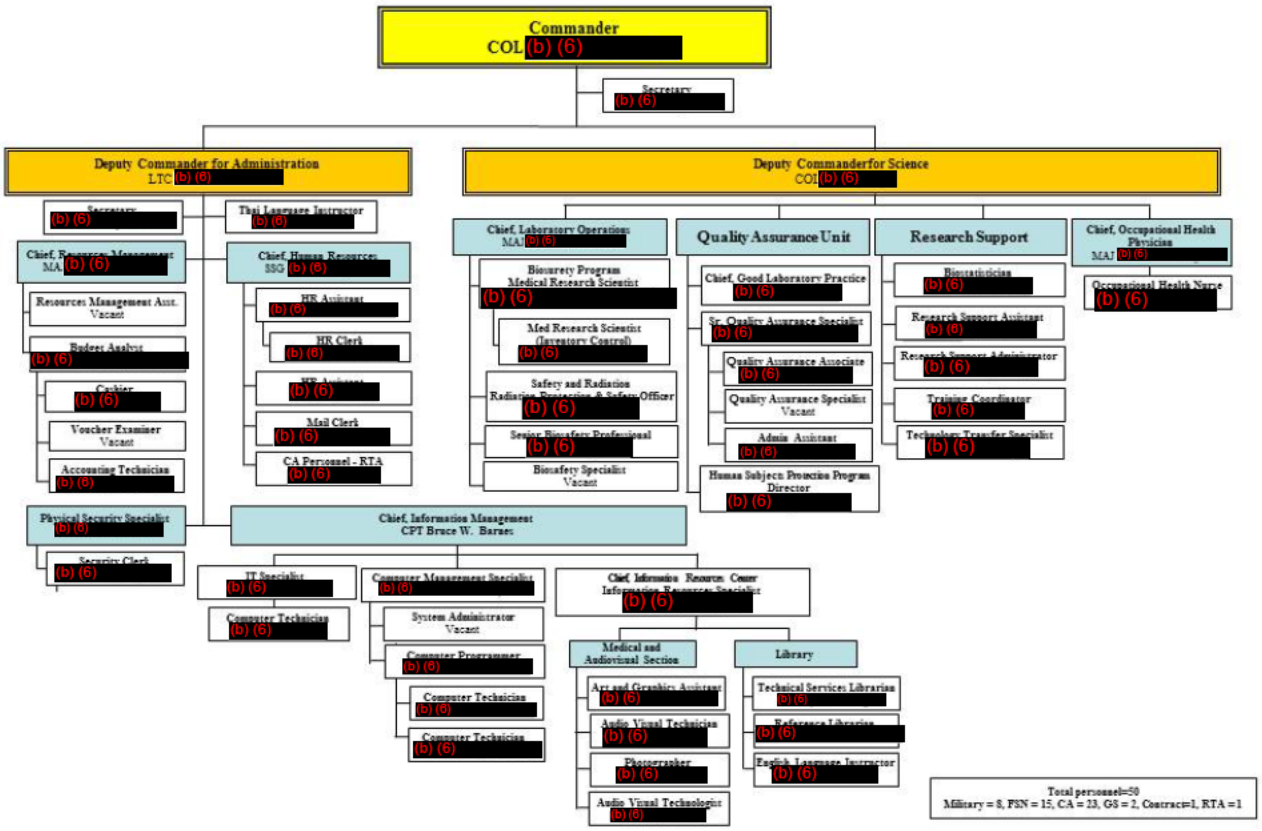
d. Position was also created to attempt to bridge the gap in the future retirement of current Senior Systems Administrator in 2018.

DEPARTMENT OF ADMINISTRATION

Mission:

The mission of the Department of Administration is to provide administrative support to the USAMC-AFRIMS research departments in the areas of personnel administration, resource management, protocol management, publication clearance, quality improvement, information management, library research, audio-visual products, physical security, Thai language instruction, English language instruction, safety, biosurety, radiation protection monitoring and occupational health.

Organization and Personnel:

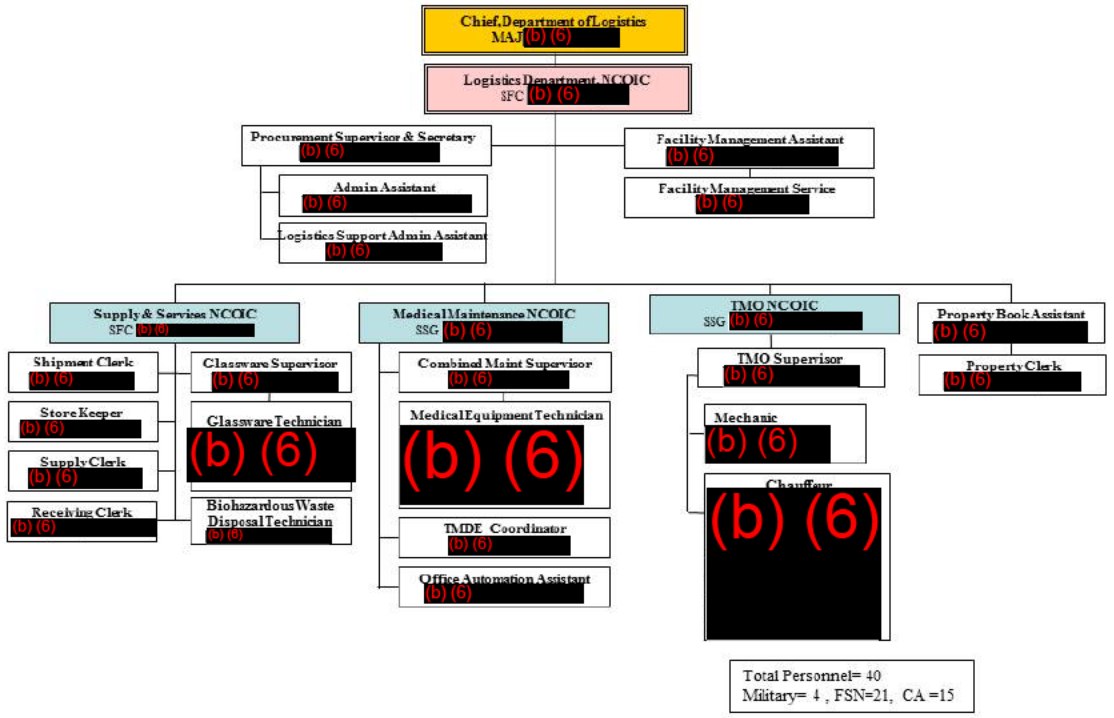


DEPARTMENT OF LOGISTICS

Mission:

To ensure that the USAMC-AFRIMS research departments, and other supported U.S.Government agencies, as directed, receive required general and laboratory supplies, equipment,biomedical maintenance, facilities maintenance, transportation, glassware, shipping, property accountability, and life cycle management services in an efficient and cost effective manner. This logistics support extends to various field sites and laboratories located throughout the Kingdom of Thailand, Nepal, Philippines, Cambodia, Bhutan, and in other countries in the PACOM AOR as required.

Organization and Personnel:



Training and Education:

In-House Training of Personnel

- Defense Medical Logistics Standard Support Facilities Module(DMLSS-FM) training
- General Fund Enterprise Business System
- Intermediate medical acquisition course (IMAC)
- NBC Training
- DMLSS RPIE Inventory Training

- DCO -DMLSS Online Training
-

Outside Training of Personnel

- ThermoFisher advanced refrigeration repair course (Singapore)
- Certification of Transport of Biomedical Material Course
- State Department Writing Effective Position Description Class
- Driver's Training and Safety course
- DAU Class: Contracting Officer Representative with a Mission Focus CLC106 Section 892
- DAU Class: Contracting Officer 's Representatives CLC222
- Annual Firefighting training
- Annual ABSL3 Training
- Biological Safety Cabinet repair and certification training

Core Accomplishments

In 2014, the Logistics Department completed the inventory and cataloging of all U.S. Army Real Property Installed Equipment (RPIE) in the Defense Medical Logistics Standard Support System (DMLSS). This has significantly improved the facilities maintenance team ability to plan for, schedule, and complete cyclical scheduled maintenance to all AFRIMS facilities and prevent systems failures. The cataloging of RPIE items in DMLSS also provides the U.S. Department of Defense with visibility of all AFRIMS buildings and facilities. This has paved the way to secure funding to establish a full scale multi-year Operations and Maintenance (O&M) contract through the U.S Army Corps of Engineers. It is anticipated that this O&M contract will be in place by February 2016.

The facilities management office contracted and completed nearly $1 Million in facilities upgrades and construction projects throughout AFRIMS in 2014. Of note, the fire alarm system upgrade to an “addressable” type was completed for the Main Research Building (MRB), Headquarters, and Library Buildings and the lightning protection system was upgraded and repaired for MRB and Yothi Annex. At the vivarium, the roof insulation was replaced with non-combustible insulation, the animal feed system was upgraded, and an improved exhaust system was installed to reduce odor emissions. The vivarium also had the epoxy flooring replaced in wing A & B. To address concerns with the structural integrity of building 5, an independent contractor was hired from the U.S. to conduct a structural and life expectancy assessment for the building. All 6 emergency power generators throughout AFRIMS received automatic transfer switch upgrades which will separate all life safety items from main power insuring uninterrupted operation in the event of power failure. A project to remove and replace asbestos flooring in multiple locations throughout AFRIMS was also completed. Lastly, facilities management completed the design plan phase for renovation of the MRB 2nd floor with start of renovations anticipated for late 2015.

In an effort to reduce excess within AFRIMS the property management section established new procedures for turning in property. Through the US Embassy Assets to Cash (ASTOCA) process, they were able to turn in 900 excess items which also generated a profit of several thousand dollars for the US Treasury. Coordination was also made to donate an additional 90 items to the Royal Thai Army for their continued use.

In 2014, the logistics supply section established a formal command supply discipline program (CSDP) - the first time AFRIMS has had such a program. Multiple supply discipline inspections have since been conducted helping to educate AFRIMS staff in supply policies and procedures to reduce waste.

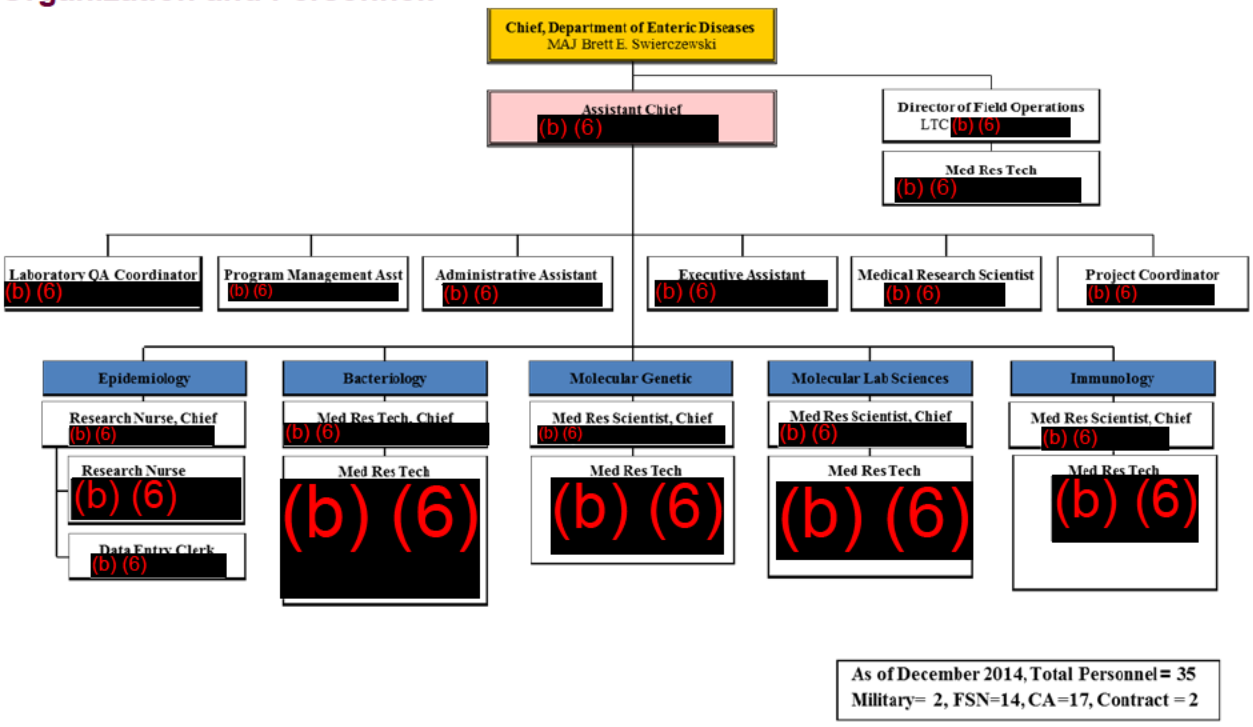
Lastly, the motor pool closed 2014 having conducted nearly 1,300 transportation missions in support of AFRIMS research and administrative staff. During this time the chauffeurs logged over 108,000 km with 8 out of 9 receiving driving safety awards. The motor pool was also able to turn in 4 vehicles which were no longer needed to support their mission.

DEPARTMENT OF ENTERIC DISEASES

Mission:

Develop and evaluate interventions to diagnose, treat, and prevent diarrheal disease.

Organization and Personnel:



Training and Education:

A. Provided

1) Laboratory Training for Public Health Laboratory Technician, Thimphu Bhutan – 8-13 September 2013

2) Multiplex PCR for Diarrheagenic Escherichia coli Detection Training for Public Health Laboratory Technician, Thimphu Bhutan – 11-14 March 2014

3) Microbiology and Real-time PCR Detection for *Salmonella* Typhi Workshop for State Sanitary and Epidemiological surveillance Service (SSESS) Technicians, Dushanbe, Tajikistan – 3-9 April 2014

4) Laboratory Method for Detection of Enteric Pathogens Training for Battambang Referral Hospital (BRH) Technicians, Battambang, Cambodia – 20-25 April 2014

5) Real-time Detection of salivirus (RNA extraction and RotorGeneQ) Training for US Naval Medical Unit2, PhnomPenh, Cambodia, 25-28 August 2014

6) Laboratory Training for Nepalese collaborator – CIWEC Laboratory, Kathmandu, Nepal – 2-8 September 2014

7) Intensive Course for Multiplex PCR Detection of Diarrheagenic E.coli for Public Health Laboratory Technician, Thimphu Bhutan – 8-11 September 2014

B. Received

1) The 17th International Workshop on *Campylobacter*, Helicobacter and Related Organisms, University of Aberdeen, UK, 15-19 September 2013

2) Fundamentals of International Clinical Research Training provided by NIAID, NIH, International Clinical Studies Support Center, FHI 360, Peninsula Hotel, Bangkok - 15-20 September 2013

3) Workshop on Clinical Trial and Immuno monitoring provided by ICDDR,B, Dhaka, Bangladesh – 25 May – 5 June 2014

Research and Development:

1. **Surveillance for Epidemiology of Diarrhea and Post-Infectious Sequelae in Travelers to Thailand**:

A prospective case-control study to determine the etiology of traveler's diarrhea and to describe development of post-infectious sequelae and chronic intestinal symptoms after the diarrhea episodes is ongoing. The study has been conducted in travelers who are adult residents of North America, Europe, Australia, New Zealand, Japan, Taiwan and South Korea with and without diarrhea at Bumrungrad International Hospital, Bangkok, Thailand. Enrollment began in Jan 2012. After obtaining written informed consent, a stool specimen was collected, processed and examined for enteric pathogens by standard microbiology, ELISA or PCR at AFRIMS. A short questionnaire regarding demographic and clinical data was collected. Internet-based surveys at 7 days; 3, 6 and 12 months after enrollment have been conducted to address occurrence of post-infectious sequelae and chronic intestinal symptoms.

During this reporting period, we enrolled 34 subjects with acute diarrhea and 26 non-diarrhea controls. A three-year enrollment has been completed on 24 Dec 2014 with a total of 173 cases and 165 controls enrolled. Major pathogens found among diarrhea cases were *Campylobacter*, norovirus, and *Plesiomonas*, *Salmonella* and major pathogens found among non-diarrhea controls were Enteroaggregative *Escherichia coli* (EAEC), *Campylobacter*, and *Salmonella*. No enteric pathogens were identified in 18% and 73% of cases and non-diarrhea controls respectively. The antimicrobial susceptibility pattern of bacterial isolates from this study revealed high resistance of *Campylobacter* isolates against nalidixic acid and ciprofloxacin.

2. **Surveillance for Diarrhea Etiologic Agents at the Public Health Laboratory in Stool Samples from Children in Bhutan:**

As planned, expansion of the diarrhea surveillance effort and improvement of reporting capabilities to multiple sites in Bhutan particularly in sites close to India and China has been conducted. A hospital based surveillance of enteric pathogens and antimicrobial resistance of bacteria among children aged 3 months to 5 years with acute diarrhea and non-diarrhea controls at the Jigmi Dorji Wangchuk National Referral Hospital, Thimphu, and 3 regional hospitals in Mongar, Phuntsholing and Gelephu, Bhutan. Enrollment and sample collection started on 23 July 2013. Stool specimens have been collected, processed and examined at the Public Health Laboratory (PHL), Thimphu, Bhutan and subsequently confirmed at AFRIMS. The Department of Enteric Diseases, AFRIMS has continued providing consultation and training to the local microbiologists on isolation and identification of enteropathogens.

During this reporting period, 540 cases with acute diarrhea and 552non-diarrhea controls were enrolled. Rotavirus, norovirus and *Shigella* were major pathogens found among diarrhea cases and infrequently found in controls. Enteroaggregative *E.coli* was detected in both cases and controls in approximately 25% of each. The antimicrobial susceptibility pattern of bacterial isolates in Bhutan revealed a high proportion of *Shigella* isolates resistant to ciprofloxacin and trimethoprim/sulfamethoxazole (TMP-SXT).Resistance to nalidixic acid and ciprofloxacin among *Campylobacter* isolates was also observed.

3. Surveillance for Epidemiology of Diarrhea and Post-Infectious Sequelae in Travelers to Nepal:

A 2-year prospective case-control study to determine the etiology of traveler's diarrhea and to describe development of post-infectious sequelae and chronic intestinal symptoms after the diarrhea episodes was implemented in November 2012. The study has been conducted at the CIWEC Travel Medicine Clinic in Kathmandu, Nepal. After obtaining written informed consent, a stool specimen was collected, processed and examined for enteric pathogens. Specimen processing, microscopic examination and microbiology work was conducted in the CIWEC clinic laboratory in Nepal with confirmation and further characterization of organisms at AFRIMS. A short questionnaire regarding demographic and clinical data was collected. Internet-based surveys at 7 days, 3, 6 and 12 months after enrollment have been conducted to address occurrence of post-infectious sequelae and chronic intestinal symptoms.

In CY14, 208 cases and 58 non-diarrhea controls were enrolled. Enteroaggregative *E.coli*, *Campylobacter*, norovirus, Enterotoxigenic *E.coli* (ETEC) and rotavirus were commonly identified among travelers with diarrhea. ETEC, Enteropathogenic *E.coli* (EPEC) and *Campylobacter* were commonly identified among in controls. Antimicrobial susceptibility testing of bacterial isolates revealed a high proportion of *Campylobacter* isolates resistant to ciprofloxacin and nalidixic acid (97%). *Shigella* isolates were resistant to nalidixic acid (82%), ciprofloxacin (79%) and TMP-SXT (71%).

4. Evaluation of Safety, Immunogenicity and Efficacy of an Oral Trivalent Inactivated Whole Cell *Shigella* Vaccine in Healthy Thai Adults:

An evaluation of a trivalent inactivated whole cell *Shigella* vaccine containing three major serotypes of *Shigella* (*S.sonnei*, *S. flexneri* 2a and *S.flexneri* 3a) was initiated during CY12. A clinical trial protocol and regulatory documents are in review. The study is planned for implementation in late CY 15 in collaboration with the Vaccine Trial Centre, Mahidol University in Bangkok, Thailand.

5. Validation of capsule types and characterization of *C. jejuni* isolates lacking sialic acidand prevalence of genes associated with Type 6 secretion system in C.jejuni isolates from Southeast Asia.

In CY 14, a total 379 *C. jejuni* isolates belonging to Penner HS4 cpx (n=158), HS2 (n=146), HS1 (n=53), and HS15 (n=22) were screened for lipooligosaccharide (LOS) genes (cgtA, cgtB, cstII). These three genes encoded for enzymes in LOS biosynthesis. Twenty-three *C. jejuni* isolated from archived samples were negative for cgtA, cgtB and cstII genes. Two *C. jejuni* isolates did not hybridize to LOS gene probes and suggested that two *C. jejuni* isolates naturally lacked sialic acid. The two isolates were serotyped to HS4cpxB and Penner type HS1 (or HS1/44) by Penner scheme. These two isolates and eight more isolates from the previous 23 *C. jejuni* isolates were sent to the Naval Medical Research Center (NMRC) for further characterization for a human challenge *Campylobacter* vaccine study.

A total of 462 *C. jejuni* with different Penner types previously determined by capsule multiplex PCR: HS 3 (n=83), HS4 cpx (n=158), HS2 (n=146), HS1 (n=53), and HS15 (n=22) were selected for detection the presence of hemolysin-coregulated protein (hcp) gene which confers a Type 6 secretion system (T6SS).We observed that hcp varied from 46-94% from our archived *C. jejuni* isolates from human cases of diarrhea. The prevalence of hcp among *C. jejuni* were 94% in HS3, 93.7% in HS4cpx, 92.5% in HS2, 71.7% in HS1 or HS1/44, and 45.5% in HS15.

Amplified products of hcp of selected *C. jejuni* were submitted for sequencing. Sequence analysis and blast results showed 100% identity to *Campylobacter* strain TGH 9011 Sequence ID: AY501927.1 and *C.jejuni* strain 108 type VI secretion gene locus Sequence ID JX436460.1.

6. Prevalence of Antibodies to Infectious Diseases of Public Health Importance among Recruits in the Royal Thai Army

A total of 7,760 serum samples were tested to measure prevalence of antibodies to the following pathogens of public health importance: measles virus, *Leptospira*, Hepatitis E, Orientiatsutsugamushi (scrub typhus), Spotted Fever Group *Rickettsia* and *Rickettsia typhi* (murine typhus). The overall unadjusted seroprevalence (seropositive) antibodies were as follows: 77% measles virus, 23% *Leptospira*, 13% Hepatitis E virus, 12% *O.tsutsugamushi*, 3%Spotted Fever Group *Rickettsia* and 6% *Rickettsia typhi*. Data was analyzed in correlation with demographic information. A geographic information system (GIS) database was applied to better understand the spatial distribution of these pathogens in different regions of Thailand. Seroprevalence of Hepatitis E virus was published as title "Pork Consumption and Seroprevalence of Hepatitis E Virus, Thailand, 2007–2008" in Emerging Infectious Diseases Journal, volume 20, Number 9—September 2014. The current status is on manuscript preparation for seroprevalence of measles virus and *Leptospira*.

7. Defining the Therapeutic Efficacy of Polypropyletherimine Dendrimer Glucosamine (PETM-DG), a Non-Antibiotic Based Drug, in Rhesus Monkeys after *Shigella* dysenteriae 1 Infection:

The GLP study started in May 2013. The primary objective of this protocol was to evaluate the efficacy of PETIM-DG as a useful new therapeutic medicine in Rhesus monkeys: i) for safety in rhesus monkeys after oral administration, by monitoring the presence and severity of clinical signs (ii) protective/therapeutic efficacy by challenging PETIM-DG treated monkeys with *S. dysenteriae* 1 1617 strain, (iii) measuring the cytokine mediated inflammatory responses in the ileum, jejunum, colon and rectum, (iv) histopathological outcome in the ileum, jejunum, colon and rectum and (v) obtaining Rhesus monkey data for a novel therapeutic approach for *S. dysenteriae* 1 infection to support an "Investigational New Drug Application". The groups were a DG treatment group and a control group. The study was performed in three phases, 4 monkeys in each phase with 2 monkeys per group. Monkeys were randomly assigned, regardless of sex, to the DG group or control group. The DG group monkeys were given prophylactic DG (6 mg/kg body weight) on study days 0, 1, 2, 3 and 4 by intragastric administration of the 20 ml DG solution by a naso-gastric tube, after administration of 20 ml bicarbonate buffer. The control group received a placebo (20 ml sterile water) by intragastric administration via naso-gastric tube. On study day 00 (4±1 hour after DG treatment or placebo given), the DG treatment group and control monkeys were challenged by intragastric administration with wild type strain *S. dysenteriae* 1 1617, via naso-gastric tube, with a dose of 2x109 CFU in 20 ml of sterile PBS, after administration of 20 ml bicarbonate buffer. This study was conducted to evaluate whether PETIM-DG can prevent gut wall tissue damage in rhesus monkeys infected with wild type *S. dysenteriae* 1 1617 strain and without the use of antibiotics.

Real-time PCR analysis support was provided to detect *Shigella* from stool samples during the pre-infected and infection periods. Evaluation of cytokines post-infection from tissues samples was performed using real-time reverse transcription (RT)-PCR.

The animal work has been completed and preliminary results suggest PETIM-DG may have clinical utility in the management of the mucosal damage produced by both gastrointestinal infection and inflammation. ELISAs were conducted for measuring IgA, IgG and IgM antibody titers against *S. dysenteriae* 1 LPS and Invaplex antigens. The data is under analysis process. Method validation was performed to validate RT-PCR to detect various cytokines (IL-1β, IL-6, IL-8, TNF-α) and a housekeeping gene (GAPDH) from a set of plasmids and tissue samples. The results for each validation parameter showed that RT-PCR is a suitable cytokine detection system. Detection of cytokines and GAPDH by real-time RT- PCR was performed on tissues (jejunum, ascending colon, transverse colon, descending colon, rectum, and mesenteric lymph nodes) collected from monkeys in both groups. Tissue sections were stained with hematoxylin and eosin and are currently under analysis for pathological assessment. Intracellular cytokine assays showed a total of 56 specimens detected the inflammatory cytokines (IL-1β, IL-6, IL-8, and TNF-α) in T cells and other lymphocytes population. Peripheral blood mononuclear cells on Day (-3), and 4, 5

or 6, and spleen lymphocytes and mesenteric lymph node lymphocytes on Day 4, 5 or 6 were collected from a total of 14 monkeys were assayed. Data acquisition for FACS analysis was completed. The data is currently under analysis process.

8. Evaluation of the Next Generation Diagnostic Platforms for Enteric Pathogens:

This was the last year of collaboration with the University of Virginia (UVa) as part of a network to evaluate the next generation diagnostic platforms: Luminex, real-time multiplex PCR, and TaqMan® Array Card (TAC) for the identification of enteric pathogens from stool samples collected from children participating in the MAL-ED birth-cohort study in Nepal. TAC was selected for further evaluation. A set of 300 diarrhea samples were selected for testing in the previous year and resulted in a publication (Liu, Lancet Infect Dis 2014). For further evaluation of TAC, selected monthly stool samples and diarrhea samples from 59 children collected from birth to 2 years were tested. 800 samples were tested and completed in 2014.

9. Development, Optimization and Standardization of Real-Time PCR Assays for Detection and Characterization of Enteric Pathogens:

The focus of development and optimization was on a recently discovered pathogen called salivirus. Samples known to contain salivirus were obtained from a collaborator to be used as positive controls in the development of the detection assay. Archived frozen stool samples from previous traveler's diarrhea studies that were identified to be pathogen negative (over 350 samples) were tested and salivirus was detected at 1.4%. The assay was also transferred to NAMRU-2 where pathogen negative stool samples (over 200 samples) were tested and salivirus was detected at 1%.

10. Population-Based Sero-Prevalence Survey of Human Infection with Avian Influenza (H5N1) in Vietnam:

This study was completed in CY2011. We conducted the study in three provinces in Vietnam. A total of 9,564 blood samples were collected (HaTay - 4,197, Thua-Thien Hue - 2,023 and TienGiang - 3,344) with associated information to determine risk factors of exposure; e.g., age, sex, exposure to poultry, etc. Antigens for hemagglutination inhibition assay (HI) assay were beta-propiolactone inactivated for six different Influenza A viruses (3 H5N1 and 3 H5N3), which were based on available historical viruses that circulated in the region. There were 107 positive samples from 9,564 samples (1.1%) assayed by HI.

Nine of the 107 positive samples were cross reactive for 1 or more viruses. The majority of "positive" HI reactions were to HK97 and VN1203, the strains known to have infected humans in significant numbers. Microneutralization assay (MN) was performed on 107 HI positive samples and randomly selected 3% of the negative samples (approximately 300 samples). The remaining study samples are maintained in -800 F freezers at the National Institute of Hygiene and Epidemiology in Hanoi. The additional protocol for further examination avian influenza virus (H5N1) exposure in 5,336 samples was approved. An Influenza A IgG ELISA and an H5N1 ELISA was utilized as test assays. The study was completed in Sep 2014.

11. Characterization of Unknown Species of *Campylobacter* Previously Isolated from Acute Diarrhea Cases in U.S. Military, Travelers, and Other Populations in Southeast Asia

In CY 14, a collection of archived unknown *Campylobacter* spp. isolates were identified to the species level using PCR assays and compared to the species previously detected using phenotypic typing. A total of 107 unknown *Campylobacter* spp. isolates from 88 cases and 19 controls during 1987-2014 were included in this study. The phenotypes of these 107 *Campylobacter* spp. were previously identified by growth and colony morphology and biochemical reactions to include oxidase, catalase, hippurate hydrolysis and nitrate tests. Previously, we were unable to identify these 107 isolates to species level and these were recorded as C. spp or atypical C. spp. Genomic DNA of these *Campylobacter* isolates were extracted and used as templates in PCR assays to confirm the genus and 14 species of *Campylobacter*. The genus specific PCR assay of 16s rDNAconfirmed that 81.3% (83/107) belonged to *Campylobacter* whereas 24 unknown *Campylobacter* spp. were negative for genus

Campylobacter. Among the 83 isolates confirmed for the genus *Campylobacter*, 80 were positive by PCR using specific primers for each of the 14 species of *Campylobacter*. Of these 80 isolates, 29 were identified as *C. upsaliensis*, 21 *C. jejuni*, 11 *C. coli*, 8 *C. hyointestinalis*, 4 *C. lari*, 4 *C. concisus*, and 3 *C. fetus*. Three confirmed *Campylobacter* isolates could not be identified to the species level.

Furthermore, PCR for degenerate primers specific for the cpn60 gene product (Chaperonin gene) and subsequent sequencing was assayed and analyzed for typing of *Campylobacter* and closely related organisms (*Arcobacter, Helicobacter* and others). The Cpn60 sequence analyses of 107 unknown *Campylobacter* spp. and 14 ATCC & NCTC strains were compared for similarity with *Campylobacter* sequences deposited in cpn 60 sequence databases. The results of the 80 confirmed species of *Campylobacter* demonstrated a high correlation with corresponding *Campylobacter* species sequences located in the cpn60 databases (98-100 %). For the 24 isolates negative for *Campylobacter* and the three isolates negative for any of 14 species of *Campylobacter* by PCR, cpn60 typing results demonstrated that these 27 isolates matched were identified as 14 *Arcobacter butlzleri* (100% sequence similarity), 3 *A. cryaerophilus* (100%), 1 *C. jejuni* (100%), 1 *C. coli* (100%), 3 *Helicobacter* spp. (100%), 1 *Methylotenera versatilis* (78.4%), 1 *Pseudomonas pseudoalcaligenes* (81.2%) or *Mendocina* (81.2%), and 1 *C. cuniculorum* (83.1%) or *C. jejuni* (82.9%).

12. Evidence of Exposure to Human Influenza A Virus and Avian Influenza Virus (H5N1) among two High Risk Areas in Thailand:

The objective of this study is to determine the evidence of exposure to human and avian influenza virus during H5N1 outbreaks in Royal Thai Army recruits from two high risk areas : Bangkok and Suphanburi province during a 3 year period : Pre-Outbreak, (2001-2002), during the outbreak, (2004-2005) and Post-outbreak, (2010-2011). Two of the geographic sites were selected based on risk factors of exposure to influenza viruses.Pre-existing sera samples collected as a part of the ongoing HIV-1 surveillance activity, from recruits entering the RTA were used. Two-hundred samples were randomly selected from each of the 2 different sites and 1200 samples were analyzed.

Samples were tested for 1) antibodies against influenza A virus antigen by using a commercial ELISA kit, 2) antibodies specific to highly conserved regions of H5N1 influenza viruses by a H5N1-SeroDetect ELISA, and 3) subtype-specific antibodies against hemagglutinin (HA) of Influenza A H5 viruses by Hemagglutination inhibition (HI) assay which was conducted with 6 of H5 influenza A virus strains: A/Duck/Hong Kong/820/80 (H5N3), A/Duck/Hokkaido/4/96 (H5N3), rg-A/Duck/Singapore/3/97 (H5N3), rg-A/Hong Kong/156/97 (H5N1), rg-A/Viet Nam/1203/04 (H5N1) and rg-A/Duck/Laos/3295/06 (H5N1).

Of 1,200 samples, 1,149 (96%) had a positive IgG antibody response to influenza A virus antigen and 294 (24.5%) had a positive IgG antibody response specific to H5N1 influenza viruses. Based on individual virus test strain, 4 out of 1,200 samples had HI positive against each virus test strains except for the rg-A/Duck/Laos/3295/06 (H5N1). Among the four H5 peptides, HA2 had the highest specific response, followed by M2e, PB1-F2, and HA, respectively. Antibody response to HA and IgG antibody response specific to H5 peptides significantly correlated with the IgG antibody response to influenza A antigen.

13. Establishment of an ICR mouse (Musmuculus) Challenge Model for *Salmonella* typhimurium and Enterotoxigenic Escherichia coli, and Evaluation of Recombinant S.typhimuriumSTΔ aroA/ΔhtrACJ0113/PAL/cHMGB1 and Killed Bacillus subtilis 1A857 Vaccine Candidates in the ICR Mice Model:

The objectives of this protocol were to: (i) establish a viable challenge model for *Salmonella typhimurium* (ST) and ETEC infection in ICR mice and to evaluate recombinant live double-attenuated *S. typhimurium* STΔaroA/ΔhtrA CJ0113/PAL/cHMGB1 and killed *B.subtilis* 1A857 vaccine candidates for (ii) safety in mice after oral administration of single or double dose by monitoring the presence and severity of clinical signs after immunization, (iii) protective efficacy by challenging immunized mice with ST and ETEC strains, and (iv) evaluation of immune responses in blood and intestinal washes and inflammatory responses in gut tissue samples. In a pilot study, a challenge with

ETEC via intra peritoneal (IP) route showed to be effective in mice to develop moribund sickness and death (8 of 9 mice showed moribund sickness/death within 48 h).

A challenge with both ETEC and ST via intra peritoneal (IP) route was completed. These studies showed that oral-gavage inoculation with a dose of 2x109 CFU of ETEC or ST did not produce any clinical symptoms in any mice. However, ST at a dose of 2x109 CFU oral inoculations, ST invaded the spleen, liver and mesenteric lymph nodes (at 7 days after inoculation). Based on the obtained results, ICR mice developed ST and ETEC infection/illness via IP challenge, however internalization & colonization of challenge strain as well as gut pathology without clinical illness resulted via oral gavage in ICR mice.

Subsequently, BALB/c mice were utilized to determine if oral challenge with ST and ETEC can produce moribund illness. The protocol title was changed to "Establishment of a murine challenge model for *Salmonella* typhimurium and ETEC and evaluation of recombinant *S. typhimurium* STΔ aroA/ΔhtrA CJ0113/PAL/cHMGB1 and killed *Bacillus subtilis* 1A857 vaccine candidates in a murine model."

The objectives for this study were to: (i) establish a murine model for ST infection and ETEC colonization, (ii) to evaluate safety of recombinant live double-attenuated *S. typhimurium* STΔaroA/ΔhtrA CJ0113/PAL/cHMGB1 and *killed B.subtilis* 1A857 (with and without adjuvant) vaccine candidates in mice after oral administration of single or double dose by monitoring the presence and severity of clinical signs after immunization, (iii) to evaluate protective efficacy of the vaccines by challenging immunized mice with ST and ETEC strains, and (iv) to evaluate immune responses in blood and intestinal washes and inflammatory responses in gut tissue samples.

For the oral challenge route, BALB/c mice (two per group) were orally inoculated with three escalating doses (5x108, 5x109 and 5x1010 CFU) of ST and ETEC. For the IP challenge route, BALB/c mice (two per group) were inoculated with three/two escalating doses. For ST the doses are 5x104, 5x105 and 5x106 CFU and for ETEC the doses are 5x106 and 5x107 CFU. Mice that develop moribund illness were euthanized and healthy mice were maintained for 15 days before euthanasia as a study endpoint. In conclusion, the optimal dose for ST via oral route was 5x109 CFU and for ETEC was 5x1010 CFU via oral route and 5x106 CFU via IP route.

Enteritis was assessed histopathologically in the ileum, cecum and colon and compared with control animals. Colonization of the challenge strain in spleen, liver, mesenteric lymph node, and intestinal contents (ileum, cecum and colon) was evaluated. A total of 945 stool samples have been collected and processed for bacterial isolation. Real-time PCR was used to detect *S. typhimurium* and ETEC. ELISAs were performed to determine IgA, IgG, IgG1 & IgG2a, IgG2b and IgG3 antibody titers in serum samples. Intestinal wash collected at euthanization will be used to measure s-IgA and IgG antibodies by ELISA. The assay is under processing.

14. Antimicrobial Resistance Patterns and Molecular Characterization of *N. gonorrhoeae* Isolates in Bhutan:

A study of antimicrobial resistance patterns and molecular characterization of *Neisseria gonorrhoeae* (NG) isolates collected in the Jigm iDorji Wangchuk National Referral Hospital (JDWNRH), Thimphu, Bhutan has been conducted. Isolates kept at -70°C at Clinical Laboratory of JDWNRH have been shipped to AFRIMS for further examination. Isolates are sub cultured for a rapid identification confirmation and also detection of □-lactamase production by a commercially available API NH (bioMérieux, Inc., Durham, NC, USA). Antimicrobial susceptibility testing of the confirmed isolates has been performed by using E-test method to determine Minimal inhibitory concentration (MIC) (µg/mL) against Penicillin, Tetracycline, Ciprofloxacin, Ceftriaxone, Cefixime, Azithromycin, and Spectinomycin.

During this period, 146 frozen NG isolates were shipped to AFRIMS. Confirmation of isolates and antimicrobial susceptibility testing by MIC has been completed on 36isolates. Of these, all NG isolates show no resistance to Ceftriaxone, Cefixime and Spectinomycin. All except one isolate showed either resistances (28/36 or 78%) or intermediate susceptibility (7/36 or 19%) to ciprofloxacin. 24/36 (67%), 7/36 (19%), 5/36 (14%) were resistant, intermediate susceptible or susceptible to tetracycline, respectively. Twenty four isolates (67%) were found positive for beta lactamase production as tested by API NH. Selected NG isolates will be submitted for molecular characterization of resistance genes.

In CY14, a total of 132 NG isolates were selected for characterization of antimicrobial resistance genes. Characterization was aimed to detect NG isolates showed resistance to penicillin and reduced susceptibility to multiple antibiotics especially ceftriaxone and cefixime. By MIC, resistance to penicillin was found in 47/87 NG isolates. However, none of 84NG isolates were resistant ceftriaxone and cefixime. Selected NG isolates were amplified for penA, ponA, and mtr genes and submit for sequencing for baseline mutational data for NG isolates.

Furthermore, 23 selected NG isolates with ranges of MICs for ciprofloxacin resistances [≥32 (n=5), 16 (n=3), 12 (n=3), 8 (n=2) , 6 (n=2) and 3 (n=1) µg/mL]; intermediate susceptible [1 (n=1), 0.75 (n=1), 0.5 (n=2) and 0.25 (n=1), and 0.19 (n=1) µg/mL]; and susceptible [0.003 (n=1) µg/mL] were amplified for gyrA and parC genes. These amplified products were sequenced and analysis was compared with NCBI databases of resistance NG isolates and standard sequences for controls. The results showed that all NG isolates resistant to ciprofloxacin (MIC ranges 0.19 ≥ 32 µg/mL had two point mutations on gyrA gene at position 91 (serine to phenylalanine) and 95 (aspartate to alanine). The mutation of parC gene was observed from selected NG isolates showing resistance at MIC ranges 3-≥32 µg/mL. At these MIC ranges, one to two point mutations at parC gene were observed for amino acid changes at the position 86 (aspartate to asparagine), 87 (serine to asparagine) and/or 91 (glutamate to lysine or glysine).Other selected NG isolates having MIC ranged 0.003-1µg/mL did not show any mutation on parC compared to the susceptible NG isolates and control ATCC strain.

Resistance to penicillin among NG isolates can be mediated by plasmid. A total of 132 NG isolates were characterized for resistance for β-lactamase gene by PCR reactions to differentiate plasmid types (African, Asia, Toronto and Rio). Seventy percent (92/132) of NG isolates were encoded by plasmid of African type β lactamase. All 92 NG isolates were positive PCR for TEM gene. Analysis of partial sequencing of TEM gene of selected NG isolates and alignment with ATCC isolates for NG showed that these sequences were bla-tem1.

15. Clinic-based Surveillance for Diarrhea Etiologic Agents in Children and Military Personnel in Battambang, Cambodia:

A human use protocol for diarrheal disease surveillance in military population and children at the Military R5 and Battambang Regional hospital (BRH), Battambang, Cambodia was approved on 13 May 2014. Subject enrollment and specimen collections were started on 15 Jul 2014. After obtaining written informed consent, demographic data, clinical data and a stool specimen was collected. Specimen processing, microscopic examination and microbiology work has been conducted at the laboratory in BRH with confirmation and further characterization of organisms at AFRIMS in Thailand.

During this reporting period, we enrolled 119 subjects with acute diarrhea and 121 non-diarrhea controls. Major pathogens found among diarrhea cases and non-diarrhea controls were *Aeromonas*, enteroaggregative *E.coli*, *Salmonella*, Plesiomonas and *Campylobacter*. No enteric pathogens were identified in about 44% of diarrhea cases and 39% of non-diarrhea controls. The antimicrobial susceptibility pattern of bacterial isolates from this study revealed high resistance of *Campylobacter* and *Shigella* isolates against nalidixic acid and ciprofloxacin. High resistances to ampicillin among enteric agents were also observed among Aeromonas (100%), *Shigella* (75%), Vibrio(75%), Plesiomonas (72%) and *Salmonella* (66%).

16. The Global Travelers Diarrhea (GTD) Study: an evaluation of study design and laboratory methodologies standardization in a multisite protocol assessing the epidemiology and etiology of acquired diarrhea among a U.S. military or civilian traveler's

This is a multi-site collaboration with NMRC to implement standardized detection and characterization of norovirus and enterotoxigenic *E. coli* (ETEC) among military and similar traveler populations. Proficiency testing was performed successfully for norovirus by real-time RT PCR and for ETEC by multiplex PCR. Retrospective samples from two study sites of Surveillance for Epidemiology of Diarrhea and Post-Infectious Sequelae in Travelers to Thailand and Nepal (Bumrungrad Hospital and CIWEC clinic) were included in the GEIS-GTD study.

A total of 199 samples were tested for norovirus resulting in 55 norovirus positive samples (28%). The detection also determined the genotype of norovirus: GI (14/55), GII (29/55), mixed GI/GII (12/55).

A total of 204 *E. coli* isolates/44 pooled-retrospective samples were performed for detection of ETEC and colonization factors (CF) by multiplex PCR assays according to NHRC-SOP. The prevalence of ETEC was detected as 21.5% (31/144) of all *E. coli* isolates. Among ETEC-positive isolates, there were 4% lt (9/204), 9% st (18/204) and 2% ltst (4/204). Seventy-one percent (23/31) of CF were identified from ETEC-positive isolates and 29% of ETEC isolates were unknown CF by multiplex PCR assay according to NHRC SOP. The two most common CF found in this study was CS6 (11/31), CS2, 3 (4/32) from ETEC-positive isolates.

17. Genomic sequencing of *Shigella* spp. and *Salmonella* typhi

A collaboration with Oxford University Clinical Research Unit (OUCRU) in Vietnam to study phylogeography of *Salmonella* typhi and *Shigella* spp. from various locations including Bhutan, Thailand and Southeast Asia. Samples were selected from available archive of frozen bacterial isolates. Over 1,000 isolates were cultured and DNA were extracted for whole genome sequencing.

18. Testing bacteriophage cocktails active against *Shigella*

Department of Enteric Disease has a collaborative project with the WRAIR Department of Emerging Bacterial Infections (EBI) to study bacteriophages (phages) candidates and phage cocktails against Southeast Asian pathogen strains. The main objective of this study is to develop a multivalent bacteriophage therapeutic cocktail active against *Shigella*, a major cause of military diarrheal infections, focused on strains circulating in Southeast Asia. The initial specific aims include: (1) isolate bacteriophages that are lytic against diverse *Shigella* pathogens (*S. sonnei*, *S. flexneri* and *S. dysenteriae*) and (2) test the isolated phages against diversity panels of *S. sonnei*, *S. flexneri* and *S. dysenteriae* from Southeast Asia including military isolates.

During this period, 89 *Shigella* species were tested to eight single phages and four set of phage mixes (#1, #2, #3 and #15). The phage mixes #15 was active against 6/6 (100%)*S. sonnei* and 92.7% *S. flexneri* strains of all serotypes whereas *S. dysenteriae* 9 and 12 are resistance to phages. The further study is to search for *Shigella* phages active against *S. dysenteriae* 9 and 12 and improve the phage cocktails formulation against *Shigella*.

19. Prevalence of Antibodies against Avian Influenza (H5N1) viruses in Viet Nam:

Objective of this study is to determine the seroprevalence of antibodies against Influenza A and Avian Influenza viruses in populations with a potential exposure to poultry or other birds or infected humans. A total of 5,336 human sera collected from the study of Population-Based Sero-Prevalence Survey of Human Infection with Avian Influenza (H5N1) in Vietnam, were used. Samples were collected from populations with a potential exposure to poultry or other birds or infected humans in two provinces (Tien Giang or TG 1,998 samples and Thua Thien Hue or Hue 3,338 samples) and were previously tested by hemagglutination inhibition (HI) and microneutralization (MN) assays for avian influenza (H5 subtype) viruses.

Samples were tested for 1) antibodies against influenza A virus antigen by using a commercial ELISA kit and 2) antibodies specific to highly conserved regions of H5N1 influenza viruses by H5N1-SeroDetect ELISA. Of 5,336 samples, 5,312 (99.6%) had IgG antibody response to influenza A virus antigen and 1,956 (36.7%) had IgG antibody response specific to H5N1 influenza viruses. Among four H5 peptides, M2e had the highest specific response, followed by HA2, PB1-F2, and HA, respectively. IgG antibody response influenza A antigen has correlation with H5 peptides specific response.

Laboratory assays were completed. The obtained laboratory data and geographic data will be integrated to analyze to determine association of risk factors of exposure; e.g., age, sex, exposure to poultry, etc. Manuscript writing is on preparation.

20. Influenza sequencing project:

The objective of this study is to identify whole genome sequence of Influenza A H1 and H3 subtypes from clinical isolates in remote area of Thailand.

Nasal and Nasopharyngeal swab samples from patients met the Influenza-like Illness criteria were collected from eight Royal Thai Army border hospitals in Chiang Rai, Chumporn, Kanjanaburi, Nakorn Phanom, Nan, Pattani, Sakaeo and Ubon Ratchatani provinces during Mar 2007 to Feb 2013. Positive respiratory samples for H1 or H3 base on real-time RT-PCR sub-typing results performed by Department of Virology, AFRIMS were selected to represent different location and time. A total of 174 samples (103 of H1 and 71 of H3) were received for influenza virus isolation by cell culture technique using MDCK cells. Whole genome sequencing using MiSeq, Illumina platform for120isolates (80H1N1and40H3N2) was performed by the WHO collaborating for Research and Training on Viral Zoonoses, Chulalongkorn University, Bangkok, Thailand.

Whole genome sequencing of influenza virus (8 segments/isolate) was completed on all 120 isolates (80 H1N1and 40H3N2). Submission of sequences to GenBank is in process.

Resource Management and Budget:

Funding sources:

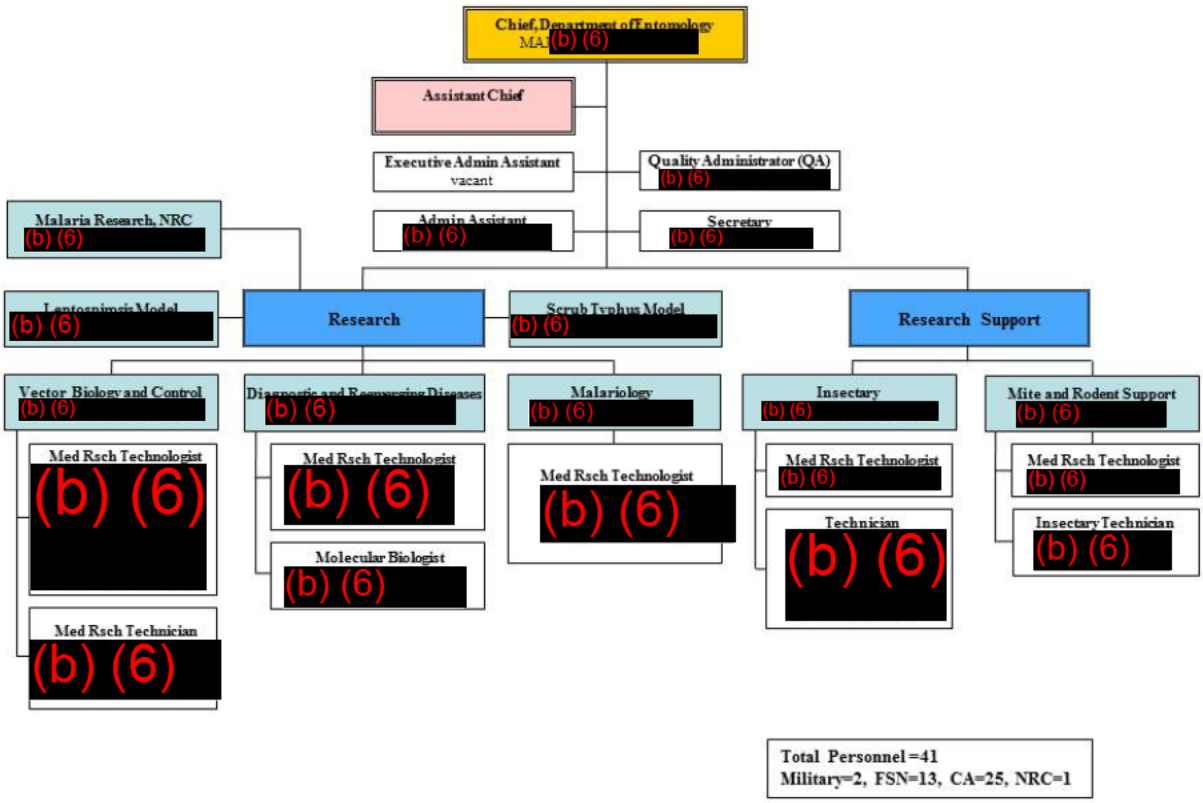
1) National Institutes of Health Interagency Agreement
2) The Global Emerging Infections Surveillance and Response System
3) Military Infectious Diseases Research Program

DEPARTMENT OF ENTOMOLOGY

Mission:

To identify vector- and rodent-borne disease threats of military and global health importance and to develop and evaluate interventions and products in order to mitigate those threats.

Organization and Personnel:



Statistical Data:

The Department of Entomology processed over 18,200 administrative actions in CY 14. These supported 15 research projects, 19 protocols and 20 agreements. The collection of over 38,200 laboratory and field samples resulted in 24 publications for CY 14. Research support maintained seven species of mosquitoes and eight *Leptotrombidium* mite colonies, producing over eight million mosquitoes and 80,000 mites.

Training & Education

The Department of Entomology provided training, by Laboratory, to:

a. Department-wide

i) One student from the Bhutan Ministry of Public health, sponsored by the Asia Pacific Malaria Eradication Network, received hands on training in all sections for 60 days.

b. Vector Biology & Control

i) Twenty five Pubic health officials from 5 provinces in Thailand received one day of training in proper calibration and use of pesticide application.

ii) Three students from Chulalongkorn University trained on voctor identification and surveillance.

iii) One student from Cornell University trained on vector identification and surveillance.

iv) Two students from the University of Phayao trained on vector identification and surveillance.

v) Twelve public health officers from the Vector-borne Disease Research Training Center, Hetauda, Nepal received 3 days of training in vector identification, surveillance and control at AFRIMS.

vi) One student from the Bernhard Nocht Institute for Tropical Medicine, Germany received training in vector identification and surveillance.

vii) Twelve Public health officers from the Vector-borne Disease Research Training Center received 3 days of training in vector surveillance at Hetauda, Nepal.

c. Diagnostic & Reemerging Diseases

i) Two students from the University of Phayao trained for 90 days on molecular detection and identification of vector-borne disease.

ii) One student from Faculty of Veterinary Medicine, Khon Kaen University trained for 5 days on molecular detection of *Bartonella* spp. from small mammals.

iii) Two WHO sponsored public health professionals from Bhutan received two weeks of hands-on training in the diagnosis and identification of scrub typhus vectors and pathogens using PCR/ELISA techniques.

iv) Two students from Burapha University received training in tick-borne disease detection and identification.

v) One student from Ubon Ratchathani University received four months training in molecular detection and characterization of Coxiella symbiont in ticks collected from small mammals in Thailand.

d. Malariology

i) Two students from the University of Phayao received four weeks training in polymorphism and genetic analysis of *Plasmodium vivax* genomes using a microsatellite assay method.

e. Insectary

i) One student from Kasetsart University received 8 weeks training in mosquito rearing

Research and Development

2) Vector Biology & Control

a. Development of an Integrated Push-Pull System for the control of biting flies

i) This MIDRP funded research was to develop an integrated push-pull system for the control of arthropod vectors of disease. Attractants were evaluated under semi-field conditions in the Large Mosquito Enclosures, Kampang Phet. The attractants were evaluated for their efficacy in pulling biting flies away from potential hosts and into traps where they are killed. Spatial repellents were evaluated for their efficacy in pushing biting flies away from potential hosts. The results demonstrated that all three attractant devices (Mega-Catch 3000, Octenol, and Lurex) were attractive as "human bait" and can be used in regular dengue vector surveillance program. Results of the spatial repellents showed that the ThermaCell was the only effective

repellent device against the yellow fever mosquitoes under the semi-field conditions in Thailand. The results were presented at the SOVE annual meeting 2014, San Antonio, Texas.

b. Field evaluation of the CO_2 generators against *Anopheline* and *Aedes* vectors in Thailand.

   i) We evaluated the efficacy of Centers for Disease Control and Prevention (CDC) light traps connected to the different CO_2 generators for the collection of malaria and dengue vectors under the field conditions. The CO_2 generators included: TDA Research's CO2 generator, the CUBE CO_2 generator, and the MED-E-CELL CO_2 generator. These were compared against dry ice and non-baited traps. The CDC light trap baited with dry ice collected the greatest number of total mosquitoes and Anopheles mosquitoes (42.25%, 273±46 and 31.6%, 75.8±9.2), respectively.

c. Field evaluation of modified CDC light traps and attractive sugar baits for the surveillance of *Anopheline* mosquitoes.

   i) We evaluated the efficacy of the standard CDC Light Trap against modified CDC Light Traps (a BG-sentinel fan was attached below the CDC Light Trap collection net) using different attractive sugar baits (ASB) for the collection of malaria vectors in Thailand. The field experimental study against malaria vectors was carried out in Tak Province, western Thailand. The CDC Light Trap was more efficient in collecting Anopheles than the modified CDC Light Trap. Among both trap types, the combination of attractants including BG-Lure, CO2, and ASB attracted more Anopheline mosquitoes than other attractant combinations.

d. Evaluation of a sticky trap baited with candidate phytochemical attractants for the control of *Aedes aegypti* (L.)

   i) The overall goal of this research is evaluate the relative attractiveness of the plant infusion-baited sticky traps for the control of the yellow fever mosquitoes, *A. aegypti*, under the semi-field conditions. This experiment is being carried out in large mosquito enclosures using laboratory reared *Ae. aegypti* males, host-seeking females, blood-fed females and gravid females (4 days post blood feeding) . Three plant infusions were used in this experiment: Lemongrass (*Cymbopogon citrates*), basil (*Ocimum tenuiflorum*) and dried hay. We recaptured 81% of released *Ae. aegypti*. Only the mosquito's physiological stage significantly affected recapture ($P < 0.05$). The mean numbers of gravid *Ae.aegypti* attracted to each sticky ovitrap baited with hay infusion, basil infusion, lemongrass infusion and filtered water were 11.0, 8.8, 5.7 and 6.7, respectively. We found that the proportions of mosquito attracted by each infusion were significantly different for blood fed and gravid mosquitoes ($P < 0.05$). Significantly fewer numbers of blood-fed mosquitoes was collected by sticky ovitraps baited with basil leaf infusion. Lower numbers of gravid mosquitoes was attracted by lemongrass infusion than other infusion. No significant correlations were detected in the proportion of both males and host seeking females among these plant infusions and water control.

e. Field efficacy of CDC Updraft Blacklight (UV) Trap for surveillance of *Anopheline* vectors in Thailand.

   i) The objective of this study was to evaluate the efficacy of CDC Updraft Blacklight (UV) Trap (model 1312) against CDC Miniature Light Trap (model 1012) for collecting malaria vectors in Thailand. A total of 17 mosquito species (180 adults) were collected over 4 days of the study. The most common species were Cx. (Cux.)vishnui (31.11%), Ar. (Arm.)subalbatus(28.33%), and An. (Cel.)minimus (16.11%). The results showed that the CDC light trap collected significantly more Anopheles females than the CDC Updraft Blacklight (UV) Trap.

3) Diagnostics & Reemerging Diseases

a. Rodent and vector-borne diseases surveillance in Thailand focusing on leptospirosis, scrub typhus, Rickettsial disease, and Bartonellosis.

i) We conducted regional rodent and vector-borne diseases surveillance and research in arthropod vectors, and rodent populations to characterize the tropical diseases endemic to Thailand. Two regions in Thailand were studied; the North (Nan, Mae Hong Son provinces), and the Northeast (Loei, Nong Bua Lam Phu provinces). Rodents and vectors were collected and species identified. The pathogens screening were completed. All positive pathogens were identified and characterized into species. Distribute surveillance data to public health officials as widely as possible to facilitate timely and accurate epidemiological determination of geographic risk factors for disease. 706 rodents were captured and surveyed from September 2013-October 2014. Of these, *Rattus exulans* (28%), *Bandicota indica* (15%), and *R. rattus* (15%) were the three most common species, representing 58% of all rodents collected. Additionally, we collected ectoparasites from domestic animals (cats, cattle, chickens, and dogs) in villages where rodent surveillance was conducted. Rodent tissue and pools of ectoparasites (351 chiggers pools, 80 ticks pools, 102 fleas pools, and 6 lice pools) were evaluated for the presence of leptospirosis (*Leptospira* sp.) scrub typhus (*Orientia tsutsugamushi*), rickettsiosis (*Rickettsia* spp.), and bartonellosis (*Bartonella* spp.). Low prevalence of scrub typhus, leptospirosis, and rickettsiosis in rodents were observed, however, high prevalence of bartonellosis (33%) in rodents was recorded in these regions. Ticks and fleas collected from rodents carried high prevalence of *Rickettsia* (23%) and *Bartonella* (25%), whereas fleas from dogs have high infection rate of *Rickettsia* (54%).

b. Collection and Identification of Arthropod Vectors of Rickettsial Diseases from Regions of Highest Seroprevalence in Thailand.

i) This was a collaborative project with the Department of Enterics, AFRIMS to collect and identify arthropod (chiggers, ticks, fleas, and lice) vectors of rickettsial diseases from regions of highest seroprevalence in Thailand. The presence of scrub typhus and rickettsiosis were determined for these vectors. Over 270 pools of ectoparasites (chiggers, fleas, ticks, and lice) were collected from rats and small mammals trapped in 3 provinces of Thailand: Nan (the North), Buri Ram (the Northeast), and Chumphon (the South). Prevalence of *Orientia* and *Rickettsia* in vectors was determined. Likewise, *Orientia* genotype and *Rickettsia* species were identified and characterized. Data were sent to the Department of Enterics, AFRIMS for analyses.

4) Malariology

a. Active surveillance for *Plasmodium falciparum* drug resistance with assessment of transmission blocking activity of single dose primaquine in Cambodia.

i) This is a collaborative project with Department of Immunology and Medicine, AFRIMS for the active surveillance for *Plasmodium falciparum* drug resistance in Cambodia. We also evaluated the effect of primaquine on asexual stages of the malaria parasite and potential transmissibility of infection to *Anopheles dirus* mosquitoes using a membrane feeding assay. The results have been submitted to the Department of Immunology and Medicine for analysis.

b. Evaluation of drug susceptibility of *Plasmodium vivax* to chloroquine in vitro in western Thailand (Mae Sod District, Tak Province, Thailand, along the Thailand-Myanmar border region).

i) This study is the active surveillance for *P. vivax* drug resistance along Thai-Myanmar border. We conduct *in vitro* drug susceptibility testing of *P. vivax* to Chloroquine and parasite genetic analysis to determine and analyze genetic polymorphism among clinical *P. vivax* isolates. This project is the collaborative project with Bansomdejchaophraya Rajaphat University. This project is ongoing.

c. Production of *Plasmodium cynomolgi*-infected blood products utilizing a Rhesus Monkey (*Macaca mulatta*) Malaria Model.

i) AFRIMS has the capabilities in the Department of Entomology and Veterinary Medicine to infect non human primates with *Plasmodium cynomolgi* malaria parasites and feed mosquitoes on

infected animals. This will enable AFRIMS to supply and ship freshly isolated *P. cynomolgi* sporozoites to Novartis for development of an *in vitro* anti-hypnozoite assay. This project is ongoing until mid FY15.

d. Induction of sterile protective immunity in rhesus monkeys immunized with live *P. knowlesi* sporozoites under drug treatment.

i) This is a collaborative project with the Department of Immunology and Medicine, AFRIMS. In this study, we propose to use rhesus monkeys as a model to investigate protective immune response after immunization with live *Plasmodium knowlesi* sporozoites under chloroquine prophylaxis. We will conduct an immunization-treatment-vaccination experiment, whereby 8 Rhesus macaques will be effectively vaccinated against *P. knowlesi* through repeated mosquito-borne challenges while being given chloroquine, a drug which kills only blood-stage parasites. Seven animals will serve as controls by being given chloroquine alone without *P. knowlesi* immunization (uninfected mosquito bites only). Rhesus effecter memory (T_{EM}) and central memory (T_{CM}) T cell frequencies in PBMC and tissue monocytes from liver, spleen and lymph nodes will be assessed, as will antibody responses by immunofluorescence staining. In so doing, we hope to further elucidate potential mechanisms for development of liver-stage immunity to *P. knowlesi*. Entomology produced the *P. knowlesi* infected mosquitoes for the immunization and challenges. This project is ongoing.

e. Evaluation of transmission blocking efficacy of Ivermectin against *Plasmodium vivax.*

i) This is a collaborative project with (b) (6) , a National Research Council Fellow hosted by the Department of Entomology, AFRIMS investigating whether ivermectin is sporontocidal to *Plasmodium vivax* in *Anopheles dirus* and *An. minimus*. Ivermectin at the concentration that kills 25 (LC_{25}) and 5 (LC_5) percent of mosquitoes will be fed before, concomitantly, or after ingestion of *Plasmodium vivax* parasites. Seven and fourteen days after parasite ingestion mosquitoes will be dissected to determine oocyst and sporozoite development. This project is ongoing.

5) Scrub Typhus Model

a. Scrub Typhus Immunopathophysiology Model in Nonhuman Primates (STIMP)

i) V This is a collaborative effort with Mahidol Oxford Research Unit (MORU). The overall objective is to establish a non-human primate model to more closely mimic the immunopathophysiological parameters of natural infection with, and vaccine-induced protection against scrub typhus. The immediate objective is to establish effective mechanical infections of mites with the human pathogenic Karp strain of *Orientia tsutsugamushi*. We established the intial conditions for microinjection (micropump pressure, injection time and volume) using methylene blue. Then uninfected adult female *Leptotrombidium chiangraiensis* (Lc) mites were selectively injected with L929 cell culture alone (control) or a culture prepared with infected mouse liver-spleen homogenate (treatment). All microinjection steps were performed in the Animal Biosafety Level 3 (ABSL3) laboratory. Injected adult mites were maintained until they produced offspring (F1 generation). Uninfected adult female *Leptotrombidium imphalum* and *Leptotrombudium deliense* were also injected with semi-purified *O. tsutsugamushi* in L929 cell. The new (F1) progenies were identified to species using multiplex PCR. The trans-stadial and trans-ovarial infection rates were analyzed using qPCR. The inoculum was prepared using AFRIMS human-pathogenic *O. tsutsugamushi* strains cultured in L929 cells provided by MORU. Over 82% (SE = 3%) of injected mites survived to produce offspring. Trans-ovarial transmission only occurred in 45% (SE = 7%) of mites injected with non-purified *O. tustusgamushi* in from the L929 cell culture. However, over 85% (SE = 5%) trans-ovarial transmission occurred in mites injected with a mixture of semi-purifed *O. tsutsugamushi* from the L929 cell culture and semi-purified tick cells.

b. Evaluation of r56 Vaccine Candidates in Homologous Chigger Challenge Mouse Model

i) This is a follow-on study to an earlier MIDRP project, "Establishment of a Chigger Challenge Model. Determination of Optimum Inoculation Doses of Two *Orientia tsutsugamushi* Strains in ICR Mice", and "Evaluation of Scrub Typhus Vaccine Candidates by Natural and Artificial Challenge Models in ICR Mice (*Mus musculus*)". In order to eliminate contributing factors due to homologous versus heterologous immunogens, to elucidate protective immune responses and simplify data analysis, we amplified the *Orientia* 56kDa gene from Lc-1 infected chiggers and produced the recombinant protein r56Lc-1. The protective efficacy of this r56Lc-1 was evaluated by challenge with *Orientia* strain Lc-1 infected chiggers. Our data demonstrated that r56Lc-1 provided 20-30% of protection consistently upon challenge by an infected chigger which carries the same *Orientia* strain based on the sequence of 56 kDa antigen.

6) Leptospirosis Epidemiology

a. Surveillance of pathogenic *Leptospira* strains in rodent population in the epidemic areas.

i) The overall goal of this research was to do surveillance of pathogenic *Leptospira* strains in the epidemic areas for predicting the route of transmission. The major reservoir host, rodent population, and the water around the area that rodent were trapped were collected both in wet and dry season. The infected rodents were evaluated for their efficacy in the attribution of *Leptospira* in the environment. The recovered *Leptospira* isolates from both rodents and water samples were evaluated for natural circulating *Leptospira* that may cause an incidence of leptospirosis infection. The majority of rodent infection (14.9%) was found in rodents from the rice fields. The most abundant pathogenic Leptospira spp. were *L. borgpetersenii* (56.2%) and *L. interrogans* (41.9%). A few rodents were infected with *L. kirschneri* (1.8%). The circulating Leptospira spp. recovered and isolated from water samples (29%) were identified as non-pathogen, intermediate strains, and pathogenic, however analysis is still ongoing.

B. Resource Management and Budget

TABLE 1: Department of Entomology 3-year budget

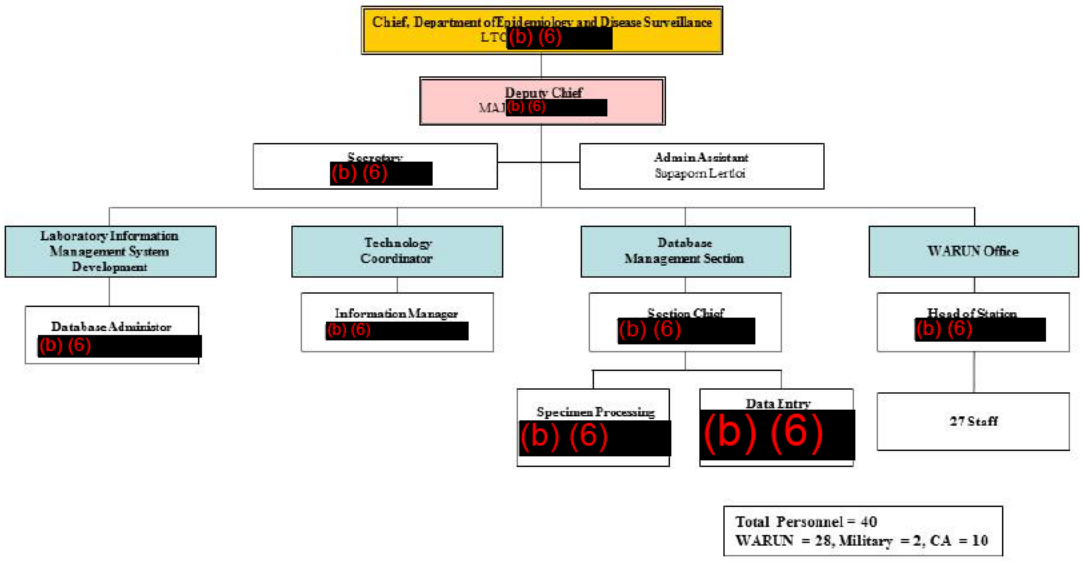
Fiscal Year	Department Income	Project Costs	FSN Salary	CA Salary
FY 13	1,874,340	859,792	448,809	565,739
FY 14	1,554,017	560,164	558,029	435,824
FY 15	1,506,716	643,364	458,714	404,640

DEPARTMENT OF EPIDEMIOLOGY AND DISEASE SURVEILLANCE (EDS)

Mission:

The mission of the Epidemiology and Disease Surveillance Department is to support AFRIMS and AFHSC-GEIS goals and objectives pertaining to bio-surveillance, epidemiology, and capacity building for emerging infectious disease outbreak detection and response in Southeast Asia.

Organization and Personnel:



Statistical Data:

Detailed data on EDS efforts is available in GEIS reports submitted on the PROMIS website. Respiratory disease surveillance data for the institute is collated by EDS and submitted to the AFHSC-GEIS "dashboard," and bi-weekly in a brief update to partners.

Training and Education:

EDS is actively engaged in training programs throughout the year in order to support its various surveillance projects and capacity building efforts in epidemiology and outbreak response, particularly in the area of public health informatics, where EDS personnel provided training to AFRIMS and outside personnel on how to use Geographical Information System (GIS) software such as ArcView GIS, Google Earth, and Epi-Map for scientific research; as well

as training on MS Office Excel, Epi-Info and freely available tools for alert, early warning and outbreak investigation and response; validation and analysis of influenza data using PivotTable and PivotChart; and SAGES electronic disease surveillance software in support of the collaboration with the Royal Thai Army.

EDS surveillance and capacity building efforts also require microbiology, biosafety, laboratory management and program management training including human subjects protections. Cascade training* resulted in successful implementation of safe, high quality diagnostics for Q fever in 7 Thai Ministry of Agriculture Veterinary Research and Diagnostics Centers (*the identical training was conducted previously at the national reference laboratory – the National Institute of Animal Health, with the intent that it be tailored but largely repeated at the VRDCs).

AFRIMS Epidemiology and Disease Surveillance (EDS) Dept and Human Subject Protection Office (HSPO), in coordination with the Mongolia National Center for Communicable Diseases (NCCD), organized and presented an "IRB 101 Course" in Ulaanbaatar Mongolia from 22-24 September 2014. Presenter support came from WRAIR HSPO (Ms. Teresa Soderberg and Ms. Sarah Rule), and a regional ethical review board capacity building organization [Forum for Ethical Review Committees in the Asian and Western Pacific Region (FERCAP)]. Local Mongolian participants included 30 leaders, ethical review board representatives, and/or scientists from the Ministry of Health, NCCD, Mongolian National University of Medical Sciences, Mongolian Academy of Sciences, National Center for Public Health, National Center for Transfusion Medicine, General hospital of defense and law enforcement, Institute of Medical Sciences, National Center for Maternal and Child Health, and the National Center for Zoonotic Diseases. At the same time, AFRIMS EDS/Virology/HSPO and WRAIR HSPO personnel continued coordination of a Human Subject Mongolian Army Respiratory Disease study being conducted by AFRIMS, the Mongolian Armed Forces (MAF), and the NCCD. The course and study coordination were resounding successes, building upon/strengthening local ethical review capacity, ethical research understanding, and relationships between and among WRAIR, AFRIMS, MAF, and Mongolia NCCD/MOH.

AFRIMS serves as a training site for U.S. military and civilian medical students, residents and infectious disease fellows pursuing careers in tropical medicine and research. EDS helps to arrange for the approximately one dozen students who will come to AFRIMS each year to conduct AFHSC-GEIS sponsored training on HIV and tropical infectious diseases.

EDS facilitate training on novel diagnostics for TB at the German Nepal TB Project laboratory in Kathmandu, Nepal. Trainers came from other members of a GEIS-supported consortium led by USAFSAM.

Research and Development:

The following studies are funded by GEIS:

1. Nepal Acute Febrile Illness serology study (WRAIR 1513). In 2014, further laboratory analysis for Q fever and Brucellosis was completed on the ca. 2000-paired sample serum set. Final laboratory analysis will be obtained and the manuscript will be drafted by summer 2015.

2. Nepal TB diagnostics validation (WRAIR 1887). Final work plans were developed, training was accomplished and the laboratory work is expected to be completed by summer 2015.

3. Nepal One-health anti-microbial resistance pilot study (WRAIR 1960). The pilot study was initiated in fall, 2014. The effort represents a novel approach to One Health for AFRIMS, wherein the process begins with a case of bacterial acute febrile illness in a human patient, and continues with assessment of commensal bacteria of domestic animals in contact with the patient for the presence of genetic elements of resistance. If successful, the pilot effort could be expanded to result in critical information on the exchange of genetic elements of resistance between bacterial commensals of animals and human pathogenic bacteria.

4. Mongolian Armed Forces (MAF) deployment serology study (WRAIR 1928). Ca. 95 % of the laboratory work was completed by the end of calendar year 2014 and the study and associated manuscript are expected to be completed by summer 2015.

5. MAF burden of respiratory disease (WRAIR 2025). 2014 represented the second year of implementation of the study and was highly successful (see "Special Training" above). The burden of disease is significant and the data may provide MAF the basis to implement policy changes including vaccination.

6. Philippines TB diagnostics capacity building (WRAIR 2091). The effort was highly successful (see Accomplishments) and is now integrated with Enterics Dept. efforts in the Philippines.

7. Thailand RTA STI retrospective study (WRAIR 2012). The study showed a measurable prevalence of HSV, HPV and syphilis in RTA recruits and will be the basis for a comparison study with one or more previous recruitment years (see Accomplishments).

8. Thailand RTA antibiotic resistant Gonorrhea study (WRAIR 2039). The study is well established as of calendar year 2014 (see Accomplishments) and is expected to continue long-term.

The effort listed below is funded by DTRA CBEP:
9. Capacity building for risk reduction in the Thai veterinary diagnostics system. Diagnostic capability was extended to the VRDCs (see Special Training). Future efforts will focus on further enhancement of the diagnostic repertoire.

Resource Management and Budget:

AFRIMS EDS manages and coordinates the roughly $5 Million GEIS budget for the institute and implements projects valued at approximately $1 Million. This is expected to continue into the future.

Accomplishments

Provided training on how to use the UBS-SAGES database application.

Provided all-encompassing data management in support of RTA recruit HIV surveillance.

Successfully coordinated the five-pillar GEIS program, with the most important result being the high quality influenza data reported in bi-weekly reports to all stakeholders.

Continued assisting Department of Enteric Disease, AFRIMS with management of prior EDS created online questionnaires for the "Epidemiology of Diarrhea and Post-Infectious Sequelae in Travelers to Thailand and Nepal" projects.

Oversaw a landmark surveillance activity for Q fever in livestock in Thailand, clearly demonstrating the high prevalence in apparently normal ruminant placentae, validating a novel surveillance technique and providing information that probably answers the long-standing epidemiological conundrum of how individuals in Thailand with no known animal contact have been infected with Q fever.

Paved the way for AFPMC to become the Philippine national leader in TB care through added gold-standard / point of care TB and MDR-TB GeneXpert diagnostic and LED microscope capability, improved overall clinical and public health TB care, and future capability for AFPMC to provide all TB care (regular AND MDR/XDR) in house. In so doing, the US is now able to obtain for the first time reliable TB and MDR TB incidence data among Philippine armed forces (perhaps eventually capturing the entire armed forces population) and the Philippine military-US military TB transmission risk is reduced. The project was fully incorporated into the Philippine national TB Public

Health network (one year ahead of schedule) and thereby obtained their “blessing,” support, and training assistance. AFRIMS’ lead Filipino collaborator obtained global fund support for an additional / dedicated AFPMC TB DOTS nurse, all AFPMC TB care related cost support (x-rays, medications, etc., to include all supplies necessary to continue this project), and hopefully future equipment support for AFPMC, thus ensuring sustainability.

Executed a Retrospective Royal Thai Army (RTA) STI study in 2014, completing statistical analysis and drafting abstract/oral presentation/manuscript which was presented at the GEIS partner call and is planned for presentation at ICMM conference and China Trilateral SMEE in Summer 2015. EDS initiated work on repeating this effort in 2 other year cohorts in 2015.

Executed Prospective RTA STI study in 9 RTA hospitals: In calendar year 2014, ca. 40 isolates were obtained and characterized for antibiotic resistance.

Executed MAF Respiratory Burden of Disease Study in 15 MAF clinics, providing very valuable respiratory disease incidence and impact data, which has helped the MAF Command support establishment of routine respiratory surveillance as part of their force health protection policy. Coordinated, implemented, and presented an “IRB 101 Course” for 30 Mongolian Science and Ethical Review Body leaders from 11 institutions; a monumental and hugely successful effort working with Mongolia NCCD, AFRIMS/WRAIR HSPO, and FERCAP.

Coordinated 10 AFRIMS research and/or international tropical medicine clinical rotations. Created a new international tropical medicine elective site at Mahidol University for Tropical Diseases.

Assisted in 2014/2015 Cobra Cold and Balikatan exercises.

EDS transitioned management/oversight of WARUN to AFRIMS Department of Enteric Diseases.

AFRIMS Epidemiology and Disease Surveillance (EDS) Department and Human Subject Protection Office (HSPO), in coordination with the Mongolia National Center for Communicable Diseases (NCCD), organized and presented an “IRB 101 Course” in Ulaanbaatar Mongolia from 22-24 September. Presenter support came from WRAIR HSPO ([redacted]), and a regional ethical review board capacity building organization [Forum for Ethical Review Committees in the Asian and Western Pacific Region (FERCAP)]. Local Mongolian participants included 30 leaders, ethical review board representatives, and/or scientists from the; Ministry of Health, NCCD, Mongolian National University of Medical Sciences, Mongolian Academy of Sciences, National Center for Public Health, National Center for Transfusion Medicine, General hospital of defense and law enforcement, Institute of Medical Sciences, National Center for Maternal and Child Health, and the National Center for Zoonotic Diseases. At the same time, AFRIMS EDS/Virology/HSPO and WRAIR HSPO personnel continued coordination of a Human Subject Mongolian Army Respiratory Disease study being conducted by AFRIMS, the Mongolian Armed Forces (MAF), and the NCCD. The course and study coordination were resounding successes; building upon/strengthening local ethical review capacity, ethical research understanding, and relationships between and among WRAIR, AFRIMS, MAF, and Mongolia NCCD/MOH.

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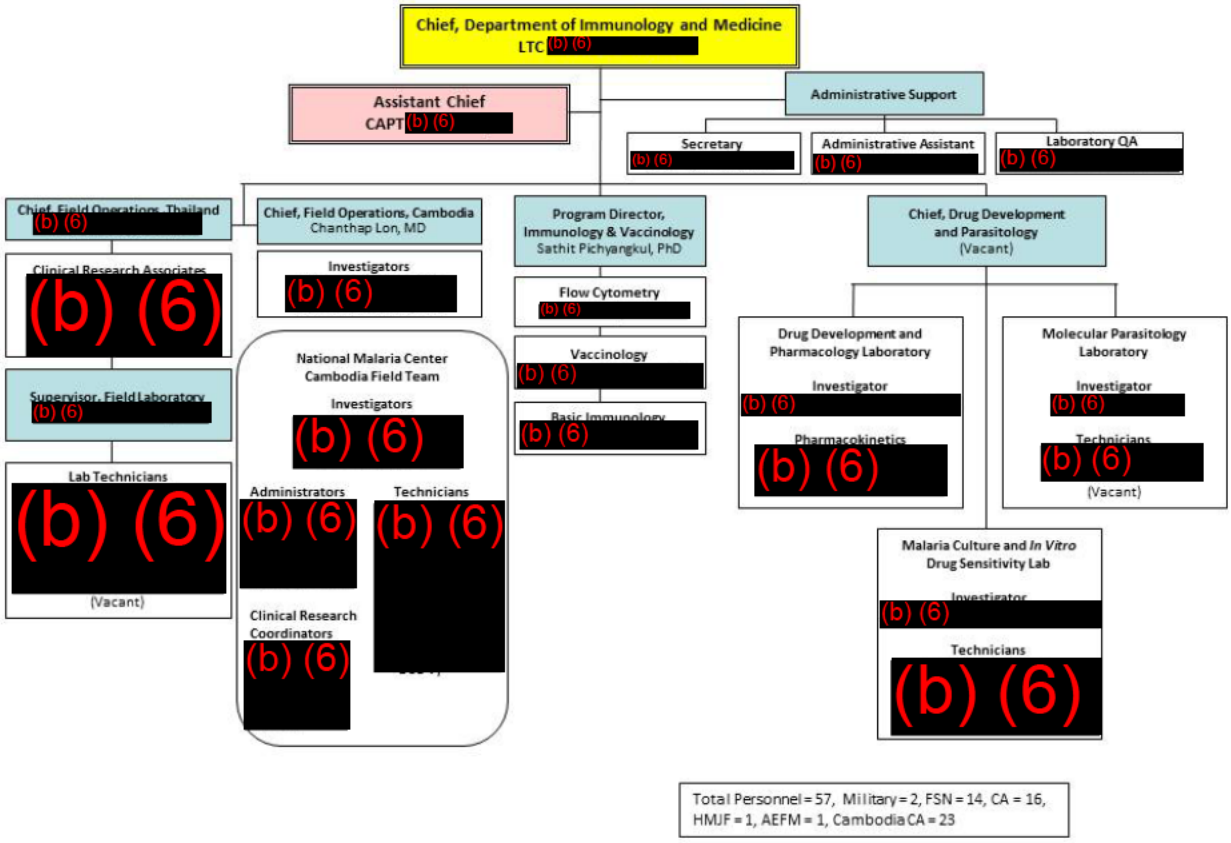
DEPARTMENT OF IMMUNOLOGY AND MEDICINE

Mission:

To support medical product development, to protect the war fighter and host nation citizens, and conduct surveillance of diseases of military importance in South East Asia for our Sponsors: U.S. Army Medical Research and Materiel Command, extramural collaborators; and other Department of Defense and U.S. Government Entities (GEIS).

Organization and Personnel:



Training and Education:

A. In-house Training

- Laboratory strengthening workshop training lead by AFRIMS Biosafety Team from 29 April to 1 May 2014 at Apsara Angkor Hotel, Siem Reap, Cambodia.

- In preparation for conducting WR#1877, CITI and SSP training lead by AFRIMS Study Team for nurses (Clinical Research Coordinators), 12-13 May 2014, at Anlong Veng Referral Hospital, Cambodia.
- Molecular Biology Team, Department of Immunology and Medicine, AFRIMS, trained Cambodian medical research technicians (Field Team) on Multiplex real time PCR techniques characterize *Plasmodium* spp., *P. falciparum* and *P. vivax* to support clinical studies, including proper pipette use, PCR master mix preparation, extraction of DNA from clinical samples, multiplex real-time PCR assay methods and machine programming, 22-23 August 2014, at Anlong Veng Referral Hospital, Cambodia.
- Molecular Biology Team, Department of Immunology and Medicine, AFRIMS, trained Cambodian medical research technicians (Field Team) on Multiplex real time PCR techniques characterize influenza and subtypes and non-influenza respiratory pathogens to support clinical studies, including proper pipette use, PCR master mix preparation, extraction of total DNA and RNA from clinical samples, real-time PCR assay methods and machine programming, 15-19 October 2014, at Battambang Referral Hospital, Cambodia.
- Surveillance Investigation and Outbreak Response to Rapid Response Team (RRT) Exercise workshop, 6-7 November 2013, at Battambang Referral Hospital, Cambodia.
- Prior to initiation of WR#1917, AFRIMS Bangkok staff conducted training for local field team staff at Srisaket and Ubonratchathani, Thailand, on protocol performance, SOPs, SSPs and GCP.
- Prior to initiation of WR# 2017, AFRIMS Bangkok staff conducted training for clinical study team at Kwai River Christian Hospital, Sangklaburi, Kanchanaburi, Thailand on protocol performance, SOPs, SSPs, and CITI.

B. Outside Training

- Hosting of U.S. military physicians pursuing a career in tropical medicine and research for a clinical rotation at Kwai River Christian Hospital in Sangklaburi, Thailand; and at AFRIMS field sites in Cambodia.
- Hosting of Ph.D. candidate from UNC-Chapel Hill at AFRIMS-Bangkok and at field labs in Cambodia to assist with his PhD dissertation project and to train up in molecular biology techniques applied to the study of malaria transmission.
- In vitro analytical methods, Institute Pasteur du Cambodge, Phnom Penh, Cambodia, September 2014.

Accomplishments:

The Department of Immunology and Medicine applies a variety of classical and state-of-the-art technologies to execute a multi-faceted clinical and preclinical research program. A mobile epidemiology team conducts clinical work in remote field locations in malaria endemic areas, including field sample collection and processing, screening, reference microscopy, assessment of rapid diagnostics for various tropical infectious diseases, and a staff well-versed in performing clinical trials to GCP and ICH standards. Drug susceptibility profiling of fresh clinical *Plasmodium falciparum* and *P. vivax* isolates from malaria patients is routinely conducted using antibody- and microscopy-based methods to help interpret efficacy outcomes, detect cases of drug resistant infections, and actively track drug resistance geographical and temporal trends in Thailand and Cambodia. Routine cultures of reference *P. falciparum* clones are maintained and new drug resistant isolates are cloned for molecular and phenotypic characterization. State-of-the art molecular methodologies are available for the study of the efficacy of vaccine and drug candidates, to include advanced molecular biology methods such as sequencing, SNP analysis, and real-time PCR. Technologies for detecting and monitoring safety signals in clinical trials include high resolution melting real-time PCR detection of glucose-6-phosphate dehydrogenase (G6PD) deficiency mutations and electrocardiogram monitoring of patients administered test drugs. Cellular immunology techniques are available, such as flow cytometry and sorting technologies, ELISPOT, and molecular methods. The preclinical research

teams are all trained in laboratory animal research and regulations, current AALAAC requirements, and laboratory animal test and observation methods. Pharmacology assays include HPLC, LC-MS, and LC-MS/MS analyses of *in vivo* levels of drugs and drug candidates evaluated in nonhuman primates and in clinical trials, as well as a unique malaria bioassay to measure the *ex vivo* anti-malarial bioactivity of preclinical and clinical plasma samples to ascertain correlations between pharmacokinetics and pharmacodynamics of antimalarial evaluation.

Research and Development

A. Malaria Drug Development

1) Preclinical malaria drug development in nonhuman primates

The AFRIMS Department of Immunology and Medicine, Pharmacology Section, supports preclinical development of new drug candidates for the U.S. Military Malaria Research Program (MMRP). We investigate in rhesus monkeys the pharmacokinetic/pharmacodynamic (PK/PD) properties of promising lead candidate molecules. Primaquine, the standard antimalarial drug used as a radical curative agent in the relapsing monkeys, was administered as racemic mixture of two opposite enantiomers (the *d*(+) and *l*(-) forms). Previous studies at AFRIMS have shown that these two enantiomers have differential antimalrial potency, toxicity and metabolism both in mouse and primate. The study of two primaquine enantiomers in healthy rhesus monkeys were conducted in 2010 by administration of dose escalation at 1.3, 3.0 and 4.5 mg/kg/day for 7 days with a 2-week wash-out period between dose and crossover of enantiomers. This study was intended to evaluate the concentration-effect relationship of primaquine on liver function, red cell mass and methemoglobin formation to better understand the differential hepatic and erythrocytic toxicities of primaquine enantiomers. There is an evidence for differential oxidative stress with a concentration-dependent rise in methemoglobin with increasing rises of (+)-primaquine greater than that seen for (-)-primaquine. There was a marked, reversible hepatotoxicity in 2/3 animals dosed with (-)-primaquine at 4.5 mg/kg. The relevance of the liver injury and methemoglobin formation generated by primaquine are complex and poor understood, but the findings suggest that the two enantiomers have different patterns of metabolism and disposition. In 2011, an abstract was presented at ASTMH and a manuscript was published in AAC in September 2014 (Saunders *et al*). In 2014, the AFRIMS Department of Immunology and Medicine evaluated the PK/PD properties of a triazine and acridone compound candidates for the MMRP. The result of this investigations lead to the selection of a new drug class for further development as a new blood stage antimalarial agent. Further studies with MMRP are currently being planned to explore the PK/PD properties of another preclinical drug candidate.

2) *Plasmodium vivax* human challenge model

AFRIMS Immunology and Medicine supported the WRAIR in obtaining a new Investigational New Drug (IND) application from FDA for a safe, effective human *Plasmodium vivax* challenge model. The department implemented *P. vivax* infected blood donor screening processes to FDA standards to ensure challenge subject safety. In collaboration with the Department of Entomology, we supported the first human challenge in healthy volunteers at the WRAIR using *P. vivax* infected mosquitoes produced under regulated IND from donors in Thailand. We now seek, in collaboration with investigators from the Royal Thai Army, to replicate this model at AFRIMS in Thailand to demonstrate that volunteers can be safely and reproducibly infected with *Plasmodium vivax* (*P. vivax*) by the bites of experimentally infected *Anopheles dirus* (*An. dirus*) mosquitoes carrying *P. vivax* sporozoites in their salivary glands. The study protocol was finalized by the end of 2010, yet was put on hold by the institutional review board due to relapse concerns in primaquine treated patients.

3) Clinical trials to support malaria prophylaxis drug development for the U.S. Military

Populations of military personnel in the region continue to suffer from an inordinate burden of malaria, particularly in forward deployed areas. A strategy to prevent malaria infection is regarded as a critical

element of appropriate force health protection measures. Most militaries in the region do not use anti-malarial chemoprophylaxis on a routine basis, relying instead on personal protective measures to prevent mosquito bites. In the Royal Cambodian Armed Forces, this approach has had limitations with an ongoing burden of malaria in some areas. In the target study population, the incidence of malaria may be as high as 5-10% per month, with a high proportion of malaria naïve soldiers and dependents likely to benefit from anti-malarial chemoprophylaxis. The U.S. Army Medical Materiel Development Activity, in cooperation with the Walter Reed Army Institute of Research are currently establishing field sites to evaluate new products for anti-malarial chemoprophylaxis which are badly needed. While several viable prophylaxis drug candidates exist, no new studies to evaluate the efficacy for a prophylaxis indication have been conducted in more than a decade. As a response, our department conducted, in collaboration with the national Cambodian malaria program (CNM) an active malaria epidemiology cohort study in personnel and dependents of the Royal Cambodian Armed Forces (RCAF) in 2010 comparing safety and efficacy of 2 vs 3 days of DHA-piperaquine for the treatment of uncomplicated malaria. Incidence of malaria was as high as 5-10% per month – even higher in some locations. Further, it was found that there were no differences in DHA-piperaquine efficacy whether the same dose was given over 2 or 3 days. The rates of malaria recurrence at 42 days were very similar in both groups with 89% per protocol efficacy for two days of DP (95% CI = 76-96%) and 92% for 3 days (95% CI = 80-97%) of DP. The effect on the cardiac QT interval was also studied intensively. EKGs were obtained at screening, pre-dose, daily for 3 days, and then weekly for 4 weeks if prolongations were seen during the dosing period. Overall, QTc prolongations were mild and transient in nature. The drug effect was modest in this population, and similar to what has been seen in the other large phase 3 studies. This study was the first step in determining the feasibility of conducting future malaria prophylaxis studies at this site, and characterizing the population, malaria epidemiology and effectiveness of currently prescribed anti-malarial therapy with 2 days of DHA-piperaquine. Data about malaria burden in RCAF and baseline effectiveness of DHA-piperaquine in RCAF and dependents was analyzed and disseminated to partners in 2011 and will be used to design rigorous, carefully controlled clinical research studies. Results from this DHA-piperaquine efficacy trial were published in PLoS One in 2014. In 2011, the department prepared, in collaboration with USAMMDA for the first prophylaxis study in the Royal Cambodian Armed Forces, which started in May 2012. The purpose of this study was to determine if a 2 day course of DHA-piperaquine taken monthly is safe and effective as a chemoprophylaxis regimen in an area of multi-drug resistant falciparum and vivax malaria. The study was halted once a pre-determined cardiac safety signal was reached. The results from this important clinical safety and efficacy study were presented at the annual meeting of the American Society of Tropical Medicine and Hygiene. A manuscript is under review by the journal Antimicrobial Agents and Chemotherapy.

4) Tafenoquine Detective Study

In 2014, AFRIMS received successful approval to begin Clinical Trial TAF112582/WR2134 –
A study to evaluate the efficacy, safety and tolerability of tafenoquine (TQ) in subjects with Plasmodium vivax in Cambodia as part of a multicentre trial (NCT01376167). This is a phase 3 clinical trial of tafenoquine in combination with chloroquine for the treatment of relapsing *P. vivax* malaria. Tafenoquine (TQ, SB-252263 and WR 238605), is a new 8-aminoquinoline antimalarial drug being co-developed by GlaxoSmithKline and the Medicines for Malaria Venture with the assistance and historic support of the Walter Reed Army Institute of Research. TQ is a synthetic analogue of primaquine. TQ has shown to be well-tolerated in the treatment and prevention of plasmodial infections in pre-clinical models and during Phase 1, 2 and 3 clinical studies in >4000 subjects. Of note, TQ possesses activity against all stages of the Plasmodium lifecycle, including the dormant *P. vivax* hypnozoite. Part 1 of the current study (TAF112582) has completed and an efficacious and well tolerated TQ dose (300mg) to be used in combination with CQ has been selected. Part 2 will investigate the selected TQ/CQ regimen and its safety and efficacy in the treatment and radical cure of *P. vivax* malaria.

B. Malaria Drug Resistance Surveillance

Artemisinin based combination therapies (ACTs) are the first line treatment for drug resistant *Plasmodium falciparum* malaria. The current major global investment in ACTs is threatened by emerging and spreading of resistance to artemisinins, as signaled by a trend of increasing ACT treatment failures on the Thai-Cambodian border, which has historically been an epicenter of drug resistant malaria. There are no effective alternatives to artemisinins for the treatment of malaria either on the market or nearing the end of the drug development process. Strategies for containing artemisinin resistance require the ability to detect it rapidly and accurately, both in humans (*in vivo*) and in collected parasite isolates (*ex vivo*). AFRIMS' proven ability to monitor artemisinin resistance with a consistent regionally applied method and standards for its *ex vivo* drug sensitivity testing and *in vivo* efficacy trials is critical in this regard. Artesunate in combination with mefloquine has been the first-line drug for uncomplicated falciparum malaria on the Thai side of the border since 1995 and in Cambodia since 2000. Therapeutic efficacy monitoring is regularly conducted by both the Thai and Cambodian malaria control programs. Both progressively increased parasite clearance times and unusually high failure rates with artesunate-mefloquine have been reported recently on both sides of the border. Funding for anti-malarial drug resistance work is sourced from DoD-GEIS, WHO, MMV and the Bill and Melinda Gates Foundation.

1) Thailand

AFRIMS began working in collaboration with the Thai MOPH in Trat Province, Thailand, to investigate why the artemisin-based treatment failures described by the Thai National Malaria Program (Vijaykadja, 2006) were occurring. An integrated *in vivo*-*in vitro* approach was adopted using existing protocols. This approach comprised anti-malarial treatment in accordance with MOPH guidelines (directly observed treatment with AS (6mg/kg daily for 2 days), MQ (25mg/kg split into 2 doses) and PQ (0.5mg/kg single dose on Day 2) with all doses given as DOT), and *in vitro* culture of parasites with drug sensitivity assays at admission to the study and subsequently if treatment failure occurred. Parasite growth inhibition was used as a measure for drug sensitivity of fresh samples in a HRP2 double-site antigen capture ELISA. Follow-up had previously been to Day 28 in accordance with WHO guidelines (WHO 2003) but was extended to 42 days when AFRIMS became involved since this is the preferred duration of follow-up following MQ therapy. We found that the PCR-corrected ACPR (cure rate) at 42 days for Trat in 2005 was 81% (7 out of 42 enrolled patients failed therapy and 5 were reinfected). The second Trat study, (WRAIR #1327) started in September 2007. The study also uses an in vivo/in vitro approach yet incorporates a more detailed human use (*in vivo*) study, with plasma drug level measurements and a comparison of 2 and 3 days AS treatment. AFRIMS and the Thai MOPH worked on these trials as collaborative efforts to study and better understand artemisinin resistance resulting in malaria treatment failures, an important public health policy concern.

The *in vivo* component of these efforts aimed to compare the efficacy and tolerability of artesunate (12mg/kg) and mefloquine (25mg/kg) given over 2 or 3 days for the treatment of uncomplicated *P. falciparum* malaria in Trat Province, Thailand. Due to the changed local epidemiology of malaria in Trat and the malaria containment efforts in border districts in Trat, this site did not generate a sufficient number of enrolled volunteers with *P. falciparum* malaria before the end of the trial in 2012. The protocol is currently kept open for data analysis and submission of a final manuscript reporting results from these trials.

Concerns with regard to artemisinin resistance in *P. falciparum* parasites have extended to the Thai-Myanmar border, where cases of poor response to standard antimalarial regimens are rapidly emerging. Furthermore, *P. vivax* parasite resistance to chloroquine (CQ), the recommended first-line drug for treatment of vivax malaria, appears to be spreading towards Thailand, evidenced by elevated IC_{50} levels to CQ detected *in vitro* in *P. vivax* parasites from Thai patients, and a recent case report described a case of high-grade CQ resistance in a vivax malaria patient from western Thailand.

In collaboration with our colleagues at the Royal Thai Army (RTA) Medical Department, in 2013 we expanded our anti-malarial drug resistance work to include malaria patients presenting to RTA facilities along Thailand's other international borders. AFRIMS Department of Immunology and Medicine staff recently initiated a new malaria drug resistance surveillance clinical study with the RTA. This on-going trial,

WRAIR 1917, entitled “Evaluation of Molecular Markers of Antimalarial Drug Resistance and *In Vitro* Antimalarial Drug Sensitivity in *P. falciparum* Malaria Parasites from Patients Presenting to Thai Military Health Facilities in Thailand” involves active surveillance of malaria drug resistance in *P. falciparum* cases occurring at sentinel sites of multidrug resistance emergence along the Thai–Cambodian border. Emergence of artemisinin resistance, especially along the Thai–Cambodian border, is currently the largest threat to malaria control.

The findings from WRAIR 1917 are of significant global public health relevance. The team is responsible for providing malaria disease and drug resistance surveillance data for military populations not covered by other Thai national surveillance mechanisms. The team is developing geospatial and longitudinal associations of in vitro drug sensitivity trends, newly identified molecular resistance markers and clinical data to dramatically improve the ability to monitor and curb emerging resistance to the artemisinins and partner drugs. Through this new AFRIMS-RTA initiative, *in vitro* drug sensitivity and molecular data are being obtained to augment the harmonized data currently being generated by our other anti-malarial drug resistance projects in Cambodia. Furthermore, we wish to expand our current role to increase host nation capacity by establishing labs for analysis of known molecular markers of anti-malarial drug resistance within Thailand. Selected RTA field staff were trained in malaria microscopy in 2010 and the study initiated in June 2013, with continuing ongoing patient enrollment. We expected to enroll 40-50 cases per year during the 5 year study period.

The solidarity of the joint AFRIMS Immunology and Medicine and RTA staff was critical in establishing successful study sites capable of supporting clinical trials of rigorous international regulatory standards. Starting in 2012, the AFRIMS team skillfully and efficiently conducted field site development at two sites: a military healthcare facility at Pusaron in Kantharaluk District, Srisaket Province and at a second site in Kabchoeng District, Surin Province. The team professionally demonstrated diplomacy to surmount logistical and administrative challenges, such as acquiring RTA command level approval and training in laboratory research and study design procedures for local healthcare staff who never before conducted clinical studies. The team’s training efforts successfully resulted in developing a local healthcare staff team capable of independently conducting key clinical trial procedures, such as applying subject selection criteria, obtaining informed consent from prospective volunteers, data collection, blood collection per specific testing, adverse events recording and reporting, and timely specimen shipment to a central laboratory in Ubon-ratchathani. A further testament to the team’s dedication to the AFRIMS research mission is building Thai healthcare capacity to achieve compliance with the International Conference on Harmonization of Good Clinical Practices guidelines.

AFRIMS Department of Immunology and Medicine also initiated a second malaria drug study in Thailand in 2013. The clinical trial WRAIR 2017 is a DoD GEIS effort involving close collaboration of 3 different DoD research labs in Kenya, Peru, and Thailand at our site at the Kwai River Christian Hospital (KRCH) in Sangklaburi, close to the Thai-Myanmar border. The study required extensive coordination and frequent teleconferences and site visits to plan a methods-harmonized trial and to achieve IRB approval. The main focus of the study is to investigate artemisinin resistance trends in the 3 countries by examining the efficacy of artesunate-mefloquine (AS-MQ) in uncomplicated *P. falciparum* malaria patients and studying key parasitological, pharmacological, molecular drug resistance marker, and immunological endpoints. AS-MQ is one of the five ACT combinations recommended for the treatment of uncomplicated *P. falciparum* malaria, is commonly used in many malaria endemic regions, and is a standard treatment regimen in all three study venues. This integrated *in vivo-in vitro* therapeutic efficacy surveillance study was initiated at the AFRIMS’ malaria research center at KRCH in October 2013, and to date 8 subjects were enrolled and have completed 42 days follow up without recurrence. A total of 59 evaluable volunteers are required, and active enrollment is on-going.

2) Cambodia

Data from AFRIMS' earlier Artemisinin Resistance in Cambodia trial 1 (ARC1) study conducted in Western Cambodia in 2006 suggest that along parts of the Cambodian-Thai border, there are *P. falciparum* isolates that are highly resistant to artemisinins. Although the prevalence of these isolates was low, the overall sensitivity of the parasite isolates was significantly reduced as compared to western Thailand. In ARC1, some individual isolates were associated with greatly increased parasite clearance times, treatment failures despite 7 days of artesunate monotherapy (4mg/kg), and very high inhibitory concentrations for artemisinins *in vitro*. Reports from the Ministries of Public Health on both sides of the Thai-Cambodian border indicate increasing numbers of treatment failures with artemisinin-based combination therapies.

In 2009, the Department of Immunology and Medicine completed the Artemisinin Resistance in Cambodia 2 (ARC2) trial, a follow-up study to ARC1. The aim was to determine whether regimens with increased artesunate doses could overcome the problem of reduced drug sensitivity to artemisinins and to determine whether these experimental regimens, particularly the high-dose regimen, were safe and well tolerated. Similarly like in ARC1, the study was conducted in a purpose-built AFRIMS study ward at Tasanh Health Center in Western Cambodia, due south of Pailin and close to the border with Thailand. Tasanh Health Center and its referral health clinics stand in the middle of the crucial area of the growing reports of emergence of artemisinin resistance. The study was conducted in a designated study ward and staffed by a team of Cambodian and Thai nurses, physicians, microscopists and laboratory technicians, in close collaboration with the National Center for Parasitology, Entomology and Malaria Control (CNM) in Cambodia.

The study determined that increasing doses of artesunate monotherapy given for 7 days did not improve clinical or parasitological outcomes in Cambodian patients with uncomplicated *P. falciparum* malaria. Even with high-dose treatment (6mg/kg/day for 7 days) cure rate was 88%, comparable to previous AS monotherapy studies in terms of efficacy. However, when patients receiving AS 4 mg/kg/day in this study were compared to those treated with exactly the same regimen in our previous 2006 study at the same site, the proportion of patients still parasitemic at 72 hours had almost doubled from 29 to 56%. This finding confirms the emergence over the last 3 years of parasite strains that are more resistant to AS *in vivo*, and underscores the importance of current containment strategies.

The pharmacokinetics and pharmacodynamics of oral artesunate monotherapy were also explored as part of the ARC2 trial. Despite weight-based dosing, a wide variability in artesunate concentrations were observed. There were significant reductions in plasma concentrations between day 1 and day 7 of dosing, suggesting auto-induction of metabolic clearance pathways. Dose limiting hematologic toxicity with neutropenia in 5 of 26 subjects occurred at the 6mg/kg dose level.

In vitro drug sensitivity assays have been used as a tool to characterize the drug susceptibility phenotype of clinical *P. falciparum* isolates and to screen new candidate drugs in development. Variability in *in vitro* drug sensitivity testing throughout the malaria research world makes comparison between different data sets, different labs, and different time periods difficult. In order to develop a testable model system for generating IC50 values with patients' specimens, we finalized the evaluation of dynamics of W2 standard clones as a mechanism to establish a validated control in 2009.

After these stringent method validations, the ARC 2 study has successfully managed to culture malaria parasites and generate IC50 values for a range of anti-malarial drugs (AS, DHA, chloroquine, mefloquine, lumefantrine, quinine) from 136 fresh patient samples, the largest number of fresh parasite isolates from a single clinical study in the region. IC50 values for DHA (major artemisinin metabolite) were higher in isolates of patients with delayed parasite clearance times, indicating that prior exposure to AS and its metabolites may select for development of resistance. The *in vitro* methodology used in the ARC2 trial was used to initiate a dedicated *in vitro* survey (#WR1576) in Cambodia in 2009 for the purposes of measuring

the distribution of resistant phenotypes, as defined in ongoing clinical trials of artemisinins, and obtaining adequate numbers of samples for ongoing genome-wide association studies.

To further characterize malaria parasites collected in surrounding areas at risk, we established a reference lab at the Battambang Referral Hospital (BRH) which was put into operation in September 2009 and inaugurated by the U.S. Ambassador and the Cambodian Ministry of Health in 2010. The lab in Battambang is unique to western Cambodia, as it is the first fully functional and permanent molecular diagnostics facility in this part of the country and has provided useful data to the CNM to help identify communities at risk for drug resistance. The lab is fully equipped to support advanced malaria culture and drug efficacy studies, as well as, the analytic support for influenza molecular testing.

The major outcome of the Cambodia *in vitro* study in 2010 was to demonstrate that parasites collected in Battambang province in Western Cambodia had significantly different IC50 values for the artemisinins than parasites collected in northern Cambodia with a preliminary indication that the spread of the artemisinin resistance phenotype has not moved very far within Cambodia. More than 200 parasite samples were collected. However, in order to identify genetic signatures conferring clinical artemisinin resistance, larger numbers of parasites will need to be collected to fully characterize the underlying parasite population structure. Expansion into more provinces will provide a more robust sample set for large scale analyses.

In 2011, the study expanded to cover more areas of Cambodia including provinces in the North (Oddar Meancheay, Preah Vihear), West (Battambang, Pailin), and East (Kampong Cham, Kampong Speu) to provide comparisons between the more resistant parasites in the West, and less resistance parasites in the East. More systematic parasite collections were performed from patients with uncomplicated *P. falciparum* in an effort to improve representativeness of the sample population. To date (Dec 31 2011 update), 748 specimens have been collected of which 420 (or 56.14%) were positive for *P. falciparum*, 291 (or 38.90%) for *P. vivax* and 37 (or 4.94%) were mixed *P. falciparum/P. vivax* infections. Approximately 13.5% of the subjects tested G6PD-deficient.

In late 2012, the Department integrated 2 new components in our anti-malarial surveillance studies that will address key questions in Cambodia's goal of malaria elimination by 2025. Firstly, and in collaboration with the AFRIMS Department of Entomology, an entomological vector surveillance component was added to compare parasites from human hosts to those in circulation within vectors, including genomic signatures of selection for resistance, and the multiplicity of infection. Secondly, Immunology and Medicine added a transmission-blocking component (sexual stage) to the therapeutic efficacy monitoring of standard 3-day DHA/piperaquine treatment by randomizing volunteers in arms that do or do not receive a single oral dose of primaquine 45mg given on day 3.

Isolates of Thai and Cambodian malaria patients with treatment failures were screened for molecular markers of artemisinin resistance, in collaboration with the University of Maryland. The findings from these efforts were presented in several research symposia at recent annual meeting of the American Society of Tropical Medicine and Hygiene and also were published in peer-reviewed scientific literature. This molecular biology research has proven to be useful in measuring the present extent of resistance and guiding rational containment strategies to deter its further spread. AFRIMS also conducted drug sensitivity assays in 2009 of new and unknown anti-malarial drug candidates (on blood samples containing malaria parasites, both from patients that have successfully completed and that have failed artemisinin treatment) developed by the Medicines for Malaria Venture (MMV), a non-profit foundation created to discover, develop and deliver new, affordable anti-malarial drugs through effective public-private partnerships. The MMV project findings are soon to be published in the journal Antimicrobial Agents and Chemotherapy.

In 2012-2014, AFRIMS Department of Immunology and Medicine initiated a malaria drug treatment study in Cambodia that produced findings of great significance to the U.S. Military Malaria Research Program (MMRP) and the global health community. The focus of the trial, WRAIR 1877, entitled "Active surveillance

for *P. falciparum* drug resistance with assessment of transmission blocking activity of single dose primaquine in Cambodia" was to evaluate the efficacy and safety of dihydroartemisinin-piperaquine (DP), recently adopted as first-line artemisinin combination therapy in Cambodia. WRAIR 1877 was a two arm, open-label treatment study of adults with acute, uncomplicated *P. falciparum* malaria comparing the efficacy (42 days PCR-corrected malaria recurrence rate), safety, tolerability and pharmacokinetics of a three day course of DP with or without a single dose of primaquine. The trial was completed collection data in 2013, with the goal of enrolling 150 patients, but was ended earlier after evaluating 96 patients because the team found DP treatment failure rates that were elevated compared to a previous AFRIMS trial conducted only 3 years earlier in the same region. The result shown that PCR-adjusted 42-day recrudescence rate was 54% by modified intention-to-treat analysis. Median parasite clearance half-life was 6.4 hours, with 57% of subjects parasitemic at 72 hours. Two K13 propeller gene mutations associated with artemisinin resistance (C580Y and R539T) were found in all but 4 infections, and C580Y accounted for two-thirds. Unlike R539T, C580Y was accompanied by two other mutations associated with prolonged parasite clearance (MAL10:688956 and MAL13:1718319) not seen in a study at the same site in 2010. "Triple mutants" had higher piperaquine IC50s (34nM vs. 24nM, p=0.003) and 5.4-fold greater risk of treatment failure (HR 95% CI=2.4-12, p<0.001) compared to other infections. These findings suggestive of piperaquine efficacy being lost to resistance were critical to the MMRP's decision to de-prioritize DP as a potential malaria prophylaxis drug for use in protecting deployed Soldiers. Furthermore, the outcome of this trial is also being incorporated into national policy by Cambodian and World Health Organization public health officials in updating national malaria treatment guidelines to find an alternative to DP as first-line treatment of drug resistant malaria in South East Asia.

C. WRAIR# 1576 - Survey for *In Vitro* and Molecular Markers of Antimalarial Drug Resistance in Cambodia

Since 2009, i*n vitro* and molecular surveillance for antimalarial drug resistance has been conducted in different regions of Cambodia, aiming to define temporal and geographical trends in malaria drug resistance emergence and spread. Up to now, 932 malaria isolates have been collected from western (Pailin and Battambang), northern (Preah Vihear and Oddar Mean Chey), and southern (Kampong Speu, Preah Sihanouk, Kampot, and Koh Kong) Cambodia and tested for *ex vivo* drug susceptibility and genetic markers of resistance. In 2014, the ring stage survival assay (RSA), the new microscopy-based phenotypic assay for detecting artemisinin resistance, was established and run. Our results show emerging PPQ resistance in northern Cambodia since 2010. Artemisinin resistance markers, *P. falciparum* Kelch13 (K13) mutation and RSA results, show a high degree of artemisinin resistance in this region. Our findings suggest the reported rapid progression of clinical DHA-PPQ failure (Spring et al 2015) is associated with emerging PPQ resistance in a background of artemisinin resistance. These data were reported at the ASTMH meeting 2014, and submitted for publication in the journal, *Antimicrobial Agents and Chemotherapy*. In collaboration with the Medicines for Malaria Venture (MMV), we also conducted blinded *ex vivo* activity testing of several compounds against 200 *P. falciparum* isolates from western and northern Cambodia during 2009 and 2010, and the results were published in *Antimicrobial Agents and Chemotherapy* (Lanteri et al 2014). In addition to the *P. falciparum* resistance survey, in 2013 we also established a *P. vivax* drug susceptibility assay using a plasmodium lactate dehydrogenase (LDH) ELISA to monitor vivax drug resistance in fresh isolates. During 2013-2014, 57 fresh *P. vivax* isolates from Oddar Meanchey (northern Cambodia) were assessed for *ex vivo* sensitivity to antimalarials using the microscopy-based schizont maturation test (SMT) and *Plasmodium* pan-species lactate dehydrogenase (LDH) ELISA and genetic markers of resistance. The findings were presented in ASTMH meeting 2014, and are being prepared for manuscript publication.

The in vitro lab will continue antimalarial resistance surveillance using the standard IC50 assay, RSA, and molecular markers. The PPQ-resistant isolates with extremely high PPQ IC50 collected from Cambodia in 2014 will be sent to the University of Maryland for whole genome analysis to identify genetics responsible for PPQ resistance. To continue method validation for RSA, LDH-ELISA and/or other methods for parasite growth measurement will be tried and compared with microscopic readings, aiming to find a measurement system with less variation of RSA results than microscopic reading. To continue method validation for *P.*

vivax drug susceptiblity assay, flow cytometry and other novel methods, new media or supplements that can increase *P. vivax* growth may be tried.

D. Vaccinology & Immunology Studies in Support of Malaria Vaccine Program and Influenza Studies

1) Malaria Immunology and Vaccinology

In FY 2014, the Immunology and Vaccinology section explored local immunity which is required for protection against localized infections such as influenza, TB and malaria. We have completed a study looking at tissue distribution of memory T, B and plasma cells in rhesus monkeys following 2009 pandemic H1N1 infection. The results of this work are expected to be published in 2015. We currently investigate the role of liver-resident memory T cells in protection against *P. knowlesi* liver stage parasites in rhesus monkeys. The results from this study will help to better design malaria vaccines aiming to induce protective immune response in the liver.

2) Influenza Research

a. Evaluation of *In Vitro* Cross-Reactivity with Avian Influenza H5N1 and Swine Flu H1N1 2009 Viruses in Healthy Volunteers Vaccinated with a Prime Boost Regimen of Seasonal Influenza Vaccine

Recent studies demonstrated that vaccination with inactivated seasonal influenza vaccine elicited heterosubtypic antibodies which neutralized avian influenza H5N1. However, the induction of heterosubtypic antibodies was observed in only a small proportion of vaccines. In order to enhance HSI and evaluate the hypothesis that a prime boost seasonal vaccine regimen would enhance its development, we administered 2 dose regimens of 2009-2010 seasonal influenza vaccine 8 weeks apart to healthy adult volunteers. Twenty-six subjects, 9 male and 17 female, were randomized to receive either 2 doses of intranasal live, attenuated influenza vaccine (LAIV) (n=6), 2 doses of intramuscular inactivated seasonal influenza vaccine (IIV) (n=6), LAIV then IIV (n=8), or IIV then LAIV (n=8).

Results: We found that a prime boost regimen of seasonal influenza vaccine did not enhance cross-reactive immunity against H5N1 and 2009 pandemic H1N1.

Update: Manuscript published in PLoS One. 2013; 8(3):e59674.

b. Cross-Reactive Antibodies to Avian Influenza H5N1 and 2009 Pandemic H1N1 in Non-Exposed U.S. Military Personnel

In humans, the role of cross-protective immunity against influenza A viruses is unclear. Epidemiological data indicate that avian influenza H5N1 and 2009 pandemic H1N1 (pH1N1) unlike seasonal influenza, is less common in older persons ($\geq$60 years). This suggests that the elderly may have pre-existing immunity against some influenza A viruses. Here we comprehensively evaluated the presence of cross-reactive antibodies against H5N1 and 2009 pH1N1 in serum samples (N = 200) collected from U.S. military personnel born between 1936 and 1977 (4 cohorts, N=50/cohort; $\leq$1949, 1960-1965, 1966-1971, 1972-1977).

Results: Our results demonstrate that some U.S. military personnel have functional cross-reactive antibodies against H5N1 and 2009 pH1N1. These pre-existing antibodies may play a role in protection and reduce the severity of disease.

Update: Manuscript published in Am J trop Med Hyg, 2014, 90:149.

3) Influenza Surveillance (DoD-GEIS)

This DoD-GEIS-funded project allows for ongoing surveillance of Influenza-Like-Illnesses (ILIs) and detection of influenza and highly pathogenic influenza among vulnerable military and civilian populations in Cambodia. GEIS participates in the collection and characterization of influenza viruses circulating within the human population in Asia. Various AFRIMS departments collect respiratory specimens from sites in Cambodia, Thailand, Nepal, the Philippines, Bhutan and U.S. Embassies in Southeast Asia with plans on expansion to Cambodia and Vietnam, and definitive test results are shared with the Ministries of Health and WHO Flu Net. These surveillance data contribute towards the annual re-formulation of the influenza vaccine as well as early detection of novel influenza strains or existing subtypes with pandemic potential which can increase the lead time for implementation of control and prevention measures.

a. Sentinel Human Surveillance for Influenza in Western Cambodia (Molecular Parasitology)

i) DTRA capacity building

Since the new amendment to the protocol addressing dignitaries was approved by the Commander on 19 Sep 2014, the new program has been developing and validating rapid PCR diagnostics for characterizing influenza A/B and subtypes, as well as 24 non-influenza respiratory pathogens. Multiplex real time PCR has been developed to increase the diagnostic capacity of PCR. The term multiplex refers to the fact that detection of more than one pathogen is carried out simultaneously in one tube, as opposed to detection in several tubes carried out in parallel in which each tube contains the reagents required to detect only one pathogen. To support the mission, AFRIMS used multiplex real time PCR techniques as a unique tool for integrated training and education services. From the 15th to the 19th of October 2014, ten Cambodian field team medical research technicians received training in advanced molecular methods.

Of the 89 specimens collected in 2014, nineteen were positive (21.4%). The predominant influenza subtypes detected for 2010, 2011 and 2012 respectively were influenza B (15.2%), 2009 A/H1N1 (6.2%), and A/H3N2 (5.7%). Despite occasional occurrence of human cases in Western Cambodia, no influenza A/H5N1 has been detected at AFRIMS sentinel sites through laboratory surveillance. All the influenza positive samples were sent for sequencing at Institute Pasteur in Phnom Penh.

In order to detect influenza A/B, influenza subtypes and 24 non-influenza respiratory pathogens, researchers at Battambang Referral Hospital in Cambodia evaluated multiplex real-time PCR data collected from subjects who enrolled from four sentinel sites in four provinces in Western Cambodia starting in October 2014.

- From October 2014 to February 2015, diagnosis of respiratory pathogens taken from influenza-like illness (ILI) samples was done using multiplex real-time PCR. Of the 105 ILI patients tested, 25 were positive for influenza virus type A/H3 (24%) and 1 was positive for influenza virus type 2009 A/H1N1 (1%).

- Most of our cases from ILI samples were not caused solely by influenza. Rather, they were caused by other viruses or a combination of influenza and another virus, such as *Respiratory syncytial virus A/B, Parainfluenza 2 and 3, Adenovirus, Coronavirus NL63, Enterovirus, Human Parechovirus, Human metapneumovirus A/B* and *Human Bocavirus-infection*.

- In some patient samples, *Streptococcus pneumonia*, *Staphylococcus aureus* and *Bordetella* were detected, although these cases were less common.

- Influenza and other viruses, as well as certain bacterial infections, can cause worsening symptoms in ILI patients. Secondary bacterial pneumonia is suggested by persistence or recurrence of fever.

Regional Malaria Elimination Initiatives

Regional Malaria Elimination Initiatives: defining effective, appropriate, implementable strategies for malaria elimination in military forces in Cambodia as a model for mobile migrant populations - funded by Bill and Melinda Gates Foundation.

As multidrug resistant (MDR) malaria outpaces the development of effective antimalarial drugs, the focus of research is shifting to elimination of MDR malaria along the Thai-Cambodia border. In collaboration with the Royal Cambodian Armed Forces, this project will focus on identifying 'real world' tools via a rigorous head-to-head approach of various strategies in soldiers and nearby border populations. The primary objective will compare the effectiveness of monthly malaria prophylaxis of dihydroarteminsin-piperaquine and weekly primaquine versus a focused screen and treat protocol using Cambodia's national treatment guidelines. Secondary objectives will compare the effectiveness of permethrin-treated uniforms versus sham as well as compare commercially available rapid diagnostic tests for both malaria and G6PD deficiency versus laboratory gold standards. The trial design is a cluster-randomized controlled trial in up to 1200 soldiers stationed along the northern Thai-Cambodian border. Enrollment is tentatively scheduled to begin May 2015 pending IRB approval.

A. Status: The protocol received AFRIMS Scientific Review Committee approval in February 2015 and was subsequently submitted to WRAIR IRB.

B. Manuscripts:

1) A review of the military's role in malaria elimination was published in *Trends in Parasitology* in December 2014.

Mannig JE, Satarath P, Gaywee J, Lopez MN, Lon C, Saunders DL. Fighting the good fight: the role of militaries in malaria elimination in Southeast Asia. Trends Parasitol. 2014 Dec;30(12):571-81

2) A draft manuscript of the protocol is under preparation for submission to *Implementation Science.*

Overview of Research Projects

A. WR1877 - Active Clinical Surveillance for *P. falciparum* drug resistance and therapeutic efficacy monitoring with assessment of evidence for transmission blocking activity of primaquine in Cambodia. Status: Study initiated in December 2012 and enrollment ceased on 19 Mar 2014, as a result of detecting a relatively high proportion of treatment failures with the artemisinin combination therapy (ACT) being evaluated, dihydroartemisin-piperaquine (DHA-PPQ).

B. WR2017 - Study at the Thai-Myanmar Border as Part of a Harmonized Global Malaria Drug Resistance Surveillance Program at Overseas DoD Laboratories. Status: Study initiated in October 2014; active enrollment ongoing, 43 of 59 complete.

C. WR1917 - Evaluation of Molecular Markers of Antimalarial Drug Resistance and In Vitro Antimalarial Drug Sensitivity In *P. Falciparum* Malaria Parasite from Patients Presenting to Royal Thai Army Health Facilities in Thailand. Status: Study initiated in June 2014; active enrollment ongoing.

D. WR1317 - Efficacy of Artesunate-Mefloquine Combination Therapy for the Treatment of Uncomplicated Falciparum Malaria in Trat Province, Thailand. Status: Completed 2008. Manuscript remains in preparation.

E. Evaluation of In Vitro Cross-Reactivity with Avian Influenza H5N1 Virus in Healthy Volunteers Vaccinated with a Prime Boost Regimen of Seasonal Influenza Vaccine. Status: Completed 2012. Manuscript published in Am J Trop Med Hyg, 2014, 90:149.

F. WR1576 - Survey for *In Vitro* and Molecular Markers of Antimalarial Drug Resistance in Cambodia. Status: Enrollment Open; Multiple Publications, 1 manuscript submitted.

G. WR1630 - Human Influenza Sentinel Surveillance in Cambodia. Status: On-going at 3 sentinel sites–over 800 ILI-specimens collected since 2010- more than 30% of total specimens were influenza positive and genomes obtained for spatial molecular analysis. Manuscript in preparation.

H. WR1849 - A Randomized, Double Blind, Placebo-Controlled Clinical Trial of Monthly DHA-Piperaquine for Malaria Prevention in Cambodia. Status: Study initiated in May 2012; halted in June 2012 after reaching pre-specified cardiac safety endpoint; DSMB reviewed 15 Mar 2013. Manuscript published in Antimicrobial Agents and Chemotherapy.

I. WR1737 - An Active Malaria Epidemiology Cohort Study in Personnel and Dependents of The Royal Cambodian Armed Forces with Evaluation of a 2 Day Versus 3 Day Treatment 7 Regimen of DHA-Piperaquine for Patients with Uncomplicated Malaria. Status: Completed. Primary manuscript published in PLoS ONE 2014. 9(3): e93138, and a second manuscript published in J Clin Micro, 2014.

J. WR1396 - Artemisinin Resistance in Cambodia II (ARC2 study). Status: Approved by WHO and Cambodia; parasite data included by WWARN/MORU for meta-analysis. Last manuscript is in preparation.

K. Sentinel Human Surveillance for Influenza in Thailand. Status: Closed 2013. Data analysis is ongoing by Department of Virology.

L. Comparison of Malaria SYBR Green I Fluorescence (MSF) and Histidine-Rich Protein 2 Enzyme-Linked Immunosorbent (HRP2 ELISA) Assays for measuring *in vitro* drug susceptibility of *Plasmodium falciparum* reference clones and fresh ex vivo field isolates from Cambodia. Status: Manuscript published in Malaria Journal 2013, 12-239.

M. Ex vivo activity of anti-malarial candidate compounds from MMV against multi-drug resistance *P. falciparum* isolates from Western Cambodia. Status: Manuscript published in Antimicrobial Agents and Chemotherapy.

N. *Ex vivo* drug susceptibility and *Plasmodium falciparum* multidrug resistance gene 1 (pfmdr1) profiling of clinical isolates from Cambodia in 2008-2013 suggesting emerging piperaquine resistance. Status: Manuscript submitted to Antimicrobial Agents and Chemotherapy.

O. A comparison between *ex vivo* and *in vitro* antimalarial susceptibilities for *P. falciparum* from Cambodia. Status: AFRIMS *In vitro* analyses of samples complete; undergoing molecular characterization at University of North Carolina.

P. Analysis of plasma samples from malaria patients for *ex vivo* antimalarial activity in a *P. falciparum* bioassay to help with interpretation of clinical findings in malaria trials. Status: Continuing project; sample testing and data analysis ongoing.

Q. Building Capacity for Disease Surveillance in Cambodia, Defense Threat Reduction Agency (DTRA) funded project. Status: AFRIMS team is supporting and augmenting the febrile diseases surveillance mechanisms and reporting used by the Ministry of Health (MoH) of the Kingdom of Cambodia. Training on Surveillance Investigation and Outbreak Response, was conducted by AFRIMS on 3-5 June, 2013 at the Apsara Angkor Hotel, Siem Reap, Cambodia with 15 Trainers and 67 participants. Since 2013, our surveillance team in

Cambodia detected 6 new human cases of avian influenza H5N1. To further build capacity of the Cambodian field team to detect a panel of common febrile illnesses, the AFRIMS team is conducting training and transfer of laboratory technology, to establish the capabilities of a multiplex real-time PCR assay with Fast track diagnostic kits, for CNM medical research technicians.

R. Development of a Safe and Reproducible Human Sporozoite Challenge Model for *Plasmodium vivax* for Use in Healthy Adults in Thailand. Status: WRAIR DHSP unilaterally withdrew the protocol after 1 year, pending USAMMDA DRAC review. New plan underway to collaborate with Faculty of Tropical Medicine, Mahidol University.

S. *Leptospira* (LPS assay) RAPID PCR Validation Using JBAIDS Molecular Assay Transition Package. Status: This MIDRP Sto L project completed in 2013. Poster of results presented at the ASTMH annual meeting in Washington, DC, Nov 2013. Manuscript is in preparation.

T. A multi-centre, double-blind, randomized, parallel group, active-controlled study to evaluate the efficacy, safety and tolerability of tafenoquine (SB-252263, WR238605) in subjects with *Plasmodium vivax* malaria, Phase 3 trial in Cambodia (in collaboration with GSK). Status: Study initiated January 2015, actively enrolling.

U. Comparison of atovaquone-proguanil and artesunate atovaquone-proguanil for the treatment of uncomplicated *P. falciparum* malaria in areas of multidrug resistance in Cambodia (in collaboration with NAMRU2). Status: Study initiated December 2014, actively enrolling.

V. Defining effective, appropriate, implementable strategies for malaria elimination in military forces in Cambodia as a model for mobile migrant populations. Status: Bill and Melinda Gates Foundation new research award 2013; Protocol submitted to the WRAIR IRB Feb 2015.

Other:

Awards:

A. Group Eagle Award for FSN staff, U.S. Embassy Bangkok

B. AFRIMS Group Award for CA staff, Armed Forces Research Institute of Medical Sciences

These group awards are for outstanding teamwork and performance of the AFRIMS Department of Immunology and Medicine's clinical, research and administrative staff in successfully establishing and executing two clinical field studies in Cambodia and Thailand in 2012-2013: WRAIR# 1877 and
WRAIR# 1917.

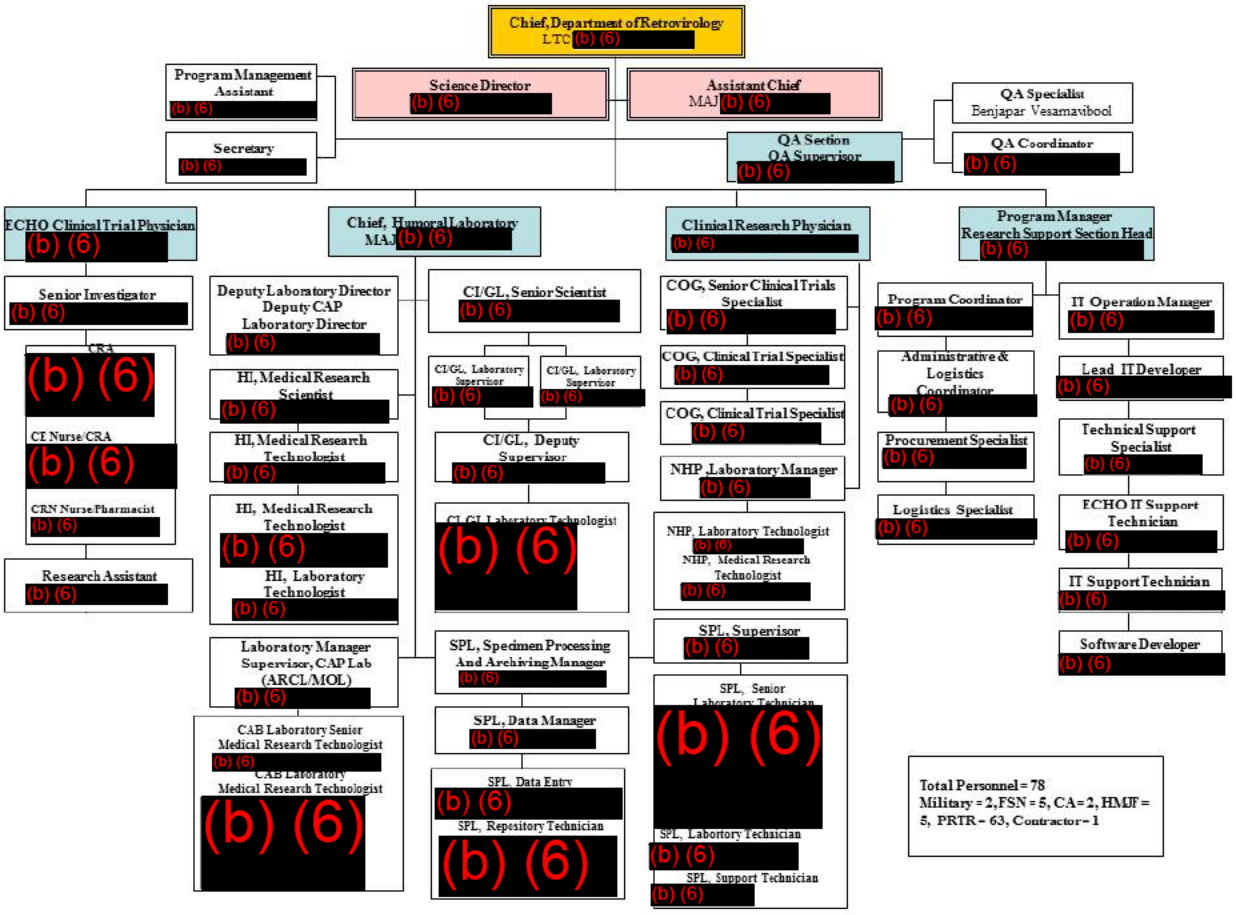
DEPARTMENT OF RETROVIROLOGY

Mission:

The Department of Retrovirology will support the mission of the Military HIV Research Program (MHRP) to protect the U.S. Military from HIV and improve global health by conducting research to develop an HIV vaccine, reduce new infections and find a cure.

Organization and Personnel:

The Department of Retrovirology consists of 78 total personnel, led by 2 active duty U.S. Army (1 Medical Corps and one Medical Service Corps). In addition, the Department includes 5 Foreign Service Nationals, 2 RTA-Cooperative Agreement personnel, and 64 total contract personnel.



Statistical Data:

There are many possible output measures that could speak to the productivity of the Department. One of those is the number of clinical studies that are supported. At the end of 2014, The Department supported 15 active human clinical trials, 4 under investigational new drug (IND) status, and 11 non-IND. In addition, the Department continues to support 5 human clinical trials that are no longer active in the clinical phase but are still open for laboratory analysis. Gearing up for such studies takes a tremendous amount of work in every case. During 2014, the Department supported initiation of 11 studies that will soon commence: 6 IND studies, and 5 non-IND studies.

The clinical and research laboratories were extremely busy, conducting 18 discrete assays on a total of 31,590 samples, in addition to all required specimen processing, shipment, and handling. Nine additional assays were performed to support exploratory scientific analyses, with in excess of 1,200 of these performed. Finally, the Non-human primate laboratory performed 14 different processes, including 3401 individual assays.

Healthcare Delivery:

The Department does not provide healthcare delivery per se. However, good clinical practice requires very high quality laboratory standards when clinical trials require laboratory testing on human volunteers be given to those volunteers. Because of this requirement, the Department's clinical laboratory has been and remains, accredited by the College of American Pathologists, and possesses a Clinical Laboratory Improvement Program (CLIP) high complexity registration.

Training and Education:

Extensive training activities occur every year. In 2014, the following took place:

A. **In-House Training Programs Provided by/or to the Department**

1) CITI Program Training on "Biomedical Research Support Staff", OnlineTraining

2) DAIDS Guidelines for Good Clinical Laboratory Practice Standards Version 3.0, 09 July 2013: Self Reading

3) Training for fire alarm system at HVRC Lab [5/29/2014]

4) BioRad Genscreen Ultra HIV Ag-Ab Assay, Bio-Rad Thailand [6/3/2014]
5) NIAID GCP Learning Center (Course 1: History, Course 2: Regulatory Framework, Course 3: Planning Human Subject Research, Course 4: Conducting Human Subject Research), Completion, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Online Training [10/15-16/2014]
6) Human Subjects Protection (HSP) and Good Clinical Practice (GCP) Training: Introduction [10/16/2014]

7) Accuracy checking and operation of the Electronic Balance, METTLER TOLEDO Model: AX205DR, MELTTLER Thailand [11/13/2014]

8) Praxair LN2 Silo Operation and Maintenance training, PRAXAIR Thailand [12/11/2014]

B. **Outside Training**

1) The 17th Bangkok International Symposium on HIV Medicine 2014 [1/14-16/2014]
2) Effective Use of Biological Cabinet and Certification Overview Workshop: Myths and Facts" by CDC and AFRIMS, Rama Gardens Hotel, Bangkok, Thailand [1/15-16/2014]

3) Retroviruses and Opportunistic Infections (CROI) 2014, Boston, USA [3/3-6/2014]

4) Transport of Biomedical Material (TBM) Course by (b) (6) and (b) (6) [4/28/2014]

5) Henry M. Jackson Foundation International Management Workshop,USA [9/15-19/2014]

6) HIV RESEARCH FOR PREVENTION (HIVR4P), the Cape Town International Conference Centre, Cape Town, South Africa [10/28-31/2014]
7) Thailand Laboratory Accreditation (LA) Forum 2014, IMPACT Forum, Muangthong Thani, Nontaburi, Thailand [11/30-12/2/2014]

C. **Millitary**

1) Privacy Act and HIPAA Operations Refresher, OnlineTraining

2) Science and Technology Management (STM) Course - Prerequisites: STM 202 [11/14/2014]

3) Science and Technology Management (STM) Course - Prerequisites: STM 303 [11/21/2014]

4) Military Malaria Research Program [3/18/2014]

Research and Development:

The Department conducted activities in four major areas: HIV vaccine trials, acute HIV infection trials, non-human primate studies, and laboratory quality assurance support for the President's Emergency Plan for AIDS Relief.

Resource Management and Budget:

The Department operates on an $11M annual budget. The largest proportion of funds come from the Division of AIDS, National Institute of Allergy and Infectious Diseases, National Institutes of Health, and the U.S. Army. Minor contributors include the State Department via the President's Emergency Plan for AIDS Relief, and the Bill and Melinda Gates Foundation.

Information Management:

The Department supports specialized information systems to manage clinical trial visits (CAST), and to manage specimens (Freezerworks). Both of these systems are extremely important to efficient operation of research activities.

Modernization:

A major effort completed in 2014 was installation and activation of a liquid nitrogen distribution system for the HIV Vaccine Research Center of Excellence specimen repository. This system not only saves electricity cost, it also provides more secure storage for precious clinical trial specimens.

Construction:

Health and Environment: Department personnel are fully integrated into the occupational health programs administered by USAMC-AFRIMS. These include prevention and management of occupational exposures to bloodborne pathogens, as well as a latent tuberculosis management program.

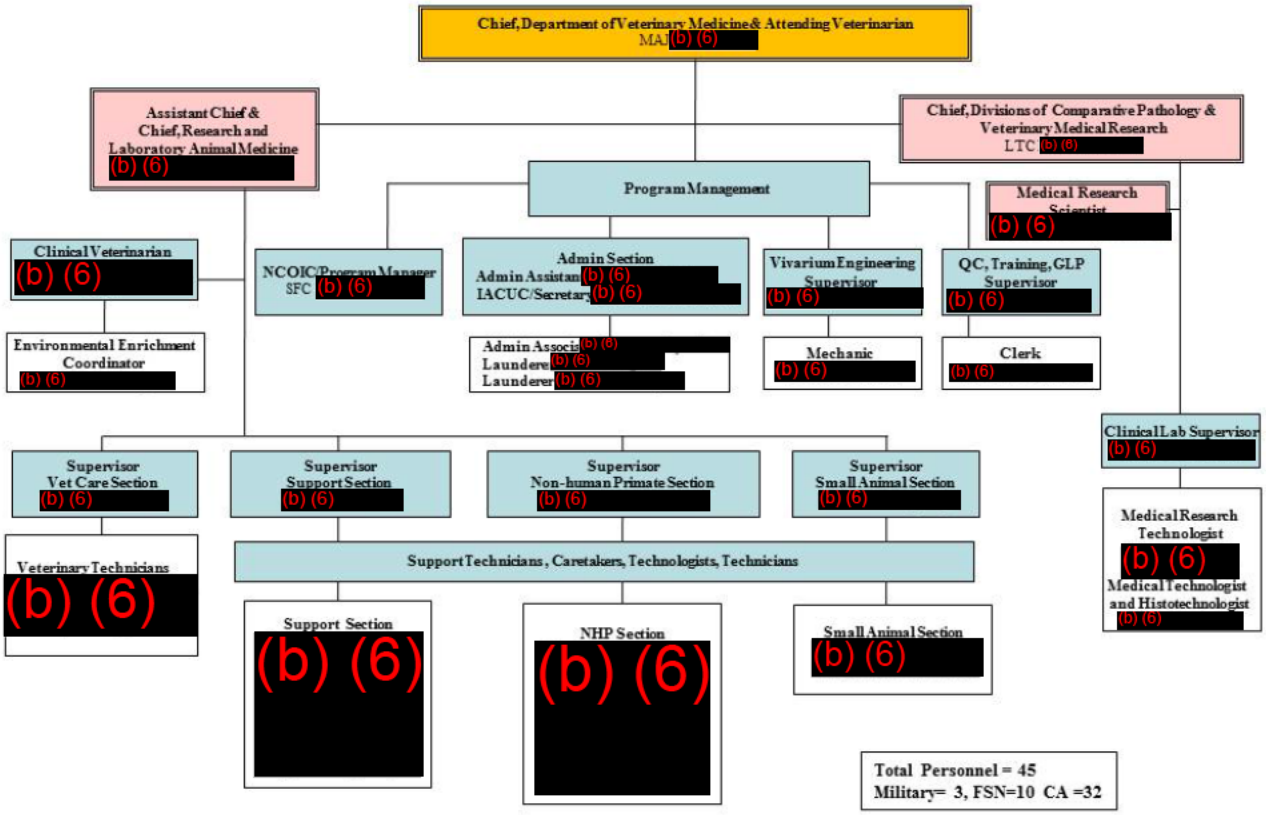
DEPARTMENT OF VETERINARY MEDICINE

Mission

To protect military personnel and their families against tropical disease threats through pre-clinical product development of new prophylactic and therapeutic drugs and new or improved vaccines.

To fulfill this mission, the Department of Veterinary Medicine (DVM) conducts bio-medical research in animal models and zoonotic disease surveillance, provides veterinary expertise and research animals that are free of confounding diseases to intra- and extra-mural collaborators, and ensures that all animals receive humane, proper, and safe care and that the USAMC-AFRIMS' Animal Care and Use Program complies with appropriate laws, regulations and guidelines.

Organization and Personnel:



The department has three branches: 1) Program Management, 2) Pathology, and 3) Research and Laboratory Animal Medicine (RLAM). The Department Chief directly supervises the Program Management and RLAM branches and provides administrative oversight to the Pathology Branch. The RLAM branch provides administration of animal resources, animal health and surveillance, veterinary care, research and protocol support,

personnel training, and lab animal conduct and is divided into four sections: Nonhuman Primate, Small Animal, Support, and Veterinary Care.

The department currently consists of 3 military, 10 FSN, and 32 Cooperative agreement personnel. A new position was approved in 2014, and the title is "Environmental Enrichment Coordinator." This position is responsible for developing, managing, and coordinating the enrichment program to provide well socialized laboratory animals for research purposes in compliance with standard operating procedures, DoD, federal and local agency regulations. The position ensures appropriate compliance with social housing requirements of the most recent version of the "Guide for the Care and Use of Laboratory Animals" (NRC, 2011).

Statistical data:

Malaria Research

1) One experiment for the ongoing efficacy model for drug development and therapeutics in the nonhuman primate (*Macaca mulatta*) was conducted in 2014. This model provides a mechanism to identify effective new drugs for the enhanced prevention and treatment of malaria infections. The experiment conducted was for WRAIR-ET. 2 naïve monkeys were used for control. 20 naïve monkeys were used for prophylaxis treatment, and subsequently analog triazines, antimalarial compounds, were administered.

2) An experiment was conducted evaluating the use of Methylene blue as a radical cure agent for severe malaria in the Rhesus macaque. This model was refined through repeated experiments in 2014 and validated through the use of the model in this drug study. Six (6) research experienced Rhesus macaques were used for model refinement and description of pathogenesis of disease induced by *Plasmodium coatneyi* and 9 research experienced animals were used for the drug trial, which comprised of 2 cohorts of different drug doses.

B. Research Support

1) Active research: The DVM provided research support to five departments at the USAMC-AFRIMS for 15 active animal use protocols studying disease mechanisms of and developing therapeutics and vaccines for tropical disease threats in Southeast Asia.

2) Breeding Colony: The DVM maintains breeding colonies of rhesus monkeys and rodents to support the USAMC-AFRIMS research needs. Sixty-one (61) baby rhesus macaques were born in the colony. 4264 ICR mice (*Mus musculus*) were produced and 1864 mice were used for active protocols. Thirty six (36) ICR mice were used for one protocol to maintain mosquito colonies.

3) Clinical Laboratory support: The veterinary clinical laboratory is an integral part of the research support efforts for malaria drug development, malaria vaccine testing, drug-drug interaction investigation, dengue anti-viral drug development, diarrhea model development, and SHIV model development. The clinical laboratory performed nearly 2577 malaria parasite counts, 864 doses of test compounds, 2281 complete blood counts, 4936 serum chemistries, and 3861 tissue sections.

C. Publications: The DVM has directly contributed to 133 published scientific articles dating back to 1966. In 2014, a total of 12 journal articles were published with DVM authors.

Veterinary Services:

Departmental goals

A. Continue to use and improve animal models of malaria in nonhuman primates. This effort will include not only the relapsing malaria model for *Plasmodium cynomolgi* but also a model of severe cerebral malaria (*Plasmodium coatneyi)* and the fifth human malaria *Plasmodium knowlesi.*

B. Develop new animal models of human disease, including a natural challenge Rhesus scrub typhus model in collaboration with Mahidol-Oxford Research Unit.

C. Rhesus dengue vaccine models for two large long-term immunity studies.

D. Maintain GLP capabilities for preclinical studies.

E. Continue to develop partnerships for testing vaccines and therapeutics against dengue fever in the rhesus macaque model.

F. Continue to develop animal models of human disease, including a Rhesus simian-human immunosuppressive virus (SHIV) model in collaboration with the Military HIV Research Program (MHRP).

G. Develop the training program in rhesus monkeys for blood collection techniques utilizing positive reinforcement.

H. Provide expertise and assistance to support development of a regional primate center in Thailand

I. Provide expertise, training and assistance to the Chulalongkorn University, Department of Veterinary Pathology, through technician exchanges and direct training of faculty and students.

J. Continue to support the USAMC-AFRIMS research mission by providing veterinary expertise and animal resources for product testing.

K. Continue to maintain an exceptional animal care and use program and prepare for the 2017 AAALAC site visit.

Training and Education:

A. Outside Training of Departmental Personnel

1) The 8th Thai Association for Laboratory Animal Science Annual Training and Workshop "Institutional Animal Care and Use Committee (IACUC) and Current Issues in Laboratory Animal Research" Bangkok, Thailand, 17-19 September 2014.

B. Training of non-AFRIMS personnel

1) AALAS certification training/testing: The DVM organizes and conducts weekly American Association for Laboratory Animal Science (AALAS) certification training and serves as an official testing site. Training was held for one hour twice weekly (8 times per month) for a total of 35 classes in 2013. All DVM personnel and personnel from outside collaborating institutions who work with laboratory animals are encouraged to participate in the AALAS certification course. The supervisors and qualified technicians conducted the regular classroom training for staff seeking all levels of AALAS certification. The AFRIMS' English teacher set up a course called "Essential English for AALAS ALAT Certificate Seekers," which was held every week on Wednesday from 1500-1700 (total of 32 classes). The 3 levels of certification (in order, from most difficult to least difficult) are Laboratory Animal Technologist (LATG), Laboratory Animal Technician (LAT), and Assistant Laboratory Animal Technician (ALAT). AFRIMS-DVM serves as Thailand's AALAS Certificate official testing site for institutes and agencies outside of AFRIMS; (i.e., Chiang Mai University, Chulabhorn Institute of Research, etc.). Twenty (20) personnel were trained. AALAS certification exam was held on 3 July 2013 with 10 personnel testing from AFRIMS, CRI, and Chiang Mai University.

2) Pathology training:

a. The pathology division has provided direct training to veterinary pathologists, veterinary students and PhD students at Chulalongkorn University as well as at several regional meetings on topics of zoonotic disease pathology, fish and wildlife pathology, histopathology description, macroparasite histopathology and has been involved in the early stages to enable the establishment of a Thai veterinary pathology training center with a regional board examination.

b. Additionally, the veterinary pathologist has led necropsy training in Lao-PDR in support of their National Animal Health Laboratory, providing both didactic and hands-on practical training in a variety of areas deemed to be lacking in the Lao public health infrastructure. The intent of the ongoing project is to train from "death to diagnosis," extending from the incident (field site, slaughter house, necropsy floor) to the point of sample receipt and subsequent diagnosis by laboratory personnel.

Research and Development:

A. The research protocols supported in FY14 included the following:

1) *Antimalarial Drug Efficacy Testing in the Rhesus Monkey (Macacamulatta)/ Plasmodium cynomolgi Malaria Models.* One experiment using 22 naïve monkeys for prophylaxis treatment was conducted in 2014 for WRAIR-ET. Subsequent analog triazinescompounds were tested.
2) *Care and Maintenance of Rhesus (Macacamulatta) and Cynomolgus (Macacafascicularis) Monkeys and Management of Breeding Colonies:*Sixty-one baby rhesus monkeys were born this year. Our production of rhesus in the USMAC-AFRIMS colony was slightly higher than the target goal of 50 this year: two protocol studies using 23 naïve monkeys were conducted this year.
3) *Care and Maintenance of Laboratory Rodents and Rabbits, Maintenance of Rodent Breeding Colonies and Quality Assurance/Quality Surveillance Program:* 4264 ICR mice (*Musmusculus*) were produced, and 1864 ICR mice were used for six active protocols. This year, 502 mice (BALB/C and C57BL6) were outsourced from National Laboratory Animal Center (NLAC) for utilization on two studies.
4) *Mosquito Feeding Using In Vitro and In Vivo Techniques with Mice (Musmusculus) as a Blood Source:* 36 culled mice were used to maintain mosquito colony.
5) *Pathological Response to Infection by O. tsutsugamushi and Dissemination in Inbred Mice, Based on Variable Duration of Feeding By Naturally Infected Leptotrombidium Chiggers:* 20 mice (10 BALB/C and 10 C57BL6) were used in 2014.
6) *Maintenance of the Leptotrombidium Larval Mite Colonies: Chigger Feeding on ICR Mice (Mus musculus):* 611 mice were used to maintain the chigger mite colony.
7) *Inoculation of Dengue Viruses in Suckling Mice:* 855 mice were used to produce high titers of dengue virus antigens.
8) *Potential Protective Activity of a Novel Capsid- Envelope Domain III Dengue Virus Vaccine Delivery by BCG Nanoparticle:* There were 2 experiments using 144 mice that conducted this year to validate the level of dengue viremia and to test vaccine-derived immunity.
9) *Establishment of an ICR mouse (Mus muculus) challenge model for Salmonella Typhimurium and enterotoxigenic Escherichia coli, and evaluation of recombinant S. TyphimuriumSTΔ aroA/ΔhtrA CJ0113/PAL/cHMGB1 and killed Bacillus subtilis 1A857 vaccine candidates in the ICR mice model:* 168 ICR mice and 482 BALB/C mice were utilized for establishing a viable challenge model for *Salmonella*Typhimurium (ST) and ETEC infection in ICR mice and to evaluate recombinant live double-attenuated *S.* Typhimurium STΔaroA/ΔhtrA CJ0113/PAL/cHMGB1 and killed *B.subtilis* 1A857vaccine candidates
10) *Efficacy of IV Methylene Blue vrsus IM Quinine as Antimalarial Therapy in the Rhesus Monkey (Macacamulatta)/Plasmodium coatneyi Model of Severe Blood-Stage Malaria:* The rhesus monkey/*P. coatneyi* severe malaria model to evaluate the overall safety of IV Methylene blue (MB) in severe malaria was also conducted in 2014. This model appears to mimic closely several features of human severe malaria *P. falciparum*. Besides this, MB has been shown previously in both human and animal studies to be safe and efficacious in the clearance of blood stage malaria parasites in uncomplicated malaria. However, it is unknown how subjects with severe malaria and, in particular, those with cerebral malaria will respond to MB. 3 experiments were commenced this year. 15 splenectomized and 4 spleen-intact monkeys were used for refining the *P. coatneyi*severe malaria model and MB efficacy testing.

11) *Polytopic Monovalent Dengue Vaccination Compared to Monotopic Tetravalent Dengue Vaccination in Macaca mulatta:* There were 4 monkeys that were utilized for determining thepolytopic monovalent vaccination immunity and performing efficacy testing.
12) *Characterization of the Disease Course and Immune Response of Scrub Typhus in Rhesus Monkey (Macaca mulatta) to Increasing Doses by Intradermal Injection of Orientia tsutsugamushi:* 20 monkeys were used for establishing the model in rhesus monkeys by using three different inoculation dosages (10^6, 10^7, and $10^{7.8}$ $muLD_{50}$). In addition, the study also determined the temporal dynamics of clinico-immuno-pathological correlates associated with higher inoculum dosages ($10^{7.8}$ $muLD_{50}$ vs. 10^6 $muLD_{50}$ and evaluated a new disease severity scoring system, which allows severity stratification according to a panel of selected markers.
13) *Development of a Challenge Model of Simian Immunodeficiency Virus Infection Utilizing Simian-Human Immunodeficiency Virus (SHIV) in the Rhesus Monkey (Macacamulatta) based on a Clade C Human Immunodeficiency Virus Isolate from Eastern Africa:* There were 14 monkeys that were utilized within this year for identifying the minimal dose of SHIV-C required to consistently infect male macaques via the intrarectal route and female macaques via the intravaginal route.
14) *Induction of sterile protective immunity in rhesus monkeys immunized with live P. knowlesi sporozoites under drug treatment:* One naive monkey was used this year for evaluating whether treatment with oral chloroquine (CQ) inhibits *P. knowlesi* blood stage infection and to determine the time required to completely eliminate CQ levels in the blood.
15) *Generation of antigen-specific memory T cells in the lungs of rhesus monkeys infected with influenza viruses and the impact of aging:* Animals of 2 different age groups (old >18 years old and young adult 6-8 years old), consisting of a total 20 rhesus monkeys, were using for comprehensively investigating the generation of antigen-specific memory T cells in the lungs after infection with influenza A/California/07/09 H1N1 virus.

Resource Management and Budget

A. Agreements:

1) MOUs: No active MOUs.
2) CTAs: No active CTAs.
3) CRADAs:
    a. Mahidol-Oxford Research Unit, AFRIMS-Entomology and AFRIMS-DVM engaged to perform work on Scrub typhus development in rhesus monkeys.
    b. GlaxoSmithKline, Belgium, AFRIMS-Virology and AFRIMS-DVM engaged to perform work on novel anti-viral compounds for dengue fever virus using a collaborative research and development agreement.
    c. Novartis, AFRIMS-Entomology and AFRIMS-DVM engaged to produce *Plasmodium cynomolgi*-infected blood products utilizing a Rhesus Monkey (*Macaca mulatta*) Malaria Model

B. Budget:

Federal funding supports a portion of the animal research conducted at USAMC-AFRIMS. Typically one third to one half of the annual budget for animal research comes directly from a combination of Department of Defense funding sources, including general and administrative (G&A) WRAIR funding sources, the Military Infectious Disease Research Program (MIDRP). Additional research funding is received from private sector sources through Cooperative Research and Development Agreements (CRADAs).

The Department receives an annual allocation of funds to support the departmental operating budgets. The majority of the allocated funding to maintain the animal colony is derived from MIDRP and G&A. Based on the data from preceding years, the majority of the allocated amount is used to support the departmental salaries and benefits. The allocation amount tends to increase each year.

Budget changes will directly impact the operational expenses, resulting in rearrangement of expense priority (operational items, must-have or should-have items) as well as new facility planning or renovation of the existing facility which requires a long-term budget forecast.

Information Management:

There have been significant improvements and upgrades in network security initiated by the AFRIMS' IT group over the past year; however, these activities have not negatively impacted the Department. Section supervisors utilize personal computers which are connected to the LAN, and work stations are shared among the technicians.

Operations:

A. Operational Success: Association for the Assessment and Accreditation of Laboratory Animal Care, International (AAALAC) accreditation renewal, Feb 2014
B. During the AAALAC site visit in February 2014, site inspectors provided six notes of commendations, no issues of significant concern, and a few suggestions. Formal AAALAC Council provided official results in May of continued full accreditation.
C. The AFRIMS DVM, safety, occupational health, QAU, IACUC and other support functions were critical components of this successful site visit. Also, input from MRMC facilities, WRAIR facilities, WRAIR Vet Med, and ACURO office were exceedingly helpful to ensure mission success.
D. Operational Risk: CITES
E. In addition to the protocol support and departmental goals of DVM, outlined previously, for the several years we have been working through a complex issue related to both CITES and the Nagoya protocol. In 2011, the Government of Thailand promulgated regulations to implement the 1992 Convention on Biological Diversity and the 2011 Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity. These regulations were adopted in Thailand as the National Conservation and Utilization of Biodiversity Commission's Rules and Measures for Access to Biological Resources and Benefits Arising from Their Utilization B.E. 2554 (2011). The intent of the regulations is to ensure the conservation of biological diversity, the sustainable use of its components, and promote and safeguard the fair and equitable sharing of the benefits arising from the utilization of local genetic resources.
F. It is a point already settled by MRMC lawyers and Thai lawyers that AFRIMS colony of non-human primates (NHP), though they are of Indian origin and bred entirely for research purposes, are considered a Biologic Resource of Thailand and the Royal Thai Army is the Government Agency which has the power and duties to study, research, publish, possess or distribute the biological resource under the law. Therefore, in order for USAMC-AFRIMS researchers (foreign researchers) to "access" this resource (i.e., conduct experiments using the NHP), sharing of benefits with the RTA and Thailand must be demonstrated. The Nagoya protocol specifies the types of "benefits" that can be shared and these include monetary and non-monetary.
G. Despite these challenges, we have developed a process by which we successfully received several CITES export permits from DNP after an 18 month period in which none were given. We have been successful when we have been clearly able to demonstrate the research project was basic science in nature (no commercial interest), and the highly technical and specific testing to be done on the NHP samples could not be done anywhere in Thailand.

Modernization:

The Department has evaluated equipment and processes in order to optimize and modernize the facility. To improve the facility's capability, a the department acquired both a fluorescent microscope which will be used for double labeling immunofluorescent staining and a pressure cooker for antigen retrieval method. Both pieces of equipment will markedly improve the quality and productivity in the newly established immunohistochemical (IHC)

staining laboratory under the Department's pathology section. This new laboratory will allow the Department to perform high quality IHC staining in support of a wide range of research studies, as well as support routine diagnostics of the health of the vivarium. Additionally, a second Olympus light microscope was installed and equipped with both a teaching arm and an updated DP73 digital camera.

Logistics:

A. Medical Maintenance Branch (MMB, Logistics Department) provides preventive maintenance services semi-annually and repairs medical equipment as needed. In some cases where local distributors are available, preventive maintenance of medical equipment is contracted. Such equipment includes steam sterilizers, cage washers, x-ray machines, and steam generators. In these cases, all work activities for medical equipment is monitored by MMB.

B. Facility Management Office (FMO, Logistics Department) in 2014 completely registered all facility equipment in the vivarium into the computerized database DMLSS. This allows FMO to track preventive maintenance services and repair work. DMLSS is designed to be a tool for the user and FMO to improve the lifecycle management of facility equipment and infrastructure.

C. Some MMB technicians have not been able to enter into the vivarium for approximately six months (Sep 14-Mar 15), which has impaired their ability to provide services effectively. A DVM occupational health representative is assigned to coordinate with MMB and the Occupational Health Office to perform health screening and training (IAW SOP VET-GP-001) on an annual basis. However, it should be closely coordinated to ensure that all MMB staff members are in compliance with the requirements prior to scheduled vivarium entry.

Construction:

A. Significant planned construction projects for FY15 and FY16

1) Construct dirty airlock for the vivarium loading dock (COR 9 - west)
2) Repair broken partitions in sewage tanks for the ABSL-3 containment (AB2)
3) Construct interstitial floor above ABSL-3 containment (ABSL-3)
4) Install ventilation system for the clean airlock of the vivarium (M5)
5) Renovate roof, gutter, and stairway for the office loading dock (COR 10 – west)
6) Upgrade BAS for ABSL-3 HVAC system (A12)
7) Upgrade fire pump system for Building 5 (Pump house)
8) Elevate booster pumps up 0.5m to prevent damage by flooding (Pump house)
9) Install RO system and feeders for animal rooms (CD roof)
10) Install RO system for steam generators & cage washers (M4)
11) Elevate towers for water backup tanks to 15m height in order to generate 30psi (CD roof)
12) Upgrade duct heaters for the ABSL-3 (B-roof)
13) Renovate the clean cage storage to be able to keep all cages (BC1, M3)
14) Upgrade roof gutters and downspout for the vivarium (wing)
15) Upgrade roof membrane on roof of Building 5 (Roof)

B. Ongoing significant construction projects

1) New epoxy floor in wing A and wing B.
2) New ventilation system in wing C and wing D.

C. Completed projects with effective dates

1) Upgrade feed storage, room 002: February 2015.
2) Replacement of roof insulation of the vivarium: December 2014
3) New lightning protection system: September 2014.

4) New ethylene oxide sterilizers in room A13: June 2014.

Health and Environment:

All potential exposures, accident, injury/illness, exposures to an infectious substance and unsafe or unhealthful working conditions are reported to the immediate supervisors and the Occupational Health and Safety Officer for evaluation in accordance with AFRIMS and DVM SOPs. Diagnostics, therapeutics, and other medical treatments are provided to potentially exposed employees as required.

In 2014, one monkey was euthanized and necropsied as part of a research protocol and was subsequently found to be positive for tuberculosis. The Occupational Health and Safety Department, in concert with the DVM, performed an epidemiologic investigation for both humans and animals, screened for TB, and provided follow-up for two potentially exposed DVM personnel who demonstrated serologic conversion.

Other:

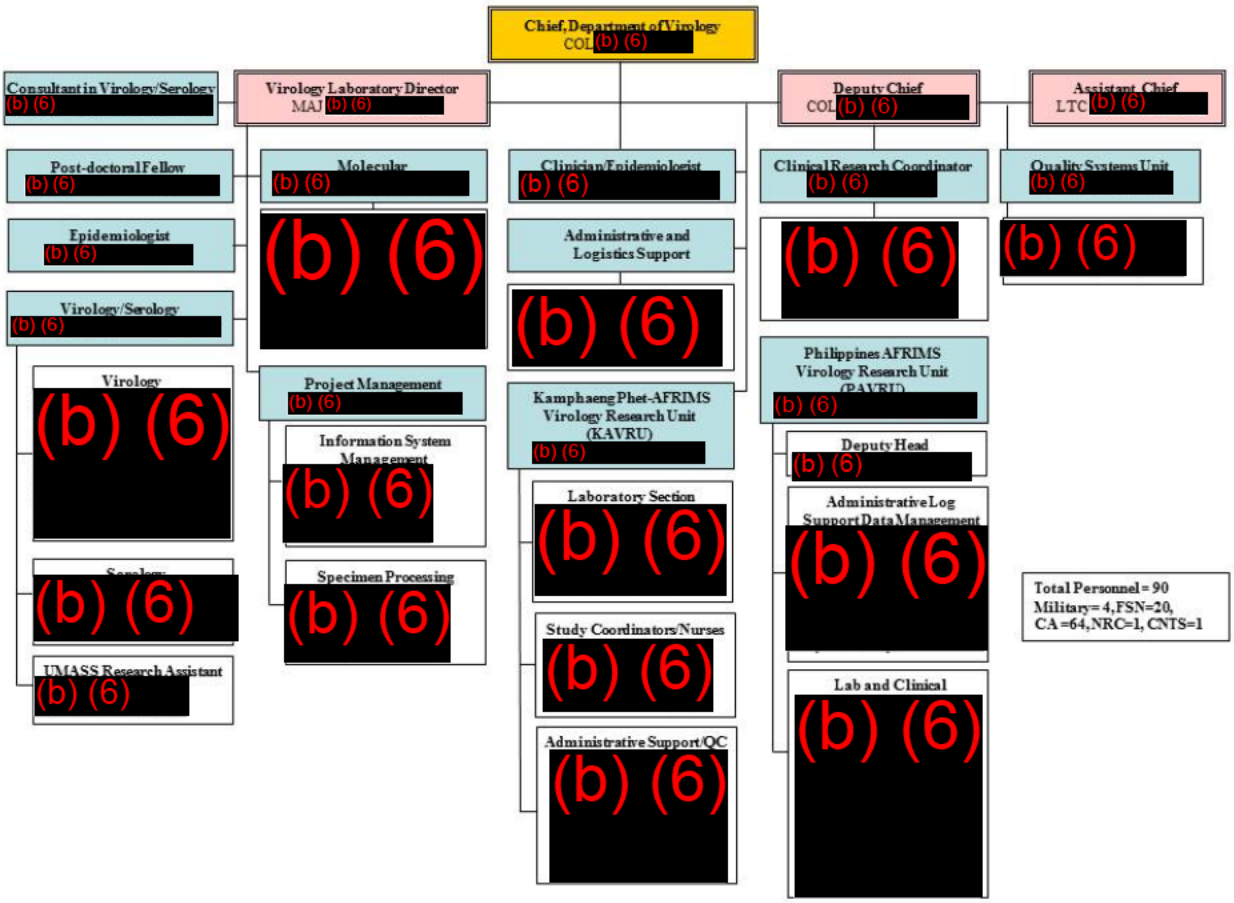
In 2014, a new position, that of a full-time Environmental Enrichment Coordinator, was created to manage behavior issues and pairing and group housing (including all associated documentation) and other aspects of animal social housing mandated by the newest version of *The Guide for the Care and Use of Laboratory Animals* (NRC, 2012).

DEPARTMENT OF VIROLOGY

Mission:

To develop and evaluate products, and collect epidemiologic data to protect the soldiers and citizen from infectious diseases.

Organization and Personnel:



Statistical data:

FIGURE 1: Workload Summary

Function	Workload	Workload Count
Function #1: Clinical trials and research execution	Research studies prepared and conducted	30
	Datasets analyzed	15
	Reports generated to stakeholders and regulators	100
	Reports in medical literature	20
Function #2: Biological sample and data management	Samples received, processed, inventoried, stored and monitored	15000
	Freezers maintained and monitored	40
	Reagents/supplies received, inventoried, stored and distributed	1000
	Databases developed and maintained	20
	Data entries into databases	50000
Function #3: Research coordination and compliance	Research studies or experiments coordinated, monitored, or regulatory files maintained	30
	Audits or reviews conducted or coordinated	10
Function #4: Public health testing, training and capacity building	Public health samples received, processed and tested	5000
	Individuals trained	100
	Public health consultations and assessments	30
Function #5: Serological laboratory support	Serological assays performed	20000
	Cultures performed	1000
	Reagents or assays developed	100
Function #6: Molecular laboratory support	PCR/Sequencing assays performed	10500
	Reagents or assays developed	100
	Bioinformatics tools developed	100
	Bioinformatics analyses performed	500

Healthcare Delivery:

During 2014, we increased our surveillance and response capabilities by developing the necessary procedures to accept, process and test (by Polymerase Chain Reaction-PCR) biological specimens suspected of Ebola Hemorrhagic Virus.

Training and Education:

A. Support for academics pursuing degrees

1) 2 Medical Research Technologist attending Microbiology (International Program) in the Doctor of Philosophy (PhD) program at Faculty of Science, Mahidol University, Thailand. One is expected to graduate in year 2015

2) 1 Medical Research Technologist attending Bioinformatics and Biology System in the PhD program at the King Mongkut's University of Technology Thonburi, Thailand

B. Other training offered to external personnel

1) Summer training/Overseas rotation, part of their academic program/rotations for a few months

a. Two undergraduate students, Department of Molecular Biotechnology and Bioinformatics, Faculty of Science, Prince of Songkla University, Thailand for Bioinformatics data analysis training

b. One undergraduate student, Faculty of Allied Health Sciences, Burapha University, Thailand for Reverse Transcription-Polymerase Chain Reaction (RT-PCR) to detect dengue, zika, and mumps viruses, enterovirus, and coronavirus, AND nucleotide sequence and bioinformatics data analyses

c. One LT, Naval Medical Center, Virginia, USA for rotation program

d. One student, University of San Francisco in Quito, Ecuador for Dengue virus culture and serology hands on training and Dengue RT-PCR and bioinformatics data analysis training

2) Short laboratory visit

a. Seven students, Department of Biotechnology, Thammasat University, Thailand

b. 1 Japanese medical officer, North Eastern Army Medical Unit, Japan

c. 11 physicians from Siriraj Hospital, Buddhachinaraj Hospital, King Chulalongkorn Memorial Hospital, Chiangmai University, and Chulalongkorn University, Thailand

d. 1 professor and 6 medical students, East Ramon Magsaysay Medical Center, Philippines

e. 10 physicians, Epidemiology Bureau, Ministry of Public Health, Thailand

f. 1 associate professor+ 11 students (4 vet, nursing/pharmacy/public health students), Department of Pediatrics, University of Wisconsin, USA

g. 105 3rd year Medical Cadets, Phramongkutklao College of Medicine, Thailand

3) Specific training

a. PhD postdoctoral fellow, University of Liverpool for Plaque Reduction Neutralization Test (PRNT) training

b. Two technicians, National Public Health Laboratory, Nepal for Nucleotide Sequencing Technique for Influenza Hemagglutinin and Dengue Envelope Genes

c. Two technicians, Public Health Laboratory, Bhutan for Qualitative RT-PCR and Real-Time RT-PCR assays for detection of Dengue Virus and Respiratory Viral Pathogens training

d. Two U.S. Embassy personnel from Nepal/India for Influenza samples handling/packaging and Influenza Viral Ribonucleic Acid (RNA) extraction/real time RT-PCR

e. Two Master degree student (technician from Public Health Laboratory, Bhutan) from the faculty of Medical Technology, Mahidol University, Thailand for the dengue RT-PCR, nucleotide sequencing, and dengue virus isolation techniques training

f. Master degree student (technician from AFRIMS, Royal Thai Army) from the faculty of Allied Health Sciences, Chulalongkorn University for pyrosequencing and phenotypic assay techniques to detect the drug resistance influenza virus strains training

g. PhD student from the faculty of Medicine Siriraj Hospital, Mahidol University for sample preparation and next generation sequencing techniques for a dengue virus study

C. Training given by the department of virology outside of Thailand

1) 12 members of the Philippine Animal Health Center, Manila, Philippines were given a one week training animal influenza detection and animal blue tongue virus detection by real-time RT-PCR.

Research and Development:

A. The Dengue Hemorrhagic Fever Project IV: Continued Prospective Observational Studies of Children with Suspected Dengue

1) The study involves children who have been admitted with suspected dengue virus infections to the Queen Sirikit National Institute for Child Health (QSNICH), Bangkok, Thailand. The proposed research extends our past studies of dengue immunopathogenesis to more severely ill children, with the additional objectives of testing the utility of new non-invasive continuous monitoring devices and identifying positive and negative predictors of disease complications.

2) Presently, there are 256 enrollees in the study: 55, 51, 122, 28 cases were enrolled in 2010, 2011, 2012 and 2013 respectively. Clinical, serologic and molecular diagnostic studies have been completed in enrollees recruited in 2010-2013. There were 216 dengue cases and 40 non-dengue cases. The dengue cases were classified into 140 dengue fever (DF) cases and 14, 35, 25, and 2 DHF grade I, II, III, and IV respectively. Infecting viruses were identified by PCR in 84% of all dengue cases. DENV1, 2, 3 and 4 made up 32%, 30%, 36.4%, and 1.6% of dengue cases. All DHF cases had serologic evidence of a secondary infection while 10.7% of DF cases had a primary infection. Plasma viral RNA levels were measured from samples from 2010-2013. Quantitative RT-PCR revealed similar viral RNA levels cases classified as DF or DHF. However, due to a primer mismatch for DENV3, the quantitative PCR for this viral serotype is being reevaluated. Plasma NS-1 levels in DF and DHF cases enrolled in 2010-2011 were determined and were found to be similar. The measurement of NS-1 levels in samples from 2013 enrollees is on-going. The NS-1 levels were not different between cases with either a primary or secondary DENV infection.

3) Determination of cardiac enzyme levels including CPK-MB and troponin-T revealed non-detectable to normal range in most cases. Sporadic abnormally elevated levels were found more frequently in DHF cases compared to DF cases. Analysis of cardiac anatomy and function revealed changes in both systolic and diastolic function in dengue cases. These changes were temporally related to the onset of plasma leakage in DHF cases. Few DHF cases with pericardial effusion have been detected. Serial ultrasonographic studies confirmed the pattern of plasma leakage in DHF cases as previously reported.

B. Sentinel Influenza Surveillance in Asia

1) This study collects respiratory samples in order to characterize influenza viruses circulating within the human population at the respective host sites. This data is used to provide influenza surveillance data to the US CDC and WHO surveillance network towards the annual re-formulation of the influenza vaccine. We also report the results of the circulating influenza strains and other respiratory pathogens to the respective host sites and countries.

2) From April 2014 to March 2015, 5,556 samples were collected from Bhutan, Nepal, Philippines and Thailand. Of these, 18.4% were influenza positive. Selected samples collected in the duration were sent for isolation. During this report period, we have completed isolation for 1,545 samples. To date, we have completed 2,791 of the selected samples.

C. Prospective Study of Influenza A Transmission from and to Household Animals in Thailand

1) This study conducts surveillance of influenza A viruses isolated from birds and mammals kept in the households of humans with documented influenza A viruses. We determine the capability of influenza A viruses to naturally infect a variety of mammalian species and document potential interspecies transmission of influenza A viruses.

2) During April 2014 to February 2015, 224 ILI subjects were enrolled. Of these subjects, 28 were positive for influenza A (H3 subtype = 18 and pdmH1 = 10), and 52 for influenza B. Of the 28 influenza A subjects, 3 live outside the study site (Muang District, Kamphaeng Phet province), 12 did not have any pet or livestock, and 2 did not permit the study staff to conduct household animal investigation. Of the remaining 11 subjects, there were 10 households that allowed study staff to collect animal samples from their pets/livestock (some subjects reside in the same houses). A total of 37 animals (7 chickens, 5 fighting cocks, 4 cats, 16 dogs and 5 rodents) were sampled. Respiratory or cloacal samples were collected for virus detection and isolation, and serum specimens for detection of antibody to influenza viruses. Preliminary results of virus detection from respiratory/cloacal samples sent to the NIAH laboratory using real-time RT-PCR technique were negative.

D. Collaborative Electronic Disease Surveillance Project in the Philippines

1) This study evaluates the ongoing SMS text-based fever surveillance system in Cebu City, Philippines to detect early spikes in febrile illnesses within the Cebu City Health Department (CCHD). Integrate the SMS fever surveillance system with laboratory-based sentinel influenza surveillance to determine in real time if influenza is the cause of detected spikes in febrile illnesses. Implement the SMS reporting system into other public health initiatives by the CCHD.

2) A formative evaluation report was completed and discussed with the Cebu City Health Department Medical Officers. Based on the report, the project can be a model of practice in future surveillance activities. Confidentiality, privacy, security and restrictions mechanisms were in place to make sure that the data were safeguarded and free from manipulation. AFRIMS has provided technical and financial support to its project partners and has expanded its reach rapidly.

3) By and large, the SMS-FS project have succeeded to jumpstart the harnessing of energies and talents of the community health workers, the LGUs and the CHO in combining technology with experiences and skills to enrich their analysis, decisions and actions on the health concerns of the covered communities. SMS text-based activities were discontinued in October 2014.

E. Efficacy and Safety of a Novel Tetravalent Dengue Vaccine in Healthy Children Aged 2 to 14 years in Asia (CYD14)

1) This study assess the efficacy of CYD dengue vaccine after three vaccinations at 0, 6, and 12 months in preventing symptomatic virologically-confirmed dengue cases, regardless of the severity, due to any of the four serotypes in children aged 2 to 14 years at the time of inclusion.

2) Results after one year of active surveillance demonstrate an overall vaccine efficacy against symtomatics dengue of in children aged 2 to 14 years old after a three-dose vaccination schedule. Sub-analyses showed an 88.5% reduction in dengue hemorrhagic fever and a 67% reduction in hospitalized dengue. The preliminary efficacy and safety results were available at the end of 2014.

F. Pathological and Immunological Events in Fatal Dengue Based on Autopsy Evaluation.

1) The goals of this study are to define the pathology associated with fatal dengue using up-to-date histological techniques to analyze tissue samples obtained from fatal dengue cases in both children and adults and to identify the cellular targets of dengue virus in vivo and to identify molecular changes of the endothelium and serosal epithelium in anatomical locations where plasma leakage occurs.

2) Four autopsy cases have been obtained from Vicente Sotto Memorial Medical Center: 2 dengue cases and 2 control non-dengue cases. Laboratory evaluations are currently being performed on these tissue samples at AFRIMS, Bangkok.

G. Prospective Cohort Study of Influenza and Dengue Infection in Children and Adults, Cebu City, Philippines (CPC Study)

1) The purpose of this study is to prospectively monitor a cohort of subjects age greater than or equal to 6 months old in Cebu City, Philippines for evidence of influenza infection in order to determine the age-specific incidence of influenza in the cohort population, to determine the clinical spectrum of influenza infection from inapparent disease to severe disease, to assess the relationship of pre-existing influenza A antibodies to incidence and disease severity of influenza A infection, to determine transmission dynamics among household contacts of cohort subjects with influenza A infection and to assess the degree and duration of respiratory viral shedding during the course of influenza A transmission.

2) In this study a cohort of 1000 subjects at least 6 months of age are followed for 2-5 years with blood samples being collected at enrollment and at 12 month intervals for influenza antibody testing. This is accompanied by active surveillance for fever and collection of respiratory samples during acute illness. Household contacts are also enrolled.

3) A total of 891 subjects completed their 24-month annual follow-up visits from 03 March 2014 to 28 May 2014. All study activities involving surveillance and study visits of all cohort subjects were discontinued and completed on 31 May 2014. There were only 3 samples tested for this reporting period from April 2014 to March 2015. Only 1 sample was positive for Flu B by RT-PCR testing.

H. Immunological Correlates of Clinical Outcomes in a Tetravalent Dengue Vaccine Cohort - an Ancillary Study (Cebu City, Philippines) (NMC Study)

1) The overall purpose of this ancillary study is to identify immunologic correlates of clinical outcomes in participants in the parent CYD vaccine efficacy trial.

2) There were seven hundred and seventy seven (777) cases of acute febrile episodes since the start of the study, with two hundred and fifty (250) cases occurred for 111 pre-vaccination volunteers and five hundred and twenty seven (527) cases occurred for 496 post-vaccination volunteers**.**

I. Sentinel Human Influenza Surveillance in Royal Thai Army Recruits

1) The purpose of this study is to identify influenza virus and other respiratory pathogens causing disease in Royal Thai Army (RTA) enlisted personnel living in barracks, study seasonal trends, determine the burden of influenza virus, to study transmission patters of influenza, determine influenza seroconversion rates, and to measure the frequency, duration and seasonal variation of person-to-person contact amount recruits in the Royal Thai Army barracks setting. This can be used to develop models of disease transmission and the possible impact of different transmission interventions.

2) The study enrolls new RTA recruits and follows them at routine intervals for up to 24 months, obtaining a small amount of blood at baseline and occasional respiratory samples and additional respiratory samples during episodes of acute illness. Radiofrequency badges are on occasion worn in order to tract movement and transmission dynamics.

3) To date, total 3386 blood samples were collected for the routine baseline, three month follow-up, six-month follow-up visits. 1,281 acute respiratory samples were collected from subjects enrolled in the study. Despite the low acute influenza positivity rate, HAI 4-fold seroconversions of the influenza HAI titers provided evidence of the circulation of influenza virus within the study population.

J. Phase II, randomized, double-blind, placebo-controlled study of the safety and immunogenicity of the recombinant live- attenuated tetravalent dengue virus vaccine admixtures TV003 and TV005 in healthy adults, adolescents, and children in Thailand.

1) The study evaluates the immunogenicity and safety of two admixtures of a live attenuated partial chimeric dengue vaccine attenuated with direct mutagenesis developed at the NIAID/NIH in the United States. The study first evaluates an adult cohort and then engages in an age de-escalation set of cohorts after one of the two formulations is chosen to continue with after an evaluation of the adult cohort.

2) 100 Adult volunteers were screen on 15-16 November 2014. The study enrollment for the first adult cohort began on December 2014. Eighty four adult subjects were enrolled and randomized to receive either 2 dosed of TV003/placebo or TV005 followed by placebo. No safety issue concerns were noted.

3) While outside the reporting period of this report, 80 Adolescent volunteers were screened on 21-22 February 2015. 70 Adolescent subjects were enrolled on 14-15 March 2015.The subject were completed study activities visit 1-4. No safety issue concerns were noted.

Resource Management and Budget:

TABLE 2: 3-year budget

Funding sources	FY2013	FY2014	FY2015
U.S. Army Medical Materiel Development Activity	589,361	616,335	441,032
Military Infectious Diseases Research Program	817,920	619,830	718,110
Armed Forces Health Surveillance Center-Global Emerging Infections Surveillance and Response System	1,303,580	1,654,018	1,781,063
National Institute of Health-University of Rhode Island	839,219	677,811	956,292
Defense Threat Reduction Agency	220,419		688,920
U.S. Department of State- Biosecurity Engagement Program	255,600		

Naval Medical Research Center	113,600	60,350	
Others	50,872	88,646	
Total	4,190,571	3,716,990	4,585,417

Information Management

Several servers were utilized to handle large information (approximately 1.7 Terabytes during 2014) from the next generation sequencing (NGS). One server is served for storage only. Two servers, a Linux operating station 8 core processors for an in-house bioinformatics pipelines and another Linux operating system containing Empowering the Development of Genomics Expertise (EDGE) v.1.0, are currently used for bioinformatics data analysis.

1) Strength: Our current capacity is enough to manage the output information from the NGS in 2014.

2) Shortcoming: A separate network to transfer large amount of data with large bandwidth among servers and NGS machine is absolutely required for sufficient operation. In addition, the information keeps growing, we also continuously require larger computational capacity for storage and data analysis.

Operations:

Surveillance for diarrhea etiology was performed on diarrhea stool samples collected from military personnel participating in an annual joint military exercise, Balikatan, between the Republic of the Philippines and the United States in 2014. The department of virology led this effort providing 3 staff to the effort and was supported by the EDS and enterics departments. Seven stool samples were collected and tested using TaqMan® Array Card (TAC) and results were compared with pathogen specific real-time PCR assays. TAC yielded multiple bacteria as the responsible etiology with *Campylobacter* spp. as the main etiology. In comparison to pathogen specific real-time PCR assays, results from TAC matched 5 out of 6 comparative assays with 2 assays that required extended interpretation. The application of TAC in acute diarrhea stool samples from a US military population demonstrated its versatility as a potential candidate for Next Generation Diagnostics Platform in a military setting.

Modernization:

We received the Global Bio-Surveillance Technology Initiative (GBTI)-MiSeq next generation sequencing machine (MiSeq) during 2014. The MiSeq, part of the GBTI effort, will be part of a wider disease surveillance network. It is also utilized in the role of capacity building; recently, the Department of Virology, AFRIMS, offered a week-long, DTRA-funded, viral identification workshop. This workshop, attended by laboratory staff in the South East Asia region, was centered on the operation of the MiSeq platform and analyses suite.

Construction/Renovation:

During the reporting period, the department of virology received funds sufficient to initiate several renovation projects.

During the reporting period, the department of virology received funds sufficient to initiate several renovation projects.

A. Vicente Soto Memorial Medical Center (VSMMC) elevator shaft renovation in new VSMMC laboratory building. VCMMC awarded a contract to build a new four-storey laboratory building on their campus in Cebu, Philippines. AFRIMS/ Philippines-AFRIMS Virology Research Unit (PAVRU), utilizing The Naval

Facilities Engineering Command (NAVFAC) contracting services, awarded a contract to complete a renovation to this structure by installing and elevator shaft. After completion of this project, the AFRIMS/PAVRU Cebu laboratory will occupy the fourth floor of this laboratory in order to increase our ability to collaborate with VSMMC and the local public health agencies. A second contract was awarded through NAVFAC to a U.S. firm to complete detailed architectural and engineering plans for the actual renovation of the fourth floor of the laboratory building that the AFRIMS/PAVRU laboratory will occupy.

B. Contract was awarded in Bangkok to complete the detailed architectural and engineering drawings for a planned renovation to the second floor of the main research building on the AFRIMS campus. This project will allow for better utilization of space and modernization of our laboratory facility.

US ARMY MEDICAL RESEARCH UNIT-EUROPE

Sembach, Germany

Mission

Conduct applied psychological research for the purpose of protecting, optimizing, and enhancing warfighter psychological resilience and well-being.

Leadership, Organization and Personnel

Commander: LTC (b) (6)
Deputy: MAJ (b) (6) (Thru SEP 2014)
NCOIC: SGT (b) (6) (OCT-DEC 2013), SGT (b) (6) (JAN-MAY 2014), CPL (b) (6) (MAY-OCT 2014)
Chief Science Officer: (b) (6) (GS-15) (Thru JUL 2014)
Adm. Officer: (b) (6) (GS-12)
Principal Investigators: (b) (6) (Thru MAY 2014). (b) (6) (GS-12, MA)
Staff: SPC (b) (6) (From JAN 2014), SPC (b) (6) (Thru June 2014) (b) (6)

Major Research and Development Projects by Task Area

A. Task Area W1A: Novel Strategies to Reduce Aggression and Risk-Taking Behaviors and Enhance Behavioral Health

1) Behavioral Health Leadership and Resilience Study: During FY14 USAMRU-E continued its longitudinal assessment of 2nd Cavalry Regiment over the course of their OEF deployment. The purpose of the assessment is to examine the relationship between specific leadership behaviors and behavioral health, sleep, and resilience (see (b) (6) , 2014). Moreover, this study provided more strategic data with an entire Regiment-based implementation of master resilience training or "dragoon total fitness". This study with 2CR is unique in that not only were data collected from 2CR Soldiers in Afghanistan but also at the same time from their ready reserve/rear detachment.

Data during this phase was collected in the Fall of 2013 with over 2,600 surveys collected in Afghanistan and 950 in Vilseck with the ready reserve. In February of 2014, USAMRU-E surveyed a squadron (n=450) from 2CR who returned early and implemented a sleep actigraphy study in support of the larger study goals (n =113). The team followed these 113 Soldiers 3 weeks later and collected the watches and back-briefed participants on their sleep performance. In April of 2014, USAMRU-E surveyed 2CR as they redeployed from OEF for Time 3 of the study (n = 3000). In June, the squadron who returned in February was surveyed as the first part of the Time 4 phase of the study (n = 550). Later in July, USAMRU-E surveyed the majority of 2CR for its Time 4 phase of the study with over 2500 Soldier surveys collected. This study represented the most comprehensive assessment ever undertaken within the research program with a Regiment/Brigade sized element. Thus far, 4 time-waves with at least 2500 Soldiers participating at each phase have been collected.

Noteworthy Deliverable: Data from this study was used to address a Congressional line-item question from the National Defense Authorization Act of 2014. Specifically, Congress asked for data showing that master resilience training was correlated with positive behavioral health and climate. Initial data from the study answered this question and provided feedback for the NDAA.

Publication Referenced: Adler, A.B., Saboe, K.N., Anderson, J., Sipos, M.L., & Thomas, J.L. (2014). Behavioral Health Leadership: New directions in occupational mental health. Current Psychiatry Reports, 16, 484. doi:10.1007/s11920-014-0484-6

B. Task Area W1: Develop evidence based recommendations for identifying and addressing difficulties with post-combat adjustment

1) US Army Europe Transformation Study: A US Army Europe (USAREUR) community-based study was undertaken in FY13 examining the community behavioral health impact of force-restructuring or 'transformation'. Essentially transformation results in closing military communities with indirect effects on other communities who gain personnel and units from the closing location. While studies of company closures are not uncommon in the civilian sector and have mostly been studied by behavioral economists, there had never been a study examining the effects of military base closing and shuffling of personnel and units within DOD. Given the DOD goes through a great deal of force restructuring and transformation (sometimes in the form of Base Realignment and Closure most notably), data from this study can inform leadership and policy surrounding future transformation efforts with evidence-based data from a community behavioral health perspective. In the Fall of 2013, the final data collection results from Heidelberg and Mannheim community closures were outbriefed. Bamberg and Schweinfurt communities were able to be assessed with over 50% of all stakeholders in the communities assessed at 2 time points (DA Civilians, Military, Spouses). In the Winter of 2014, data collections began in the Wiesbaden and Kaiserslautern communities. These communities were indirectly affected in that they gained personnel and units from the closing communities of Heidelberg and Mannheim, and Bamberg and Scwheinfurt (to some extent). During the Spring/Summer of 2014, multiple data collections occurred in the Kaiserslautern and Wiesbaden areas in support of the Transformation Study. During

the Summer, initial results were outbriefed to ERMC and IMCOM-Europe leadership. A data collection was planned in the Vicenza Italy military community in October of 2014 I(FY15) and the study will be concluded shortly after.

Study Deliverables: Planned study deliverables include comprehensive technical brief and report for USAREUR stakeholders, lessons-learned guide for leaders faced with 'transforming' a community (for IMCOM), a manuscript on community behavioral health, a manuscript on Spouses/Families undergoing transformation, and a special focus on DA Civilians—a part of the Army team with little to no behavioral health data collected.

C. Task Area W1A: Novel Strategies to Reduce Aggression and Risk-Taking Behaviors and Enhance Behavioral Health

1) Deployed Medical Staff Study: A USAMRU-E Study with 30th MED (stationed in Germany) during their deployment to Afghanistan sought to collect data on medical provider prevalence rates for behavioral health, risk/resilience factors, the use of evidence-based practices in BH for deployed providers, and initial data on perceptions of return-to-duty decision making (PTSD and mTBI). The study also provided the first even data from providers that will lead to a joint DOD/VA registry of best practices. Over 400 surveys were collected from deployed medical staff downrange in Afghanistan concluding in October of 2013. 30th MED was outbriefed on the results in January of 2014. Moreover, results from the study were immediately implemented into the Master Resilience Training for Medical—this was a significant gap in evidence-based training that this study helped address.

Study Deliverables: Transitioned evidence-based data to Comprehensive Soldier and Family Fitness and the Army Medical Department Center and School in support of the training for Master Resilience Training-Medical modules. Moreover, data from this study formed the foundation for a DOD/VA provider registry being established in FY15/16.

Initiating Relocation Activities:

During FY14, USAMRU-E continued work on AR 5-10 Restationing Package and gained approvals through MEDCOM for relocation. Because of the significant downsizing of the US Army in Europe (European Infrastructure Consolidation), USMARMU-E is slated to relocate to Joint Base Lewis McChord, WA in FY15 (in accordance with the National Military Strategy shift to the Pacific). USAMRU-E will continue with its same competencies and capabilities in working with operational units in order to provide the Army and PACOM/Western region with evidence-based behavioral health and resilience research.

Resource Management and Budget

The Fiscal Year 2014 US Army Medical Research Unit-Europe was funded by the Research, Development, Training, & Evaluation (RDT&E) appropriation through the US Army Medical Research and Materiel Command (USAMRMC) Military Operational Medicine-Research Program (MOM-RP) under the Army's intramural research

program, titled, "Psychological Health and Resilience Program. The Annual Funding Plan (AFP) was $1.878M, and there were not any significant changes to the funding level when compared to the previous budget year.

US Army Medical Research Unit-Georgia (USAMRU-G)

Background and Mission

Background

In support of the Nunn-Lugar Cooperative Threat Reduction legislation, the Defense Threat Reduction Agency (DTRA), in cooperation with the Government of Georgia (GoG) constructed a laboratory, the Richard G. Lugar Center for Public Health Research (Lugar Center), in Tbilisi. In a memorandum dated 20 January 2011, the Deputy Secretary of Defense (DEPSECDEF) requested the development of an implementation plan for establishing a medical research unit in the Republic of Georgia and assigned Executive Agency responsibility for establishing this unit to the Department of the Army (DA). Within the DA, the US Army Medical Research and Materiel Command (MRMC) tasked its subordinate unit, The Walter Reed Army Institute of Research (WRAIR), to develop the implementation and concept plans due to its 50 years of experience operating medical research laboratories in overseas locations.

Mission

The mission of USAMRU-G is to promote global health security, identify infectious disease threats to global health security, and develop interventions to mitigate those threats; collaborate and assist the Government of Georgia in its efforts to combat endemic disease threats of military importance as well as to participate in cooperative surveillance and research projects addressing military and public health issues; and provide for extensive capacity-building to train Georgian scientists, physicians, students, and technicians in a wide range of bioresearch-related topics. The USAMRU-G Director and staff also will serve as technical liaisons and support for US and allied forces deployed in relevant regions of the US European Command and US Central Command by addressing issues dealing with local disease threats.

Organization and Personnel

Organization

The Army was officially tasked to write an Implementation Plan and Concept Plan (CONPLAN) for the establishment of this unit, both of which have been approved and are being implemented. A major step in the implementation of the CONPLAN was the assignment of the Director, a microbiologist and a veterinarian to Georgia in August and September 2014 as the first permanent staff bringing the unit to initial operating capacity. This permanent US presence provided leadership to the existing USAMRU-G locally-employed contract science staff and one contracted service support manager. Initial Operational Capability (IOC) was achieved at the completion of FY14 with a Director supported by a Service Support Manager and an Acting XO (microbiologist) in the Headquarters element. The microbiologist formally was assigned as the Lab Manager, overseeing research efforts by the contracted science staff. The veterinarian was assigned primary duties to provide capacity building expertise in support of training for the Georgian staff of the Lugar Center vivarium.

Personnel

At the conclusion of FY14, the USAMRU-G personnel were as follows:

B. Headquarters

2) LTC (b) (6), Director

3) (b) (6), Science Director (temporary duty from WRAIR/EBI)

4) (b) (6), Support Services Manager (Georgian Contractor)

B. Research and Development

1) LTC (b) (6), Lab Operations Chief (and Acting XO)

a. Laboratory Staff

i) (b) (6), Microbiologist

ii) (b) (6), Lab Technician

b. Clinical Research Unit

i) (b) (6), Principle Investigator

ii) (b) (6), Principle Investigator

iii) (b) (6), Principle Investigator

Training and Education

Background

The mission of USAMRU-G includes providing for extensive capacity-building to train Georgian scientists, physicians, students, and technicians in a wide range of bioresearch-related topics. An additional implied mission speaks more broadly to support the Government of Georgia in developing the Lugar Center as a regionally and internationally recognized public health research laboratory.

Achievements

The first two months of USAMRU-G operations provided platforms by which WRAIR TDY scientists in concert with USAMRU-G staff established Brucella MLVA subtyping in the Lugar Center, trained Eliava Institute and Georgian National Center for Disease Control (NCDC) collaborators, and subtyped 11 previously uncharacterized human isolates from Eliava's historic archive. This team also helped NCDC troubleshoot Brucella molecular diagnostics.

LTC (b) (6), Chief of Veterinary Services, was charged with assembling a lab animal health training program for current and future vivarium technical and support staff. FY14 yielded the framework of this training program. LTC (b) (6) defined two critical national needs: 1) genetically-defined animal models raised under precisely-standardized conditions, free of all detectable disease, and 2) an organized community of skilled animal scientists and technicians who are able to maintain these animals, and who are empowered to continue their own professional scientific development. The Lugar Center vivarium is ideally poised to act as the "seed" of the solution to both of these stated needs. USAMRU-G proposed the establishment of a rigorous training program for Georgian animal scientists and technicians, consisting of approximately 200 hours of didactic (lecture-based) training and 200 hours of practical (hands-on) training. Although lectures could be held in any suitable academic setting, the practical training component would require the use of Lugar Center's advanced facilities and equipment. A class size of 15 to 20 students, sourced from a wide variety of different biomedical research organizations in Georgia, would allow for student attrition and facilitate the use of group projects in the didactic portion of the course. The subsequent development of tight professional relationships among students from different institutes will, in turn, help to create a formalized professional community after the culmination of the training program – exactly parallel to the

organizational beginnings of the American Association for Laboratory Animal Science (AALAS) in the US, and the Federation of European Laboratory Animal Science Associations (FELASA) in the EU. The practical portion of this course would ensure these students attain world-class technical skills, while also making available standardized, disease-free, genetically-defined animal models – both for use within the Lugar Center, and for sale or distribution to other facilities throughout Georgia.

LTC (b) (6) also took initiative to start a veterinary advice column in the monthly "Satave" newsletter, co-written with (b) (6) of the US Center for Disease Control. This publication is provided by the Embassy Community Liaison Office (CLO), whose mission closely aligns to a garrison's Army Community Service office and MWR services. Efforts such as these better leverages USAMRU-G talents and expertise for the betterment of the US Embassy community

Research and Development

Background

The incorporation of a US-led medical research and development program along with the experience of the Armed Forces Health Surveillance Center-Global Emerging Infections Surveillance and Response System (AFHSC-GEIS) program provides an opportunity to integrate the Georgian laboratory platform into an international site for infectious disease surveillance and research. The US component provides subject matter expertise in a broad range of pathogen research methods and technologies, medical product development, grants writing training, and research marketing. Execution of these programs in the country of Georgia offer a solid foundation from which the Georgian government can build and sustain critical internal research laboratory capabilities for future operations.

Achievements

The USAMRU-G research portfolio in FY14 was supported by Georgian contractor science staff and led primarily by WRAIR/EBI research staff on TDY throughout the year. The addition of permanent staffing in August and September 2014 established the unit IOC for full-time on-site leadership and program management. Considerable achievements are noted by project:

A. **Surveillance of Febrile Illness Etiologies in Georgia.**
   1) Objectives:
      a. Determine burden of infectious causes of acute, prolonged undifferentiated febrile illnesses and hemorrhagic fever/septic shock in Georgia.
      b. Determine epidemiological risk factors by pathogen.
      c. Build capability for febrile illness surveillance among hospitals, NCDC laboratory network.
      d. Provide baseline data for future clinical studies.
   2) Project Highlights:
      a. Enrollment started in June 2013 and there were 432 subjects enrolled by the end of FY14.
      b. Blood culture and Antibiotic Susceptibility Testing were performed for all enrolled subjects.
      c. Serologic testing was conducted for Leptospira spp., Brucella spp., Coxiella burnetii, Rickettsia (spotted fever group, scrub typhus group and typhus group), Hantavirus and Crimean-Congo haemorrhagic fever.
      d. Epidemiological information database was created.

B. **Prevalence of Selected Sexually Transmitted Infections in Georgian Military Personnel.**

2) Objectives:

a. Determine prevalence of Chlamydia trachomatis and Neisseria gonorrhoeae in Georgian military personnel.

b. Compare laboratory diagnosis at Ministry of Defense (MoD) hospital with Nucleic Acid Amplification Testing (NAAT) at Military HIV Research Lab, WRAIR.

c. Determine sexually transmitted infection risk factors for Georgian military.

d. Determine patterns of antibiotic resistant gonorrhea.

2) Project Highlights:

a. Enrollment started in August 2013 and there were 89 subjects enrolled by the end of FY14.

b. Bacteriology was performed for all sampled subjects.

c. Determined five culture positive cases, with two confirmed N. gonorrhoeae isolates.

d. Epidemiological information database was created.

e. Genprobe DTS System was acquired and delivered to the USAMRU-G lab for this and future sexually transmitted infection surveillance projects.

f. Training was provided for Antibiotic Susceptibility Testing in September 2014.

C. **GEIS Global Travelers' Diarrhea Study.**

1) Objectives:

g. Determine the prevalence of norovirus (NoV) and enterotoxigenic Escherichia coli (ETEC) in military and US Embassy populations in nation of Georgia.

h. Determine prevalent ETEC and NoV genotypes.

i. Determine antimicrobial resistance of ETEC isolates.

2) Project Highlights:

a. Protocol approved by WRAIR Scientific Review Committee in January 2014. WRAIR IRB review of amended protocol was near completion by the end of FY14.

b. MicroScan automated bacterial identification and antibiotic susceptibility testing delivered to USAMRU-G and installation was completed in June 2014.

c. ABI 7500 real-time PCR system was delivered to USAMRU-G in September 2014.

D. **Vector Surveillance.**

1) Objectives:

d. Coordinate collaborative vector surveillance and vector related research programs in the Caucasus and Central Asia.

e. Establishment of entomology section at the Lugar Center in Tbilisi, Georgia supported by USAMRU-G.

2) Project Highlights:

a. Continued support of Georgian-related research, to include vector-related SOP integration.

b. Conducted onsite training on tick collection and identification for DTRA related projects in Kazakhstan.

c. Developed training plan for biosurveillance of medically important arthropods and their associated pathogens.

d. Sponsorship of a fellow for the Georgian Early Career Scholar Program focused on sand fly identification and barcoding.

E. **Epidemiology and Ecology of Tularemia in Georgia (CBR GG-19).**
1) Objectives:
e. Establish sentinel surveillance in historical hot spots (endemic foci) of tularemia in Georgia.
f. Measure seroprevalence of tularemia.
g. Assess ratio of clinical to subclinical infections.
h. Assess presence of antibodies in vaccinated people (if found).
2) Project Highlights:
a. Conducted Study-Specific and Human Subjects Protection training for clinical personnel and epidemiologists engaged in both clinical studies.
b. Enrollment for seroprevalence human protocol started in October 2013 and there were 230 subjects enrolled by the end of FY14.
c. Enrollment for active surveillance (case finding study) human protocol enrollment started in January 2014 and there were eight subjects enrolled by the end of FY14.

F. **Human Disease Epidemiology and Surveillance of Especially Dangerous Pathogens in Georgia (CBR GG-21).**
1) Objectives:
a. Assess epidemiology and clinical manifestations of selected pathogens among patients with undifferentiated fever or hemorrhagic fever/septic shock syndrome.
b. Measure seroprevalence of selected pathogens.
c. Implement/evaluate diagnostic methods.
2) Project Highlights:
a. The military seroprevalence study human subjects protocol was approved by NCDC and WRAIR IRB in June 2014.
b. Approved by Government of Georgia in May 2014.
c. Project officially initiated by DTRA on 1 July 2014.

G. **Acute Infectious Neurologic Disease project.**
1) Objectives:
a. Determine frequency of infectious acute infectious neurologic disease etiologies.
b. Determine antimicrobial susceptibility of bacterial meningitis pathogens.
c. Determine burden of vaccine-preventable encephalitis.
d. Determine overall incidence of acute flaccid paralysis and vaccine-associated paralytic poliomyelitis.
e. Describe risk factors, clinical features associated with meningitis and encephalitis.
2) Project Highlights:
a. There were 203 patients enrolled in study first phase.
b. Manuscript describing clinical and laboratory data was accepted for publication by PlosOne in September 2014.

c. All archived cerebrospinal fluid and serum samples have been consolidated at USAMRU-G.

d. Retrospective West Nile Virus, tick-borne encephalitis ELISA testing performed with support from US CDC.

e. Human subjects protocol for second phase completed for submission to IRBs.

H. **Acute Respiratory Infection Surveillance in the Georgian Military.**

1) Objectives:

a. Describe the clinical presentations of acute respiratory infections in military recruits who present at the Gori Military Hospital.

b. Determine the etiologic causes of acute respiratory infections in military recruits who present at the Gori Military Hospital.

c. Characterize molecular epidemiology of selected pathogens of special interest.

2) Project Highlights:

a. Proposal first awarded funding by GEIS in Oct 2013 and received in May 2014.

b. The study's Material Transfer Agreement was approved by the Georgian MoD in July 2014 and executed by WRAIR in August 2014.

c. Study protocol, questionnaire and ICD were submitted to the Georgian MoD and WRAIR IRBs in May 2014 and approved by the Gori Military Hospital IRB in September 2014.

I. **Diagnostic and Genetic Characterization of Pathogen Strain Collections.**

1) Objectives:

d. Screen archival pathogen strain repositories in Georgia, Armenia, and other FSU states using DoD diagnostics, basic phenotypic, genotypic analysis.

e. Create databases of metadata and genetic fingerprints to select regionally unique pathogens strains for further genomic analysis.

f. Build assays for differentiation of regional pathogen subtypes.

2) Project Highlights:

a. Screened Georgian strain collections of Bacillus anthracis, Brucella species, Francisella tularensis and Yersinia pestis using published DoD PCR diagnostics.

b. Performed in depth genetic analysis of Georgian pathogen strain collections (Multiple Locus Variable Number Tandem Repeat Analysis/MLVA and Single Nucleotide Polymorphism/SNP; whole genome sequencing of selected strains).

J. **Anthrax vaccines (NATO SFP 94208)**

1) Objectives:

c. Describe human immune response to anthrax infection and vaccination.

d. Identify immunogenic domains of protective antigen, lethal factor and edema factor.

e. Identify new immunogenic spore proteins.

2) Project Highlights:

a. Completed screening of Georgian archived serum samples and Human serum samples (with diagnosis of anthrax) received from Turkey to quantify anti-protective antigen, lethal factor and edema factor antibody.

b. Presentation of results at "Anthrax Biology" workshop in Cardiff, UK, 11-12 March 2014.

K. **Identification of etiology, clinical outcomes, incidence and epidemiological patterns of hospitalized febrile patients (TAP-H1-Armenia).**

1) Objectives:

c. Define etiology, clinical outcomes, incidence and epidemiological patterns of hospitalized patients with fever at major infectious disease center for Armenia.

d. Collect baseline data for future collaborations in Armenia.

2) Project Highlights:

a. Conducted study-specific and human subjects protection training by WRAIR, USAMRIID and USAMRU-G team for the Armenian collaborators.

b. USAMRU-G conducted 2nd on-site training on data extraction and entry into the database.

c. Data analysis initiated in May 2014.

d. Final report completed in September 2014.

L. **Fever of Unknown Origin among Military Patients in Azerbaijan.**

1) Objectives:

a. Establish collaborative agreement between WRAIR/USAMRU-G and the Azerbaijani MoD.

b. Evaluate select infectious causes of acute febrile illness among military personnel referred to military hospitals in Azerbaijan.

2) Project Highlights:

a. White paper proposal developed by Azerbaijani military scientists with USAMRU-G Science Team support was approved by Azerbaijan MoD authorities.

b. White paper proposal currently being revised by Azerbaijani MoD and USAMRU-G Science Team collaborators for resubmission to DTRA.

Key Leader Engagements

Background

The Lugar Center represents the largest single investment of its kind by the United States in the region. As such, USAMRU-G is placed in a critical position to not only assume its role as Executive Agent over the transition of the Lugar Center operations from DTRA to the Government of Georgia, but to establish itself as a key stakeholder for national and international collaboration.

A. On 18 August 2014 (b) (6) from the House Armed Service Committee consisting of (b) (6) , all Professional Staff Members for Subcommittee on Military Personnel, were in Tbilisi Georgia and visited the US Embassy and Lugar Center. MAJ(P) (b) (6) provided the STAFFDEL with a short information brief on USAMRU-G. (b) (6) asked how the Army mission differed from the US CDC mission. The CDC Director in Georgia and MAJ(P) (b) (6) explained the differences in the mission and the areas of overlap. (b) (6) then asked about the financial sustainment of the Lugar Center and USAMRU-G post DTRA. MAJ(P) (b) (6) pointed out that funding was POM'd for USAMRU-G for sustainment costs, to include sharing of Lugar Center facility costs, and scientists were pursuing science funding through research projects. The group then toured the Lugar Center and the main focus was on biosafety and biosurety and WRAIR's role. It was explained that USAMRU-G will not work with biological select agents and toxins (BSAT) but will be available to advise the Georgians as needed. Due outs to CPT (b) (6) for the STAFFDEL is an overview of USAMRU-G current funding and projected funding in Georgia.

B. On 22 September 2014 SEC Army was in Tbilisi, Georgia to visit the Georgian Ministry of Defense and allotted time to visit the Lugar Center and USAMRU-G. The USAMRU-G Director provided the delegation that included the US Chargé d'Affaires Nicholas Berliner and Office of Defense Cooperation representatives, a brief overview of USAMRU-G mission, staff, and future collaborative opportunities. Additional time was spent highlighting the long history the US Army has developing treatments and diagnostics for endemic diseases. A facility tour by Georgian and USAMRU-G leadership highlighted technical capabilities, opportunities for collaboration and the important role capacity building plays in the USAMRU-G mission. The work of Army researchers in the broader Caucasus region and military collaborations at Gori Military Hospital were also discussed. SEC Army was notably impressed with the facility and work being conducted, complimenting the dedication of the staff in combatting infectious disease. He stressed the fundamental importance of partnership with the Georgians. No due outs were recorded.

C. On 30 September, the USAMRU-G Director met with the US Ambassador and Deputy Chief of Mission. USAMRU-G Director emphasized his commitment to building partnerships that support the Soldier mission, while also bolstering Georgian capacity and capabilities at the Lugar Center. Projects of the last several years highlighted the necessity of USG work in the area, but also touched on endemic diseases of interest to Georgia. The US Ambassador expressed the importance of USAMRU-G to US policy and to the Georgians. He emphasized the need to advertise – where we can – the work we do as a constant reminder of our transparency.

Section 27

Fiscal Year 2014
Annual Historical Report

U.S. Army Medical Material Development Activity

Introduction

Authority

In accordance with Army Regulation (AR) 40-226, Annual Historical Report, The Army Medical Department (AMEDD) Activities Report [Reports Control Symbol (RCS) MED-41 (R4)], the Annual Historical Report - AMEDD Activities of the U.S. Army Medical Materiel Development Activity (USAMMDA) for Fiscal Year (FY) 2014 is submitted.

Mission/Vision

USAMMDA Mission: Develop and deliver quality medical solutions to protect, treat, and sustain the health of Our Service Members.

USAMMDA Vision: USAMMDA is the premier developer of world class military medical solutions.

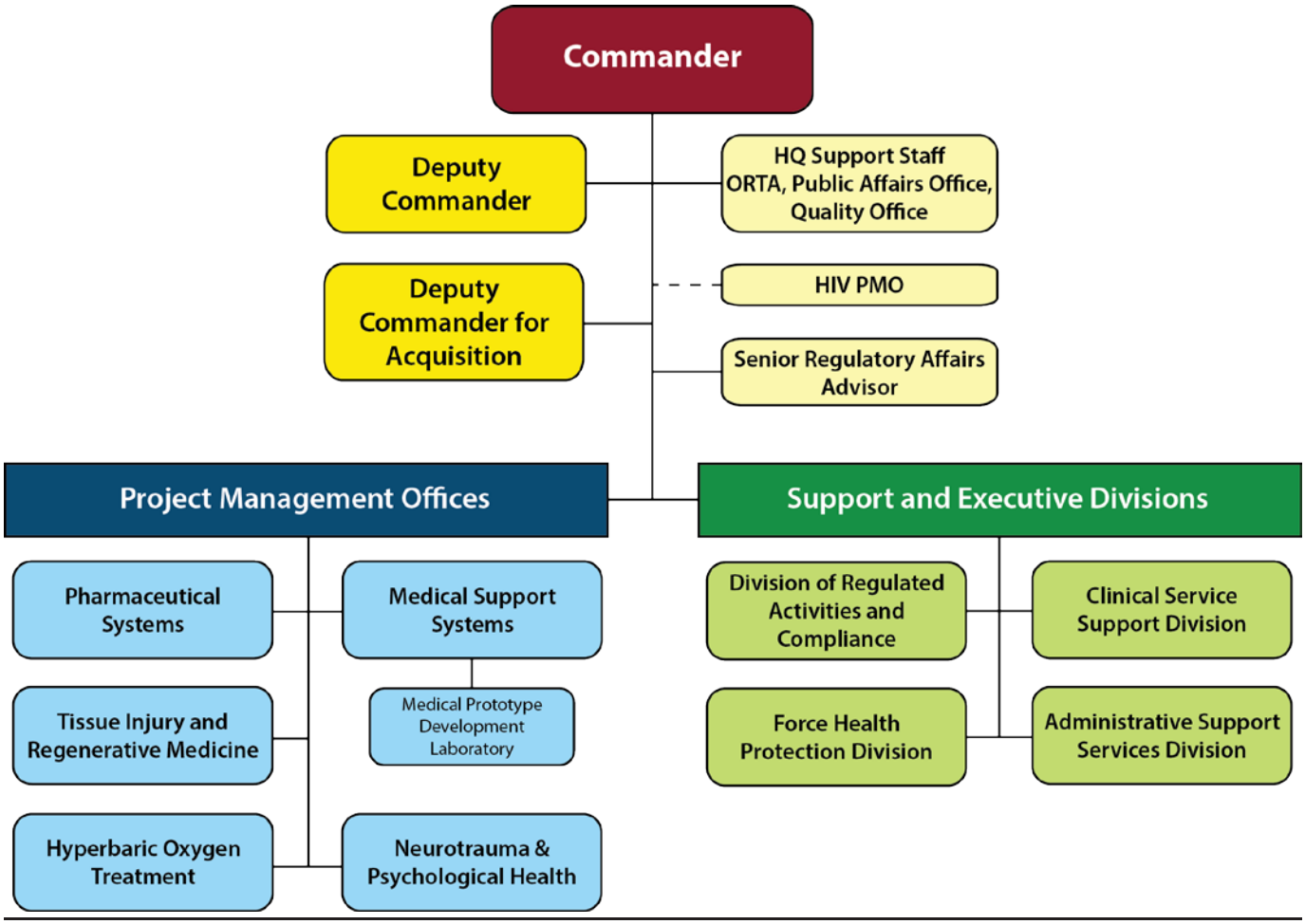
Organization

A. Changes occurring in each division/office are reflected in the respective sections.

B. The USAMMDA Organizational Chart, Figure 1, appears on page 2.

C. Personnel data are shown in Appendix A

FIGURE 1: Organization Chart



Office of the Commander

A. **COMMANDER.** Colonel Stephen J. Dalal.

B. **DEPUTY COMMANDER.** Lieutenant Colonel (b) (6) .

C. **DEPUTY COMMANDER FOR ACQUISITION.** (b) (6)

D. **STAFF.** 19 Personnel. 4 Military, 4 Civilians, 10 Contractors and 1 U.S. Food and Drug Administration (FDA) Consultant.

Supporting Divisions

Office of Quality Management

The Quality Office was established January 2009 to provide broad quality support to all of USAMMDA. The name was changed to Office of Quality Management (OQM) in July 2014 to recognize its multifunctional role. The mission of the OQM is to partner with USAMMDA divisions to implement best practices that continuously improve the organization's critical processes for developing quality medical products.

A. **General.** Chief. (b) (6) served until 7 May 2014. Major (b) (6) assumed the responsibility on 1 July 2014.

B. **Personnel.** 4 Personnel. 1 Military and 3 Contractors.

C. **Military Relevance.** OQM provides quality support to USAMMDA by ensuring compliance with regulatory requirements and adherence to all applicable procedures and guidelines. OQM takes an active role in achieving life-cycle appropriate solutions for all advanced development activities within the organization.

D. **Focus Area.**

1) The Chief, OQM reports to the Commander through the Deputy Commander, and is supported by the USAMRMC Quality Management Office (QMO).

2) The OQM supports all USAMMDA divisions, staff, and integrated product teams (IPT) by facilitating and enabling the use of quality standards and tools such as document development and control, internal auditing, corrective action and preventative action, risk analysis, process mapping, strategy development and implementation.

E. **Accomplishments.** One of the critical roles of the OQM is to coordinate and host inspections, and manage the resultant corrective actions. The OQM successfully hosted three significant inspections in FY14, including an audit of the EDC-CRDMS in coordination with the U.S. Army Medical Research Institute of Infectious Disease (USAMRIID), and an evaluation from the Organizational Inspection Program (OIP). This OIP inspection exhibits clear organizational improvement, identifying fewer and less significant deficiencies than the last inspection, in FY12. The OQM has performed all Managers' Internal Control Program evaluations on schedule, has established a re-organized internal audit program, and drafted an SOP for an organization-wide Continuous Process Improvement program. In addition, the OQM manages Document Control, leads the Balanced Scorecard strategic effort and provides quality assurance support on 24 IPTs and their associated working groups.

Office of Research and Technology Application

USAMMDA was granted Laboratory status on 03 January 2007 in a memo from (b) (6) ., Assistant Secretary of the Army (Acquisition, Logistics and Technology), and in accordance with AR 70-57. USAMMDA was authorized to directly participate in the Army Domestic Technology Transfer Program, and with this authorization, its Commander was also granted the authority to execute technology transfer agreements.

A. General. Chief. (b) (6)

B. Staff. 4 Personnel. 2 Civilians and 2 Contractors.

C. Focus Area.

1) The USAMMDA Office of Research and Technology Application (ORTA) Officer and staff reports directly to the Commander and is supported by the U.S. Army Medical Research and Materiel Command (USAMRMC) ORTA and by the USAMRMC Office of the Staff Judge Advocate.

2) The ORTA supports all USAMMDA project management offices (PMO), divisions and executive agency staff.

3) The Command successfully executed many technology transfer agreements with domestic and foreign industry partners, and universities to collaborate in advanced product development towards product licensure and product commercialization to benefit the Service Member.

D. Accomplishments.

1) Executed a total of 117 new Tech Transfer and Interagency agreements in FY14, bringing into the Command ~$1,921,600.00 from external partners.

2) In-kind industry partner contribution for the fiscal year was estimated at $13,250,000.00.

3) USAMMDA has a total of 399 active agreements. They are as follows: 101 Cooperative Research and Development Agreements (CRADA), 14 Memorandum of Understanding, 77 Memorandum of Agreement (MOA), 24 Material Transfer Agreements, 81 Interagency Support Agreements, 22 Interagency Agreements, 63 Nondisclosure Agreements, and 1 Patent License Agreement, 7 Over-arching Agreements and 9 Other.

Public Affairs and Marketing Office

The Public Affairs and Marketing Office was responsible for delivering the USAMMDA message to internal audiences (Military) and external audiences (corporate and potential partners and the general public) by attending tradeshows, VIP events, submitting articles and press releases, and participating in community and educational activities.

The USAMMDA Public Affairs and Marketing Office was responsible for assisting the USAMRMC Public Affairs Officer in gathering Command information and accomplishments, as well as submitting updates on Command projects and programs.

A. General. Public Affairs Specialist. (b) (6)

B. Personnel. 2 Personnel. 1 Civilian and 1 Contractor.

C. Accomplishments.

1) Supported USAMMDA and USAMRMC in seven VIP events, one congressional event.

2) Participated in two community and educational events.

3) Published one press release and nine news stories.

4) Increased social media following on Facebook, Twitter and YouTube.

Administrative Services Division

Administrative Services Division

The Administrative Services Division (ASD) centrally manages a variety of business support functions in support of the USAMMDA Operating Divisions. ASD provides support in three specific areas that include Resource Management, Information Management/Information Technology, and Acquisition Management.

A. General. Director. (b) (6)

B. Personnel. 17 Personnel. 8 Civilians and 9 Contractors.

Resource Management and Budget

Resource Management (RM) is the section within ASD that deals with a variety of aspects of the money that flows both into and out of USAMMDA. The office manages a budget, annually on average, of approximately $120 million dollars. The activity receives a variety of funding consisting of different appropriations such as Research Development Test and Evaluation (RDT&E), Operations and Maintenance Army (OMA), Other Procurement Army (OPA), Defense Health Program (DHP), Defense Threat Reduction Agency (DTRA), Joint Warfighter funds and incoming reimbursable funds. The RM shop is responsible for the execution of all current year dollars and for planning and programming of dollars for the short term (one future year) through the Command Budget Estimate. The execution of funding occurs through Military Interdepartmental Purchase Requests (MIPR), funding is provided to USAMRMC labs, and through all internal and external Purchase Requests (PR) which are processed through the General Fund Enterprise Business Systems (GFEBS) web-enabled accounting system. RM is responsible for reporting financial information by validating data and making corrections on a daily basis. There is a final validation at the end of each month. A larger validation takes place once a year in September to close out the financial data for that year. RM is responsible for populating and maintaining an Activity Based Costing Model as required by Headquarters, putting together and briefing a monthly report to the Principal for Acquisition on all contracting actions, obligation rates and disbursement rates, and annual spend plans. The RM shop is responsible for answering a variety of taskers from Headquarters, for payroll for the organization, for validating that there are funds within Defense Travel System for all travel, and for reconciling the monthly bill for the purchase card.

Information Management and Information Technology

The Information Management/Information Technology (IM/IT) section of ASD maintains the Authority to Operate (ATO) from the Designated Approving Authority. The ATO is maintained so that the networks will remain active, maintaining access to the Army network. Maintaining the ATO entails documentation, ensuring that all updates to new regulations are implemented and compliant with Army directives and regulations, as well as implementing hundreds of software updates in any given year. USAMMDA received a new ATO on 25 August 2014. In FY14 the branch deployed the mandated Office 2010 to all USAMMDA personnel. The branch also worked to convert USAMMDA servers from a physical environment to a virtual environment. IM/IT deployed the new Video TeleConference (VTC) capabilities at the request of the Commanding General. IM/IT coordinates all USAMMDA testing and activities regarding the Continuity of Operations. IM/IT operates the USAMMDA Help Desk that supports all USAMMDA personnel and averages approximately 25 requests in a day. IM/IT supports all Microsoft applications, Local Area Network (LAN) and connectivity issues, all internal applications unique to USAMMDA, printers, approximately 217 laptops and over 90 blackberries.

Acquisition Management

In the area of Acquisition Management, ASD acts as the primary liaison with U.S. Army Medical Research Acquisition Activity (USAMRAA) through the Acquisition Management Liaison Officer (AMLO). The AMLO assists Contracting Officer Representatives (COR) in contracts management and strategic planning for future products and programs. The AMLO helps gather Command requirements to develop an annual contracting forecast, provides

guidance on building a complete acquisition package, and works with USAMRAA to determine the path forward. The AMLO also helps in standardizing and developing processes, policies and procedures for planning and execution of contracts.

Military Relevance

The essential administrative, budgetary, and IM/IT support functions accomplished by the ASD provide the physical and financial stability and infrastructure necessary to sustain USAMMDA, as division and product managers carry out their duties to develop medical products to protect and sustain Service Members. ASD provides the link in support of external activities that are part of the operating environment for USAMMDA.

Fiscal 2014 Performance

In total, including Core-Direct Advanced Development RDT&E, OMA, DHP (both O&M and RDT&E), reimbursable, and Congressional funding, USAMMDA managed $80.0M and the Labs managed $10.5M of Core-Direct Advanced Development RDT&E in FY14 for a total of $90.5M.

A. In-House. In FY14, the USAMMDA In-House fiscal execution of Core-Direct Advanced Development funds fell short of the Office of the Secretary of Defense Obligation Target by 8% and also fell short of the Disbursement Target by 14%. The FY14 In-House total direct funds included Advanced Development funds ($30.5M), Tech Base funds ($1.2M) for quality assurance and clinical monitoring, DHP Operation and Maintenance funds ($1.9M) for Adenovirus Vaccine and Force Health Protection - Investigational New Drug support, DHP, Defense (DTRA) funds for the Special Immunization Program ($900K), DHP RDT&E funds ($5.1M) for Hyperbaric Oxygen for Traumatic Brain Injury (TBI) Research, Enhanced DHP RDT&E funds ($23.0M) for Division Management and Program Support, Congressional DHP RDT&E funds ($14.9M) for Tissue Injury and Regenerative Medicine, and Operations & Maintenance Army funding ($243K) for Division Support and Special Medical Command (MEDCOM) Response Capabilities Team.

FIGURE 2: In-House and Lab Funds (Core-Direct Advanced Development)

	Allotment	Obligations	Disbursements
Fiscal 2014 In-House Dollars ($000)	30,476	25,131	12,583
Fiscal 2014 Lab Dollars ($000)	10,516	10,174	5,931
Total	40,992	35,305	18,514
Target (%)		90	55
Actual In-House (%)		82	41
Actual Lab (%)		97	56

B. In-House. In addition, USAMMDA In-House managed $2.5M in reimbursable funds in FY14. This included funds from Medical Countermeasures Systems (MCS), Glaxo Smith Kline (GSK), Geneva, Sanofi Pasteur, Meridian, Navy, and Special Immunizations Program (SIP) funds from several Universities and external customers.

FIGURE 3: Fiscal 2014 Program*: Advanced Development & Other Funding*

		Percent					
Direct – Advanced Development	**Allotment**	**In-House**		**Lab**		**Total**	
Project	**($000)**	**OBL**	**DISB**	**OBL**	**DISB**	**OBL**	**DISB**
808	6,511	90	46	95	47	91	46
811	516	100	0	96	70	96	66
836	4166	98	4	65	47	97	4
Total 6.4	**11,193**	**93**	**26**	**94**	**52**	**94**	**31**
812	3,657	100	53	100	74	100	73
832	14,467	73	50	86	76	74	51
849	11,675	86	42	96	43	90	42
Total 6.5	**29,799**	**78**	**47**	**97**	**58**	**83**	**50**
Total Advanced Development	**40,992**	**82**	**41**	**97**	**56**	**86**	**45**
OMA	243	98	35	0	0	98	35
Tech Base	1,189	37	26	0	0	37	26
DHP, O&M	1,852	97	28	0	0	97	28
RDTE/DEF	900	28	19	0	0	28	19
DHP/RDTE	5,062	37	5	0	0	37	5
Congressional, DHP RDTE	14,850	1	0	0	0	1	0
DHP/RDTE(Enhanced)	23,010	30	5	0	0	30	5
Total Direct – Other	**47,106**	**25**	**5**	**0**	**0**	**25**	**5**
Total Direct	**88,098**	**47**	**20**	**97**	**56**	**53**	**24**
	Allotment	**In-House**		**Lab**		**Total**	
Project	**($000)**	**OBL**	**DISB**	**OBL**	**DISB**	**OBL**	**DISB**
Reimbursements	2,458	34	4	0	0	34	4
Total Reimbursements	***2,458***	***34***	***4***	***0***	***0***	***34***	***4***
	Allotment	**In-House**		**Lab**		**Total**	

	($000)	OBL	DISB	OBL	DISB	OBL	DISB
Total Program	**90,556**	**47**	**19**	**97**	**56**	**53**	**23**

Division of Regulated Activities and Compliance

Division of Regulated Activities and Compliance

The Division of Regulated Activities and Compliance (DRAC) is a multidisciplinary team of regulatory affairs and compliance professionals dedicated to support the USAMMDA mission. The DRAC provides full-service regulatory support for products through the Department of Defense (DoD) acquisition spectrum, from individual investigator-initiated clinical studies to products in the advanced development pipeline. USAMMDA DRAC carries out the regulatory responsibilities required to support to the Office of The Surgeon General (OTSG) Sponsor's representative for the Army regarding medical materiel development, and its operations are mandated in, DoD, and Army regulatory requirements. The DRAC supports investigators at military medical centers and laboratories, Institutional Review Boards (IRB), product development teams in laboratories and advanced development organizations throughout the Army and the DoD.

At the end of FY14, DRAC was organized as a Division office with three Branches, including two Regulatory Affairs (RA) branches and a regulatory operations branch. The regulatory operations branch is responsible for all submissions to the U.S. FDA or other regulatory agencies, to include creation and maintenance of the complete official regulatory files for TSG-sponsored products. This branch includes medical writing and editorial support, as well as responsibility for serious adverse event reporting in collaboration with the USAMMDA Clinical Services Support Division. The Medical Writing team wrote or reviewed annual reports and maintained complete sponsor regulatory files for more than 70 TSG-sponsored U.S. FDA applications for medical products in support of the Service Members. The Regulatory Operations (RO) branch is also responsible for the archiving, storage, and upkeep of all Sponsor-related and regulated documentation.

The DRAC regulatory affairs mission is allocated to two regulatory affairs branches: Regulatory Science and the Medical Devices and Diagnostics Branch.

The branches are staffed with regulatory scientists with specific experience to support the type of product assigned. The role of the regulatory affairs representative is to provide expert regulatory advice, product development strategy and support for medical products in all stages of development, to serve as a liaison between the IPT and other parties needing support, and to assure that all product development efforts comply with appropriate DoD and Army regulations and policies.

A. **General.** Director. (b) (6) .

B. **Staff**. 28 Personnel. 12 Civilians, and 16 Contractors (includes one contractor providing direct support to the Walter Reed Army Institute of Research (WRAIR)).

Regulatory Operations Branch

The Regulatory Submissions team within DRAC is responsible for receiving, formatting, and sending accurate and complete formal regulatory communications and submissions in a timely manner. This includes preparation of cover letters and regulatory forms; formatting and pagination of overall document submissions; and printing, binding, and mailing documents to the appropriate regulatory agency. In 2013, the team added the capability to submit electronic submissions using publishing software. All new/initial applications are submitted electronically and no paper copies of communications or submissions are generated as of 18 February 2013. The Document Control team is responsible for internal and external tracking of submissions, document control, and trial master file record-keeping and archiving. Efforts are being made (initiated in 2013) to bring all active Investigational New Drugs (IND) up to the current electronic standard for Sponsor's Records. The Medical Writing team is responsible for writing regulatory documents such as clinical protocols, final clinical study reports and Investigators Brochures in support of Army-

sponsored medical product development efforts. This team is also responsible for the training regulatory document authors in the use of eSubmission documents using the USAMRMC document templates.

A. General. Chief. (b) (6) .

B. Staff. 10 Personnel. 3 Civilians and 7 Contractors.

C. Mission. Provide world-class regulatory submissions, medical writing support and document control services to Army-sponsored medical product development efforts.

D. Accomplishments.

1) In 2013, the Regulatory Submissions team prepared and submitted 273 formal submissions to the U.S. FDA in support of approximately 80 different medical product (drugs, vaccines, and devices) development efforts as of the close of the fiscal year (30 September 2013).

2) The Medical Writing team prepared numerous protocols, final clinical study reports, annual reports, Investigator Brochures and other documents in support of medical product development.

3) The e-publishing Software for electronic regulatory submissions was implemented late August 2013 and user training was completed in September 2013. The Submissions team successfully submitted the first electronic Common Technical Document (eCTD) to the agency successfully on 16 September 2013.

Regulatory Science Branch

A. General. Chief**:** (b) (6) .

B. Staff. 9 Personnel. 3 Civilians, 6 Contractors (one of which provides direct support to the WRAIR).

C. Mission. Provide world-class regulatory support, through RA Scientists, to Army-sponsored development of pharmaceutics, vaccines and blood products in support of the Service Members.

D. Focus Areas. The RA scientist serves in three primary roles: Agency liaison, developer of regulatory strategies, and provider of regulatory guidance for vaccine and blood product development efforts.

1) As liaison, the RA scientist is the primary point-of-contact for communications with federal regulatory agencies including the U.S. FDA and Environmental Protection Agency (EPA); other Federal agencies; non-government organizations; public health organizations; and product co-developers. The RA scientist is an interface between the IPT and the other members of DRAC and a resource of regulatory information and support for IPTs and IPT Chairs, working with each IPT individually to tailor support to the needs of the team. The RA scientist-IPT interaction helps to ensure effective and accurate regulatory and scientific communication between product development teams and the regulatory agencies.

2) As a product development and regulatory strategist and core IPT member, the RA scientist works with the other members of the IPT to develop the overall regulatory strategy or approach to guide product development. The RA scientist draws on technical and scientific or medical knowledge to help IPTs develop the best plan for optimizing outcomes of studies and label claims. The RA scientist reviews all documents in detail to ensure clarity of information and data presentation, accuracy of data interpretation, logic, consistency, and compliance with regulatory requirements prior to endorsement for submission to regulatory agencies.

3) An additional role of the RA scientist is to provide guidance to the USAMRMC staff involved in the process of product development and manufacture and assembly of data to ensure that regulatory and statutory requirements are met and commitments to regulatory agencies or co-developers are fulfilled in a timely manner. As the subject matter expert (SME) in regulatory information, the RA scientist must keep track of changing U.S. legislation, regulatory agency guidance documents, International Committee of Harmonization (ICH) guidance documents, and Public Health issues/concerns as related to OTSG-sponsored products. This will ensure that OTSG-sponsored products meet the needs of the Service

Members as stated through the Combat Developer Representative as well as the challenges of public health threats.

Medical Devices and Diagnostics Branch

A. General. Acting Chief. (b) (6) .

B. Staff. 3 Personnel. 1 Civilian (not including Branch Chief), and 2 Contractors.

C. Mission. Provide world-class regulatory support, through RA Scientists, to Army-sponsored development of medical device products in support of the Service Members.

D. Focus Areas. The focus areas of the Device and Diagnostics Branch is essentially the same as for the Vaccines and Blood Products branch except the focus is on medical device development efforts. The branch interfaces primarily with the U.S. FDA Center for Devices and Health Radiological (CDRH).

Clinical Services Support Division

Clinical Services Support Division

Clinical Services Support Division (CSSD) is a Division composed of the following five branches: Clinical Operations, Product Safety Surveillance, Biostatistics, Product Technical Operations and Data Management. CSSD provides support for the life cycle development of regulated medical products (pharmaceuticals, biologics and devices) sponsored by the OTSG, as well as for other non-OTSG sponsored studies of interest to the DoD. CSSD carries out its responsibilities to assure sponsor's regulatory compliance of OTSG-sponsored products in the areas of clinical study monitoring, clinical data management, biostatistics, product adverse event safety reporting and surveillance, investigational product manufacturing, product release and stability testing, nonclinical evaluation, and product accountability. In addition, CSSD provides consultation and support in clinical, nonclinical, and manufacturing aspects of medical product development and compliance oversight in Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP) and Good Clinical Practices (GCP).

CSSD personnel work closely with staff of the DRAC and ORTA, as well as tech based and advanced development Product Managers and IPTs, to assure that FDA, DoD, and Army regulatory requirements are met as well as to develop efficient and effective strategies and plans to achieve approval of medical products.

A. General. Director. Lieutenant Colonel (b) (6) . Deputy Director. (b) (6) .

B. Staff. 29 Personnel. 1 Military, 10 Civilians and 18 Contractors.

C. Mission. The CSSD provides an integrated regulatory capability providing consistent, competent and timely management and oversight for both DoD sponsored and extramurally sponsored products to mitigate risk and accelerate delivery of U.S. FDA regulated products to Service Members.

Clinical Operations Branch

A. General. Chief. (b) (6) .

B. Staff. 10 Personnel. 5 Civilians and 5 Contractors.

C. Mission. The primary mission of the Clinical Operations (CO) branch is to fulfill the responsibility of the Sponsor, the OTSG, for monitoring clinical studies at continental United States (CONUS) and outside the continental United States (OCONUS) study sites.[19]

[19] See Code of Federal Regulations at 21 C.F.R. 312.50 and ICH E6 Good Clinical Practice Guideline.

1) CO is charged with ensuring that the rights and safety of the study subjects are protected and the quality of the data is adequate to support further development of the investigational product intended to protect the Service Member. CO supports Phase 1, Phase 2 and Phase 3 studies for investigational products.

2) Clinical monitors act as the point-of-contact between the sites and the Sponsor's Representative. Monitoring visits at the study sites involve site qualification for the proposed study, training site staff on study procedures and document completion, verification of adequate informed consent procedures for study participants who meet enrollment criteria, study data verification, ensuring compliance with the protocol, and ensuring the Principal Investigator provides adequate oversight of the study. Clinical monitors ensure that appropriate investigational product receipt, storage and accountability procedures are in place at the study site, and are followed. Prior to study conclusion, study records archival facilities at remote study sites are inspected to ensure study records are protected and retrievable. Qualified research laboratories are periodically monitored to ensure that sample storage and accountability procedures are in place and procedures for research assays are followed by laboratory staff.

D. Focus Areas.

1) Clinical monitors are strategically located in the United States and Thailand in order to provide efficient and effective monitoring capacity. There are three civilian monitors located at Fort Detrick that in addition to monitoring various clinical studies, provide direct face-to-face consultation services to the command as well as oversee external contract monitors.

2) CO supports product studies for Advanced Development and Tech Base and continues to support the SIP at the USAMRIID.

3) CO supports the Force Health Protection program treatment protocols.

4) CO provides consulting services for site assessments and monitoring plan writing for non-OTSG sponsored studies as requested by the Command.

5) Clinical monitors work with industry partners by providing training to clinical sites on principles of GCP, and performing site assessments.

6) CO provides monitoring and training, services for a wide variety of medical device studies sponsored by OTSG and other partners.

7) CO has clinical monitors that are trained in adverse event and concomitant medication coding to assist in preparing data for safety reviews and submission to U.S. FDA.

E. Accomplishments.

1) Provided clinical monitoring and data management support for over 44 clinical studies.

2) Participated in monitoring two studies for the Leishmaniasis Rapid Diagnostic Device product that has now received FDA clearance.

3) Provided oversight monitoring for three clinical sites in Panama including two sites new to clinical research in support of the Topical Paromomycin Pivotal Phase III Study.

4) Provided extensive site selection support to the Portable Neuromodulation Stimulator (PoNS) device Project Management Office to prepare for a pivotal study in patients with traumatic brain injury.

5) Provided monitoring support to begin a study of anti-plaque chewing gum, establishing a positive partnership with a new clinical site.

6) Provided monitoring support for U.S. Special Operations Command (SOCOM) in order for freeze dried plasma to be provided as treatment on the battlefield for severely wounded Soldiers.

7) Continued work on bringing a clinical trial management system to USAMMDA to enable the Command to have for the first time, a complete view of the status of all clinical trials in one database. This program

was successfully transferred to EIT-PMO under the leadership of the CSSD Director which will result in a more efficient implementation of the product.

Product Safety Surveillance Branch

A. General. Acting Chief. (b) (6) .

B. Staff. 3 Personnel. 1 Civilian and 2 Contractors.

C. Mission. The primary mission of the Product Safety Surveillance Branch is to provide safety pharmacovigilance and oversight for all OTSG-Sponsored clinical trials involving human subjects, and to ensure compliance with U.S. FDA safety monitoring and reporting requirements.

D. Focus Areas.

1) Responsible for pharmacovigilance, risk/benefit analysis and management of safety data related to OTSG-sponsored clinical studies, as well as trending of safety data for potential safety signals.

2) Responsible for management of safety data including all aspects of safety data reporting, monitoring, tracking, evaluation, and distribution to include review of line listings, data discrepancy and data reconciliation for medical coding of adverse events, using a 21 CFR Part 11 compliant USAMRMC safety database, Empirica Trace.

3) Responsible for safety consultation including the review of safety information in protocols, investigator brochures, clinical trial agreements, U.S. FDA submissions and consultation to IPTs and clinical sites

4) Responsible for establishing and coordinating Data Safety Monitoring Boards, as required.

5) Responsible for the medical evaluation & analysis of adverse events associated with OTSG sponsored studies; and, provides medical narrative summary and Sponsor assignment of causality on all reported cases.

6) Prepares and completes all MedWatch safety reports as needed for U.S. FDA submission including a medical assessment of all prior cases. Collaborates closely with the DRAC for the submission of serious adverse events to the U.S. FDA within mandated timelines.

7) Provides safety training to site personnel to support the implementation of a clinical study.

8) Performs continuous process improvement to development and revise processes to enhance efficiencies and operations, as well as implementation of new regulatory guidance.

E. Accomplishments.

1) Continued successful use of 21 CFR Part 11 paperless electronic safety databases, Empirica trace, for processing clinical trial safety cases, and use of the electronic data management system for document archiving and serious adverse event case flow processing.

2) Collaborating with other USAMRMC proponents to implement improved safety signal detection processes. Developed a procedure for emergency unblinding of subjects in blinded U.S. FDA regulated clinical trials.

3) Processed 31 reported serious adverse events. None were deemed to be immediately reportable to U.S. FDA.

4) Processed 7 reported pregnancies. Closed out 5 in this reporting period. None of the pregnancies resulted in congenital defects or abnormalities, and therefore did not result in a serious adverse event.

5) Provided safety training for clinical sites conducted by the monitors during study initiation.

6) Managing 2 active data monitoring committees, one for Anti-Plaque chewing gum, and one for Cryo-preserved platelets. Establishing a charter and selecting members for a new data safety monitoring board for the planned Dengue Human Infection Model clinical trial.

7) Achieved successful reconciliation with the data management branch on multiple different studies for annual reports and study close outs prior to data base lock.

8) Provided safety consultation and review of 12 clinical trial agreements and 47 protocols and associated clinical trial documents.

Biostatistics Branch

A. General. Chief. (b) (6) .

B. Staff. 2 Personnel. 1 Civilian and 1 Contractor.

C. Mission. To ensure the integrity, appropriateness and regulatory-compliance of study designs and statistical analyses used in OTSG-Sponsored, U.S. FDA-regulated clinical studies of investigational products.

D. Focus Areas.

1) The Biostatistics Branch provides USAMMDA and the USAMRMC subordinate commands with statistical regulatory advice, consultation, support and oversight.

2) The Biostatistics Branch provides a forum for discussing and addressing USAMRMC-wide regulatory biostatistical issues.

3) The Biostatistics Branch provides oversight and management of contract research organizations responsible for the provision of full statistical support of OTSG-Sponsored, U.S. FDA-regulated clinical studies of investigational products.

4) The Biostatistics Branch provides the following comprehensive services:

a. Statistical Consultancy

i. Clinical Development Planning

ii. IND Preparation

iii. Study Design

iv. Data Analysis

v. Presentation of data and analyses in Clinical Study Report (CSR)

vi. Data submissions to U.S. FDA and other Health Authorities

vii. New Drug Application (NDA), Biologics License Application (BLA), Premarket Approval, 510 K Preparation

b. Regulatory Oversight

i. All statistical aspects associated with regulated non-clinical and clinical research.

ii. Represents OTSG Sponsor-representative at the U.S. FDA and other Health Authorities

E. Accomplishments.

1) The branch continued to provide guidance to USAMRMC subordinate command statistical groups and investigators on the design and analysis of both learning and confirmatory regulated clinical trials.

2) The branch continued to provide guidance to WRAIR's statistical group and investigators regarding assay validation analyses for the new Haantan Puumala antibody assay.

3) The branch continued to provide State University of New York (SUNY) Upstate Medical School, Biostatistics Group, Syracuse, NY with guidance on how to design dengue learning regulated clinical trials.

4) The branch continued to work with Sigma Tau Rome (both in the United States and in Italy) on the Intravenous Artesunate (IV AS) legacy malaria treatment trials with respect to creating Clinical Data Interchange Standards Consortium data deliverables for the New Drug application (NDA); assessing U.S. FDA compliance of the legacy trial clinical data (statistical data sets); oversight of the integrated summary of safety (ISS)and efficacy meta-analysis for regulatory submission to FDA; oversight of the preparation of the ISS and efficacy meta-analysis Statistical Analysis Plans (SAP) and Tables, Listing and Figures (TLF); and oversight of the preparation of module 5 of the eCTD. Dr. McCarthy worked with Pharmaceutical Product Development, LLC (PPD) and Sigma Tau Rome with the creation of all 5 eCTD modules for the NDA. Planned submission of the NDA to U.S. FDA is 2015.

5) The branch worked with PPD on the tafenoquine legacy prophylactic trials: Validation of CSRs and TLFs; Mapping raw and analysis statistical data into CSRs and TLFs; Assessing Therapeutic Goods Administration (TGA)and U.S. FDA compliance of the legacy trial clinical data (statistical data sets); Assessing TGA and U.S. FDA compliance of the legacy trial Pharmacokinetics (PK) data; Preparing the ISS and integrated summaries of efficacy (ISE)and clinical data (statistical data sets)for regulatory submission (TGA and U.S. FDA); Preparing the ISS and ISE SAPs and TLFs; Preparing the integrated analyses for safety and efficacy; and Preparing Common Technical Document (CTD) module five of the NDA submission.

6) The branch co-authored a report on the re-assessment of the malaria epidemiology of East Timor and the GSK 033 trial sites in Bobonaro District and presented a new statistical methodology for assessing protective efficacy based on data from the East Timor active control (tafenoquine versus mefloquine) clinical trial. This is an important component for the TGA NDA submission: Dow GS, McCarthy WF, Reid M, Smith B, Tang D, Shanks GD (2014). A retrospective analysis of the protective efficacy of tafenoquine and mefloquine as prophylactic anti-malarials in non-immune individuals during deployment to a malaria-endemic area. Malar J. 2014 Feb 6;13(1):49. [Epub ahead of print] PMID: 24502679. This is an important component for the TGA and FDA NDA submission for tafenoquine(http://www.malariajournal.com/content/13/1/49).

7) The branch worked with bioCSL in Australia to review the adequacy and completeness of the CTD module 5 efficacy and safety data for the Q fever vaccine Q-Vax. The Australian vaccine developer, bioCSL, is considering a BLA submission to FDA for U.S. approval of Q-Vax. The branch performed a gap analysis for CTS module 5 content and a meta-analysis for vaccine effectiveness was performed.

8) The branch worked with WRAIR on the validation design of a polymerase chain reaction (PCR) assay for determining exposure to malaria.

9) The branch provided training in regulated clinical statistics and regulated clinical trial methodology for Decision Gate and the Congressionally Directed Medical Research Program (CDMRP).

Product Technical Operations Branch

A. **General.** Chief. Major (b) (6) served as Chief until 14 July 2014. (b) (6) assumed responsibility as Acting Chief 14 July 2014.

B. **Staff.** 6 Personnel. 3 Civilian and 3 Contractors.

C. Mission. The mission of the Product Technical Operations branch is to provide life-cycle product support through technical oversight to ensure quality compliance of both OTSG-sponsored and non-OTSG sponsored, -regulated medical products intended for use by the Service Member.

D. Focus Areas.

1) Provide quality review of regulatory submissions such as IND, NDA, BLA, Premarket Notification 510(k) packets, amendments, and annual reports with special emphasis on Chemistry, Manufacturing and Controls (CMC) and non-clinical studies.

2) Perform technical review of raw data, batch production records, in-process control, assay qualification/validation reports, product specifications, Certificates of Analysis, and contracting documents and agreements as well as non-clinical study reports.

3) Conduct site visits for qualification, pre-award assessment, due diligence and for-cause investigation to ensure current GMP and GLP compliance.

4) Participate in the IPT meetings and pertinent working groups for proposed clinical studies and serve as subject expert to provide regulatory guidance on CMC and non-clinical issues.

5) Implement non-compliance management plan and ensure corrective action plan is in place and being followed.

6) Maintain accountability of investigational products from manufacturing to release for use in clinical trials and testing, through proper destruction.

7) Review stability protocol and testing data, and analyze the testing results to evaluate the acceptability of use.

E. Accomplishments.

1) PTO works with Force Health Protection for the coordination, release and inventory management of products used in emergency use authorization protocols.

a. CSSD actively worked with FHP to revise and implement a treatment protocol for the Use of IV-Artesunate under IND 64769.

b. PTO and FHP worked together to coordinate the successful positioning (shipment) of IV-Artesunate to Monrovia, Liberia for the potential treatment of severe malaria for U.S. Soldiers and civilian staff during the Ebola crisis.

2) Maintain 21 CFR Part 11 compliant product accountability database to manage inventory, track shipment status and create accountability reports for >100 products.

3) Contributed to the CMC sections of regulatory submissions, successfully submitted to the FDA:

a. IND 15883, Capsule-Conjugate Camplylobacter jejuni Vaccine 1 (CJCV1)

b. IND 16055, Plasmodium falciparum Malaria Protein FMP012 Administered Intramuscularly with AS01B Adjuvant System (pfCelTOS2)

c. Pre-IND package, Dengue Human Infection Model

d. Pre-IND package, Artificial Shigella invasin complex (InvaplexAR) vaccine

e. Pre-IND package, Monophosphoryl lipid A in liposomes (L(MPLA))

f. Pre-IND package, Shigella Artificial Invasin Complex (InvaplexAR) Vaccine

4) Assisted in the selection of a new qualified Freeze Dried Plasma manufacturer, and establishment of a CRADA outlining Contracting Manufacturing Organization (CMO) responsibilities for all manufacturing operations.

5) Conducted a gap analysis of the Syracuse University, New York, clinical research site for the Dengue Human Infection Model study and provided a corrective action plan to be implemented prior to study initiation.

6) Successfully completed tasks associated with the current Good Manufacturing Practices (cGMP) production of a new ricin vaccine to include development of lot release specifications, batch production records and product stability protocols. (Final drug product lot and diluent to be produced at WRAIR the end of January 2015).

7) Release and inventory management, for the potency testing, of eight products used in the SIP clinical trials at USAMRIID.

8) Conducted seven CONUS and OCONUS site visits and provided technical support and consultation to more than 80 investigational products including drugs, vaccines, blood products and medical devices.

a. Site visits in support of manufacturing:

i. Alfa Wasserman, Italy (Artesunate)

ii. Slovenia (Bacteriophage)

iii. China (Topical paromomycin)

iv. Italy (Topical Paromomycin)

v. Althea, San Diego, CA (Hantaan and Puumala DNA vaccine)

vi. Advantar, San Diego, CA(Topical Paromomycin)

vii. Vascular Solutions, Maple Grove, MN (Freeze Dried Plasma)

Data Management Branch

A. General. Chief. (b) (6) .

B. Staff. 6 Personnel. 1 Civilian, 5 Contractors.

C. Mission. In support of the USAMRMC and its partners, the Data Management Branch is committed to ensuring the highest quality clinical data for overall final study analyses.

D. Focus Areas.

1) Protocol Review to ensure standard data collection measures is appropriately documented.

2) Management and oversight of Case Report Form Development.

3) Management and oversight of study database development and Maintenance.

4) Management and oversight of all data entry and cleaning activities.

5) Management and oversight of Medical Coding using MedDRA and WHO-Drug Dictionaries.

6) Management and oversight of Serious Adverse Events Reconciliation.

7) Management and oversight of study database lock and unlock processes.

8) Management and oversight of internal and external Study Data Transfer and Achieve.

9) Assist with data management budget Estimates.

10) Primary oversight of data management activities contracted out to vendors.

11) Responsible for ensuring implemented data management systems are tested and validated.

E. Accomplishments.

1) Successfully managed all of data management activities during the upgrade and implementation of USAMRMRC's 21 CFR Part 11 compliant Electronic Data Capture-Clinical Research Data Management System (EDC-CRDMS) This will led to the more efficient and user-friendly EDC-CRDMS upgrade approval by USAMRMC.

2) Successfully managed over 12 database development and implementations in the USAMRMC's EDC-CRDMS.

3) Successfully supported site evaluations regarding data management activities.

4) Successfully managed study site, Sponsor InForm and Central Designer training.

5) Successfully reviewed over 10 clinical data managements Standard Operating Procedures (SOP) that are accessible to all Commands under USAMRMC performing clinical data management activities.

6) Successfully evaluated study sites regarding data management processes and procedures.

7) Continued to participate in the overall implementation of a Service Tracking Database (now part of RAMS) that will be used to track projects and protocols for the command.

8) Continue to provide 100% in-house and oversight data management support for all OTSG studies and non-OTSG studies as needed.

9) Continued to participate in strategic meetings focused in business process improvements within the command.

Force Health Protection

Force Health Protection

The USAMMDA Force Health Protection Division (FHP) Division is the OTSG Executive Agencies (EA) Directorate Lead Component for the use of investigational products under IND protocols or Emergency Use Authorization (EUA) mechanisms for force health protection programs. This authority, originally established in 2002, and currently supported by DoD Instruction (DoDI) 6200.02 and Health Affairs Policies 03-003 and 04-026, directs that U.S. Forces are provided safe and effective medical countermeasures to chemical, biological or radiological warfare and endemic disease threats. FHP product managers coordinate all administrative, clinical, and regulatory activities necessary to maintain and execute the IND protocols worldwide. In addition, FHP maintains the Specialized MEDCOM Response Capabilities-Investigational New Drugs (SMRC-IND) team for deployable protocol execution under the direction of MEDCOM OPORD 10-28. Formerly a branch under USAMMDA Medical Affairs Division, FHP became a separate division in 2010.

A. **General.** Director. Lieutenant Colonel (b) (6) . Deputy Director. Lieutenant Colonel (b) (6) .

B. **Staff.** 7.5 Personnel. 1 Civilian, 2 Military and 4.5 Contractors.

C. **Mission**. The USAMMDA FHP provides urgent treatment, diagnostic or prophylactic capabilities to protect U.S. Forces against man-made or natural threats using investigational countermeasures in accordance with federal regulations, DoD Instructions, and other guidance documents.

D. **Accomplishments.**

1) FHP Division expanded several strategic communications links and strengthened existing relationships in FY14. FHP briefed and established a regular presence at the Defense Health Agency (DHA) Services monthly meeting, where Services Surgeons offices establish and evaluate vaccination policies for DoD, and at the Health and Human Services – DoD Portfolio Advisory Committee, which has operational oversight of the U.S. Government Chemical and Biological Defense preparedness and is a

lead committee under the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). FHP Division continued to conduct monthly meetings with regulatory counterparts at the CDC for IND and EUA planning, and with the USAMRMC IRB for contingency preparedness. In addition, FHP Division met regularly with counterparts at the Assistant Secretary of Defense for Health Affairs, who has overall authority for protocol approval under the DoDI 6200.02.

2) FHP Division worked with the EA Directorate for course of action (COA) development for Lead Component and Executive Agency potential transition to the DHA. From February to May 2014, FHP, in collaboration with Headquarters (HQ), USAMRMC and the EA Directorate, developed and submitted COA recommendation which was dependent on the DHA Advanced Development Program COA to ensure mission success. Participation in this strategic process was critical to maintain and potentially enhance FHP's capability to provide investigational countermeasures to the DoD against high consequence threats.

3) FHP Division supported the development of the Interim Fielding Capability (IFC) concept, an initiative from the Office of the Assistant Secretary of Defense for Nuclear, Chemical and Biological Defense, to potentially make developmental medical countermeasures available for DoD use prior to FDA approval, and is dependent on product maturity, availability and intended use. FHP Division was a key leader in the process and participated in an IFC focus group at the National Academies of Sciences in May 2014. This collaboration under the IFC concept will enable optimal integration of FHP Division's existing policy and regulatory processes under the DoDI 6200.02. In addition, FHP's Medical Countermeasure Surveillance (MCMS) advisor established regular relationships with the Armed Forces Health Surveillance Center (AFHSC) Epidemiology Chiefs team, which entails global epidemiological surveillance across all services and several Federal agencies, and the JJ-3/DD-Nuclear, Homeland Defense & Current Operations cell at the National Military Command Center. Surveillance of emerging infectious diseases and outbreaks that could affect U.S. Forces allowed FHP to prepare for troop support and enables FHP leaders to improve preparedness for support to Service Members.

4) Two FHP products were presented as posters at the FDA Medical Countermeasures Initiative (MCMI) 2014 Research Symposium at the White Oak Campus, Silver Spring, MD in June 2014. The posters highlighted Arbekacin, an aminoglycoside treatment for multidrug resistant bacterial infections, and Tecovirimat, a treatment for smallpox/orthopox exposures or adverse reactions to the smallpox vaccine.

5) FHP Division responded to several emergency cases involving FHP products in FY14, facilitating improved processes and collective, collaborative responses for serious and life-threatening cases. In June 2014, FHP Division deployed Tecovirimat for a smallpox vaccine contact case in a Service Member in San Antonio, TX in coordination with Military Vaccine Agency-Vaccine Healthcare Centers Network (MILVAX-VHCN), military providers, Biomedical Advanced Research and Development Authority (BARDA) and the Centers for Disease Control and Prevention (CDC), ensuring a rapid response and support for a CONUS case requesting this investigational product.

6) In August 2014, FHP Division responded to a request for investigational intravenous Artesunate (IV AS) to treat a severe falciparum malaria case at the Landstuhl Regional Medical Center (LRMC). The patient was successfully treated upon issuance of an emergency IND number from the U.S. FDA for use of the product under U.S. FDA's expanded access provision. FHP Division responded to a third emergent case in FY14; Heptavalent Botulinum Antitoxin (H-BAT) was deployed from FHP inventory in response to a request from U.S. Forces-Korea involving a case of botulism in a Korean citizen. H-BAT, recently licensed by FDA in 2013, was deployed form FHP stockpiles to Brian Allgood Army Community Hospital (BAACH) in Seoul, Korea to support the U.S. Forces, Korea (USFK) request. Each of these emergency responses solidified and improved FHP's response processes and strategic and operational relationships with Combatant Command Surgeons and interagency partners, while ensuring optimal support to medical providers and safe use of products for Service Members.

7) FHP Division collaborated with USAMRIID and Joint Project Manager-Medical Countermeasures Systems (JPM-MCS) in the development of an Ebola Zaire diagnostic test capability based on assay design histories previously reviewed and accepted by the U.S. FDA in 2010 as pre-EUA packages. The DoD Ebola Zaire (Target 1) Real-Time PCR (TaqMan®) (EZ1 rRT-PCR) Assay, developed by USAMRIID and manufactured by the DoD Critical Reagents Program, was granted an EUA on 05 August 2014 by the U.S. FDA for diagnostic testing of individuals with signs and symptoms of infection with, or suspected exposure to, Ebola Zaire virus from the outbreak in West Africa and became the gold standard test for the U.S. Government. This test was the first test authorized by U.S. FDA for diagnostic testing of U.S. citizens for Ebola Zaire infection, was adopted by the CDC Laboratory Response Network in August 2014, and as of 31 December 2014 it was fielded to 16 qualified DoD laboratories and 52 U.S. public health laboratories. FHP continues to support this EUA, providing technical and regulatory input, and serves as primary contact for product accountability tracking.

8) The SIP PMO finalized personnel transition to include hiring of a Project Manager, encompassing of a core SIP Key leader team, leading the monthly operational meetings with the clinical site and storage and testing leads, and initiating the first SIP Integrated Product Team that included DoD and interagency partners.

9) The SIP PMO conducted several operational and strategic efforts in FY14, to include an independent market research in 2013 to assess current SIP vaccines, customers and protocols. This assessment addressed the following: review FDA annual reports; consider workload, activities, staffing, storage, testing, regulatory and other requirements; compare industry standards; and recommend courses of action for the path forward. An SIP IPT Working Group was formed in April 2014 to evaluate the proposed COAs for clinic location and develop a recommendation for the larger IPT and executive approval, and securing of funding and associated Interagency Support Agreement for potency testing and characterization of the portfolio's Rift Valley Fever vaccine and challenge stock as required by FDA, and an alphavirus Plaque Reduction Neutralization Test (PRNT) validation/cross validation bridging study conducted at USAMRIID.

E. **Budget.** FHP budget is $1.5M which covers labor costs; direct costs associated with maintaining IND protocols, including purchase of drugs, GMP storage of IND products, and regulatory files maintenance; indirect costs of supporting the IND protocols to include training, maintaining professional credentials and SMRC-IND team equipment; and mission-related travel expenses.

The SIP budget of nearly $8M is under a cost-savings transition, which resulted in direct funding of regulatory support to USAMMDA and a significant decrease in overall budget for both the clinical site and the regulatory support. Currently, the budget includes components at USAMRIID for clinical site operations, data entry/management, statistics support; at USAMMDA for project management and regulatory support, protocol writing and reviews, FDA communication, clinical monitoring, product technical oversight; and Joint Vaccine Acquisition Program (JVAP) under JPM-MCS for storage and potency testing of IND vaccines.

FIGURE 4: Current FHP protocols

IND #	Title
65480	Department of Defense Protocol for the Use of Cidofovir as a Treatment for Adverse Reactions Associated with Vaccinia Virus Vaccination, USAMRMC IRB A-11801
65480	Department of Defense Contingency Protocol for Emergency Use of Cidofovir as a Treatment for Smallpox, USAMRMC IRB A-11161
3723	Protocol for Vaccination of Selected Volunteers with Pentavalent Botulinum Toxoid to Protect against Botulinum A Toxin Toxicity, USAMRMC IRB A-12006
117,933	Clinical Protocol to Treat Individuals with Tecovirimat (ST-246) after Exposure to Orthopox Viruses, USAMRMC IRB M-10331
10081	Contingency Protocol for Anthrax Vaccination to Protect against *Bacillus anthracis* Spores, USAMRMC IRB A-10184
16,666	A Phase 2 Treatment Protocol of Intravenous Ribavirin in Adult Subjects with Hemorrhagic Fever with Renal Syndrome (HFRS) in Landstuhl Regional Medical Center (Landstuhl, Germany) Brooke Army Medical Center (BAMC) Human Use Committee (HUC) C.2008.197; USAMRMC IRB A-15314. A Phase 2 Treatment Protocol of Intravenous Ribavirin in Adult Subjects with HFRS in the 121st Combat Support Hospital (Seoul, Korea) TAMC HUC 23H07; USAMRMC IRB A—14474
16,666	Treatment of Viral Hemorrhagic Fever (Crimean-Congo Hemorrhagic Fever or Lassa fever) with Intravenous Ribavirin in DoD Associated Medical Treatment Facilities: A Phase II Study, BAMC HUC C.2009.140
14150	DoD Protocol for the use of Sodium Stibogluconate (Pentostam®) as a Treatment for Leishmaniasis, Walter Reed Army Medical Center HUC WU#04-19011; USAMRMC IRB A-12631
112536	Arbekacin Treatment of Adult Patients with Infections Caused by Multidrug-resistant Bacteria, USUHS Infectious Disease IRB Infectious Disease Clinical Research Program (IDCRP)-072
50098	WR 279,396 (Paromomycin + Gentamycin Topical Cream) Treatment Program for Individuals with Uncomplicated Cutaneous Leishmaniasis, USAMRMC IRB M-10337
64769	Treatment IND Protocol: Intravenous Artesunate for Treatment of Severe Malaria in the U.S. Hospitals and Health Facilities Outside of the United States

FIGURE 5: Emergency Use Authorizations (Diagnostics)

Date	Title	Intended Use
05 August 2014	DoD *Ebola Zaire (Target 1)* Real-Time PCR (TaqMan®) (EZ1 rRT-PCR) Assay	Presumptive detection of Ebola Zaire virus (detected in the West Africa outbreak in 2014) on specified instruments in individuals in affected areas with signs and symptoms of Ebola virus infection or who are at risk for exposure or may have been exposed to the Ebola Zaire virus (detected in the West Africa outbreak in 2014)in conjunction with epidemiological risk factors, by laboratories designated by DoD
06 Oct 2014	DoD *Ebola Zaire (Target 1)* Real-Time PCR (TaqMan®) (EZ1 rRT-PCR) Assay (amended and reissued)	As above but including additional specimen types

Figure 6: Products Pre-positioned for Emergency Use in Support of Operation United Assistance (OUA)

Product	Indication
Artesunate	Severe falciparum malaria
Ribavirin	Lassa fever, Congo-Crimean Hemorrhagic Fever

Educational Training and Regulatory Activities

During the weeks of 3-7 March 2014 and 15-20 June, 2014, the FHP Deputy Director attended the Veterinary Support to Stability Operations Course at the University of Georgia in Athens, GA. This two part course series focused on conducting veterinary assessments and then global veterinary medicine. Specifically, the course covered necropsy of small ruminates and poultry as well as diagnostic testing for a number of diseases all performed under conditions of limited resources. Additional topics of discussion included education and training for local national veterinary and para-veterinary personnel, joint, combined, interagency and non-governmental organization interactions with military veterinary missions, and also development of desired public affairs messages. The FHP Deputy Director serves as the SMRC-IND team leader and is a veterinarian. This course imparted useful skills transfer to future possible missions within SMRC-IND team areas of responsibility. Specifically, topics learned about working in limited resource environments, with multiple stakeholders and with correct public affairs coverage are critical also to SMRC-IND CBRN response missions that depend significantly on excellent logistical planning, coordination, proper public relations messages, and perception of the DoD and U.S. Government.

On 18 September 2014, the FHP Director and Deputy Director completed and graduated from the Naval Postgraduate School Phase III course in Program Management. This course completed the academic requirements for Program Manager Level III for these leaders. This acquisition training and certification enhances FHP's capability to integrate medical product development with warfighter support as part of the Lead Component mission, and is aligned with DoD and USAMRMC medical acquisition mission and vision.

On 15 October 2014, Force Health Protection Division presented a refresher training class for the USAMRIID Division of Medicine and on-call staff on FHP's portfolio of investigational products and expanded access protocols. The FHP Deputy Director presented an overview of the division. FHP SME reviewed diseases covered by FHP protocols. FHP Product Managers reviewed current protocols/products followed by an overview of the SIP PMO. Familiarity with FHP products and protocols will help to provide the appropriate treatment and ensure proper

regulatory compliance when OCONUS physicians contact USAMRIID clinical subject matter experts regarding cases in military medical treatment facilities.

Project Management - Medical Support Systems

Project Management - Medical Support Systems

Medical Support Systems Project Management Office (MSS PMO) is a multidisciplinary team with broad mission capabilities for the advanced development of medical products. The MSS PMO mission is to develop, procure and sustain the best medical evacuation, combat support hospital (CSH) infrastructure, combat casualty care support, and operational and preventive medicine solutions for the Service Member.

The team consists of product and logistics managers and model makers, who have expertise in project management, lifecycle management, engineering, fabrication, and technical testing. The product managers analyze functional requirements, conduct market investigations, develop and execute technical and program strategies, and plan for all acquisition program phases from Milestone B through Full-Rate Production. Within the MSS PMO resides the Medical Prototype Development Laboratory (MPDL) that designs, develops drawings and technical data packages, and rapidly prototypes far-forward medical equipment in support of the USAMRMC. The office's early involvement with products within the technology base streamlines development efforts by combining milestones and transitioning medical products rapidly to the logistician for procurement and fielding.

MSS PMO supports 27 unit assemblages and 85 individual products for the USAMRMC as its core responsibility in the following areas:

- Preventive Medicine
- Medical Evacuation and Treatment Platforms
- Combat Support Hospital Infrastructure
- Combat Casualty Care Support Systems
- Operational Medicine
- Decision Aids/Support Systems
- Airworthiness Certification

A. **General.** Project Manager. (b) (6) . Deputy Project Manager. (b) (6) .

B. **Staff.** 15 Personnel. 12 Civilians and 3 Contractors.

Product Managers – Medical Support Systems Products

A. **General.** Product managers direct program resources and defend program content and structure during science and acquisition forums.

B. **Focus.** MSS PMO is involved in the early development of products that are within the technology base, resulting in streamlined development efforts by combining milestones and transitioning medical products rapidly for procurement and fielding. Consequently, product managers develop and execute broad acquisition strategies or monitor technology base research efforts.

C. **Research and Development.**

1) **Mine-Resistant and Ambush-Protected (MRAP) Medical Evacuation (MEDEVAC)** The Vice Chief of Staff of The Army selected the MRAP III study course of action on 14 March 2013. Recent efforts were

to support the MRAP III study and retrofit of 301 MaxxPro Plus MRAPs with independent suspension into ambulances.

FIGURE 7: Up-armored MaxxPro Plus Ambulance

a. **Purpose.** Retrofit the MaxxPro Plus MRAP with the Dash Litter Loading System. MSS PMO, AMEDD, and Directorate of Combat and Doctrine Development (DCDD) worked with the Joint MRAP Vehicle Project Office and found that the MRAP Dash litter loading system was an acceptable course of action for the Plus ambulance.

b. **Progress.**

i. MSS PMO assisted the PM MaxxPro office with the design of the MaxxPro Plus MRAP Litter Load/Lift System, which is scheduled for user testing at Navistar Defense, Madison Heights, MI, in January of FY15.

ii. The Dash retrofitted system now accommodates the new North Atlantic Treaty Organization (NATO) 7309 Army Litter, as well as the TALON II litter.

iii. The MaxxPro Plus has a longer wheelbase and can accommodate taller patients side-by-side, providing improved patient access and a better working space for the medic.

iv. Loading and unloading takes less than a minute and is much safer and easier to use than the current MaxxPro Plus litter loading system.

v. MaxxPro Plus Ambulance will be placed into Army Prepositioned Stocks for use by units requiring an up-armored ambulance capability in future conflicts.

c. **Budget.** $5K in man hours in support of the IPT. This is one of the test assets funded by PM MaxxPro for AMEDD form, fit, and function evaluation in January of FY15. Other test assets will undergo blast testing and mobility testing in FY15 at Yuma Proving Ground (YPG) and Aberdeen Proving Ground (APG).

d. **Personnel Assigned.** 1 personnel.

e. **Milestones Achieved.** MSS PMO provided support in December 2014 to the PM MaxxPro effort to field 301 MaxxPro Plus Long Wheeled Base (LWB) ambulances. Full fielding is anticipated by FY16.

2) Replacement of the M113 Medical Ambulance/M577 Treatment Variants in the Heavy Brigade Combat Teams. MSS PMO worked with the Armored Multi-purpose Vehicle (AMPV) Program Office thru the source selection process serving on the IPT. The Request for Proposals (RFP) award is

expected to take place in second quarter FY15. MSS PMO continued to provide support for integration of the Medical Equipment Sets (MES) into the two medical variants.

a. **Purpose**. Continue to support PM AMPV to find a solution leading to First Unit Equipped in FY20.

b. **Progress**. Worked with Program Manager (PM) AMPV to develop the AMPV evacuation and treatment variants for replacements of the M113 family of vehicles. Revised the MES space claims data back to the program. Continue to work with the IPT on staffing decisions and moving the program forward.

c. **Budget.** $10k in man hours to support the IPT.

d. **Personnel Assigned.** 2 Personnel.

e. **Milestones Achieved.** The Capability Development Document (CDD) was approved in January 2013. The Source Selection Evaluation Board (SSEB) completed their work and a decision on a vendor is imminent.

i. Commercial Off-The-Shelf (COTS) Litter Lift systems in AMPV Medical Evacuation Variant.

ii. Contract Award November 2012 with Tank-Automotive Research, Development and Engineering Center TARDEC to Primus (8a vendor).

iii. Work has completed with Primus:

- Surveys with Medics at Fort Sam Houston are finished.
- AMPV demonstrator finished.
- Presentation at the AMPV demonstrator to Program Manager Armored Fighting Vehicle (PM AFV) and PM Bradley was well received. More funding may be provided to build more prototypes as an interim solution to the AMPV.
- Additional funding from the FY12 contract was placed on the Medium Troop Transport System (MTTS) variant to place the Medical Mission Package within that mobile platform as a potential solution to the Ambulance gap for the infantry brigade combat teams (IBCT).

3) NATO Litter Standardization Defense Health Program Operational System Development Program (6.7). This is a joint effort with the Air Force, Navy, and Marines to develop a 7309 single litter for the DoD that will be compatible with all casualty evacuation platforms. It will be functional, easy to assemble and operate, compact and lightweight. The purpose of this contract is to modify a standard 7309 litter to allow for the length of the litter to be 78 inches when the litter handles are collapsed; all other qualities will remain the same. The specifications for the current 7309 are found in MIL-L-49511B.

a. **Purpose**. Develop a single litter that is standard across all echelons of care and capable for all ground vehicles and rotary- and fixed-wing aircraft.

b. **Progress**. Prototypes were successfully user-tested in August 2013 at Camp Bullis, TX for the standard version of this litter. The quad-fold version of this litter required redesign. Additional funds were requested from USAMRMC and accepted. Additional prototypes will be delivered in second quarter FY15 for destructive testing at the U.S. Army Aeromedical Research Laboratory (USAARL).

c. **Budget.** $130K.

d. **Personnel.** 1 Personnel**.**

e. **Milestones Achieved.** A recent critical design review at Arizona Industries of the Blind (AIB) – Ability One resulted in acceptance of the final 7309 litter. Coordination with USAARL and AIB is underway for final testing.

4) **Quadfold Litter Defense Health Program Operational System Development Program (6.7).** A quad-fold version of the 7309 litter is required that is lighter and stores with a smaller footprint in the Vehicle Medical Kit, which is used in all DoD assets. The static load requirement is less stringent than for the standard 7309 to accommodate the reduced form factor for load strength. The current load specification is from MIL-L-49511B, Section 4.6.1.2.

   a. **Purpose.** Develop a quad-fold version of the 7309 litter that is lighter and stores with a smaller footprint in the Vehicle Medical Kit.

   b. **Progress.** A redesign was initiated based on user testing by the AMEDD Test Board. The original design reflected deficiencies. The newly designed quad-fold will be tested in FY15 by the AMEDD Test Board.

   c. **Budget.** $10k in man-hours programmatic support to the program, acting as the COR.

   d. **Personnel.** 1 personnel.

   e. **Milestones Achieved.** The contract was finalized, and testing is being coordinated.

5) **Rescue and Dismounted Litters.** A compact, lightweight rescue litter is a critical piece of equipment in the air and ground MES. Current requirements to update and potentially pursue an alternative or multiple vendors of this technology are being re-evaluated. Dismounted litter is a lightweight (less than 10 pounds) version of the rescue litter, carried in a backpack or in hand by dismounted Soldiers.

   a. **Purpose**. Update and improve the standard litter for evacuation of wounded warfighters.

   b. **Progress**. Technical testing started at USAARL and is underway. Initial user testing at Camp Bullis was accomplished. Aircraft testing will be accomplished in FY15, due to delays in finalizing the required safety letter.

   c. **Budget**. $50K.

   d. **Personnel**. 1 personnel.

   e. **Milestones Achieved**. USAARL testing is underway. User testing for ground vehicles was accomplished. Aircraft testing is scheduled for FY15.

6) **Litter Transport Shock/Stressor Mitigation System.** The Litter Transport Shock/Stressor Mitigation System is a system of devices incorporating advanced vibration dampening that will allow for injury-specific TBI/spinal cord injuries evacuation of casualties from roles 1 and 2. DCDD identified external stressors as a key issue for enroute care in a 2010 white paper. MSS PMO is working with the Air Force and Joint Program Committee (JPC)-6 Joint Enroute Care Committee on requirements.

   a. **Purpose.** Provide technical expertise in support of JPC-6 on transitioning of their efforts in this area to advanced development.

   b. **Progress.** MSS PMO supported two SBIR Phase III contracts for the Next Generation Immobilization System to continue efforts and eventually transition to advanced development. These are funded by the Joint En Route Care Committee (JERC). MSS PMO initiated work with USAARL to test COTS equipment for immobilization and stabilization of casualties on rotary-winged aircraft and ground evacuation vehicles. Work is ongoing.

   c. **Budget.** No Army 6.4 or 6.5 funds used. DHP funded via JERC.

   d. **Personnel.** 1 personnel.

e. Milestones Achieved. MSS PMO supported two JERC-funded SBIR Phase III contracts to continue efforts and transition to advanced development. Air Force will take lead on role 3 capability. Army will investigate roles 1-2 capabilities.

7) **Tourniquet Upgrade DHP Operational System Development Program (6.7).** MSS PMO initiated a contract with New York City Industries for the Blind to develop mechanical and pneumatic tourniquets to replace the Combat Application Tourniquet (CAT). MSS PMO received prototypes in September 2013 for testing at Naval Medical Research Unit (NAMRU).

   a. Purpose. Develop improved tourniquets that are better at occluding blood loss without causing nerve damage, particularly in lower extremities, and are "best value" to the Government.

   b. Progress: NAMRU phase 1 and 2 testing was finalized for mechanical and 2" pneumatic tourniquets. The U.S. Army Institute of Surgical Research (USAISR) is testing these, in addition to the 3" pneumatic tourniquet. Product improvements include a secondary locking mechanism, wider band for better occlusion on lower pressure, and reduced nerve damage. This is a government-owned technical data package.

   c. Budget. $260k for phase 2 testing.

   d. Personnel. 1 Personnel.

   e. Milestones Achieved. Phase 2 testing was completed.

8) **Armored Multi-Purpose Vehicle Biologics Refrigerator.** The Armored Multi-Purpose Vehicle Biologics Refrigerator is a lightweight device for carrying biologic products for far-forward combat. It is designed to meet cube requirement, lightweight, battery-powered, and can run for 72 hours. The market investigation did not find any commercial products that met the requirements of the AMPV program; therefore, a developmental effort proceeded.

   a. Purpose. Design a refrigerator specifically to meet the requirements of the armored brigade combat team (ABCT) AMPV Medical Treatment Variant (MTV).

   b. Progress. Two contracts were awarded during FY13. One was a Phase II enhancement to Biosentinel, Inc. Biosentinel has delivered two working prototypes of a temperature-controlled shipping and storage container (cold transport container) for the Environmental Sentinel Biomonitor (ESB) system components to the U.S. Army Center for Environmental Health Research (USACEHR). This adjunct system was not carried forward as part of the ESB program. This technology addresses the need for temperature controlled biological storage in the AMPV with slight modification of scale and ruggedness.

   Thomas EMS also was awarded a contract to develop and produce two prototypes. One prototype has been delivered to TARDEC, which integrated the refrigerator into the AMPV MTV using the AMPV demonstrator.

   c. Budget. $375K for Biosentinel. $200K for Thomas EMS.

   d. Personnel Assigned. 2 Personnel.

   e. Milestones Achieved. MSS PMO performed a market investigation, which did not find any commercial products that met the requirements of the ABCT program. Therefore, a development contract and a SBIR enhancement contract for the capability were awarded.

9) **Physiological Status Monitor**. The Physiological Status Monitor (PSM) is a Soldier-worn device that integrates physiological status monitoring with situational awareness to provide Remote Physiological

Status Monitoring of enabled Soldiers. The sensor is worn on the body and can transmit wirelessly or through a USB cable. The monitor measures heart rate, respiration, skin temperature, and activity.

a. **Purpose**. Provide the Commander with greater situational awareness of his Soldiers and lessen the medic's exposure on the battlefield by not sending the medic to a Soldier absent of life signs.

b. **Progress**. The PSM is currently a product manager Soldier Protective Equipment requirement and will integrate onto the Integrated Soldier Sensor System (ISSS), a suite of sensors that monitor and record physiological status, blast overpressure, and head acceleration data onto a common Data Retrieval System. MSS PMO is a USAMRMC representative on the ISSS IPT. The PSM will transition to Program Executive Office (PEO) Soldier.

c. **Budget.** No FY14RDT&E (6.4 OR 6.5) funds.

d. **Personnel Assigned.** 1 Personnel.

e. **Milestones Achieved.** The Remote Physiological Status Monitor (RPSM), a Congressional Special Interest (CSI) developmental effort within MSS with Zephyr Technology Corporation, was included in a PEO Soldier contract awarded to BAE Systems for the ISSS. The contract is to deliver a Low Rate Initial Production (LRIP) system for 1 Brigade Combat Team in FY16. The Zephyr RPSM at USAMMDA was demonstrated to multiple VIPs during USAMRMC product displays.

10) Soft-Wall Shelter Modernization. Soft-Wall Shelters comprise the core of the CSH in regard to emergency medical treatment, intensive care, and intermediate care. The AMEDD was unable to transition all shelter requirements to Force Provider under Force Sustainment. The current path is to support Army Force Generation shelter requirements with AMEDD funding starting in FY18. An operational test was performed at Fort Benning in April 2012 on the airbeam soft-wall shelter. Test sampling of TEMPER stocks was increased and tested at U.S. Army Natick Soldier Research Development & Engineering Center (NSRDEC).

a. **Purpose**. Modernize soft-wall shelters comprising the CSH in compliance with Force 2025 initiatives (expeditionary, lightweight) and to address end-of-life issues that result in annual TEMPER testing to determine acceptability of current stocks.

b. **Progress**. MSS PMO is working with the OTSG, AMEDD Center & School (AMEDD C&S), DCDD, Combined Arms Support Command, and Headquarters Department of the Army General Staff for Operations to determine a path forward for Soft-wall Shelter requirements for Deployable Medical Systems (DEPMEDS). A new analysis of alternatives (AOA) and/or capabilities based assessment (CBA) is underway with the assistance of USAMRMC Headquarters.

c. **Budget.** $10k in man hours in support of program.

d. **Personnel Assigned.** 2 Personnel.

e. **Milestones Achieved.** MSS PMO coordinated with the Navy on a joint modernization solution. MSS PMO coordinated final repair by HDT Global of five other Force Provider Modules. This work is now finalized. TEMPER testing coordination is finalized and most testing should be done by early FY15. MSS PMO initiated "get healthy" coordination with the U.S. Army Medical Materiel Activity (USAMMA) in reference to TEMPER stocks.

11) Rigid-Wall Shelter Modernization. MSS PMO is working with Shelter Technology, Engineering & Fabrication, NSRDEC, Research, Development and Engineering Command, Army Materiel Command, and Product Manager Force Sustainment Systems to develop new shelter capabilities for the CSH. Some new capabilities in development are new efforts with composite materials, International Standards Organization (ISO) auto-leveling systems, and new light-emitting diode lights.

a. **Purpose**. Continue to support new developments in rigid-wall shelter technology that will lower lifecycle costs and provide critical hospital functions including surgery, x-ray, laboratory, and central materiel supply.

b. **Progress**. MSS PMO continued work on a rigid-wall shelter retro-fit kit using composite materials, completing the design for a nine-stack high, double-sided, expandable shelter. Besides the additional stack capability, the redesign included floor strengthening and increased energy efficiency. Redesign of the partial two-sided expandable shelter will be completed in second quarter FY15.

A second contract (18-month effort) via NSRDEC was awarded in fourth quarter FY15 to complete all the remaining panels in the two-sided ISO shelter with composites. In addition, one-sided shelter is being investigated under this contract.

c. Budget. $1200K.

d. Personnel Assigned. 2 Personnel.

e. Milestones Achieved. Final contract award was made for the 2-sided ISO shelter. IPT is working on an acquisition plan for AMEDD to be presented to the Milestone Decision Authority (MDA) in May FY15.

12) Continued Logistical Support Areas on Management of Medical Unit Assemblages. MSS PMO coordinated efforts to integrate government-furnished equipment items and supplies into assigned MES and provided routine oversight and direction to contract logistics support partners to accomplish all tasks as required by the government.

Logistics and management analysts directly managed all sustainment actions for select medical unit assemblages (UA), including conducting market research for COTS component items, updating catalog data/information in automated records, participating in formal review processes with appropriate SME from various disciplines, and providing interface with military and commercial customers to address issues associated with availability and suitability of sets and individual components.

MSS PMO manages 24 medical UAs and 49 major equipment end items. Components of assigned UAs range in quantity from 25 to 150 individual items.

MSS PMO interfaced and collaborated directly with other organizations such as USAMMA, AMEDD C&S, DCDD, and Defense Logistics Agency (DLA) Troop Support on matters and projects related to approval/documentation and fielding of medical materiel and assemblages, procurement of major equipment items, and forecasting future requirements for budget submissions.

MSS PMO coordinated efforts with military depots to receive, inventory, store, repack and transport medical shelter systems and water distribution/wastewater systems to designated Army units in the CONUS and OCONUS. MSS PMO has been testing several developmental items, including litters, wheeled litter carrier, tactical vehicle refrigeration unit, trauma bags, field sinks and expandable shelters. The objective was to adopt items for potential use in MES provided by USAMRMC.

MSS PMO logistics and maintenance support staff developed or collaborated in developing critical supportability plans for emerging technology projects such as ESB, Coliform Analyzer, freezer and thawing device for Cryopreserved Platelets and Chemical Patient Protective Wrap (CPPW). These efforts are ongoing.

a. **Purpose**. Continued annual support for UAs in our area of responsibility.

b. **Progress.** Conducted market research for replacement of the CPPW. Completed the following MES Reviews:

i. Rodent Survey Set

ii. Entomological Collecting Kit

iii. Occupational Health Survey

iv. Epidemiology Service Field

v. Clinical Psychologist Set Field

vi. Water Quality Analysis Set

vii. Industrial Hygiene Set

viii. Air Ambulance Set

ix. Ground Ambulance Set

c. Budget. $250K.

d. Personnel Assigned. 2 Personnel.

e. Milestones Achieved. Sets and UAs have been sustained/fielded as needed in projections from the Army. Major equipment/support items have been procured and fielded in support of approved requirements and theater-generated Operational Needs Statements.

13) Water Distribution and Wastewater Management System. The Water Distribution and Wastewater Management System (WDWWMS) provides potable water and removal of gray water from all functional areas within the CSH. The system is comprised of four separate assemblages: Water Distribution Set, Wastewater Set, Maintenance Set and the Connection Set. The system can be configured to support 44- 84-, or 164-bed CSH requirements. The modernization effort is focused on the current 84-bed CSH.

a. Purpose. Modernize and upgrade legacy sets by replacing components with like items made of more technically advanced materials that decrease weight/cube, improve transportability/storage, extend service life and lower acquisition and operational costs over time.

b. Progress. The MSS PMO is currently working with water engineers at TARDEC and Regional Training Site–Medical (RTS-Med) sites for set improvements and evaluations. Moving forward, MSS PMO intends to update catalog information and bill of materials for the water systems and incorporate into future set builds. MSS PMO, in coordination with fielding personnel from USAMMA, also vetted the instructions in the current manual and noted several discrepancies and issue, which will be addressed in an upcoming revision.

c. Budget. $100K DHP FY14 funds.

d. Personnel Assigned. 2 Personnel.

e. Milestones Achieved. None this year.

14) Field Deployable Carbon Dioxide Generator. The Field Deployable carbon dioxide (CO_2) Generator (FDCG) provides an effective field deployable source of CO_2 for vector surveillance. Significant issues (cost, shipping hazards, and weight) preclude the use of other forms of CO_2 during military contingency operations. The CO_2-baited CDC light trap samples a wider range of mosquito species and significantly increases the number of mosquitoes captured compared to a trap that utilizes light as the sole attractant.

a. Purpose. Provide Army Preventive Medicine personnel with a safe, non-toxic, portable source of CO_2 for vector surveillance efforts and safety/force protection through early disease detection and prevention.

b. **Progress.** MSS PMO received production-ready Carbon Dioxide Generators from two development contracts. The systems are under test and evaluation. The carbon dioxide generator, in conjunction with the vector trap, will be used by preventive medicine detachments to collect vectors for the determination of endemic diseases in the area of operation.

Two additional sources of generators were obtained to include in field evaluations in Thailand. Results indicated only the TDA Research, Inc. acid-base system (developed by USAMMDA) performed well enough to be considered a viable alternative. Further testing in Greece with additional species will be completed in FY15 to validate these results.

c. **Budget**. $115K.

d. **Personnel**. 1 Personnel.

e. **Milestones Achieved**. The FDCG successfully completed a Materiel Development Decision in June 2012. CDD is scheduled for release to the Army Capabilities Integration Center in second quarter FY14. The FDCG was approved entry into the Materiel Solution Analysis phase. Milestone B is anticipated to occur in Spring FY15 at Technology Readiness Level (TRL) 6.

15) SHock Impact and Explosive Limits Dosimeter. The Shock Impact and Explosive Limits Dosimeter (SHIELD) integrates into standard helmet pads, requires no power/communication, is disposable, is very low cost and retrofits existing helmets easily. Upon blast exposure or concussive impact, fluorescent dye is released and transferred to the head. The fluorescent dye transfer to the head removes the requirement of the helmet being present (lost in action, medical transport, or other situation). The dosimeter indicates relative intensity of the blast or impact (by color) and the direction relative to the head, which provides anatomical relevance. Such a system will provide valuable knowledge to better understand and treat TBI.

a. **Purpose**. Provide actionable information to medical personnel that can be correlated with acute, short-term, and long-term TBI symptoms.

b. **Progress.** The contractor has performed some additional blast testing at Langley Air Force Base, but results were inconclusive. At present, the technology is not ready to continue development.

c. **Budget**. $0M. Exercised additional 6 month no-cost extension.

d. **Personnel**. 1 Personnel.

16) Airworthiness Evaluations. MSS PMO provides funds and serves as the point of contact for the entry of all USAMRMC carry-on medical equipment into the airworthiness evaluation process. Per Army Regulation 70-62, Airworthiness Qualification of Aircraft Systems, all “carry-on” equipment, to include medical devices, must have an Airworthiness release. MSS PMO also identifies and prioritizes medical equipment to be tested for use on all Army aircraft.

a. **Purpose**. Serve as the focal point for questions and issues pertaining to certification of efficacy, performance, and safety of medical carry-on equipment as it relates to its use on patient personnel when on board Army aircraft.

b. **Progress.** This is an on-going process. Requests and products are managed and prioritized as they arrive. Test infrastructure has been upgraded, and additional in-house test capability has been added.

c. **Budget**. $0.9M.

d. **Personnel**. 1 Personnel.

e. **Milestones Achieved**.

i. All efforts now evaluate major carry-on items on the Light Utility Helicopter-72 Platform.

ii. All items from the last Air Ambulance Medical Equipment set review have been evaluated and can be incorporated into sets.

iii. MSS PMO received two non-contact vital signs monitoring systems for operational evaluation aboard rotary wing aircraft. Hoana LifeBed effort is complete; the LifeBed performed better under flight conditions than the baseline monitor. Sensiotec system did not perform well enough to be used in flight. The system was returned to the vendor. This effort will determine whether the technology can provide caregivers vital signs in a high noise environment without an excess of external leads and connections to multiple devices. The LifeBed is being considered as a 'chair' version for monitoring of ambulatory patients.

iv. Ten additional products completed/evaluated during the period, including vital signs monitors, ventilators and negative pressure wound therapy devices.

17) Environmental Sentinel Biomonitor. The Environmental Sentinel Biomonitor (ESB) system significantly augments current detection capabilities by providing a presumptive screening capability that can rapidly identify toxicity in water from many toxic industrial chemicals that are difficult to identify in theater. The near-real time toxicity data from ESB tests will support key decisions about the quality of field drinking water. The ESB system reached Milestone B in November 2012 in partnership with USACEHR.

a. **Purpose**. Provide rapid toxicity identification for many toxic industrial and agricultural chemicals in water, including unsuspected or unknown materials and chemical mixtures.

b. **Progress.** Two leading toxicity sensors have been identified based on a formal down-selection of sensor technologies: a cell-based electric cell-substrate impedance sensing (ECIS) device (Biosentinel, Inc.) and an acetylcholinesterase (ACE) inhibition measuring device (ANP Technologies, Inc.). The ESB system is comprised of these two toxicity sensors. The AMEDD Test Board conducted a customer assessment in May 2014. The conclusion of the assessment is that the ESB is operationally suitable and supports the preventive medicine mission. Performance and environmental testing were also conducted with passing results.

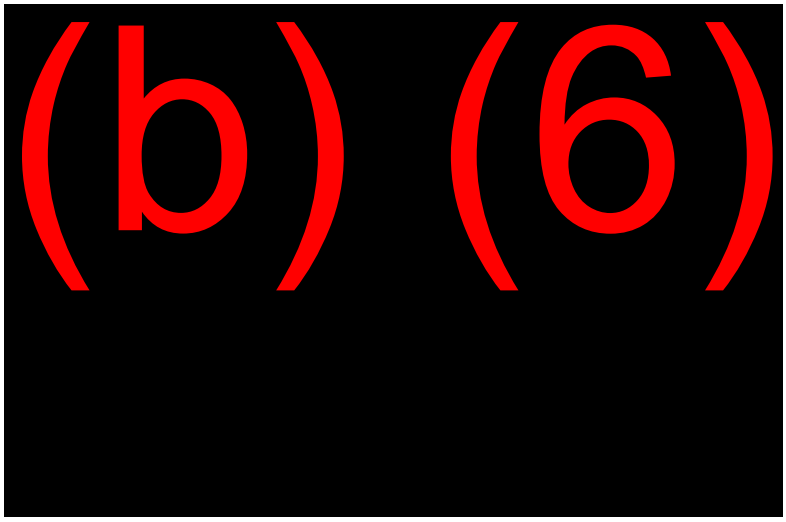
c. **Budget**. $0.6M.

d. **Personnel**. 1 Personnel.

e. **Milestones Achieved**. Milestone B at TRL 6 was reached in November 2012 and transitioned to MSS PMO. Milestone C is scheduled for third quarter FY15.

18) Long-Lasting Insecticide-Impregnated Bed Net. The insecticide-impregnated bed net is a portable, lightweight, self-supporting design constructed of a long-lasting mesh impregnated with two insecticides: permethrin and deltamethrin. The use of dual insecticides provides increased protection and efficacy against permethrin resistance in insects. The bed net provides better ventilation by using a larger mesh size of 288 holes per square inch and offers increased space under the netting for standard or larger cot, which means greater user acceptability.

FIGURE 8: Long-Lasting Dual Insecticide-Impregnated Bed Net



a. **Purpose.** Increase protection against insects that transmit diseases; maintain high efficacy while using a mixture of insecticides at low doses; increase compliance through greater breathability and ease of use to reduce disease risk.

b. **Progress.** MSS PMO worked with Triton Systems, Inc., under the Army's SBIR Program Phase III contract, and collaborated with WRAIR to develop the long-lasting dual insecticide-impregnated bed net prototype. Triton received EPA registration in December 2014.

The core technology is the proprietary Invexus® surface treatment technology. Insecticide-impregnation can be applied to other textiles, such as garments and shelters.

c. **Budget**. No FY13 RDT&E (6.4 OR 6.5) funds.

d. **Personnel**. 1 Personnel.

e. **Milestones Achieved**. The bed net is currently under a SBIR phase III contract with completion in first quarter FY15. Limited user testing was successful at the Northern Warfare Training Center, AK, in August 2014. Following EPA approval and Armed Forces Pest Management Board Review and Approval, expected third quarter FY15, a National Stock Number (NSN) will be assigned. The bed net is at TRL 8.

19) Altitude Readiness Management System. The Altitude Readiness Management System (ARMS) is an altitude acclimatization and illness decision aid software application that will predict acute mountain sickness and estimate physical work performance for personnel rapidly deployed to high altitudes.

a. **Purpose.** Estimate risk of altitude illness and performance decrement for a wide range of altitude ascent profiles, track acclimatization status, aid in acclimatization to high altitudes, and ensure mission success at high altitudes.

b. **Progress.** MSS PMO coordinated with the Maneuver Center of Excellence (MCoE) and the Army Mountain Warfare School (AMWS) regarding requirements for ARMs. The AMWS identified a capability gap the ARMS meets in their AMWS Capability Gap Information Paper, 09 September 2013. Technology Transition Agreement was completed 31 August 2012 with the Military Operational Medicine Research Program. The Core Soldier System Capabilities Production Document CARDS#02070 was completed 25 August 2009. Initial Capabilities Document: Military Operational Medicine (approved 2008). MSS PMO contracted with Massachusetts Institute of

Technology Lincoln Laboratory (MIT-LL) to perform an independent validation and verification of the ARMS app. MSS PMO is coordinating with PEO Soldier for transition of the ARMS app.

c. Budget. $75K.

d. Personnel. 0.5 personnel.

e. Milestones Achieved. ARMS transitioned in FY14 to MSS PMO. Limited User Testing of the ARMS with the AMWS occurred in July 2014. Nett Warrior certifications required for the app will be completed in 2nd quarter FY15 and will then transition to PEO Soldier.

20) Patient Simulator. The Patient Simulator is a materiel solution to bridge technological gaps in patient simulators and test equipment regarding survivability in military testing environments, particularly airworthiness. The patient simulator/analyzer must meet and survive the test criteria as well as the equipment under test.

a. Purpose. Develop a patient simulator/analyzer in cooperation with National Aeronautics and Space Administration (NASA) to conduct all environmental and vehicle (ground and air platforms) evaluation testing on medical items used in extreme environments.

b. Progress. The first prototype passed most testing with minor modifications, include noise floor testing at Eglin AFB. The prototype is being updated per these results and user feedback and is expected to be delivered, along with a second unit and technical data package, in spring of FY15.

c. Budget. $425K.

d. Personnel. 1 personnel.

e. Milestones Achieved. Phase II prototype qualification was completed successfully in August 2014.

21) Next Generation Diagnostic System. The Next Generation Diagnostic System (NGDS) is a U.S. FDA-cleared, COTS diagnostic device for the analysis of both clinical and environmental samples. NGDS will offer Combatant Commanders a medical countermeasure capability to provide situational awareness of biological hazards to support Force Protection and Force Health Protection decision making.

a. Purpose. Process and provide analysis of chemical and biological threats when presented with a wide range of sample types, either clinical or environmental.

b. Progress. MSS PMO collaborated with the Joint Program Executive Office for Chemical and Biological Defense (JPEO-CBD) to provide the U. S. military forces and the nation with a safe, effective and innovative medical solution to counter chemical and biological threats. Source selection was conducted. Expected fielding date to the services is currently under revision due to a stop work directive concerning a protest of the source selection.

c. Budget. Program is funded by JPEO-CBD. Army will begin sustainment in FY19.

d. Personnel. 2 personnel.

e. Milestones Achieved. Changes in dates and timeline in the CDD is pending.

22) Chemical Patient Protective Wrap. The Chemical Patient Protective Wrap (CPPW) is made up of a breathable laminate material for the top layer, a three-layer laminate for the ground cloth, a flexible plastic film for the window and a coated and laminated chemical and protective cover. The CPPW protects patients who cannot don a gas mask against exposure to all known potential chemical warfare agents in vapor, aerosol, liquid or thickened liquid form. The wrap is manufactured in one size and is large enough to completely encapsulate military personnel.

FIGURE 9: Chemical Patient Protective Wrap

a. **Purpose.** Establish a new source of supply for the CPPW to provide respiration and percutaneous protection for unmasked, uncontaminated patients for at least six hours.

b. **Progress.** MSS PMO conducted market research for replacement of the CPPW and is working with the Defense Logistics Agency for a request for proposal, operational testing by AMEDD Test Board and environmental testing with Edgewood Chemical and Biological Center (ECBC), source selection, and contract award in FY14. MSS PMO is also collaborating with ECBC, OTSG, DCDD and AMEDD C&S. Prior to initiating a Request for Proposal, MSS PMO is awaiting a legal opinion to ensure compliance with laws separating chemical-biological development funding from medical device development funding.

c. **Budget.** $486k for testing.

d. **Personnel.** 2 personnel.

e. **Milestones Achieved.** In June 2013, Essential Characteristics in coordination with DCDD, OTSG, AMEDD C&S, ECBC and AMEDD Test Board were validated. The Test and Evaluation Master Plan was drafted.

23) Temperature-Controlled Transport Container for Packed Red Blood Cells. The current Army solution to transport packed red blood cells is a combination of vacuum-insulated panels and phase-change material (PCM) that maintains the refrigerated temperature. However, both the vacuum-insulated panels and PCM have limited effectiveness over time, and the original equipment manufacturer cannot guarantee efficacy beyond two years. The usefulness of the technology developed under this SBIR can benefit all military medical centers worldwide, especially those in far forward areas. The feasibility of this container for temperature-controlled supply chain transport is expected to extend to other biologics (e.g., vaccines and organs) and non-biologics requiring transport in the desired temperature range (2–8°C).

a. **Purpose.** Develop and demonstrate a materiel solution for a cost-effective, passive and thermally efficient temperature-controlled transport container (cold chain container) that has a service life of not less than five years without a need for normal repairs and maintenance.

b. **Progress.** One offeror, Resodyn, was awarded both Phase I option and Phase II contract. Phase I option complete in summer of 2014. Phase II began just before the end of FY14.

c. **Budget.** $1.005M of SBIR funds.

d. Personnel. 1 personnel**.**

e. Milestones Achieved. Phase I option is complete.

24) Soldier Water Estimation Tool. The Soldier Water Estimation Tool (SWET) is a drinking water management decision aid software application that will estimate drinking water requirements based on environmental conditions, activity level, and clothing ensemble worn.

a. Purpose. Estimate drinking water requirements for an individual Soldier or for a group of Soldiers for water planning purposes; reduce the incidence of dehydration and provide more accuracy for Soldier water intake.

b. Progress. MSS PMO coordinated with the MCoE and AMWS regarding requirements for SWET. The AMWS identified a capability gap the SWET meets. Technology Transition Agreement was completed in November 2013 with the Military Operational Medicine Research Program. (Core Soldier System Capabilities Production Document CARDS#02070, 25 August 2009. Initial Capabilities Document: Military Operational Medicine (approved 2008).) MSS PMO contracted with MIT-LL to perform an independent validation and verification of the SWET app. MSS PMO is coordinating with PEO Soldier for transition of the SWET app.

c. Budget. $75K.

d. Personnel. 0.5 personnel**.**

e. Milestones Achieved. SWET transitioned in FY14 to MSS PMO. Limited User Testing of the SWET with the AMWS occurred in July 2014. Nett Warrior certifications required for the app will be completed in second quarter FY15 and will then transition to PEO Soldier.

25) Uniform Repellent Application Technology. Growing global resistance to permethrin and failures in the current application technology leaves the Soldier more vulnerable to vector-borne disease threats in many areas of operation. MSS PMO activities focused on preparing for, and evaluating, non-permethrin, military uniform insect repellent formulations and the corresponding uniform application technology.

a. Purpose. Provide Army personnel with an insect repellent uniform that will protect personnel against arthropods of military concern that have developed resistance to the current permethrin formulation; expose Soldiers wearing treated uniforms to a reduced concentration of repellent.

b. Progress. PMO MSS entered into a CRADA with Triton Systems, Inc. to apply permethrin to uniform fabrics of Army Combat Uniform (ACU) and Flame-Resistant ACU (FRACU), using their patented Invexus® plasma coating technology. Treated fabrics were sent to NSRDEC for textile chemistry analysis to determine if the plasma coating process affected the fabric in a negative way. Chemistry testing showed that the plasma coating process did not affect the fabrics from a chemistry perspective. The fabrics were then sent to the U.S. Department of Agriculture (USDA) for efficacy testing to determine if the treated fabrics protect against flying arthropods. Efficacy testing will be completed in second quarter FY15. If the results for efficacy testing of the fabrics show potential for Triton's Invexus® plasma coating technology, further optimization of the process and eventual EPA registration will need to be done.

c. Budget. $40K.

d. Personnel. 0.5 personnel**.**

e. Milestones Achieved. PMO MSS entered into a CRADA with Triton Systems, Inc. to apply permethrin to uniform fabrics. Textile chemistry analysis to determine if the plasma coating process

affected the fabric in a negative way completed by NRSDEC. Chemistry testing showed that the plasma coating process did not affect the fabrics from a chemistry perspective.

26) **Improved First Aid Kit Generation II.** The Improved First Aid Kit (IFAK) Generation II was implemented in response to a RFI from Operation Iraqi Freedom (OIF). This was funded via the Rapid Fielding Initiative. The IFAK Gen II increases individual Soldier capabilities to provide Self-Aid/Buddy-Aid and provides interventions for two leading causes of death on the battlefield – severe hemorrhage and inadequate airway – through the addition of a chest seal, eye shield, and a second tourniquet. The IFAK Gen II was also redesigned to be more compact. Once Operation Enduring Freedom (OEF) finalizes, there is no future funding for IFAKs for future conflicts.

   a. **Purpose.** Support augmentation of the current IFAK with additional life-saving materials and more compact design.

   b. **Progress.** MSS PMO is working with DCDD, the MCoE at Fort Benning, GA, OTSG, and PEO Soldier for a long term solution. Discussions have determined a MCoE CDD may solve this issue if the contents of the IFAK can be a Common Table of Allowances item.

   c. **Budget.** $10k in man hours to support effort.

   d. **Personnel.** 2 personnel**.**

   e. **Milestones Achieved.** MSS PMO held multiple collaborative meetings with MCoE and DCDD.

27) **USAARL Test Tool.** Currently many devices that go into MES require testing with humans. Testing with humans usually requires a human use protocol. The test tool is a human surrogate that can replace a human to get pertinent data and yet not require a human use protocol.

   a. **Purpose.** Replace human test subjects in tests that otherwise require a human use protocol to get pertinent data.

   b. **Progress.** PM MSS found a technology on the West coast that is similar to the skin compliance of a human. MSS PMO issued a contract via TARDEC to build and test several prototypes. Initial testing was accomplished and early results are favorable. The second iteration of testing, with changes based on initial testing, is occurring now.

   c. **Budget.** $10k in man hours to support the program which was contracted in FY12.

   d. **Personnel.** 1 personnel**.**

   e. **Milestones Achieved.** Initial prototypes were tested successfully. Modification to increase efficiency is underway.

28) **Remote Triage System.** The Remote Triage System is designed to detect the vital signs of a casualty from a distance and through obstacles.

   a. **Purpose.** Detect vital signs of a casualty from a distance and through obstacles.

   b. **Progress.** Phase I is complete. Phase II proposals reviewed and one offeror was accepted. Phase I option and Phase II to be awarded in 2QFY15.

   c. **Budget.** $100K of SBIR funds.

   d. **Personnel.** 1 personnel**.**

   e. **Milestones Achieved.** Phase I is complete.

29) **Hydration Status Monitor.** The Hydration Status Monitor is designed to predict and determine actionable levels of soldier dehydration.

a. **Purpose.** Develop a system to predict/determine actionable levels of Soldier dehydration.

b. **Progress.** Project oversight transferred to MSS PMO in July 2014. MSS PMO searched for requirements sources at MCoE and the U.S. Army Training and Doctrine Command (TRADOC) at Fort Eustis, VA.

c. **Budget.** $1.5m DHP 6.3 funds.

d. **Personnel.** 1 personnel.

e. **Milestones Achieved.** An option year for feasibility study was awarded.

Medical Prototype Development Laboratory

The MPDL is a small team of engineers and engineering technicians with a vast array of design and fabrication skills. This integrated team works together to design, develop drawing packages for, and rapidly prototype far-forward medical equipment in support of the USAMRMC. The MPDL is capable of rapidly prototyping medical devices in a wide range of scales and variety of materials. These capabilities are also used to harden COTS components, equipment and products for use in a field environment.

A. **General.** Chief. (b) (6) .

B. **Staff.** 3 Personnel. 3 Civilians.

C. **Military Relevance.** In an effort to provide U.S. Forces with innovative, useful and relevant field medical equipment, the MPDL collaborates with various organizations within the medical community. This unique USAMRMC resource is instrumental in providing prototype design and fabrication, evaluation/testing, and fixes for products, components, and/or systems. Key principles that drive the design of all products include the following:

1) Functional

2) Simple to operate

3) Compact

4) Lightweight

5) Easy to assemble (no tools)

6) Interchangeable

7) Packaged in a low-volume cube

The MPDL strives to provide innovative designs and quality workmanship. Their goal is to efficiently and effectively produce materiel solutions that surpass customer expectations and requirements. As a result, numerous products been developed and several have received U.S. patents.

The MPDL continually seeks to optimize and modernize the development process. Efforts to increase capability, productivity, and quality have reduced process time. Likewise, quicker turn-around times provide a tangible effect of getting materiel fixes and the latest equipment to the Warfighter faster.

D. **Accomplishments.**

1) **WRAIR**

a. Active Avoidance Device, TBI project

2) USACEHR

a. Next Generation Detection Device

b. Water Quality Work Station

c. Zebra Fish Breeding Chambers

3) USAMMDA

a. Field Surgical Sink

b. CH47 Roll-On/Roll-Off Treatment POD

c. Universal Litter Backrest

4) Air Force Special Operations Command

a. Litter Adapters (C-130 Litter Stanchions)

b. Collapsible Litter Stand

5) USAMMA

a. Noise Cancelling Stethoscope's Anti-Roll Accessory

E. Research and Development.

1) Active Avoidance Device. The Active Avoidance Device is a collaborative effort between WRAIR and USAMMDA. The device is used to evaluate the effects of TBIs; i.e., pre/post testing of the rodent to determine the efficacy of the medical procedures and treatments. WRAIR presented design requirements and working parameters to USAMMDA for prototype development.

FIGURE 10: Active Avoidance Device

a. Purpose. Design and fabricate an upgraded drive mechanism for the Active Avoidance Device. Drive system includes higher torque, programmable motor and gearbox with capability of controlling rpm of motor.

b. Progress. The design, acquisition of commercial parts, custom fabrication and assembly of the newly designed drive system is complete. WRAIR's testing and evaluation of apparatus is ongoing. The prototype is being used to verify TBI treatment as a standard procedure.

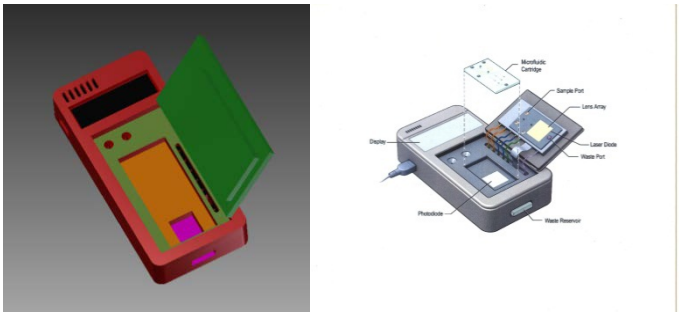
c. Budget. $2.5K.

d. Personnel assigned. 3 Personnel.

e. Milestones achieved. Project completed.

2) **Next Generation Diagnostic System**. The Next Generation Diagnostic System is a collaborative effort between USACEHR and USAMMDA to develop a device to aid in the detection of industrial chemicals. Detect toxic industrial chemicals (TIC) in humans. USACEHR tested several animal models with TICs and have discovered biomarkers of toxicity in those animals. The NGDS will utilize those novel biomarkers of TICs for the detection of toxicity in humans.

FIGURE 11: **Next Generation Detection Device**



a. **Purpose**. Design a device to detect TICs in humans using novel biomarkers of TICs detected in animal models.

b. **Progress.** Non-working prototype unit has been designed/modeled and 3-D printed.

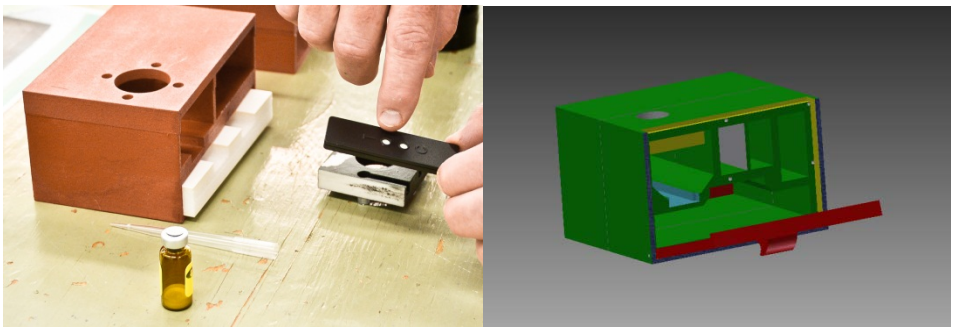
c. **Budget.** $0.5K.

d. **Personnel**. 3 Personnel.

e. **Milestones Achieved**. Initial design delivered for evaluation.

3) **Water Quality Work Station.** The Water Quality Work Station was a collaborative effort with USACEHR and USAMMDA to develop a work station to test water quality in the field. This self-contained kit has all the necessary items needed to test water for the presence of pesticides. This prototype was being designed to work in conjunction with a Smart phone's camera and custom app to analyze results real time.

FIGURE 12: Pesticide Detection Kit for Water Quality Work Station



a. **Purpose**. Prototype a work station to be used in field testing of water quality for pesticides.

b. **Progress.** Work station has been computer aided designed (CAD), modeled and a working 3-D printed prototype has been fabricated.

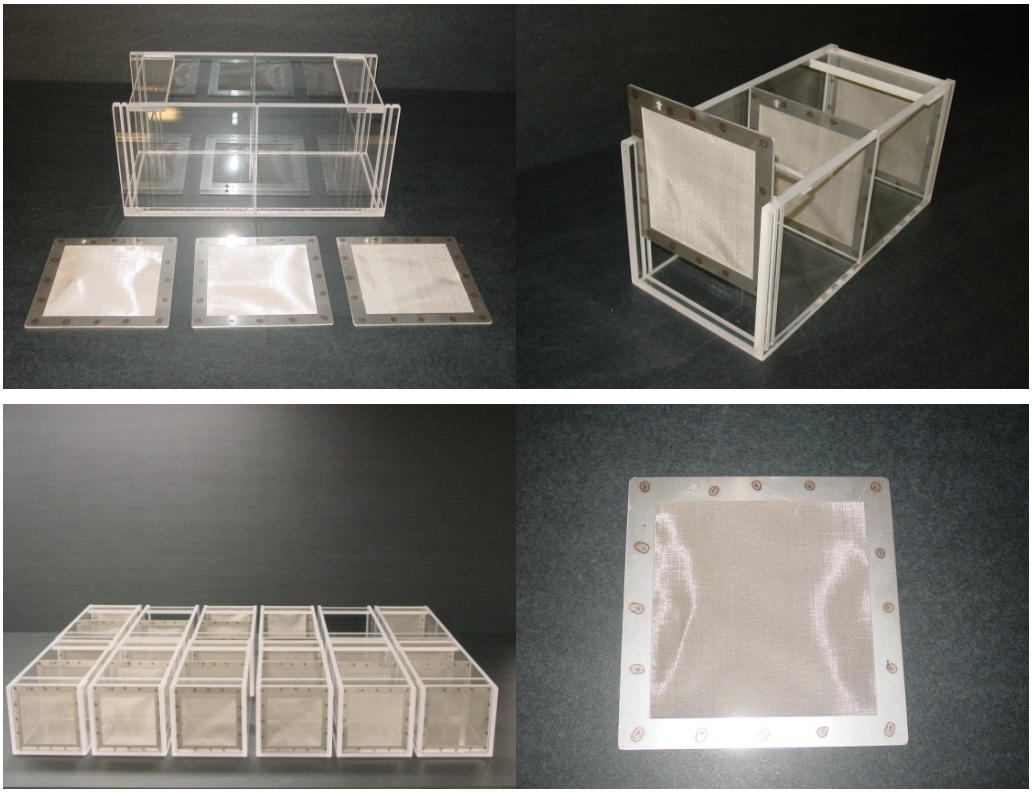
c. **Budget.** $0.5K.

d. **Personnel**. 3 Personnel.

e. **Milestones Achieved.** Project ongoing.

4) **Zebra Fish Breeding Chambers.** The Zebra Fish Breeding Chambers project was a collaborative effort with USACEHR and USAMMDA to develop breeding chambers for their research efforts.

FIGURE 13: Zebra Fish Breeding Chambers



a. **Purpose**. Design and fabricate twelve zebra fish (Danio rerio) breeding chambers. This prototype provides a way to allow waste removal in a flow-through water system, while still retaining zebra fish within the mesh. This design also enables food to be flushed at a reasonable rate.

b. **Progress.** Twelve chambers were designed, fabricated, tested and currently in use.

c. **Budget.** $1K.

d. **Personnel**. 3 Personnel.

e. **Milestones Achieved.** Project completed.

5) **Field Surgical Sink.** The Field Surgical Sink project is a USAMMDA project. The effort is to take the existing Army owned project (NSN 6530-01-308-7740) and update the technical data package to current standards. Effort includes updating drawings, specifications and commercial parts to that which is relevant and commercially available.

FIGURE 14: Field Surgical Sink

a. **Purpose**. Locate and update technical data package to facilitate procurement capability. Current technical data package is incomplete, outdated format and includes commercial parts that aren't available.

b. **Progress.** Three designs were modeled, 3-D printed and fabricated using traditional materials. Associated drawings were produced to accommodate future requirements. Prototypes were used in the development effort.

c. **Budget.** $2.8K.

d. **Personnel**. 3 Personnel.

e. **Milestones Achieved.** Project ongoing.

6) **CH47 Roll-On/Roll-Off Treatment Platform.** The CH47 Roll-On/Roll-Off Treatment Platform, a USAMRMC project, is a mobile medical treatment platform. This platform is a self-contained mobile unit that provides an enclosed workspace with medical equipment and a treatment table. It is designed with the capability to be used in one of three different modes: on the CH47, off loaded at location of operation or off loaded and towed to a remote location. The platform is expandable while off the CH47. The sides are hinged to facilitate an extra five feet of width and include additional height as well.

FIGURE 15: CH47 Roll-On/Roll-Off Treatment POD

a. **Purpose**. Design and fabricate roll-on/roll-off medical treatment platform. Design parameters included a physical size requirement that would accommodate the ability to stow/setup/utilize platform both on and off CH47. Additionally, requirements included towable, self-contained power, heating/ventilation/air conditioning (HVAC), medical equipment, treatment, table, surgical lighting, and sterility/cleanliness.

b. **Progress.** A full scale working prototype has been designed and fabricated to test proof-of-concept. A CH47 has been acquired and brought to Fort Detrick MPDL to accommodate true test of the prototype both inside and outside the airframe.

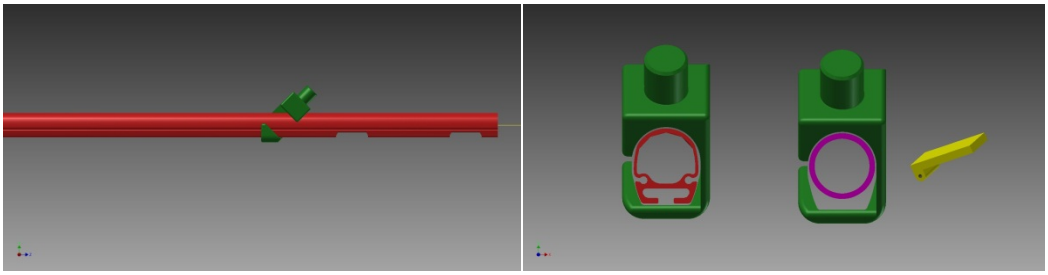
c. **Budget.** $100K.

d. **Personnel**. 3 personnel.

e. **Milestones Achieved.** Project ongoing.

7) **Universal Litter Backrest.** The Universal Litter Backrest is designed to accommodate the new improved 7309 litter pole design. It features both forward and backward compatibility i.e., fitting old and new 7309 liters. The universal litter backrest is laterally adjustable along the length of the litter pole and locks in at a 45 and 85 degree angles.

FIGURE 16: Universal Litter Backrest



a. **Purpose**. Design and fabricate a backrest to fit both the new and old style 7309 litters.

b. **Progress.** The backrest has been designed and 3-D printed to verify form, fit and function. An effort is currently underway to get industry to produce a LRIP and to follow up with testing.

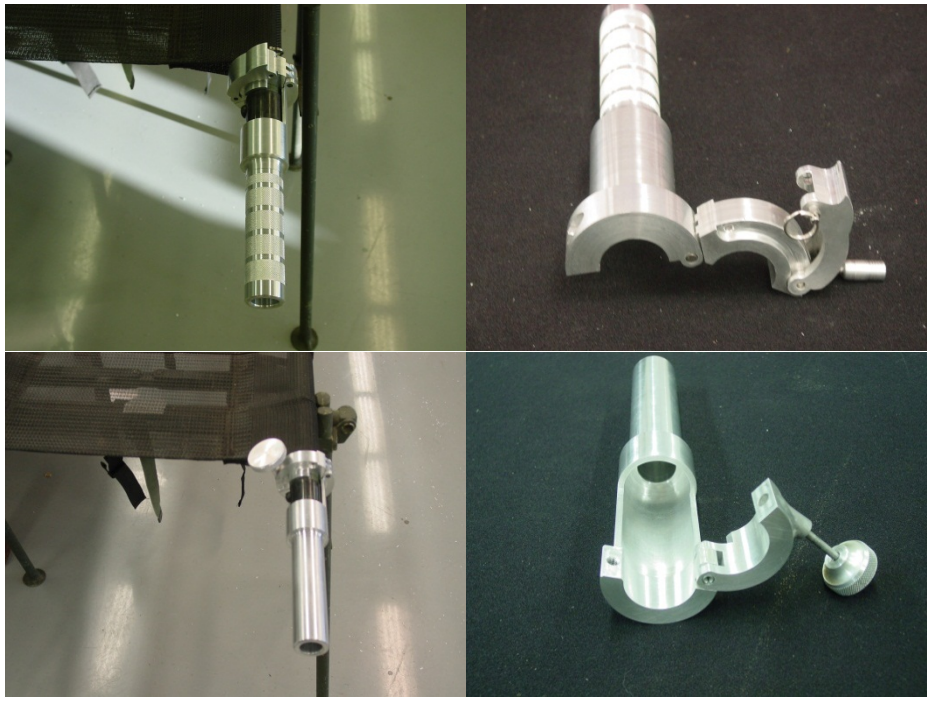
c. **Budget.** $1K.

d. **Personnel**. 3 personnel.

e. **Milestones Achieved.** Design and prototype complete.

8) Litter Adapters (C-130 Litter Stanchions). The Litter Adapters (C-130 Litter Stanchions) is a collaborative effort between the Air Force Special Operations Command (AFSOC) and USAMMDA.

FIGURE 17: Chemical Patient Protective Wrap



a. **Purpose**. Design litter adapters to provide a secure metal-to-metal connection between Talon litter and C-130 litter stanchions.

b. **Progress.** Two different styles of adapters (cam and screw type clamps) have been designed and fabricated. After initial testing a set of four preferred adapters were manufactured and provided for further evaluation and testing.

c. **Budget.** $20K.

d. **Personnel**. 3 personnel.

e. **Milestones Achieved.** Initial prototype was designed and fabricated. This unit was a 20% reduction in length with no gain in weight. Unique joint was designed with an integrated locking mechanism.

9) **Collapsible Litter Stand.** The Collapsible Litter Stand is a collaborative effort between AFSOC and USAMMDA.

FIGURE 18: Collapsible Litter Stand

a. **Purpose**. Design collapsible litter stands to be packed in a backpack.

b. **Progress.** Five different litter stands were designed, fabricated and discussed with AFSOC. The best design was selected, and a complete litter stand was fabricated for user evaluation.

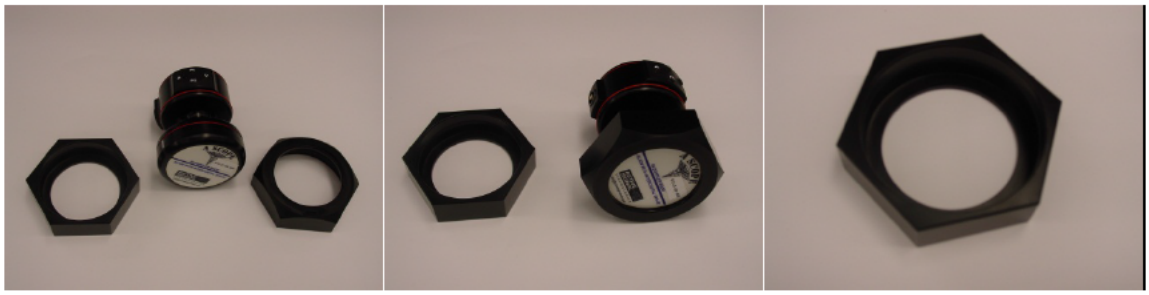
c. **Budget.** $20K.

d. **Personnel**. 3 personnel.

e. **Milestones Achieved.** Initial prototype was designed and fabricated. This unit was a 20% reduction in length with no gain in weight. Unique joint was designed with an integrated locking mechanism.

10) **Noise Cancelling Stethoscope's Anti-Roll Accessory.** The Noise Cancelling Stethoscope's Anti-Roll Accessory was a collaborative effort between USAMMA and USAMMDA to fabricate an accessory that would prevent stethoscope from inadvertently rolling off a work surface and potentially damaging the device.

FIGURE 19: Stethoscope Anti-Roll Device



a. **Purpose**. Fabricate an improved accessory to stethoscope currently under development to prevent it from rolling.

b. **Progress.** The stethoscope anti-roll device has been designed, prototyped and tested. Features will be integrated into the design of stethoscope.

c. **Budget.** $0.5K.

d. **Personnel**. 3 personnel.

e. **Milestones Achieved.** Project completed.

11) 3-D Scanning

a. **Purpose**. Obtain a system to create 3-D parametric models of organic and geometric systems for the purpose of platform integration and reverse engineering.

b. **Progress.** The equipment was obtained and two MSS persons have been trained on use of the equipment.

c. **Budget.** $65K

d. **Personnel**. 2 personnel.

e. **Milestones Achieved.** Not applicable.

Project Management - Pharmaceutical Systems

Project Management - Pharmaceutical Systems

The mission of the Pharmaceutical Systems Project Management Office (PSPMO) is to manage DoD resources applied to the advanced development of pharmaceutical products (drugs, vaccines, biologicals, diagnostics, and hemorrhage control and resuscitation products) for use by the U.S. Military to prevent, diagnose or treat infectious diseases and combat casualties. Our challenge is to move these products to U.S. licensure and fielding within the framework of DoD Acquisition Regulations and Policies and the Consumer Protection Laws of the U.S. FDA and the U.S. EPA. PSPMO accomplish the mission through the establishment of partnerships with Industry (Foreign and Domestic), other Governmental Agencies (United States and OCONUS) and academia. These partnerships range from total U.S. Government contracting and funding for the effort to USAMRMC participation as a "Contract Research Organization" in efforts of mutual interest that will lead to a licensed product available for military use. The PSPMO serves as an investor, broker, manager and facilitator for such efforts on behalf of the USAMRMC and the DoD.

Current PSPMO efforts focus on the development of drugs for the prevention and treatment of the parasitic diseases malaria and leishmaniasis, the development of vaccines to prevent viral infections (particularly Dengue and Adenovirus), diagnostics for infectious diseases (e.g., Leishmania, Dengue, diarrheal diseases) and transfusion transmitted diseases (hepatitis and Human Immunodeficiency Virus (HIV)), and blood replacement products such as freeze-dried human plasma and cryo-preserved platelets.

a. **General.** Project Manager. (b) (6) [redacted]. Deputy for Contract Management & Operations is (b) (6) [redacted]. Chief Program Analyst is (b) (6) [redacted].

b. **Staff.** 33 Personnel. 12 Civilians, 3 Military and 18 Contractors.

c. **Military Relevance.** U.S. Military Forces must be prepared to serve anywhere in the world against any threat. This could result not only in conventional injuries sustained during combat operations, but also from exposure to endemic diseases not commonly found in the United States. The development of products against these threats will help save lives, sustain the fighting Force and enhance return to duty.

d. **Research and Development**.

1) **Adenovirus Vaccine, Types 4 and 7.** The Adenovirus vaccine is used exclusively by the military to prevent Adenovirus-related acute respiratory disease (ARD) in Soldiers and other military trainees living in barrack-type environments during basic training. The vaccine consists of two orally administered, enteric-coated tablets, one containing live adenovirus serotype 4 and the other containing type 7 virus. Prior to the use of Adenovirus Vaccines, adenovirus types 4 and 7 accounted for 60 percent of all ARD in military recruits who were hospitalized. Adenoviruses are associated with pharyngitis, conjunctivitis, atypical pneumonia, and rhinitis. The development effort for the Adenovirus Vaccine was conducted primarily under a contract to Barr Laboratories, Inc. (now a subsidiary of Teva Pharmaceutical Industries Ltd.); Barr is performing post-licensure studies required by the U.S. FDA. Based on the clinical data obtained in an extensive Phase 3 trial conducted by military physicians at Fort Jackson, SC, and Great Lakes Naval Station in Evanston, IL, Barr submitted a new BLA with the U.S. FDA for licensing of the vaccine.

FIGURE 20: Adenovirus Vaccine

   a. **Progress.** The BLA was approved by the FDA in March 2011. An LRIP contract was established between Barr and the USAMRMC to provide initial vaccine supply. First immunizations with the vaccine began at recruit training centers for all Services in October 2011. In its first year of use, adenovirus vaccine prevented an estimated 15,000 adenovirus-associated cases of ARD. Vaccine safety and effectiveness have been excellent during the first three years of use. Vaccine deliveries have continued under an Interim Supply contract between Barr and the USAMRMC. The Defense Logistics Agency-Troop Support awarded a Full-Rate Production contract for the vaccine to Barr/Teva in 2014. The Full Rate Production contract will meet the military requirements through December 2019.

2) **Dengue Tetravalent Vaccine (DTV).** Dengue is the most significant arthropod-borne viral disease of man and the most geographically widespread. The distribution of dengue virus has increased 30-fold in the past 50 years. Annually, it is estimated that there are 50-100 million infections, 2.1 million clinically severe cases and about 30,000 deaths. Dengue is epidemic or endemic in over 120 countries; primarily in the tropic and sub-tropic regions where military personnel are/or be stationed or deployed. Impacted areas include: Western Pacific, Southeast Asia, Central and South America, Caribbean and Africa.

Increasingly, the United States and its territories are impacted (Ex: Puerto Rico epidemic outbreaks in 2010 and 2012; parts of Florida now considered endemic; sporadic outbreaks in Hawaii). The National Center for Medical Intelligence (NCMI) sets incidence rates at greater than 10%/month in parts of Southern Command (SOUTHCOM) (e.g., Colombia) and Pacific Command (PACOM) (e.g., Thailand). Dengue epidemics are explosive, with high attack rates, morbidity and with potential to rapidly incapacitate large numbers of personnel.

The illness caused by dengue virus is characterized by sudden onset of fever, severe headache, pain behind the eyes, generalized joint and muscle aches, lack of appetite, gastrointestinal disturbances and rash. In about 5% of the cases, the infection can progress to a debilitating and sometimes fatal manifestations of the disease referred to as Dengue Hemorrhagic Fever (DHF) and Dengue Shock Syndrome (DSS). Mortality for unmanaged DHF may reach 30%. In U.S. troops, it is estimated that each case of dengue will lead to 14 lost duty days at a cost of $7,500/case. NCMI estimates that a force of 100,000 would endure 2,000 cases per month in areas where attack rates exceed 10% at a cost of greater than $12M/month (assuming 80% effectiveness of personal protective measures).

There is currently no vaccine or drug to prevent the disease and treatment consists primarily of supportive care with extensive hospitalization and the potential for mortality.

a. **Purpose.** DTV is a live virus vaccine for prevention of infection against all four serotypes of the dengue fever virus.

b. **Progress.** As part of an ongoing CRADA between USAMRMC and Sanofi-Pasteur, the leading dengue vaccine industry developer, Phase 3 clinical trials of the Sanofi dengue vaccine (CYD) were completed in Thailand and the Philippines through the WRAIR OCONUS laboratory in Thailand, the Armed Forces Research Institute of Medical Sciences. These trial sites were part of an extensive, worldwide pivotal trial of the vaccine conducted by Sanofi. Results of the trials are undergoing analysis which will be completed by late Summer of CY14.

Additionally, USAMRMC is collaborating with Sanofi and the SUNY in Rochester in clinical trials of adult populations in the United States that will be supportive of U.S. licensure. A comprehensive immunological study (CYD56) is now in-progress at SUNY. FDA licensure for endemic areas is estimated in FY15. U.S. licensure is estimated FY17.

3) Topical Antileishmanial Drug, Paromomycin/Gentamicin. Soldiers who contract cutaneous leishmaniasis (CL) may be evacuated out of theater for treatment or given investigational therapies that often impart negative side effects. The present standard of care requires 10-20 daily intravenous injections of Pentostam®, an investigational drug based on the metal antimony which is associated with serious side-effects and toxicity that include vomiting, diarrhea, pancreatitis, elevated liver enzymes and at higher doses, pulmonary edema. As an investigational drug, it is approved for use only under an IND exemption protocol and must be administered under strict medical surveillance.

The Topical Antileishmanial ~~D~~rug Paromomycin (Topical Paromomycin) is a cream made from two aminoglycoside antibiotics, paromomycin (15%) and gentamicin (0.5%) formulated in an aquaphilic base. Topical Paromomycin is being developed to replace Pentostam® as the first-line therapeutic for the treatment of CL.

FIGURE 21: Tube of Topical Paromomycin/Gentamicin

a. **Purpose.** Topical Paromomycin provides an effective treatment option to care-givers to sustain Service Member and unit performance by:

   1. Allowing far-forward self-administration of the drug to minimize lost duty days or duty hours with a simplified treatment regimen (versus intravenous dosing Pentostam®).
   2. Minimizing the administrative burdens to medical personnel.
   3. Minimizing or eliminating regulatory costs associated with Pentostam®.
   4. Helping to mitigate the psychological impacts from the potentially disfiguring disease.

b. **Progress.** A Phase 3 pivotal trial for the Topical Paromomycin against Old World Leishmania in Tunisia has been completed. This study is a collaborative effort with the Tunisian Institut Pasteur and Tunisian Ministry of Health. Preliminary results indicate that the drug is highly effective (greater than 80%) against Old World CL.

   Based on guidance from the U.S. FDA, an additional Phase 3 clinical trial is in progress in Panama to determine efficacy of the drug against New World CL. A Paromomycin alone cream is being evaluated in parallel in order to demonstrate the contribution of gentamicin towards product efficacy. Simultaneously, a NDA is being prepared and discussions are occurring with potential industry partners for licensure and manufacture of the product.

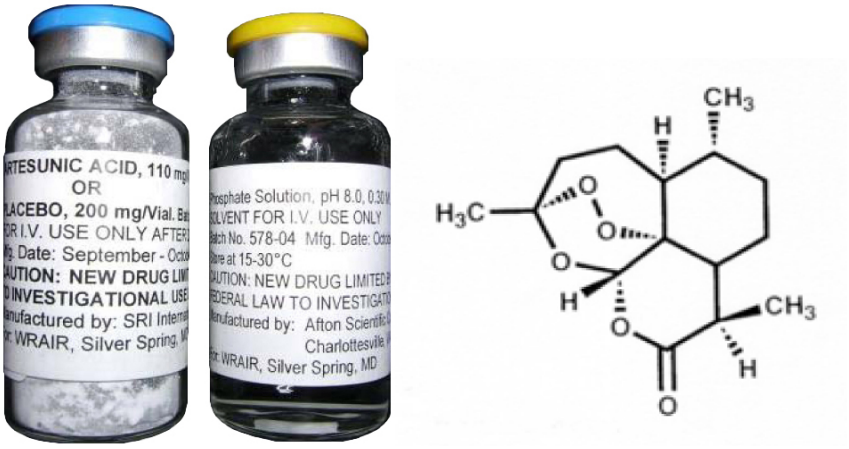
FIGURE 22: Stethoscope Anti-Roll Device

4) **Antimalarial Drug, Intravenous Artesunate.** Artemisinin, the naturally-isolated parent drug of artesunate, is extracted from 'qing hao' or sweet wormwood (*Artemisia annua* L.). It has been part of traditional Chinese herbal medicine for centuries. It was rediscovered and isolated as the active antimalarial agent in *Artemisia annua* L. in 1972 by Chinese scientists, and later independently by scientists at WRAIR seeking new treatments for malaria. Several million malarial patients have been treated with artesunate produced in China and it has been found to be highly effective in parasite clearance and fever reduction when given by the oral, intramuscular or intravenous route. Almost every publication has referred to it as being a safe, effective and predictable drug for the treatment of severe and complicated malaria. A landmark study in Southeast Asia published in 2005 found that intravenous

artesunate (IV AS) has a 35% all-cause mortality benefit over quinine for the treatment of severe malaria, proving it more effective and superior to quinine, the over 300 year old gold standard for the treatment of malaria.

Quinidine is currently the only approved drug for the treatment of severe malaria, but it is not an ideal drug. Quinidine is associated with sudden cardiac death, principally via cardiac arrhythmias, and, because of its short half-life, must be administered 2-3 times a day and best done in an intensive care setting. Most significantly, quinidine is no longer the drug of choice in treating certain electrocardiac disturbances and may soon cease to be available in the United States. IV AS has been shown to be exceedingly safe in clinical trials performed in the United States by WRAIR and the USUHS and offers both efficacy and safety for the treatment of this devastating disease.

FIGURE 23: Intravenous Artesunate



a. **Purpose.** To provide an U.S. FDA approved drug for the initial treatment of Service Members afflicted with severe and/or complicated *Plasmodium falciparum* malaria. The need for IV AS is critical in that malaria remains one of the most important infectious disease threats to Service Members during deployment to tropical and subtropical areas and has a long history as the cause of disease and non-battle injury to military personnel.

b. **Progress.** The collaboration between USAMRMC and Sigma Tau Industrie Farmaceutiche Riunite (S.p.A. Rome) for the licensing and manufacture of IV AS continues to move towards licensure of the product. Under the terms of the agreement, USAMRMC is providing the clinical and other regulatory data required to support Sigma Tau's NDA to the U.S. FDA and Sigma Tau will manufacture and distribute the U.S. FDA approved product. Pivotal clinical data supporting licensure will come from the compassionate use IND managed by the Centers for Disease Control and Prevention in Atlanta. The Product Team for this effort has been working to put that CMC data into a submittable package acceptable to the U.S. FDA. The compassionate use IND will continue to be used for treatment of U.S. cases of complicated and severe malaria until a licensed product becomes available.

5) Drug for Malaria Prophylaxis. Currently, there are no vaccines to prevent malaria. Preventive medicine measures, such as vector control, repellents, malaria chemoprophylaxis and the use of permethrin-treated uniforms and bed nets, reduce the risk of malaria infection. There are essentially four drugs approved by the U.S. FDA for chemoprophylaxis of *P. falciparum* malaria: mefloquine, doxycycline, chloroquine and atovaquone/proguanil (Malarone®). Unfortunately, these drugs have

limitations and are not always well-accepted by users. Chloroquine is markedly restricted because of widespread drug resistance of the parasite. Mefloquine is poorly tolerated by some individuals and has been associated with side effects that reduce compliance by some Service Members. Doxycycline has a number of side effects and must be taken daily for effectiveness. Currently, atovaquone/proguanil (Malarone®) is prohibitively expensive for widespread use in large numbers of deployed personnel, as it also requires daily dosing, which is very difficult to enforce in deployed units. The first three drugs must be taken for 30 days after leaving the malarious area and atovaquone/proguanil for seven days, because they have limited or no effect on developing liver stages. Lack of compliance with a 30-day regimen, after leaving the areas at risk, is reflected by the fact that 80% of recent malaria cases are due to *P. vivax* where post-exposure treatment to prevent relapsing malaria. None of these drugs can prevent relapsing malaria from *P. vivax* or *P. ovale.* Several alternatives to these drugs are being examined in the development process.

Tafenoquine (TQ) (WR238605) is an 8-aminoquinoline that has demonstrated antimalarial potential in both pre-clinical and clinical studies. Several clinical studies have indicated that TQ is very effective in preventing malaria in endemic areas.

Additionally, TQ was demonstrated to be efficacious in the radical cure for treatment of *P. vivax* malaria with a shorter treatment time than the current radical cure drug, Primaquine. However, a significant drawback of TQ is that it cannot be used by individuals with a Glucose-6-Phosphate Dehydrogenase deficiency (an X-linked recessive hereditary disease characterized by abnormally low levels of glucose-6-phosphate dehydrogenase (abbreviated G6PD or G6PDH)). While this is not a significant issue with the DoD because all personnel are tested and identified if they are G6PD deficient, it became a major concern of the USAMRMC industry partner in the TQ development effort, GSK. Therefore, GSK is currently conducting a G6PD safety study to determine if a safe dose of TQ can be calculated for use in the radical cure indication.

a. **Purpose**. To provide an U.S. FDA approved antimalarial chemoprophylaxis drug. This drug is intended to protect U.S. Service Members, DoD civilians, DoD contractors, and other supporting personnel from malaria under current and future deployment contingencies.

b. **Progress**. The TQ team has developed a tiered regulatory strategy utilizing legacy clinical data to best position TQ for licensure with the U.S. FDA. The IPT has been working with GSK, who is also in collaboration with the Medicines for Malaria Venture, in pursuing a Radical Cure indication for *P. vivax* malaria. Additionally, GSK has indicated its continuing support of the U.S. Army in developing a prophylactic indication for TQ. The team has been focused on preparing the required documentation for upcoming regulatory meetings.

6) Leishmania Rapid Diagnostic Device. CL, in its various forms, constitutes a serious infectious disease threat to the U.S. Forces, including operations other than war, in all tropical and sub-tropical regions of the world.

a. **Purpose.** The Leishmania Rapid Diagnostic Device (LRDD) is a U.S. FDA-cleared field deployable, handheld, disposable point-of-care test to rapidly detect the presence of leishmania parasites found in samples of lesions from patients displaying symptoms of CL. The LRDD does not require the use of additional equipment to analyze appropriate clinical specimens and facilitates the early diagnosis of CL infection and prompt medical intervention.

InBios, a small company on the west coast, has successfully developed the LRDD under a SBIR contract with the USAMRMC. This company has previously successfully developed and marketed a diagnostic for Visceral Leishmaniasis.

b. **Progress.** The LRDD program entered the Production and Deployment phase of the acquisition lifecycle after a successful Milestone C brief. The LRDD has been manufactured in accordance with

all GMP and successful clinical studies in Tunisia and the United States as well as analytical studies resulted in a complete data package that was submitted to the U.S. FDA in May 2014.

7) **Dengue Rapid Diagnostic Device.** Advanced Development of this effort was terminated in FY13 by the milestone Decision Authority.

8) **Transfusion Transmitted Disease Rapid Diagnostic Device (TTDRDD)**. The most common cause of potentially preventable deaths in ongoing military operations is hemorrhage resulting from combat-related injuries. Transfusion of fresh whole blood (FWB) from Soldier donors is an important therapeutic tool in emergency life-threatening scenarios when requirements for screened, stored blood components outpace supply or when patients require blood products unavailable at their current echelon of care. Minimizing the transmission of disease is a critical aspect of these FWB transfusions.

FIGURE 24: Rapid Transfusion Transmitted Disease Detection Device

a. **Purpose.** The TTDRDD device will be an U.S. FDA-approved rapid diagnostic test intended for use as a blood donor screening assay for transfusion transmitted diseases in urgent situations where traditional licensed blood donor screening tests are unavailable or impractical. The first phase of the program will focus on the development of a multiplexed diagnostic device for the detection of human immunodeficiency virus 1/2 (HIV 1/2), hepatitis C virus (HCV) and hepatitis B core antigen (HBc). The second phase will be a concurrently developed device for the detection of antibodies to hepatitis B surface antigen (HBsAg).

   MedMira, a small Canadian biotech and life sciences company, began developing the multiplexed assay under a contract with USAMRMC. This company is known for their high quality, high performance diagnostics that use their patented rapid flow-through technology. They have successfully developed and marketed the Reveal G3 Rapid HIV-1 Antibody Test, which is the fastest point-of-care rapid HIV-1 test available in United States.

b. **Progress**. The contract with MedMira to develop the multiplexed assay (HIV1/2, HCV and HBc) was awarded, and a subsequent contract modification was approved for the concurrent development of the HBsAg assay. The IPT was officially re-chartered due to a change in Product Managers and an Analysis of Alternatives was completed for the program. Clinical studies of the device are now in progress. U.S. FDA approval is anticipated in FY16.

9) **Whole Blood Pathogen Reduction Device (WBPRD)** Currently, the operational force does not have any method of pathogen reduction for blood products collected in theater. In urgent situations, donor blood is collected and transfused before U.S. FDA-approved pathogen screening at CONUS based centers can be completed. Transfusion transmitted disease is therefore a concern, particularly since there is no in-theater method to screen donor blood for parasites (e.g. - malaria, Leishmania sp.,

Babesia sp.), bacteria (e.g. - Acinetobacter baumannii, Klebsiella pneumoniae) and many viruses (e.g., HIV variants, dengue virus, Chikungunya virus, Coxiella burnetti).

FIGURE 25: Mirasol® Pathogen Reduction Technology

a. Purpose. The pathogen reduction (PR) device will provide the capability to treat all blood products collected in theater, increasing the safety of transfusions by reducing the risk of disease transmission. This PR device will be employed in theater at locations where blood products are collected, such as combat support hospitals, medical companies and blood support detachments. It is expected that screening for known pathogens will continue to be required in order to meet current standards of care; however, the risk of transmitting disease through transfusion is mitigated by PR treatment of emergency blood products.

TerumoBCT, previously Caridian BCT, is a global medical device manufacturer specializing in blood component and cellular technologies. TerumoBCT is the manufacturer of the Mirasol® Pathogen Reduction Technology that is currently available as an approved commercial device in the European Union for plasma and platelets. TerumoBCT received a grant from the Congressionally Directed Medical Research Program to complete the pre-clinical development of the PR device. They were able to develop and verify the performance of the system for fresh whole blood including the ability to inactivate pathogens, including viruses, bacteria, parasites and donor white blood cells.

b. Progress. The WBPRD CDD is in formal Army staffing, and a Milestone B was approved for this product in fourth quarter FY12. At a developmental test event conducted at Camp Bullis, TX, the AMEDD Test Board Customer Assessment Report showed that the device met most performance attributes with the exception of the system weight, system cube, and processing time when units of blood were processed intermittently. These issues were addressed in FY13 and FY14. A pre-IDE meeting with the U.S. FDA was also held and the regulatory strategy for the Phase 3 clinical trials was approved. Planning for the Phase 3 trial is currently in progress.

10) Red Blood Cells, Extended Life. Red Blood Cells (RBC) are one of four major components (salt solution, plasma, red blood cells, and platelets) necessary for successful treatment of combat casualties who have experienced massive hemorrhage on the battlefield.

a. Purpose. Red Blood Cells, Extended Life is a new additive solution and blood collection system that extends the life of stored, packed RBCs from six weeks to eight weeks and will enhance battlefield supply and management of RBCs. The key to the new process is a new additive solution and a new bag system for collection and storage. The system also includes a leuko-filtration (white blood cell filter) device that removes greater than 99.9% of white blood cells from collected blood. The new additive solution has been developed by the University of Cincinnati and the Army during the past 20 years. The bag, filter and collection system have been developed by Hemerus Medical, LLC, St. Paul, MN.

b. **Progress.** The NDA for this product was submitted to the U.S. FDA in November 2011. Hemerus Medical, the product Sponsor, received a CE Marking for the bag, filter, and collection system (collectively referred to as the SOLX™ system) in September 2012, a noteworthy event in that it is the world's first CE Marking for a RBC 56-day storage solution. The U.S. FDA manufacturing and clinical audits were completed and the U.S. FDA posed a few questions, which were relatively minor in nature and subsequently addressed by Hemerus. The U.S. FDA has also requested additional toxicity data and manufacturing information to support licensure. These were submitted and U.S. FDA approval was received on 25 April 2013 effectively ending the USAMRMC development effort for this product. However, on FDA approval, Hemerus Medical was acquired by Haemonetics. Haemonetics moved to replace the Hemerus leuko-filtration filter with a Pall filter (the same brand used in a number of other Haemonetics products). The component change required additional data to be submitted to the FDA as part of an amended NDA. Haemonetics completed data collection in November 2014 and plans to submit the amended NDA by the end of December 2014. Market release is expected in mid-2015 at which time the product will be available to Army (and other Service) Blood Centers.

11) Freeze-Dried Plasma. Between 2001 and 2011, up to 26% of total Pre-Medical Treatment Facility combat deaths may have been potentially survivable deaths. Ninety-one percent of the potentially survivable deaths were due to hemorrhage. Plasma is one of four major components (salt solution, plasma, red blood cells, and platelets) necessary for successful treatment of combat casualties who have experienced massive hemorrhage on the battlefield.

Human plasma (usually fresh frozen plasma (FFP)) that has had the water removed, generally by freeze drying (lyophilizing), is commonly called Freeze-Dried Plasma (FDP), or lyophilized human plasma. FDP is a formulation of plasma that enhances logistical support for treatment of combat casualties by reducing freezer requirements typically needed for FFP and by reducing breakage and waste (up to 30%) that has typically been associated with FFP.

a. **Purpose.** FDP will reduce waste of plasma by eliminating breakage and outdating of FFP after thawing and reduce the logistical burden associated with storage requirements for FFP. FDP will permit positioning of plasma forward of ROC-3, potentially saving lives while simultaneously reducing the logistics burden.

The FDP product, currently under development, is a collaborative effort between the USAMRMC and Vascular solutions, Inc., of Minneapolis, MN.

b. **Progress.** Following the termination of a cooperative agreement between USAMRMC and the former development partner, HemCon Medical Technologies, Inc., the USAMRMC established a CRADA with Vascular Solutions, Inc. Under the terms of the CRADA, Vascular Solutions is responsible for the funding and work necessary to complete manufacturing development and production of a FDP product suitable for clinical testing, while USAMRMC is responsible for the FDA sponsorship, funding, and regulatory oversight of clinical trials. Vascular Solutions began manufacturing development work in 2014 while the USAMRMC developed a contract solicitation for the performance of clinical trials. USAMRMC is also preparing to submit an IND for the product, including Vascular Solutions manufacturing data, by 3QFY15, with clinical trials expected to begin shortly thereafter. On successful completion of clinical trials, Vascular Solutions will assume regulatory sponsorship, submit a BLA to the FDA and assume commercialization and post-licensure responsibilities for the product.

12) Cryopreserved Platelets (CPP). Platelets are one of the four major components (salt solution, plasma, red blood cells, and platelets) necessary for successful treatment of combat casualties who have experienced massive hemorrhage on the battlefield. Liquid Stored Platelets (LSP) have a very short shelf-life (seven days or less) once collected and are difficult to supply on the battlefield.

a. **Purpose**. CPP are human platelets frozen at -80C in 6% dimethylsulfoxide, a cellular protectant during freezing. Due to the short shelf-life of LSP, approximately 70% of LSP produced in theatre are outdated and discarded as waste. CPP will have a significantly longer shelf-life, thus eliminating waste and reducing the logistical burden of supplying platelets to the battlefield.

CPP was first developed at the Naval Blood Research Laboratory, Boston, MA, from 1972 to 2001 with funding provided by the Office of Naval Research. USAMRMC is building on that work in an effort to develop CPP for battlefield use.

b. **Progress.** The clinical development plan was restructured to ensure safety and efficacy of the product. Four Phase 1 clinical trials of the product have been completed. The product is currently going through a Phase 1/2 clinical trial, with safety as the primary study endpoint and efficacy as a secondary endpoint. Current expectations are that clinical and manufacturing development will be complete in FY20, with BLA filing intended to occur in the same year. Upon FDA approval, the manufacturing process will be transferred to U.S. Army (and other Service) blood banks.

13) Platelet-Derived Hemostatic Agent (PDHA). Platelets are a vital component of whole blood and are required to treat hemorrhage and stop bleeding. Due to the nature of the manner in which units of LSP must be stored, it is not possible to bring units of this vital product beyond ROC-3. The PDHA product will not be a direct replacement for platelets, but rather is intended to be used for acute restoration of hemostasis caused by severe bleeding due to trauma beyond ROC-3.

a. **Purpose.** By virtue of the PDHA product's powdered form that does not require refrigeration or constant agitation (as is the case with LSP) the product is intended to be reconstituted on demand as required. The PDHA will provide acute treatment of bleeding at far-forward locations until a casualty can be transported to facilities where LSP are available.

b. **Progress.** There are two PDHA products currently under development. One candidate, named Thrombosomes, is under development by Cellphire of Rockville, MD. This product, originally funded through the DoD, is now receiving funding support from the BARDA of Health and Human Services. BARDA is seeking a clinical indication for PDHA for the treatment of Acute Radiation Syndrome (ARS). Members of USAMRMC are integrated into this development program for the purpose of information sharing. USAMRMC is funding a second product, Stasix, through the Joint Warfighter Medical Research Program. Stasix is being developed by Entegrion, Inc. of Research Triangle Park, NC. Members of BARDA are integrated into this development program for the purpose of information sharing. USAMRMC is seeking a clinical indication for the restoration of hemostasis following severe bleeding due to trauma. USAMRMC awarded a contract to Entegrion in 2014 for the performance of pre-clinical studies and manufacturing development and scale-up. The contract will support work through the filing of an IND. At that time (expected to be at the end of FY16), USAMRMC will review the progress of BARDA's development program and assess whether or not to continue development of the Entegrion product. Pre-clinical studies are expected to begin in the second quarter of FY15.

Tissue Injury and Regenerative Medicine

Project Management – Regenerative Medicine

The Tissue Injury and Regenerative Medicine (TIRM) PMO is charged to apply reproducible DoD acquisition project management processes to advance maturing technologies towards standard medical practice. This includes management and analysis of the technology in the pipeline, and advancing technology through product development, and/or clinical integration. The TIRM PMO executes broad portfolio awards such as the Armed Forces Institute of Regenerative Medicine (AFIRM) Cooperative Agreements, the Biomedical Translational Initiative (BTI), the Reconstructive Transplantation Research (RTR), the Clinical Trial Awards-Regenerative Medicine, Pain and Sensory (CTA-RPS), and other regenerative medicine projects through grants and contracts.

In 2014, the TIRM PMO had a number of highlights:

- Successfully completed a Materiel Development Decision for the Extremity Injury Repair – vascular and nerve capability.
- AFIRM II $75M cooperative agreement kickoff with Wake Forest
- Presented the progress of the portfolio to the Honorable Heidi Shyu, Assistant Secretary of the Army (Acquisition, Logistics, Technology (ASA(ALT)), during the Clinical and Rehabilitative Medicine Research Program Regenerative Medicine Deep Dive.
- Initiated two regenerative medicine clinical trials (stem cell therapy for burn wounds and treating hand transplant rejection with local injection of stem cells from adipose tissue/fat).
- Hired new Director for TIRM PMO.
- Award of $15M Regenerative Medicine Clinical Trial Award (DHP).

A. **General.** Director. (b) (6) . Deputy Director. Lieutenant Colonel (b) (6) , through June 2014.

B. **Staff.** 10 Personnel. 3 Military, 2 Civilians, and 5 Contractors.

C. **Military Relevance.** The technologies and efforts in the portfolio address trauma sustained from military operations that require new, modified, or unique solutions to restore, repair, and rehabilitate the Soldier, Sailor, Airman, or Marine.

D. **Research and Development.** The TIRM PMO managed the portfolio of efforts in five categories: extremity repair, craniomaxillofacial repair, burn treatment and skin repair, vascular composite allotransplantation, and genitourinary repair. The TIRM PMO conducts weekly and monthly teleconferences with the performers based on the maturity of the technology.

FIGURE 26: Research and Development

The TIRM PMO conducted a number of site visits for performer oversight and in order for the government to anticipate and facilitate success.

FIGURE 27: Site Visits

Institution	Date
Johns Hopkins University	07 February 2014
U.S. Army Institute of Surgical Research (USAISR)	24-25 February 2014
Wake Forest University	24-25 February 2014
University of Pittsburgh	27-28 February 2014
Brigham and Women's Hospital	05 March 2014
Lonza Walkersville, Inc (LWI)	14 March 2014
University of Texas at Arlington Research Institute (UTARI)	19-21 March 2014
Naval Medical Center San Diego (NMCSD)	29-30 April 2014
University of California, Los Angeles (UCLA)	02 May 2014
New York University (NYU)	12 May 2014

The staff attended a number of conferences to better define capability gaps, to assess alignment of performers' public disclosures with their closed reporting and to identify new technology areas that may solve the capability gaps.

FIGURE 28: Conference Attendance

Institution	Date
GTC Stem Cell Summit	23-25 April 2014
Military Health Systems Research Symposium (MHSRS)	18-21 August 2014

- Developed an information paper for the Veterans Administration summarizing TIRM PMO's efforts on hand and face transplants.
- Hand Transplantation
  - (b) (6) [redacted], a quadruple amputee who received a double arm transplant in December 2012, was featured on the front page of the Washington Post on 30 June 2014 doing a pull-up.

- Facial transplantation
  - Brigham and Women's Hospital (BWH) performed the fifth and sixth face transplants under the BTI contract. Both patients are doing well with expected challenges following transplantation.
  - Cleveland Clinic performed the first face transplant under the AFIRM I cooperative agreement. The patient is doing well.
- Meeting with Centers for MediCare Services to discuss coverage of vascularized composite allotransplantation (VCA), in whole or in part (procedure itself and/or immunosuppression medications).

AFIRM II funding ($75M over five years starting in 2013), provided jointly by the U.S. Army, Navy, and Air Force, the Veterans Health Administration, the DHP, the National Institutes of Health, and Health Affairs, is a follow on award to the AFIRM I award. The AFIRM II was competitively solicited and awarded to Wake Forest Institute of Regenerative Medicine as the consortia lead for 60 unique research topic areas. Collaborations extend to more than 50 academic laboratories and industry partners. The USAISR at Fort Sam Houston, TX, serves as the primary government facility for the AFIRM. However, collaborations are in development with other MTFs.

The BTI is a program to deliver near-term therapies to clinical practice, funded through the Office of Naval Research. The BTI has two clinical investigation projects underway: one at BWH in Boston, MA (composite tissue allotransplantation of the face) and one at the University of Pittsburgh (autologous fat transfer for craniofacial trauma).

The CTA-RPS projects were awarded in 2012, aimed at identifying promising regenerative medicine solutions in early advanced development stages of product maturity. Six projects are underway.

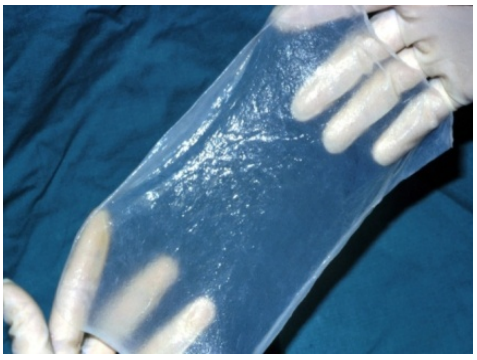
The RTR program was awarded in 2013 to fund innovative projects that have the potential to make a significant impact on improving the function, wellness, and overall quality of life for injured military Service Members and Veterans, their caregivers and family members and the American public. The focus is in applied research for immunomodulation and composite tissue allotransplantation.

1) Allogeneic Engineered Skin/StrataGraft™

a. **Purpose.** The goal of this project is to develop a universal skin graft as a "ready to use" alternative to cadaveric skin until an injured patient's own skin can be used for grafting. StrataGraft skin tissue is provided as a suturable circular patch of stratified epithelial tissue composed of a living dermal matrix (containing dermal fibroblasts) overlaid with human epidermal cells (NIKS™ cells).

b. **Progress.** A third cohort, with cryopreserved tissue, was added to the Phase II clinical trial in July 2013. The trial closed to enrollment in October 2013. Final study results are expected in 2014.

FIGURE 29: StrataGraft



2) **Autologous Engineered Skin/Lonza PermaDerm**

a. **Purpose.** This project intends to reduce the requirement for autografts used to treat burn injuries by developing autologous engineered skin. This product uses a small sample of the patient's healthy skin to grow a larger sheet of engineered skin over a 30-day period. Engineered Skin Substitute (ESS) products may be used to close burn wounds of greater than 50% total body surface area at a single operation. Following that single operation, the autologous ESS grafts heal in place.

b. **Progress.** Lonza submitted an IND in August 2012. The application is on clinical hold and Lonza has prepared and submitted a 2,000 page response to comments. Further responses are in preparation. Initiation of the trial is anticipated in 2015.

FIGURE 30: Engineered Skin/PermaDerm

3) **ReCell®/Partial Thickness Burn**

a. **Purpose.** ReCell is a stand-alone, rapid, autologous cell-harvesting, processing and delivery technology that enables surgeons to treat partial thickness burns using the patient's own cells. A biopsy of the burn victim's remaining healthy skin the size of a postage stamp can cover an area of burn 80 times larger. This product has point of care capability with an approximate 30-minute preparation time.

b. **Progress.** A multi-site, definitive clinical trial treating partial thickness burns is completed.

FIGURE 31: Recell/ Partical Thickness Burn

4) **Peripheral Nerve Scaffolds**

a. **Purpose.** The goal of this effort is to use biomaterials to repair large nerve defects, and, in so doing, to preserve limb function. When direct repair of a nerve injury is not possible, the current standard of care is an autologous nerve graft. However, autologous nerve grafts have several

drawbacks, including loss of function at the donor site, size mismatch and limited availability. An alternative to nerve autografts would enhance the current standard of care and lead to better outcomes and capabilities. NeuraLum is a surgically implanted polycaprolactone fumarate scaffold, and KeraGen is a surgically implanted keratin-derived polymer scaffold. The goal of each is to provide a conduit for nerve regeneration, which improves the current standard of care and results in better outcomes.

b. **Progress.** Studies to support an IDE application and clinical trial are underway.

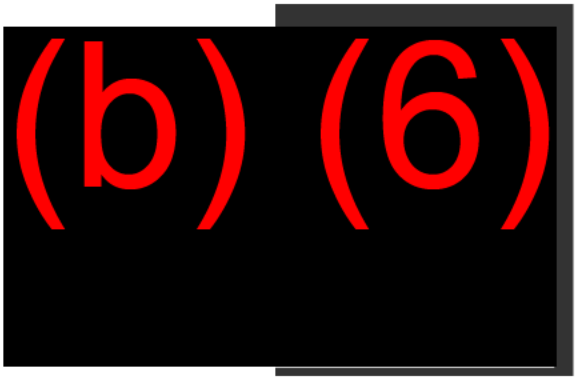
FIGURE 32: Peripheral Nerve Scaffolds

5) Vascularized Composite Allotransplantation (Hand and Face Transplantation)

a. **Purpose.** The goal of this project is to better define the risks and outcomes associated with VCA. The VCA (e.g., hand and face transplants) is a clinical reality. Despite encouraging functional results, VCA has not reached widespread clinical use both because few of the procedures have been performed, and only in the last several years, that long-term outcomes are unclear; and because recipients require lifelong, high-dose, multidrug immunosuppression to prevent graft rejection. These regimens carry a high risk for serious side effects. In an effort to minimize exposure to standard immunosuppression regimens and their attendant risks, protocols investigating recipient conditioning, donor bone marrow infusion, and monotherapy maintenance immunosuppression are under clinical investigation.

b. **Progress.** Under AFIRM funding, a face transplant protocol is enrolling at Cleveland Clinic, and a hand transplant protocol is enrolling at both Johns Hopkins University and the University of Pittsburgh (six patients have had a total of ten hand transplants, to date; ten more transplants have been funded). The BTI funding supports a face transplant protocol at BWH (four of five funded transplants have been performed). The CTA-RPS supports a hand transplantation protocol at BWH and another at Duke University. AFIRM II supports a protocol in hand transplantation at the University of Louisville.

FIGURE 33: Hand Transplant Recipient (Left) Face Transplant Recipient (Right)



6) Autologous Fat Transfer

a. Purpose. Autologous fat transfer protocols are in clinical trials through both consortia of the AFIRM, and through the BTI. This clinical technique has been established with empirical data for some time. The protocols running through the AFIRM and the BTI aim to establish its efficacy for: 1) aesthetic improvement in craniofacial defects; 2) scar mitigation, improving aesthetic and functional outcomes; 3) reducing pain at amputation sites due to poorly fitting prostheses.

Future investigations expect to include stem cell enriched fat grafts, or grafts incorporating flexible scaffolds to encourage cell engraftment and retention.

b. Progress. Four protocols have received IRB approval. All clinical trials are enrolling.

Hyperbaric Oxygen Treatment of Post-Concussive Syndrome

Hyperbaric Oxygen Project Management Office

Hyperbaric oxygen (HBO_2) therapy is the use of increasing oxygen and pressure to cause the blood oxygen levels to rise above the normal physiologic range (i.e. "supraphysiologic"). In the therapeutic range, hyperbaric oxygen increases the amount of dissolved oxygen in the blood plasma, changes vascular tone and facilitates improved oxygen delivery to tissues. The HBO_2 increases arterial and tissue oxygen tensions and is indicated for various oxygen-deprivation conditions such as acute carbon monoxide poisoning, air or gas embolism, decompression sickness, necrotizing fasciitis, acute thermal burn injury and others. The U.S. FDA has cleared hyperbaric chambers for treatment of a total of 14 indications to date.

USAMMDA is leading a government, joint DoD and Veterans Affairs (VA), and academic partnership to determine if hyperbaric oxygen is of benefit in the treatment of persistent symptoms of post-concussion syndrome (PCS) following mild TBI.

Mild TBI, also commonly called post-concussion syndrome (PCS), is caused by a blow or jolt to the head that disrupts brain function. Although there remains some controversy about the definition, the widely accepted immediate clinical sequelae include:

- Loss of consciousness for 0-30 minutes; OR
- Alteration in consciousness lasting up to 24 hours
- Amnesia lasing up to 24 hours

A normal CT scan post injury is included in some definitions, although higher resolution neuroimaging may show abnormalities. In most cases, symptoms resolve within days or weeks after a concussion. If symptoms persist for three months, the ongoing sequelae are termed PCS.

Recovery is different for each person and depends on the nature of the injury. Most people fully recover in days to three months. The most important thing that can be done is to allow time for the brain to heal. The reason why some people continue to have persistent PCSs is unknown. The negative impact of these symptoms adversely impacts military operational readiness and effectiveness.

Currently there is insufficient evidence to recommend hyperbaric oxygen to treat PCS; however, the DoD is conducting numerous clinical trials to generate scientific evidence to guide therapy.

FIGURE 34: Inside the Hyperbaric Oxygen Chamber

a. **General.** Project Manager. Colonel (b) (6) .

b. **Staff.** 6.5 Personnel. 3.5 Contractors and 3 Military in the Program Management Office at USAMMDA. (Contracts totaling 68 persons at the clinical trial site locations in various MTFs, academic institutions and subject matter experts are not included in this number.)

c. **Research and Development.**

1) Completed DoD Studies:

a. USAMMDA - multi-cohort pilot study. Double blind: 1.2 ATA air (sham) vs. 1.5 ATA O2 vs. no chamber (standard of care). Endpoints include symptoms, quality of life and neuropsychological testing. Conducted at 4 sites (Camp Lejeune, NC; Camp Pendleton, CA; Fort Carson, CO; and Fort Gordon, GA utilizing a central study coordinating center at LDS Hospital, Salt Lake City). Data analysis complete. About 20% symptom improvement in subjects receiving pressure but sham treatment group results greater than those of hyperbaric treatment group. Results consistent with expected placebo and Hawthorne effects. Results expected to be published in November 2014.

2) Current DoD Studies Underway and Supported by the HBO_2 PMO (P6 DHP RDT&E funds):

a. USAMMDA - multi-center trial with up to 72 randomized to assure 60 participants to completion. Double blind, randomized to 1.3 ATA air (sham) vs. 1.5 ATA O2 x 40 sessions. Exploratory objectives neurologic and radiologic endpoints, and compare these to symptoms, quality of life and neuropsychological testing. Sites in Fort Carson; Joint Base Lewis McChord, WA; and eventually Camp Lejeune. Completed enrollment, anticipate completion in FY15.

b. USAMMDA - normal, healthy, non-brain injured civilians and military participants (active or inactive) will undergo a battery of outcome assessments at defined test intervals to replicate the assessment battery used in a program of studies investigating the safety of HBO_2 in patients with post-concussive symptoms following mild TBI. Study currently in the recruitment phase.

c. USAMMDA – A single survey, observational cohort study of DoD research volunteers who participated in one of three DoD interventional trials evaluating the efficacy of hyperbaric oxygen therapy as a treatment for persistent symptoms after concussion/mTBI with or without PTSD. This

study is designed to provide a follow-up at a single point in time (>1 year after intervention, range 1-4 years). The purpose of this study is to determine if there is durability of any symptom improvements observed during the initial study periods in both treatment and sham groups, as well as to determine if there are any long-term differences in outcomes between individuals who received hyperbaric oxygen therapy, sham therapy, or local care.

Neurotrauma and Psychological Health

Project Management – Neurotrauma and Psychological Health

The NPH PMO was formed in May 2011 to support the advanced development of materiel (drugs) and select non-materiel (medical knowledge) products to protect, sustain and care for Service Members with TBI and Post-Traumatic Stress Disorder (PTSD).

A. **General**. Project Manager. Colonel (b) (6), U.S. Air Force, served as the Project Manager from 19 April 2013 through 1 July 2014. Lieutenant Colonel (b) (6) assumed responsibility on an interim basis through the remainder of 2014. Lieutenant Colonel (b) (6), Military Deputy Project Manager departed in May 2014 with no replacement. (b) (6) serves as the Civilian Deputy Project Manager.

B. **Mission**. The Neurotrauma and Psychological Health (NPH) PMO provides program management, medical subject matter, and DoD acquisition expertise in coordinating research and development activities relevant to the development of medical and knowledge products to protect, sustain and care for Service Members and Veterans suffering from injuries caused by TBI and post-traumatic stress. The NPH PMO provides advanced development expertise to the Military Operational Medicine and Combat Casualty Care Joint Program Committees.

C. **Personnel**. 10 Personnel. 2 Military. 3 Civilians. 5 Contractors.

D. **Focus Area**.

1) Materiel solutions. The NPH PMO provides advanced development support of clinical trials involving FDA-licensed drugs to treat the various symptom clusters of PTSD and trials to find solutions for mild, and moderate to severe TBI. The NPH PMO monitors the pharmacotherapeutic horizon to seek out, find novel opportunities, and stay abreast of non-DoD clinical trials of new drugs to treat PTSD and TBI.

2) Non-materiel solutions. The NPH PMO is collaborating with the Defense Centers of Excellence and other Federal entities to develop non-materiel/knowledge products that positively impact treatment therapies to inform current clinical practice.

3) The NPH PMO provides advanced development support and assistance to USAMRMC's Military Operational Medicine and Combat Casualty Care Joint Program Committees. Both materiel and non-materiel product development efforts benefit from USAMMDA's expertise in the areas of clinical trial design, management and oversight; regulatory expertise; and focused program management.

4) Although the USAMRMC has a variety of potential PTSD treatment solutions (device, drug and knowledge products) each product development effort is impacted by the lack of a universal standard of care. There is insufficient information to guide the use of pharmacotherapeutics for the treatment for PTSD. Many FDA-licensed drugs are used off-label by individual physicians to treat PTSD in their patient Service Member or Veteran. While these drugs reportedly show some benefit in reducing the symptoms of PTSD or in reducing the onset/severity of PTSD when given in close proximity to a traumatic event, the lack of scientific evidence to support continued use, and the lack of new drugs on the horizon remains a critical issue that must be addressed.

E. **Military Relevance**. According to the Congressional Research Service, combat-related TBI and PTSD present significant health and quality of life problems that affect over 400,000 U.S. Service Members, veterans and their families. Epidemiological studies of PTSD involving Service Members returning from

deployment in support of OEF, OIF and Operation New Dawn (OND) report a prevalence rate between 10 to 20%; the national civilian incidence rate is 8%.

F. Research and Development.

1) Drug Treatment for PTSD. After careful and deliberate analysis, the Product Lifecycle Review Committee recommended to the MDA that the phase two Randomized Controlled Trial to Evaluate the Efficacy of Trazodone Hydrochloride Versus Placebo as an Adjunct to Treatment with Antidepressants for Combat-Related PTSD in OIF/OEF/OND Service Members and Veterans be stopped due to lack of return on investment on this study of a generic drug. Because of the complex nature of the treatment issues for PTSD and the lack of new drugs in development the JPC-5 and the NPH PMO were jointly tasked by the MDA to conduct a "PTSD State of the Science" meeting bringing experts from industry, academia, and other Federal agencies together to address the critical shortfalls in PTSD pharmacotherapeutic pipeline and to develop strategies for the future. This meeting is scheduled to occur in July 2015.

2) Drug Treatment for Traumatic Brain Injury

3) Drug Treatment for Traumatic Brain Injury (DTTBI). An NPH Product Manager serves as an IPT co-chair to the DTTBI development effort currently led by researchers at the WRAIR. The DTTBI IPT is updating the Technology Transition Agreement which is scheduled for final approval in early calendar year 2015. Neuren Pharmaceuticals, Inc. is the sponsor of the NNZ 2566 Phase 2 trial for *intravenous (IV) formulation* to treat moderate-severe TBI. The IV formulation is scheduled to transition to Advanced Development in FY 2016. The phase 2 trial for the NNZ 2566 *oral formulation* to treat mild TBI is scheduled to transition to AD in FY 2017.

APPENDIX A

PERSONNEL

Key Military & Civilian Personnel

Departed in FY 2014	Division	Date
LTC (b) (6)	NEURO	30 May 2014
LTC (b) (6)	TIRM	20 June 2014
LTC (b) (6)	HBO2	25 June 2014
Col (b) (6)	NEURO	8 July 2014
Col (b) (6)	HBO2	31 July 2014
MAJ (b) (6)	MSS	1 August 2014

Arrived in FY 2014	Division	Date
None		

Personnel Strengths

Beginning 01 October 2013

Military	Civilians	Contractors
19 Army 2 Air Force	70	99

Ending 30 September 2014

Military	Civilians	Contractors
15 Army	68	100

No PROFIS positions

APPENDIX B

ACCOMPLISHMENTS

USAMMDA

1) As part of a collective USAMRMC effort, USAMMDA helped to meet and exceed the small business goals for FY14. These highly commendable achievements are unprecedented, considering the decrease in procurement actions and reduced funding experienced by the command in FY14. The collective efforts in providing maximum opportunities for small businesses to compete and win government procurements underscore the command's role to advance military medicine.

Office of the Commander

1) One of the critical roles of the OQM is to coordinate and host inspections, and manage the resultant corrective actions. The OQM successfully hosted three significant inspections in FY14, including an audit of the EDC-CRDMS in coordination with the U.S. Army Medical Research Institute of Infectious Disease (USAMRIID), and an evaluation from the Organizational Inspection Program (OIP). This OIP inspection exhibits clear organizational improvement, identifying fewer and less significant deficiencies than the last inspection, in FY12. The OQM has performed all Managers' Internal Control Program evaluations on schedule, has established a re-organized internal audit program, and drafted an SOP for an organization-wide Continuous Process Improvement program. In addition, the OQM manages Document Control, leads the Balanced Scorecard strategic effort and provides quality assurance support on 24 IPTs and their associated working groups.

2) Executed a total of 117 new Tech Transfer and Interagency agreements in FY14, bringing into the Command ~$1,921,600.00 from external partners.

3) In-kind industry partner contribution for the fiscal year was estimated at $13,250,000.00.

4) USAMMDA has a total of 399 active agreements. They are as follows: 101 Cooperative Research and Development Agreements (CRADA), 14 Memorandum of Understanding, 77 Memorandum of Agreement (MOA), 24 Material Transfer Agreements, 81 Interagency Support Agreements, 22 Interagency Agreements, 63 Nondisclosure Agreements, and 1 Patent License Agreement, 7 Over-arching Agreements and 9 Other.

Pharmaceutical Systems PMO

1) The Leishmania Rapid Diagnostic Device (LRDD), a hand-held "dipstick" device for the rapid diagnosis of cutaneous leishmaniasis, received U.S. FDA 510K Clearance on 14 November 2014. The LRDD will allow expeditious implementation of appropriate treatments which can reduce the severity of scarring, reduce lost duty time and improve healthcare and morale for U.S. military personnel in numerous areas of operations.

2) The initial Full Rate Production contract for Adenovirus Vaccine Type 4 and Type 7 Vaccine, Live, Oral was awarded by the Defense Logistics Agency to Barr Laboratories, Inc., a subsidiary of Teva Pharmaceutical Industries Ltd. The contract will provide uninterrupted delivery of vaccine to all military basic training facilities through December 2019.

3) Successfully completed a Materiel Development Decision for the Platelet-Derived Hemostatic Agent (PDHA) capability.

4) Successfully completed a Milestone C for the Leishmania Rapid Diagnostic Device (LRDD).

5) Successfully completed a Milestone B for Cryopreserved Platelets (CPP).

6) Established a Cooperative Research & Development Agreement (CRADA) with Vascular Solutions, Inc. for the collaborative development of Freeze-Dried Plasma (FDP).

7) Successful completion a Milestone B for Freeze-Dried Plasma FDP.

8) Formulated an agreement mutually acceptable to GlaxoSmithKline (GSK) and the USAMRMC for the development of the drug Tafenoquine for prevention of malaria including the establishment of a USAMRMC-partnership with an Australian company and a "shared" production facility for the drug. (GSK is developing Tafenoquine for Radical Cure of *Plasmodium vivax* malaria; The Australian company will develop the drug for prophylaxis and both companies will utilize the same manufacturer.)

Medical Support Systems PMO

1) Completed the Modular Lightweight Load-carrying Equipment (MOLLE) Medic Bag as a collaborative effort with PEO Soldier (PM Soldier Protection and Individual Equipment) and shipped more than 500 bags to Afghanistan. The new bag is lighter, lower profile, compatible with the Soldier's body armor, and modular with a tiered approach to treatment.

2) Completed the Individual First Aid Kit Generation 2 as a collaborative effort with PEO Soldier (PM Soldier Protection and Individual Equipment) as part of a Rapid Fielding Initiative and procured 134,580 kits for fielding to deploying units. The bag profile was reduced to prevent snagging on vehicle doors/hatches during emergency egress and a second Combat Application Tourniquet along with a chest seal, eye shield and a combat casualty care card were added.

3) Successfully integrated the Congressional project, Remote Physiological Status Monitor development effort, into the PEO Soldier (PM Soldier Protection and Individual Equipment) Integrated Soldier Sensor System (ISSS) development. The ISSS will allow unit leaders to track Soldier status, thus providing decision-making data for squad optimization.

4) Engaged (b) (6) , Program Executive Officer, PEO Combat Support and Combat Service Support, to ensure that medical requirements for independent suspension and litter load/unload were captured in the VCSA MRAP decision to allocate 301 Maxx Pro Plus ambulances to the AMEDD. The PEO agreed to include independent suspension and adopt litter load/unload developmental technologies produced by the PMO MSS. It was also agreed to include PMO MSS in the planning and testing events. The Maxx Pro Plus ambulances will be placed in Army Prepositioned Stock (APS) to provide up-armored ground medical evacuation capabilities in support of future conflicts.

Armed Forces Institute of Regenerative Medicine

1) Under the guidance and funding of the Armed Forces Institute of Regenerative Medicine I a Phase 2 clinical trial for a partial thickness skin substitute to treat burn injury was completed successfully in 2014. The FDA approved this technology to advance into a Phase 3 clinical trial. A skin substitute will decrease reliance on donor skin grafts to heal burn wounds.

2) Successfully completed a Materiel Development Decision for the Extremity Injury Repair – vascular and nerve capability.

3) AFIRM II $75M cooperative agreement kickoff with Wake Forest

4) Presented the progress of the portfolio to the Honorable Heidi Shyu, Assistant Secretary of the Army (Acquisition, Logistics, Technology (ASA(ALT)), during the CRMRP Regenerative Medicine Deep Dive.

5) Initiated two regenerative medicine clinical trials (stem cell therapy for burn wounds and treating hand transplant rejection with local injection of stem cells from adipose tissue/fat).

6) Hired new Director for TIRM PMO.

7) Award of $15M Regenerative Medicine Clinical Trial Award (DHP).

Force Heath Protection – Investigational New Drug Executive Agency

1) FHP Division expanded several strategic communications links and strengthened existing relationships in FY14. FHP briefed and established a regular presence at the Defense Health Agency (DHA) Services monthly meeting, where Services Surgeons offices establish and evaluate vaccination policies for DoD, and at the Health and Human Services – DoD Portfolio Advisory Committee, which has operational oversight of the U.S. Government Chemical and Biological Defense preparedness and is a lead committee under the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). FHP Division continued to conduct monthly meetings with regulatory counterparts at the CDC for IND and EUA planning, and with the USAMRMC IRB for contingency preparedness. In addition, FHP Division met regularly with counterparts at the Assistant Secretary of Defense for Health Affairs, who has overall authority for protocol approval under the DoDI 6200.02.

2) FHP Division worked with the EA Directorate for course of action (COA) development for Lead Component and Executive Agency potential transition to the DHA. From February to May 2014, FHP, in collaboration with Headquarters (HQ), USAMRMC and the EA Directorate, developed and submitted COA recommendation which was dependent on the DHA Advanced Development Program COA to ensure mission success. Participation in this strategic process was critical to maintain and potentially enhance FHP's capability to provide investigational countermeasures to the DoD against high consequence threats.

3) FHP Division supported the development of the Interim Fielding Capability (IFC) concept, an initiative from the Office of the Assistant Secretary of Defense for Nuclear, Chemical and Biological Defense, to potentially make developmental medical countermeasures available for DoD use prior to FDA approval, and is dependent on product maturity, availability and intended use. FHP Division was a key leader in the process and participated in an IFC focus group at the National Academies of Sciences in May 2014. This collaboration under the IFC concept will enable optimal integration of FHP Division's existing policy and regulatory processes under the DoDI 6200.02. In addition, FHP's Medical Countermeasure Surveillance (MCMS) advisor established regular relationships with the Armed Forces Health Surveillance Center (AFHSC) Epidemiology Chiefs team, which entails global epidemiological surveillance across all services and several Federal agencies, and the JJ-3/DD-Nuclear, Homeland Defense & Current Operations cell at the National Military Command Center. Surveillance of emerging infectious diseases and outbreaks that could affect U.S. Forces allowed FHP to prepare for troop support and enables FHP leaders to improve preparedness for support to Service Members.

4) Two FHP products were presented as posters at the FDA Medical Countermeasures Initiative (MCMI) 2014 Research Symposium at the White Oak Campus, Silver Spring, MD in June 2014. The posters highlighted Arbekacin, an aminoglycoside treatment for multidrug resistant bacterial infections, and Tecovirimat, a treatment for smallpox/orthopox exposures or adverse reactions to the smallpox vaccine.

5) FHP Division responded to several emergency cases involving FHP products in FY14, facilitating improved processes and collective, collaborative responses for serious and life-threatening cases. In June 2014, FHP Division deployed Tecovirimat for a smallpox vaccine contact case in a Service Member in San Antonio, TX in coordination with Military Vaccine Agency-Vaccine Healthcare Centers Network (MILVAX-VHCN), military providers, Biomedical Advanced Research and Development Authority (BARDA) and the Centers for Disease Control and Prevention (CDC), ensuring a rapid response and support for a CONUS case requesting this investigational product.

6) In August 2014, FHP Division responsed to a request for investigational intravenous Artesunate (IV AS) to treat a severe falciparum malaria case at the Landstuhl Regional Medical Center (LRMC). The patient was successfully treated upon issuance of an emergency IND number from the U.S. FDA for use of the product under U.S. FDA's expanded access provision. FHP Division responded to a third emergent case in FY14; Heptavalent Botulinum Antitoxin (H-BAT) was deployed from FHP inventory in response to a request from U.S. Forces-Korea involving a case of botulism in a Korean citizen. H-BAT, recently licensed by FDA in

2013, was deployed form FHP stockpiles to Brian Allgood Army Community Hospital (BAACH) in Seoul, Korea to support the U.S. Forces, Korea (USFK) request. Each of these emergency responses solidified and improved FHP's response processes and strategic and operational relationships with Combatant Command Surgeons and interagency partners, while ensuring optimal support to medical providers and safe use of products for Service Members.

7) FHP Division collaborated with USAMRIID and Joint Project Manager-Medical Countermeasures Systems (JPM-MCS) in the development of an Ebola Zaire diagnostic test capability based on assay design histories previously reviewed and accepted by the U.S. FDA in 2010 as pre-EUA packages. The DoD Ebola Zaire (Target 1) Real-Time PCR (TaqMan®) (EZ1 rRT-PCR) Assay, developed by USAMRIID and manufactured by the DoD Critical Reagents Program, was granted an EUA on 05 August 2014 by the U.S. FDA for diagnostic testing of individuals with signs and symptoms of infection with, or suspected exposure to, Ebola Zaire virus from the outbreak in West Africa and became the gold standard test for the U.S. Government. This test was the first test authorized by U.S. FDA for diagnostic testing of U.S. citizens for Ebola Zaire infection, was adopted by the CDC Laboratory Response Network in August 2014, and as of 31 December 2014 it was fielded to 16 qualified DoD laboratories and 52 U.S. public health laboratories. FHP continues to support this EUA, providing technical and regulatory input, and serves as primary contact for product accountability tracking.

8) The SIP PMO finalized personnel transition to include hiring of a Project Manager, encompassing of a core SIP Key leader team, leading the monthly operational meetings with the clinical site and storage and testing leads, and initiating the first SIP Integrated Product Team that included DoD and interagency partners.

9) The SIP PMO conducted several operational and strategic efforts in FY14, to include an independent market research in 2013 to assess current SIP vaccines, customers and protocols. This assessment addressed the following: review FDA annual reports; consider workload, activities, staffing, storage, testing, regulatory and other requirements; compare industry standards; and recommend courses of action for the path forward. An SIP IPT Working Group was formed in April 2014 to evaluate the proposed COAs for clinic location and develop a recommendation for the larger IPT and executive approval, and securing of funding and associated Interagency Support Agreement for potency testing and characterization of the portfolio's Rift Valley Fever vaccine and challenge stock as required by FDA, and an alphavirus Plaque Reduction Neutralization Test (PRNT) validation/cross validation bridging study conducted at USAMRIID.

Division of Regulated Activities and Compliance

1) All electronic submissions.

2) Sponsored the LRDD and filed the 510(k) submission leading to U.S. FDA clearance.

Clinical Services Support Division

1) Provided clinical monitoring and data management support for over 44 clinical studies.

2) Participated in monitoring two studies for the Leishmaniasis Rapid Diagnostic Device product that has now received FDA clearance.

3) Provided oversight monitoring for three clinical sites in Panama including two sites new to clinical research in support of the Topical Paromomycin Pivotal Phase III Study.

4) Provided extensive site selection support to the Portable Neuromodulation Stimulator (PoNS) device Project Management Office to prepare for a pivotal study in patients with traumatic brain injury.

5) Provided monitoring support to begin a study of anti-plaque chewing gum, establishing a positive partnership with a new clinical site.

6) Provided monitoring support for U.S. Special Operations Command (SOCOM) in order for freeze dried plasma to be provided as treatment on the battlefield for severely wounded Soldiers.

7) Continued work on bringing a clinical trial management system to USAMMDA to enable the Command to have for the first time, a complete view of the status of all clinical trials in one database. This program was successfully transferred to EIT-PMO under the leadership of the CSSD Director which will result in a more efficient implementation of the product.

8) Continued successful use of 21 CFR Part 11 paperless electronic safety databases, Empirica trace, for processing clinical trial safety cases, and use of the electronic data management system for document archiving and serious adverse event case flow processing.

9) Collaborating with other USAMRMC proponents to implement improved safety signal detection processes. Developed a procedure for emergency unblinding of subjects in blinded U.S. FDA regulated clinical trials.

10) Processed 31 reported serious adverse events. None were deemed to be immediately reportable to U.S. FDA.

11) Processed 7 reported pregnancies. Closed out 5 in this reporting period. None of the pregnancies resulted in congenital defects or abnormalities, and therefore did not result in a serious adverse event.

12) Provided safety training for clinical sites conducted by the monitors during study initiation.

13) Managing 2 active data monitoring committees, one for Anti-Plaque chewing gum, and one for Cryo-preserved platelets. Establishing a charter and selecting members for a new data safety monitoring board for the planned Dengue Human Infection Model clinical trial.

14) Achieved successful reconciliation with the data management branch on multiple different studies for annual reports and study close outs prior to data base lock.

15) Provided safety consultation and review of 12 clinical trial agreements and 47 protocols and associated clinical trial documents.

16) The branch continued to provide guidance to USAMRMC subordinate command statistical groups and investigators on the design and analysis of both learning and confirmatory regulated clinical trials.

17) The branch continued to provide guidance to WRAIR's statistical group and investigators regarding assay validation analyses for the new Haantan Puumala antibody assay.

18) The branch continued to provide State University of New York (SUNY) Upstate Medical School, Biostatistics Group, Syracuse, NY with guidance on how to design dengue learning regulated clinical trials.

19) The branch continued to work with Sigma Tau Rome (both in the United States and in Italy) on the Intravenous Artesunate (IV AS) legacy malaria treatment trials with respect to creating Clinical Data Interchange Standards Consortium data deliverables for the New Drug application (NDA); assessing U.S. FDA compliance of the legacy trial clinical data (statistical data sets); oversight of the integrated summary of safety (ISS)and efficacy meta-analysis for regulatory submission to FDA; oversight of the preparation of the ISS and efficacy meta-analysis Statistical Analysis Plans (SAP) and Tables, Listing and Figures (TLF); and oversight of the preparation of module 5 of the eCTD. (b) (6) worked with Pharmaceutical Product Development, LLC (PPD) and Sigma Tau Rome with the creation of all 5 eCTD modules for the NDA. Planned submission of the NDA to U.S. FDA is 2015.

20) The branch worked with PPD on the tafenoquine legacy prophylactic trials: Validation of CSRs and TLFs; Mapping raw and analysis statistical data into CSRs and TLFs; Assessing Therapeutic Goods Administration (TGA)and U.S. FDA compliance of the legacy trial clinical data (statistical data sets); Assessing TGA and U.S. FDA compliance of the legacy trial Pharmacokinetics (PK) data; Preparing the ISS and integrated summaries of efficacy (ISE)and clinical data (statistical data sets)for regulatory submission (TGA and U.S. FDA); Preparing the ISS and ISE SAPs and TLFs; Preparing the integrated analyses for

safety and efficacy; and Preparing Common Technical Document (CTD) module five of the NDA submission.

21) The branch co-authored a report on the re-assessment of the malaria epidemiology of East Timor and the GSK 033 trial sites in Bobonaro District and presented a new statistical methodology for assessing protective efficacy based on data from the East Timor active control (tafenoquine versus mefloquine) clinical trial. This is an important component for the TGA NDA submission: (b) (6) (2014). A retrospective analysis of the protective efficacy of tafenoquine and mefloquine as prophylactic anti-malarials in non-immune individuals during deployment to a malaria-endemic area. Malar J. 2014 Feb 6;13(1):49. [Epub ahead of print] PMID: 24502679. This is an important component for the TGA and FDA NDA submission for tafenoquine(http://www.malariajournal.com/content/13/1/49).

22) The branch worked with bioCSL in Australia to review the adequacy and completeness of the CTD module 5 efficacy and safety data for the Q fever vaccine Q-Vax. The Australian vaccine developer, bioCSL, is considering a BLA submission to FDA for U.S. approval of Q-Vax. The branch performed a gap analysis for CTS module 5 content and a meta-analysis for vaccine effectiveness was performed.

23) The branch worked with WRAIR on the validation design of a polymerase chain reaction (PCR) assay for determining exposure to malaria.

24) The branch provided training in regulated clinical statistics and regulated clinical trial methodology for Decision Gate and the Congressionally Directed Medical Research Program (CDMRP).

25) PTO works with Force Health Protection for the coordination, release and inventory management of products used in emergency use authorization protocols.

- **a.** CSSD actively worked with FHP to revise and implement a treatment protocol for the Use of IV-Artesunate under IND 64769.
- **b.** PTO and FHP worked together to coordinate the successful positioning (shipment) of IV-Artesunate to Monrovia, Liberia for the potential treatment of severe malaria for U.S. Soldiers and civilian staff during the Ebola crisis.

26) Maintain 21 CFR Part 11 compliant product accountability database to manage inventory, track shipment status and create accountability reports for >100 products.

27) Contributed to the CMC sections of regulatory submissions, successfully submitted to the FDA:

- **a.** IND 15883, Capsule-Conjugate Camplylobacter jejuni Vaccine 1 (CJCV1)
- **b.** IND 16055, Plasmodium falciparum Malaria Protein FMP012 Administered Intramuscularly with AS01B Adjuvant System (pfCelTOS2)
- **c.** Pre-IND package, Dengue Human Infection Model
- **d.** Pre-IND package, Artificial Shigella invasin complex (InvaplexAR) vaccine
- **e.** Pre-IND package, Monophosphoryl lipid A in liposomes (L(MPLA))
- **f.** Pre-IND package, Shigella Artificial Invasin Complex (InvaplexAR) Vaccine

28) Assisted in the selection of a new qualified Freeze Dried Plasma manufacturer, and establishment of a CRADA outlining Contracting Manufacturing Organization (CMO) responsibilities for all manufacturing operations.

29) Conducted a gap analysis of the Syracuse University, New York, clinical research site for the Dengue Human Infection Model study and provided a corrective action plan to be implemented prior to study initiation.

30) Successfully completed tasks associated with the current Good Manufacturing Practices (cGMP) production of a new ricin vaccine to include development of lot release specifications, batch production records and product stability protocols. (Final drug product lot and diluent to be produced at WRAIR the end of January 2015).

31) Release and inventory management, for the potency testing, of eight products used in the SIP clinical trials at USAMRIID.

32) Conducted seven CONUS and OCONUS site visits and provided technical support and consultation to more than 80 investigational products including drugs, vaccines, blood products and medical devices.

33) Successfully managed all of data management activities during the upgrade and implementation of USAMRMRC's 21 CFR Part 11 compliant Electronic Data Capture-Clinical Research Data Management System (EDC-CRDMS) This will led to the more efficient and user-friendly EDC-CRDMS upgrade approval by USAMRMC.

34) Successfully managed over 12 database development and implementations in the USAMRMC's EDC-CRDMS.

35) Successfully supported site evaluations regarding data management activities.

36) Successfully managed study site, Sponsor InForm and Central Designer training.

37) Successfully reviewed over 10 clinical data managements Standard Operating Procedures (SOP) that are accessible to all Commands under USAMRMC performing clinical data management activities.

38) Successfully evaluated study sites regarding data management processes and procedures.

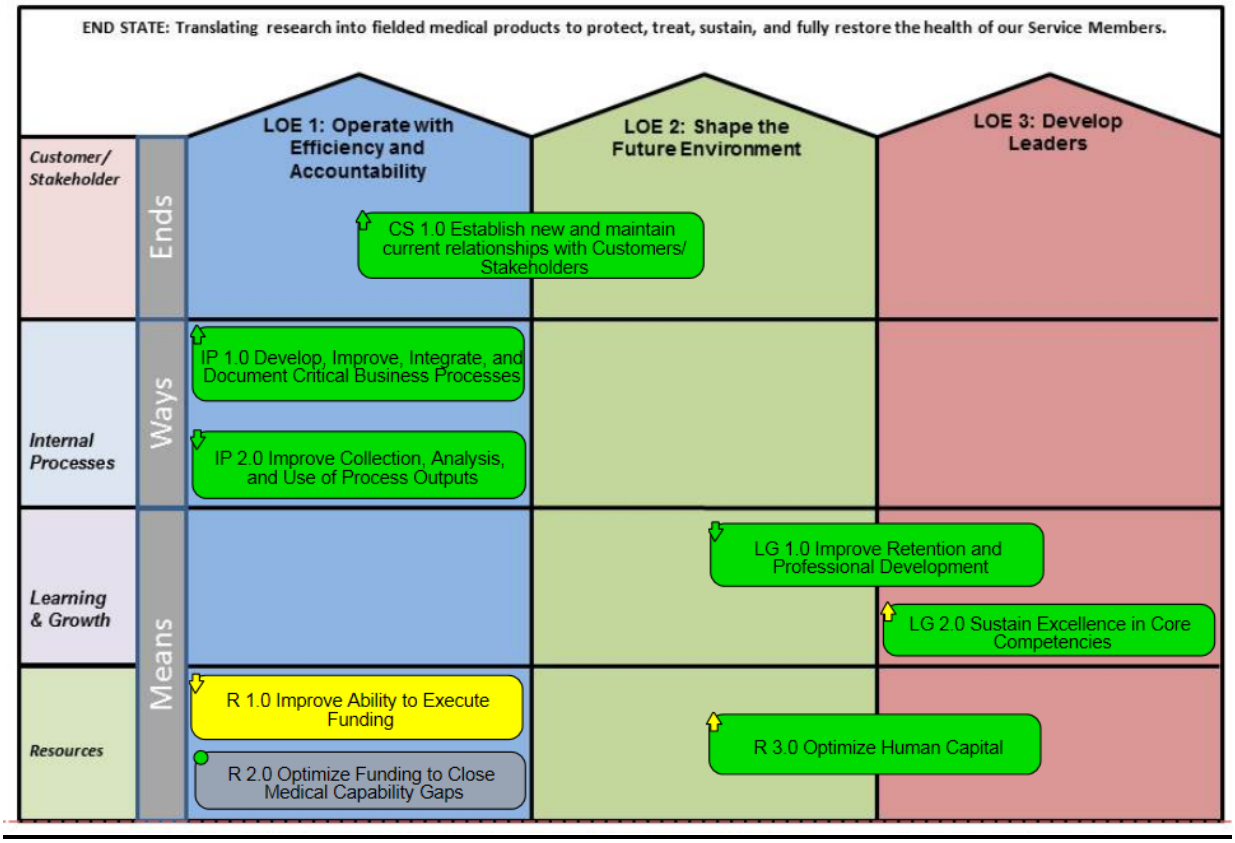
39) Continued to participate in the overall implementation of a Service Tracking Database (now part of RAMS) that will be used to track projects and protocols for the command.

40) Continue to provide 100% in-house and oversight data management support for all OTSG studies and non-OTSG studies as needed.

41) Continued to participate in strategic meetings focused in business process improvements within the command.

APPENDIX C

BALANCED SCORECARD



APPENDIX D

ACRONYM DEFINITIONS

ABCT	Armored Brigade Combat Team
ACE	Acetylcholinesterase
ACU	Army Combat Uniform
AFHSC	Armed Forces Health Surveillance Center
AFIRM	Armed Forces Institute of Regenerative Medicine
AFSOC	Air Force Special Operations Command
AIB	Arizona Industries for the Blind
AMEDD	Army Medical Department
AMEDD C&S	Army Medical Department Center and School
AMLO	Acquisition Management Liaison Officer
AMPV	Armored Multi-Purpose Vehicle
AMWS	Army Mountain Warfare School
AOA	Analysis of Alternatives
APG	Aberdeen Proving Ground
AR	Army Regulation
ARD	Acute Respiratory Disease
ARMS	Altitude Readiness Management System
ARS	Acute Radiation Syndrome
ASA(ALT)	Assistant Secretary of the Army (Acquisition, Logistics, Technology)
ASD	Administrative Services Division
ATO	Authority to Operate
BAACH	Brian Allgood Army Community Hospital
BAMC	Brooke Army Medical Center
BARDA	Biomedical Advanced Research and Development Authority
BLA	Biologics License Application
BTI	Biomedical Transitional Initiative
BWH	Brigham and Women's Hospital
CAD	Computer Aided Designed
CASEVAC	Casualty Evacuation
CAT	Combat Application Tourniquet
CBA	Capabilities Based Assessment
CDC	Centers for Disease Control and Prevention
CDD	Capability Development Document
CDMRP	Congressionally Directed Medical Research Program
CDRH	Center for Devices and Radiological Health
CL	Cutaneous Leishmaniasis
CMO	Contracting Manufacturing Organization
CMC	Chemistry Manufacture and Controls

CO	Clinical Operations
CO_2	Carbon Dioxide
COA	Course of Action
CONUS	Continental United States
COR	Contracting Officer Representatives
COTS	Commercial Off-the-Shelf
CPP	Cryopreserved Platelets
CPPW	Chemical Patient Protective Wrap
CRADA	Cooperative Research and Development Agreement
CSH	Combat Support Hospital
CSI	Congressional Special Interest
CSR	Clinical Study Report
CSSD	Clinical Services Support Division
CTA-RPS	Clinical Trial Awards-Regenerative Medicine, Pain and Sensory
CTD	Common Technical Document
DCDD	Directorate of Combat and Doctrine Development
DEPMEDS	Deployable Medical Systems
DHA	Defense Health Agency
DHF	Dengue Hemorrhagic Fever
DHP	Defense Health Program
DLA	Defense Logistics Agency
DoD	Department of Defense
DoDI	DoD Instruction
DRAC	Division of Regulated Activities and Compliance
DSS	Dengue Shock Syndrome
DTRA	Defense Threat Reduction Agency
DTTBI	Drug Treatment for Traumatic Brain Injury
DTV	Dengue Tetravalent Vaccine
EA	Executive Agency
ECBC	Edgewood Chemical and Biological Center
ECIS	Electric Cell-substrate Impedance Sensing
eCTD	electronic Common Technical Document
EDC-CRDMS	Electronic Data Capture-Clinical Research Data Management System
EPA	Environmental Protection Agency
ESB	Environmental Sentinel Biomonitor
ESS	Engineered Skin Substitute
EUA	Emergency Use Authorization
FDA	Food and Drug Administration
FDP	Freeze-Dried Plasma
FFP	Fresh Frozen Plasma

FHP	Force Health Protection
FRACU	Flame-Resistant Army Combat Uniform
FWB	Fresh Whole Blood
FY	Fiscal Year
GCP	Good Clinical Practices
GFEBS	General Fund Enterprise Business Systems
GLP	Good Laboratory Practices
GMP	Good Manufacturing Practices
GSK	GlaxoSmithKline
H-BAT	Heptavalent Botulinum Antitoxin
HBc	hepatitis B core antigen
HBO_2	Hyperbaric Oxygen
HBsAg	Hepatitis B Surface Antigen
HCV	Hepatitis C Virus
HFRS	Hemorrhagic Fever with Renal Syndrome
HIV	Human Immunodeficiency Virus
HQ	Headquarters
HUC	Human Use Committee
HVAC	Heating/Ventilation/Air Conditioning
IBCT	Infantry Brigade Combat Team
ICH	International Committee of Harmonization
IDCRP	Infectious Disease Clinical Research Program
IDE	Investigational Device Exemption
IFAK	Improved First Aid Kit
IFC	Interim Fielding Capability
IM/IT	Information Management and Information Technology
IND	Investigational New Drug
IPT	Integrated Product Team
IRB	Institutional Review Board
ISE	integrated summaries of efficacy
ISO	International Standards Organization
ISS	integrated summary of safety
ISSS	Integrated Soldier Sensor System
IV AS	Intravenous Artesunate
JERC	Joint En Route Care Committee
JLTV	Joint Lightweight Tactical Vehicle
JPC	Joint Program Committee
JPEO-CBD	Joint Program Executive Office for Chemical and Biological Defense
JPM-MSC	Joint Project Manager-Medical Countermeasures System
LAN	Local Area Network

LRDD	Leishmania Rapid Diagnostic Device
LRIP	Low Rate Initial Production
LRMC	Landstuhl Regional Medical Center
LSP	Liquid Stored Platelets
LWB	Long Wheeled Base
MCMI	Medical Countermeasures Initiative
MCMS	Medical Countermeasure Surveillance
MCoE	Maneuver Center of Excellence
MCS	Medical Countermeasures System
MDA	Milestone Decision Authority
MEDCOM	Medical Command
MEDEVAC	Medical Evacuation
MES	Medical Equipment Sets
MILVAX-VHCN	Military Vaccine Agency-Vaccine Healthcare Centers Network
MIPR	Military Interdepartmental Purchase Request
MIT-LL	Massachusetts Institute of Technology Lincoln Laboratory
MOA	Memorandum of Agreement
MPDL	Medical Prototype Development Laboratory
MRAP	Mine-Resistant Ambush Protected
MSS PMO	Medical Support Systems Project Management Office
MTF	Military Treatment Facility
MTTS	Medium Troop Transport System
MTV	Medical Treatment Variant
NAMRU	Naval Medical Research Unit
NASA	National Aeronautics and Space Administration
NATO	North Atlantic Treaty Organization
NCMI	National Center for Medical Intelligence
NDA	New Drug Application
NGDS	Next Generation Diagnostic System
NPH	Neurotrauma and Physiological Health
NSN	National Stock Number
NSRDEC	Natick Soldier Research Development & Engineering Center
OCONUS	Outside the Continental United States
OEF	Operation Enduring Freedom
OIF	Operation Iraqi Freedom
OIP	Organizational Inspection Program
OMA	Operation and Maintenance - Army
OND	Operation New Dawn
OPA	Other Procurement - Army
OQM	Office of Quality Management

ORTA	Office of Research and Technology Application
OTSG	Office of The Surgeon General
PACOM	Pacific Command
PCM	phase-change material
PCR	Polymerase Chain Reaction
PCS	Post-Concussion Syndrome
PDHA	Platelet-Derived Hemostatic Agent
PEO	Program Executive Office
PHEMCE	Public Health Emergency Medical Countermeasures Enterprise
PK	Pharmacokinetics
PM	Program Manager/Management
PM AFV	Program Manager Armored Fighting Vehicle
PMO	Program Management Office
PoNS	Portable Neuromodulation Stimulator
PPD	Pharmaceutical Product Development, LLC
PR	Pathogen Reduction
PRNT	Plaque Reduction Neutralization Test
PSM	Physiological Status Monitor
PSPMO	Pharmaceutical Systems Project Management Office
PTSD	Post-Traumatic Stress Disorder
QMO	Quality Management Office
RA	Regulatory Affairs
RBC	Red Blood Cell
RCS	Reports Control Symbol
RDT&E	Research Development Test & Evaluation
RFP	Request for Proposal
RM	Resource Management
RO	Regulatory Operations
RPSM	Remote Physiological Status Monitor
RTR	Reconstructive Transplantation Research
RTS-Med	Regional Training Site–Medical
SAP	statistical analysis plan
SBIR	Small Business Innovative Research
SHIELD	Shock Impact and Explosive Limits Dosimeter (SHIELD) integrates into standard helmet pads, requires
SIP	Special Immunizations Program
SME	Subject Matter Expert
SMRC-IND	Special MEDCOM Response Capabilities/ Investigational New Drug
SOCOM	U.S. Special Operations Command
SOP	Standard Operating Procedure

SOUTHCOM	Southern Command
SSEB	Source Selection Evaluation Board
SUNY	State University of New York
SWET	Soldier Water Estimation Tool
TARDEC	Tank-Automotive Research, Development and Engineering Center
TBI	Traumatic Brain Injury
TGA	Therapeutic Goods Administration
TIC	Toxic Industrial Chemicals
TIRM	Tissue Injury and Regenerative Medicine
TLF	Tables, Listing and Figures
TQ	Tafenoquine
TRADOC	U.S. Army Training and Doctrine Command
TRL	Technology Readiness Level
TTDRDD	Transfusion Transmitted Disease Rapid Diagnostic Device
UA	Unit Assemblage
USAARL	U.S. Army Aeromedical Research Laboratory
USACEHR	U.S. Army Center for Environmental Health Research
USAISR	U.S. Army Institute of Surgical Research
USAMMA	U.S. Army Medical Materiel Agency
USAMMDA	U.S. Army Medical Materiel Development Activity
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRIID	U.S. Army Medical Research Institute of Infectious Disease
USAMRMC	U.S. Army Medical Research and Materiel Command
USDA	U.S. Department of Agriculture
USFK	U.S. Forces, Korea
USUHS	Uniformed Services University of the Health Sciences
VA	Veteran Affairs
VCA	Vascularized Composite Allotransplantation
VTC	Video TeleConference
WBPRD	Whole Blood Pathogen Reduction Device
WDWWMS	Water Distribution and Wastewater Management System
WRNMMC	Walter Reed National Military Medical Center
WRAIR	Walter Reed Army Institute of Research
YPG	Yuma Proving Ground

Section 28

Fiscal Year 2014
Annual Historical Report

U.S. Army Medical Materiel Agency

THE USAMMA INSTITUTION

1.1 INTRODUCTION

The USAMMA is a unique, multifaceted organization globally managing strategic medical logistics contingency programs; medically equipping the Active Component, Army Reserve, and National Guard forces; and providing technical solutions at the Medical Treatment Facilities (MTF). The goal of the USAMMA is to provide America's premier medical team with innovative medical logistics solutions to ensure that every healthcare provider has the required equipment and supplies to deliver optimal healthcare to our Warfighters.

1.2 VISION

To be the premier DoD Medical Lifecycle Management Command-Improving health and saving lives with medical materiel solutions

1.3 MISSION

To develop, tailor, deliver, and sustain medical materiel capabilities in order to build and enable health readiness.

1.4 CORE COMPETENCIES

Our core competencies reflect the unique, collective abilities shared across the USAMMA in support of the Army Health System primarily for the Active, National Guard, Reserve, and Army Prepositioned Stocks (COMPOs 1, 2, 3, and 6, respectively). They relate outwardly to the USAMMA contributions to Army Medicine and the Military Health System across the medical materiel acquisition-logistics continuum in support of unified land operations.

1.4.1 EQUIPPING THE MEDICAL FORCE

Forecast, plan and execute a variety of medical materiel readiness missions by providing a full-range of medical materiel solutions and support. Developing and procuring medical technologies and materiel, performing medical set assembly functions and materiel delivery or fielding for the operating and generating forces worldwide. Provide acquisition project management and related force management expertise as the materiel developer for commercial and non-developmental items, manager for medical cataloging, integrated acquisition logistics including maintenance, and medical materiel life cycle management in support of operating and generating forces.

1.4.2 SUSTAINING THE MEDICAL FORCE

Support wide-array of program elements for the medical Army Force Generation efforts across the force pools and centrally manage the Army Prepositioned Stocks and The Surgeon General contingency program and other readiness support programs designed for all Army components during unified land operations. Deploy the medical logistics support team. Provide Army Medical Department National Maintenance Program expertise and Sustainment Maintenance functions and technical proficiency. Develop policies and procedures to ensure medical maintenance supportability and training requirements, equipment reliability and maintainability, and maintenance repair and services of medical equipment and technologies. Deploy the Forward Repair Activity-Medical.

1.5 PRINCIPAL STAKEHOLDERS, CUSTOMERS, PARTNERS, AND SUPPLIERS

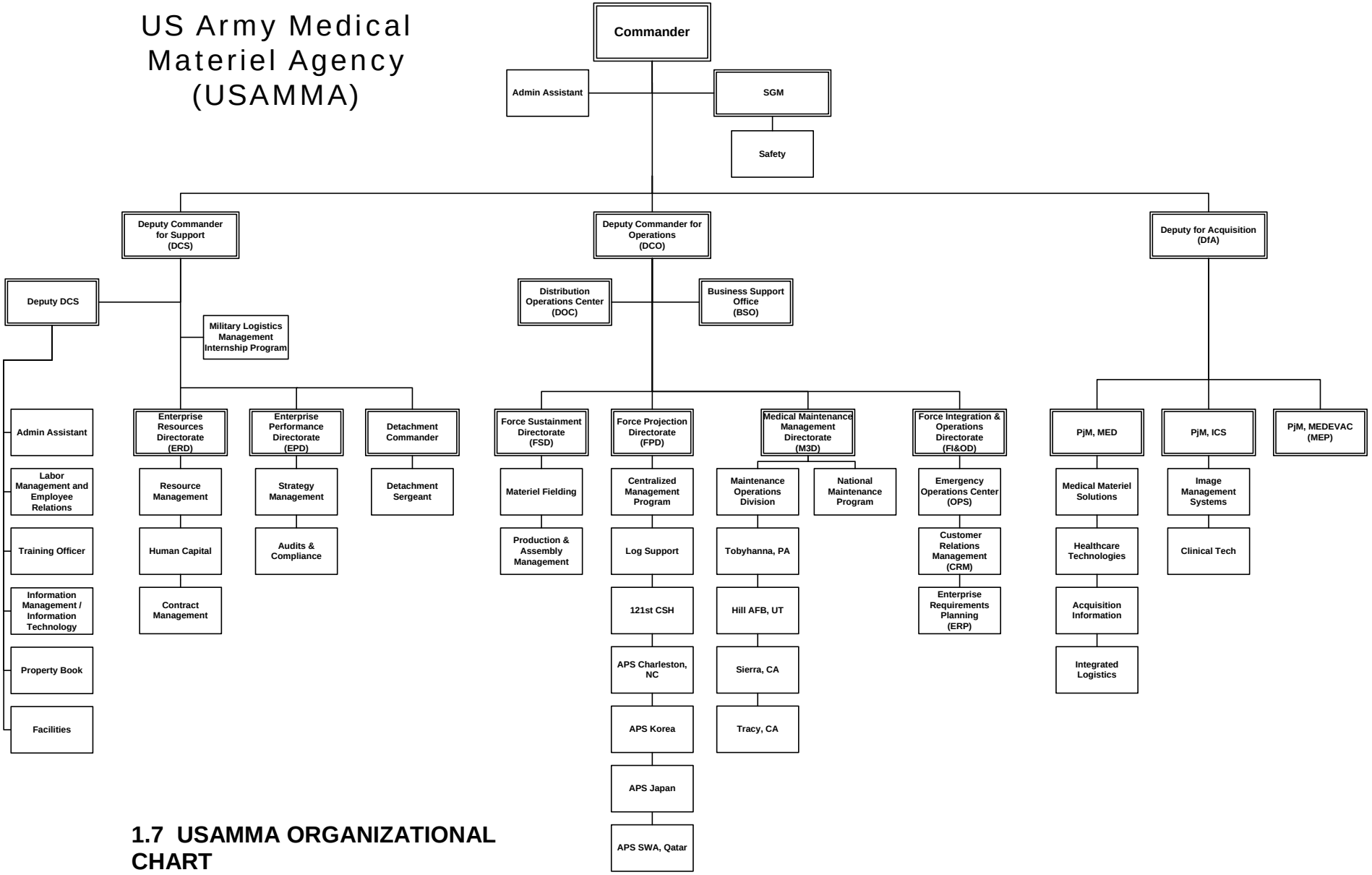
At USAMMA, our customers include partner commands and various entities that receive our products and services, including the Warfighter. Key customers for USAMMA are generating and operating force personnel; however, the organization also serves various internal and external customers. Our stakeholders are defined to include headquarters commands. Stakeholders play a critical role affecting our operations and guiding our

organization at a high level. Partners are external institutions that possess a relationship with USAMMA and whose capabilities and contributions enable or augment USAMMA's core competencies and success. Suppliers are providers of goods and services used within any stage of acquisition, production, delivery, and sustainment of USAMMA's products, programs, and services. The supplier's supplier is the original provider of material, knowledge, and expertise.

1.6 HUMAN CAPITAL (HC)

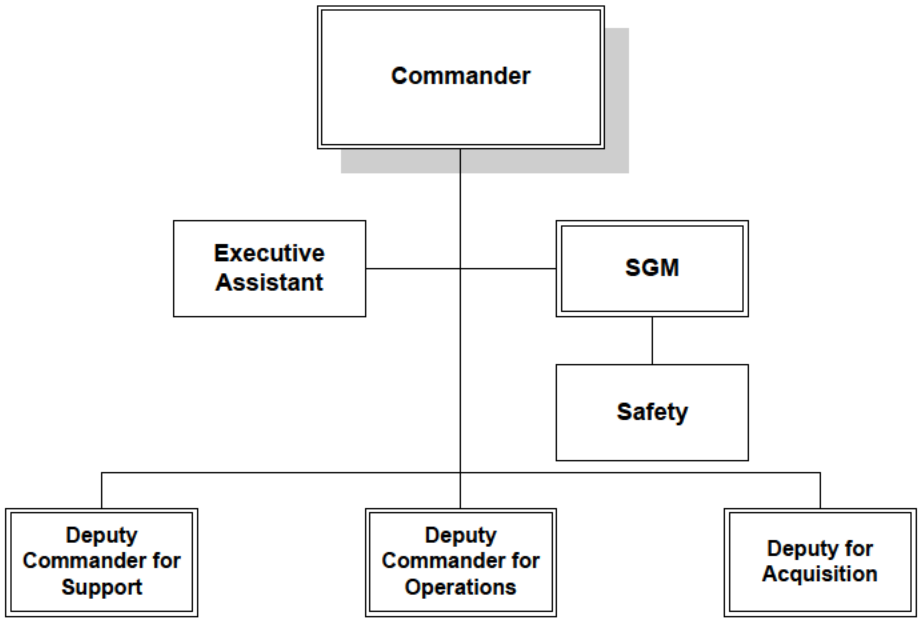
Human Capital (human resources) is essential for the success of all the Agency endeavors. The HC at USAMMA consist of military, Army civilians, and select contractor staff. Currently, of the approximately 432 total employees in the USAMMA, about 80% of them work at the DMLC in Fort Detrick, Maryland. Our employees comprise roughly 48 percent civil service personnel, 14 percent military personnel, and 35 percent contracted employees. The workforce profile for Fort Detrick staff is as follows: 13 percent entry-level, clerical, or administrative; 76 percent professional, supervisory, or mid-level management (including contractors); and 11 percent senior leadership. Fort Detrick is primarily an office environment. We have a formal safety and injury prevention program that incorporates measures to minimize the risk of injuries and adverse incidents to clients and employees.

US Army Medical Materiel Agency (USAMMA)



1.7 USAMMA ORGANIZATIONAL CHART

OFFICE OF THE COMMANDER



2.1 MISSION

The primary function of the Office of the Commander is to lead and manage the Agency ensuring that USAMMA maintains its ability to provide premier medical logistics support to America's Warfighter. As the Agency's Chief Executive Officer, the Commander is the principal decision-maker responsible for directing operations and administration to ensure the effective accomplishment of assigned and implied missions. COL Alejandro Lopez-Duke led the Agency as USAMMA's Commander during the first six months of 2014 relinquishing command to COL David Gibson in July.

2.2 FUNCTIONS

- Commander USAMMA by authority of AR 600-20, Army Command Policy.

- Assistant Program Manager, Medical as established by USA MRMC Acquisition Reorganization Directive. In the role as the Assistant PM, Medical, the Commander is responsible for the daily supervision, personnel administration, funds and facilities management in support of the life cycle management of assigned medical commercial off-the-shelf and developmental medical devices.

- Assessable Unit Manager (AUM) by authority of AR 11-2, Managers' Internal Control Program. As the AUM the CDR is responsible for providing the leadership and support needed to ensure that management controls are in place and operating effectively.

- Voting member of the Defense Medical Logistics Proponent Committee (DMLPC).

- Voting member of the Army Medical Logistics Enterprise (AMLE).

2.3 EXECUTIVE ASSISTANT

2.3.1 MISSION

Serving as the Executive Assistant for the Command Group this person has responsibility for maintaining the Office of the Commander calendars and maintaining the Command's long-range planning calendar.

2.3.2 FUNCTIONS

- Making travel arrangements and processing travel documents for the Command Group.

- Composing and reviewing command correspondence, reviewing Officer and Noncommissioned Officer Evaluation Reports and Awards for grammatical and format errors.

- Serves as USAMMA's Records Manager, performing records management and office automation task.

2.4 SERGEANT MAJOR

2.4.1 MISSION

The Sergeant Major, as senior enlisted advisor for USAMMA, is responsible for advising the Commander on the health, welfare, and morale of the workforce (military and civilian). In this role the Sergeant Major monitors personnel actions pertaining to all assigned enlisted and officer personnel, is responsible for medical readings as well as the professional development of all enlisted personnel, Noncommissioned Officer Evaluations Reports (NCOERs), promotion boards, physical fitness testing, assignments, Noncommissioned Officer Professional Development (NCOPD), common task testing, and training.

2.4.2 FUNCTIONS

- Maintain liaison through the Command Sergeant Majors (CSMs), SGMs, and senior Non-Commissioned Officers (NCOs) for the installation and other activities for the dissemination of instructions and information.

- Monitoring personnel actions pertaining to all assigned enlisted.

- Responsible for Unit Status Report (USR) as well as the professional development of all enlisted personnel.

- Administration and oversight of NCOERs, promotion boards, physical fitness testing, assignments, alcohol and drug control, weight control, NCOPD, common task testing, and training for the Agency.

- Provide mentorship for all military assigned to USAMMA as well as the military Medical Logistics Management Internship Program (MLMIP) interns.

- Provide advice and recommendations to the Commander and staff in matters pertaining to enlisted Soldiers.

- Recommend actions on unit morale and discipline.

2.4.3 SAFETY OFFICER

2.4.3.1 MISSION

Serve as the Safety Officer with associated directives in Occupational Health and Environmental Compliance on behalf of the USAMMA Commander, Deputy Commanders, Directors, and Project Managers (PJMs) at Fort Detrick, Maryland, and at forward-sites worldwide. Directs, develops, and performs safety, occupational health, and environmental compliance policies and procedures in accordance with federal, state, local, Army, and DoD standards.

2.4.3.2 FUNCTIONS

- Develops and integrates a comprehensive and multi-dimensional set of safety policies, procedures, training, and evaluation practices that emphasize prevention and when appropriate correction of safety, occupational health, and environmental compliance related issues.

- Represents the CDR and serves as a member of various installation and higher headquarters safety, occupational health, and environmental forums.

- Provides safety briefings and training to the Agency and its subordinates.

- Plans and executes safety and environmental staff assistance visits, as well as safety inspections throughout the Agency.

- Plans, establishes procedures, and chairs the USAMMA Safety Council for the CDR.

- Makes independent assessments to assist organizations within the command in integrating Federal, DoD, Army, and organizational requirements to reduce risk of accidental losses.

- Has unimpeded access to the CDR to report the status of the program and technical assistance.

- USAMMA's Safety Office provides advice, and also plan, develop, coordinate, and evaluate the SOH program by providing the following functions:

  - ✓ Report and advise the CDR on SOH issues and policy.
  - ✓ Assist all elements of the command in the implementation their specific tasks in the Strategic Safety Plan.

  - ✓ Manage and provide technical oversight of the SOH program, including identifying the metrics that best measure progress on implementing the Strategic Safety Plan and achieving the command's safety goals.

  - ✓ Develop policy and procedures for integration of SOH and accident prevention activities of the command.

2.4.3.3 MAJOR EFFORTS OF FY14

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
Command Safety Program	Continued command safety and environmental compliance committee with quarterly, command-wide VTCs.	Integrates all facets of the command by providing a venue for the USAMMA Commander and leadership to focus, address, promote, and reward safety and environmental awareness.
Appointment of Collateral Duty Safety Officers (CDSO), Additional Duty Safety Officers (ADSO) and Environmental Officers (EO) with alternates	Personnel identified and assigned to serve as CDSO/ADSO and EO within USAMMA forward sites.	USAMMA has Safety and Environmental Compliance Officers and alternates to report on all safety and environmental related matters at forward sites to the USAMMA Safety Manager.
Completed Quarterly MRMC SOHAC Tasker	Provided MRMC with USAMMA safety statistics that they report to MEDCOM on a quarterly basis.	Met tasker deadline.
Accident Report Submittal	Completed accident reporting process for FY14.	USAMMA is in full compliance with higher headquarters reporting requirements.

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
Completed USAMMA Safety & Occupational Health Strategic Plan	Provide a single, integrated framework for the USAMMA safety and occupational health mission, vision, goals, objectives, action plan, and success metrics.	Communicate the USAMMA leadership's commitment to the safety and health of our Soldiers, Families, Civilians, and contractors and its effort to reduce accidents.

2.4 DEPUTY COMMANDER FOR OPERATIONS (DCO)

The DCO acts for the Commander as directed, serving as the principal assistant and advisor to the Commander on all matters pertaining to the Agency's operating directorates: Materiel Acquisition, Support Operations, Force Sustainment, and Force Projection. The DCO takes final action on matters delegated by the Commander, providing

guidance, assistance, and coordination pertinent to USAMMA's day-to-day mission. LTC (b) (6) served as the DCO during FY14.

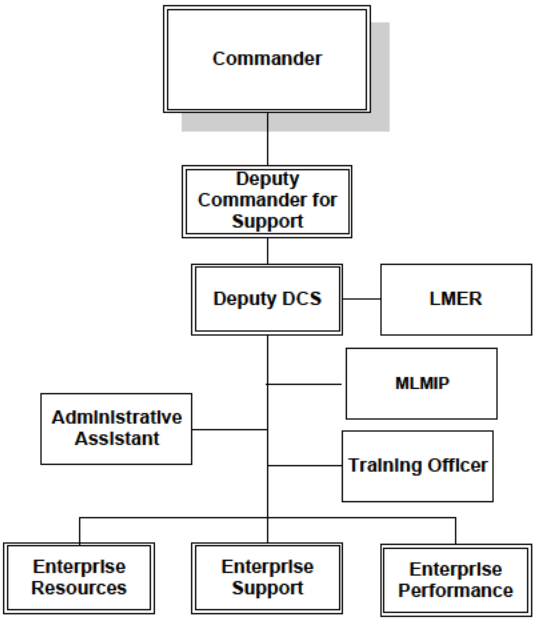
2.5 DEPUTY COMMANDER FOR SUPPORT (DCS)

As a principal assistant to the Commander, the Deputy Commander for Support (DCS) serves as the Chief Management Officer and Chief Learning Officer in support of USAMMA, a generating force institution with strategic medical programs across the acquisition-logistics continuum. Inherent in the DCS roles are leading people, leading change, applying business acumen, facilitating relationships, and attaining results. In addition to supervision of military and civilians providing a variety of shared services in support of Army Medicine, the DCS specific responsibilities and accountabilities relate to overseeing the USAMMA's Medical Logistics Management Internship Program (MLMIP), strategic performance management, organizational quality (performance excellence), internal controls administration, civilian position classification and pay pool management, property and supply discipline oversight, overseas travel approval and Timework agreement approval, and purview over other related administrative support matters. LTC (b) (6) served as the DCS during FY14.

2.6 DEPUTY FOR ACQUISITION (DFA)

The Deputy for Acquisition (DFA) is an emerging requirement in support of the US Army Medical Research and Materiel Command's acquisition realignment initiative. The new DFA position will provide leadership oversight and integration of the separate project management offices (PJM) involved with advanced technology and introduction of myriad products for the medical treatment facilities and operational forces. The DFA exists to tightly integrate and advance medical acquisition project management as part of the USAMMA missions, as well as, provide technical expertise up, down, and across the USAMRMC acquisition domain. DFA oversight and management responsibilities span the transition of products from the science and technology community, through advanced development, and into sustainment arenas. (b) (6) served as the DFA during 2014.

DEPUTY COMMANDER FOR SUPPORT (DCS)



3.1 MISSION

To advance organizational performance excellence, promote management integration and compliance, and deliver relevant and responsive services across all facets of the organization to provide consistent, value added results over the entire strategic and operational spectrums.

3.2 FUNCTIONS

The following key organizations perform the major functions within the DCS's purview:

- **Administrative Assistant.** These programs are a part of the Commander's Special Staff and responsible for Protocol, Town Hall, Installation Support, scheduling and coordination with higher headquarters).

- **Labor Relations Employee Management (LMER).** The LMER Program Manager acts and makes decisions on behalf of the commander for all matters associated with labor relations and serves as subject matter expert and senior advisor to the command group, senior leadership, managers and supervisors, labor officials and employees regarding management-employee relations matters.

- **Organizational Learning.** Organizational learning at USAMMA comprises individual and select collective training, education, development, and knowledge management.

- **Enterprise Resources Directorate.** This directorate encompasses human capital, contract management, and resource management.

- **Enterprise Support Directorate.** This directorate is responsible for information management and information technologies internally, property, command supply discipline, and facilities.

- **Enterprise Performance Directorate.** This Directorate serves as USAMMA's organizational integrator in the design, modification, and renewal practices for corporate strategic planning and business process improvement management. Responsible for institutionalizing, monitoring, and continually improving business results while ensuring that proper internal controls are in place and reported. Additionally, conducts management studies affecting internal and external aspects of the organization.

3.3 MAJOR EFFORTS OF FY14

Each of the following DCS support areas describes the major efforts for 2014. When combined the efforts epitomize the DCS contributions for this historical report.

3.4 DEPUTY DCS

3.4.1 MISSION

The mission of the Deputy DCS is to focus on the activities and key processes related to centralized support and shared services within the Agency.

3.4.2 FUNCTIONS

- **Labor management and employee relations (LMER).** Position must expertly advise the Commander, command group, senior leaders, managers, supervisors, union officials and agency employees and take initiative and directly intervened to prevent or resolve problems of particular difficulty and complexity, sensitivity or Strategic importance in order to maximize contributions to the organization and reduce potential for grievances or complaints. The time frame associated with this function is limited only by the complexity of issues involved and the number of personnel impacted.

- **Command Management Employee Relations Officer and Action Officer Commander Investigations (IG, 15-6).** Position acts on behalf of the USAMMA Commander to investigate (15-6 and commander's inquiry memorandums and assembling support documentation) allegations of misconduct, performance, illegality etc. Prepare and coordinate
with internal and external regulatory agencies and Point of Contacts (POCs) to finalize agency response in defense of multiple adverse, disciplinary and other actions. This action includes suspensions, performance, removals, reprimands, letters of warnings, counseling, other

informal disciplinary actions, Inspector General (IG) and other DoD and DA redress avenues. This function requires extensive coordination with supervisor and managers, Civilian Personnel Action Center (CPAC), the Staff Judge Advocate (SJA), in some cases union officials and can be extremely time consuming depending upon the case complexity and as case law research.

- **Command Equal Employment Opportunity (EEO) Action Officer.** Position is required to work across multiple installation EEO commands (Tobyhanna and Tracy Depots, Fort Detrick), higher headquarters and SJA agencies to successfully respond to EEO issues and complaints.

- **Command Labor Relations (LR) Program Manager.** The agency program manager must perform superbly and have expert level knowledge and subject matter expertise, to effectively represent the Commander. The function of the LR manager is to strike the right balance between LR obligations and leadership principles and mission requirements. The position acts on behalf of the USAMMA Commander to successfully engaged and completed labor relations, legal obligations for numerous matters and enable the command to continue to effectively conduct missions and operations uninterrupted. Including but not limited to: potential government shutdowns and workforce furloughs, Reduction in Force (RIF), workforce telework determinations , changes in security requirements for positions, position and organizational realignment and restructuring, office moves, changes in the collective bargaining agreement, contract administration, interpretations of a myriad of regulations, federal and other case law, Grievances and Unfair Labor Practices (ULP). Further, response for providing the command's response to Labor Organizations, demands to bargain, proposals, requests for information, Grievances, ULP and Deciding Official responses.

- **Command Freedom of Information Act (FOIA) and Privacy Act Officer.** Serves as the Command FOIA Action Officer, coordinating with Higher Headquarters to address and ensure requests for information are responded to in accordance with established laws, procedures and by suspense date. Researches case law and precedent to determine if information requested is allowable under established laws, rules or government-wide procedures or if redactions are necessary. Serves as the Command Privacy Act Officer and coordinates publications, Command articles, and establish/enforce commander policy regarding privacy act procedures and policies. Documents cases of privacy act violations and conducts periodic privacy act information security reviews.

3.5 ADMINISTRATIVE ASSISTANT

3.5.1 MISSION

To provide on time and accurate administrative services and consultation to the DCS in support of the DCS vision and goals of promoting organizational effectiveness and efficiencies.

3.5.2 FUNCTIONS

- **Administrative and Clerical Support.** Responsible for preparing a large variety of narrative materials such as correspondence, reports, technical papers, charts, statistical tables, award packages, email screening, presentations and other high level documents. Collaborate with the HC section to ensure all awards and certificates are correct and completed on time for presentation at the Agency's Town Hall Meetings.

- **Records Management.** Perform various recordkeeping duties in accordance with the Army Records Information Management System, to include meeting minutes, policy letters and memorandums. Collaborate with Directors to gather information pertaining to original issues for distribution and file storage.

- **Government Purchase Card Holder and Supply Officer.** Responsible for the procurement, management, and distribution of supplies in support of DCS Directorates and offices. Ensures all expenditures and purchases are conducted in accordance with DoD and Army regulations. Reconcile the end of the cycle monthly bank statement with complete accuracy. Responsible for the documentation and tracking of all purchases and verification of funding before any purchases are made.

- **Protocol.** Ensure all visitors are greeted, signed in, escorted accordingly to their appropriate location.

- **Town Hall Meeting Coordination.** Collaborate with the Human Capital office to ensure all awards and certificates are correct and completed for Town Hall Meeting.

- **Policy Memorandums.** Coordinates, edits, and publish of the Agency's Policy memorandums. Policy memorandums provide policy and guidance on the Agency programs.

- **Additional Duty Appointments (ADAs).** Coordinates and publish the Agency's ADAs. The ADAs are used to formally appoint individuals in the execution of additional duties.

3.5.3 MAJOR EFFORTS OF FY14

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
Established Labor Management Councils for Tobyhanna and Fort Detrick offices	The LMC was designed to improve dialog with the Union and management, especially matters at the pre-decisional stage. Fort Detrick and Tobyhanna charters were established 2014.	Management and Union jointly came up with solutions for conditions that impacted the employees. Many issues were resolved by conducting impromptu meetings in the spirit of the LMC.

3.6 TRAINING OFFICER

3.6.1. MISSION

The Training Management Office is comprised of the Agency Training Officer and is supported by the SGM and the Agency's training coordinators. It serves as advisory team on all training, education, development matters for military, civilian and select contractor personnel located at Fort Detrick and Forward Sites.

3.6.2 FUNCTIONS

- **Organizational Learning, Education and Training.** Develops and manages Agency professional development and educational programs such as plans and arranges training programs, determines requirements, and updates training systems in accordance with (IAW) all regulatory requirements.

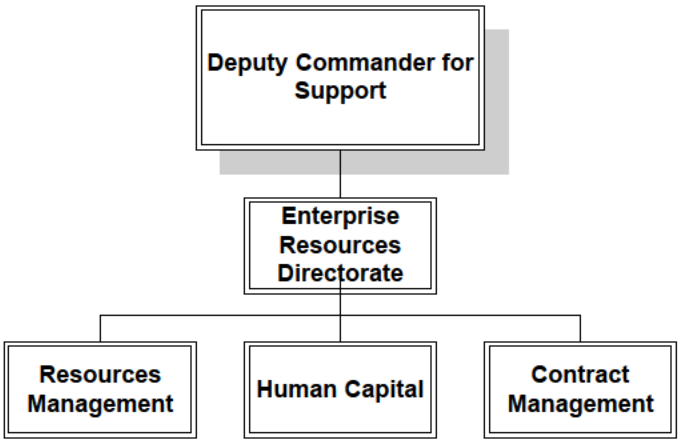
- **Mandatory Training.** Coordinates all USAMMA training requirements, ensures all personnel have completed the required annual training and reports to HQ USAMRMC.

- **New Employee Orientation (NEO).** Serves as the entry point for all new employees and is responsible for overseeing the processing and integration of new employees. Organizes and hosts quarterly NEO and distributes in-processing checklists to new USAMMA personnel ensuring completion and proper disposition of completed checklists.
- **Training Coordinator Interaction.** Coordinates mandatory and special training requirements with the USAMMA leadership and training coordinators supporting project management offices, directorates, and separate offices.

3.6.3 MAJOR EFFORTS OF FY14

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
Coordination of USAMMA's New Employee Orientation Program	Venue is to educate new employees on the Agency's mission and business practices.	New employees understand the Agency business and how they fit in. Orientation was provided to 15 new employees/soldiers.
Coordination of Agency Training Requests	SF-182 - Authorization, Agreement and Certification of Training.	Provide employees with the training necessary to accomplish the mission. Processed SF-182s for 8 civilian employees.
In-Processing of New Personnel	Provide initial and required training information and established training records.	Mandatory training requirements were briefed to 29 new employees/soldiers.
Management of the Agency's annual requirement for filing of the Office of Government Ethics (OGE) Form 450	OGE Form 450s are required for certain Agency personnel due to their official responsibilities.	Ninety-three individuals completed their annual filing requirement, with 100 percent compliance.

3.7 ENTERPRISE RESOURCES DIRECTORATE (ERD)



3.7.1 MISSION

The Enterprise Resources Directorate (ERD) is responsible for the following major areas: financial management and accounting; budgeting; manpower; defense travel; civilian personnel; military personnel; and contract management.

3.7.2 FUNCTIONS

The ERD has oversight of all matters relating to financial resources, manpower, human capital, and contract management.

3.7.3 MAJOR EFFORTS OF FY14

Each of the following ERD support areas describes the major efforts for FY14.

3.7.4 HUMAN CAPITAL (HC) DIVISION

3.7.4.1 MISSION

HC provides the full range of civilian and military personnel support services. Further, the office serves advises management and the USAMMA Commander on all civilian and military personnel matters to maintain an agile, adaptive, and well-prepared workforce.

3.7.4.2 FUNCTIONS

HC has oversight of all matters relating to Civilian and Military personnel.

- **Civilian Personnel.** Manage all personnel actions for USAMMA's DA civilian workforce including performance evaluations, awards, reassignments, PCS travel, benefits, separations, and hiring actions. USAMMA's civilian workforce includes the Personnel Demonstration Project (PDP), Wage Grade (WG), and General Schedule (GS) personnel systems. Assist leaders in reviewing and developing job descriptions. Primary systems include the Defense Civilian Personnel Data System (DCPDS) and the Defense Civilian Payroll System (DCPS)
- **Military Personnel.** Provide personnel management for USAMMA's military workforce including officer and noncommissioned officer evaluations, in processing, out processing, and awards. Primary systems include the Enlisted Distribution Assignment System (EDAS), the Electronic Military Personnel Office (EMILPO), the Officer Assignment and Distribution System, the Medical Operational Data System, and the Evaluation Entry System.

POPULATION SERVED (AT THE END OF FY14)

Populations Served	Total No of Agency Personnel
Federal Civilian Employees	199
Military Personnel	61

3.7.4.3 MAJOR EFFORTS OF FY14

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
Validated Military Personnel Asset Inventory (PAI)	A mandatory action to account for all military personnel.	Ensures accountability of military personnel.
Monthly Strength Report	Report showing numbers and types of personnel across the Agency.	Reports are provided to a number of offices (i.e. USAG & USAMRMC) to meet monthly reporting requirements.
Personnel Demonstration Project (PDP) Payout Validation	A mandatory action to validate proper pay for performance payouts.	Crosscheck each rating of record for accurate critical elements, weight ranges, and assignments for validation against performance payout dollar amounts.
Organization Inspection Program (OIP)	HQ USAMRMC scheduled to conduct an OIP inspection 26-30 January 2015	Prepared for inspection covering 27 areas/checklists
Pay and Financial Matters	Process payroll and benefit changes to employees' pay on a weekly basis.	Monitor and process all time and attendance for civilian employees. Also monitor and process all financial actions relating to pay for civilian and military employees.

3.7.5 RESOURCE MANAGEMENT (RM) DIVISION

3.7.5.1 MISSION

Resources Management focuses on aligning funds to support requirements, executing funds appropriately (purpose, time, and amount), and aligning manpower accordingly. Resources Management is responsible for financial management, accounting, budgeting, manpower, and defense travel. Major appropriations managed:

- Other Procurement, Army 3 year.
- Operation & Maintenance, Army 1 year.
- RDTE, Army, 2 year.
- Defense Health Program Procurement, 3 year.
- Defense Health Program Operations and Maintenance, 1 year.
- Defense Health Program RDTE, 2 year.

3.7.5.2 FUNCTIONS

- **Budgeting, Accounting, and Financial Reporting.** Provide accounting and budgetary support for USAMMA by receiving, controlling, recording, and reporting financial information related to the control and expenditure of funds received from a variety of Army and DoD appropriations.
- **Fund Certification.** Certify the availability of funds as to purpose, time and amount for commitments, obligations and adjustments.
- **Manpower: Management.** Work with USAMMA Directorates and Project Management Offices to maintain USAMMA's Table of Distribution and Allowances (TDA) as an accurate reflection of organizational structure. Provide Command Plan input; update TDA detail information; monitor personnel strength against the TDA; respond to manpower related taskings and requests for information; submit manpower change requests.
- **Defense Travel Administration.** Manage and support the Defense Travel System (DTS) at the organizational level. Establish the organization routing structure for approving and certifying travel. Assign roles, permission levels and retain a file of approved letters of appointment for authorizing officials and certifying officials for the organization. Establish lines of accounting in the DTS maintenance module. Allocate funds to the appropriate DTS budget module and monitor interface with the General Fund Enterprise Business System (GFEBS).
- **Government Travel Card (GTC) Administration.** Serve as USAMMA lead for the GTC web application. Responsibilities include providing monthly usage reports, adjusting accounts, and validating training.
- **Activity-Based Costing (ABC).** Analyze and evaluate data through the use of established cost centers and other cost collection methods. Develop models or other techniques that provide management information for analysis. Produce quantitative and qualitative data and reports to assist leaders in making timely and accurate decisions to improve accountability, efficiency and cost effectiveness.
- **Resource Manager for Government Purchase Cards (GPC).** Serve as USAMMA lead for the Access Online System and monitor transaction interface with GFEBS.

TOTAL MANPOWER NUMBERS AT END OF FY14

Population Served	Total No of Employees	Fund Type	Total No of Employees by Fund Type
Federal Civilian Employees	199	DHP	129
		RDTE Army	3
		OMA	62
		FMS	2
		OMA Reimbursable	3
Foreign National	20	OMA	
Military Personnel	61	N/A	
Contract Personnel	154	Various	

3.7.5.3 MAJOR EFFORTS OF FY14

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
Management of funds (legacy STANFINS and GFEBS)	Matching funds to requirements; Ensuring proper use of funds (purpose, time, and amount); Monitoring proper disbursement and system interfaces; Managing budgets.	Worked with USAMMA leadership to execute approximately $323 million dollars across multiple appropriations. Worked with myriad technical and functional points of contact to manage expired prior year funds (FY09-FY13 for O&M, FY07-FY11 for procurement, and FY11-FY12 for RDTE.
Annual Joint Reviews / Data Calls	A review of targeted prior and current year accounting records (conducted multiple times per year).	Serves due-diligence effort to ensure: 1. Accounting records are correct 2. Unpaid obligations are valid requirements 3. Obligation adjustments are proper 4. Unliquidated balances that do not support valid requirements are deobligated.
FY16 Command Plan and TDA Update	Submitting appropriate documentation to update USAMMA's TDA.	Completed USAMMA's FY15 TDA Update. During this TDA update USAMMA took appropriate action to maximize TDA alignment with current business practices and the commander's intent.
MEDCOM Financial Management Audit	MEDCOM RM Team conducted an audit of several financial management areas	Completed MEDCOM audit 6-9 May 2014 with no major deficiencies. Audit areas included inbound/outbound MIPRs, travel, civilian pay, government purchase card, contracts, and DMLSS.
DTA duties for USAMMA travel - relates to DTS workload	Statistical data relating to travel.	Over $1.5M travel supporting USAMMA missions.

3.7.6 CONTRACT MANAGEMENT DIVISION

3.7.6.1 MISSION

The Contract Management office serves as the contracting business advisor and liaison between USAMMA and the U.S. Army Medical Research Acquisition Activity (USAMRAA). This office reviews and develops Performance Work Statements (PWS); serves as the Contracting Officer's Representative (COR) for specified contracts; and screens procurement packages for completeness and compliance with applicable policy.

3.7.6.2 FUNCTIONS

COR Duties. Serve as primary or alternate COR for assigned service contracts. Responsibilities include monitoring and reporting contractor performance and approving vendor invoices. These COR duties are included in the contract administration phase below.
Pre-Award Phase (Contract Planning). Assist USAMMA requirement owners with the development, preparation, and completion of a Procurement Requirement Package.

Evaluation and Award Phase (Contract Formation). Coordinate with the contracting office and internal USAMMA requirement owners to form a Source Selection Evaluation Board (SSEB) and nominate SSEB members based on their functional and technical expertise.

Post-Award Phase (Contract Administration). Coordinate Post-Award Briefing with the contractor and contracting office; read and understand the contract; develop a COR Management Plan for each assigned contract or delivery order and maintain individual COR files for each contract. Document contractor performance in the Contractor Performance Assessment Reporting System (CPARS) for applicable contracts. Serve as a Trusted Agent in the Trusted Associate Sponsorship System (TASS); manage individual contractor in/out processing; and coordinate with the local security office for all contract clearance requirements.

Government Purchase Card (GPC) Agency Coordinator. Provide overall administration of the GPC program, to include developing and implementing policy, establishing and making changes to accounts, as well as training for cardholders and Billing/Approving Officials.

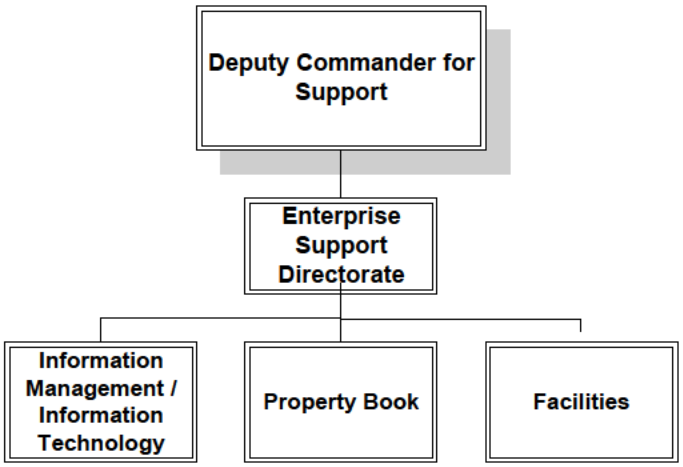
3.7.6.3 MAJOR EFFORTS OF FY14

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
Personnel - Contractor Management and Support	Served as CORs and assisted in management of 141 contractor personnel on and off-site locations (does not include those at APS forward cites).	Ensure contractor personnel were on board and had access to all the required DoD systems and services.
USAMMA Set Build IDIQ Contract	USAMMA required a new IDIQ Contract for set builds	USAMMA contract management team worked with USAMMA technical POCs and USAMRAA to ensure award of new contract
USAMMA Staffing IDIQ Option Years	Option years were exercised on seven USAMMA staffing contracts	Contracts awarded in key USAMMA support areas with no gaps in service.

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
USAMMA Materiel Fielding Support Service Contract	Worked with FSD and USAMRAA award a new contract	New contract awarded no gap in service.
Year-End Late PR Submission Waivers	PRs submitted after USAMRAA's established cut-off requires HQMRMC approval.	Contract management staff worked with USAMMA leadership to obtain approval for all critical PRs.
Complete Contract Actions	Approximately 154 contract actions valued at over $35M completed by the local contracting office in FY14. These actions cover new requirements, incremental funding, and the exercising of option years.	These actions ensure that USAMMA had continuity of services supporting mission requirements.
GPC Program Review and Update	Overall GPC Program required and updated SOP and intensive preparation for the upcoming USAMRMC OIP.	Finalized SOP, updated files; re-established working relationship with USAMRAA; trained billing officials and cardholders where necessary; GPC Program ready for OIP;
USAMMA Staffing IDIQ Contract Award	USAMMA required a new contract for staffing in several areas across the agency because existing contracts were expiring in September 2014. Areas included the BSO, PJM Medical Devices, FSD, and the DOC.	Contract and initial delivery orders awarded in September 2014 with no gap in service. The general scope of the USAMMA requirements are organized into eight (8) separate support areas: Program Management Support Services, Studies and Analysis, Performance Based Budgeting and Financial Management, Business Process Improvement, Functional Validation and Verification, Records Management, Information Management, Medical Supply Chain and Logistics Management Support.

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
USAMMA Materiel Fielding Support Service Contract	Worked with FSD and USAMRAA to exercise Option Year 10.	Exercised Option Year 10 to provide services through 31 December 2014. This action positioned USAMMA to award a new contract in FY14 with no gap in service.
USAMMA Medical Maintenance Management Directorate (M3D) contract requirement.	The existing contract covering depot locations and the NMP was expiring in September 2014.	Contract Management Staff worked with M3D leaders to ensure USAMRAA awarded the new contract with no gap in service.
Year-End Late PR Submission Waivers	PRs submitted after USAMRAA's established cut-off requires HQMRMC approval.	Contract management staff worked with USAMMA leadership to obtain approval for all critical PRs.
Serve as Chairpersons and members for Source Selection Evaluation Boards (SSEB).	Contract Management Staff participates in these forums to select contract awardee (vendor). These forums can require significant time to evaluate all vendors.	CMD staff participated in approximately 14 SSEB forums supporting USAMMA requirements, including the PASS base award evaluating 19 proposals.
Complete Contract Actions	Approximately 103 contract actions valued at over $53M completed by the local contracting office in FY14. These actions cover new requirements, incremental funding, and the exercising of option years.	These actions ensure that USAMMA had continuity of services supporting mission requirements. USAMMA successfully implemented a new acquisition strategy process/template that provided a step by step process for submitting requirements to USAMRAA and managing the contract after award.

3.8 ENTERPRISE SERVICES DIRECTORATE (ESD)



3.8.1 MISSION

The Directorate for Enterprise Systems is comprised of the Information Management and Information Technology (IMIT) User Support Branch (USB), Property Management, Facilities, and Technical Writing. Synergy exists between these branches because a high percentage of their workload dovetails into each other's area of responsibility (i.e., when one branch has a task, it frequently effects one or more of the other branches).

3.8.2 FUNCTIONS

- Enterprise management of information resources.
- Integration of property with the acquisition and distribution of Information Technology (IT) equipment.
- Integrate personnel movement within the DMLC with property, facilities, and Information Management Information Technology (IM/IT).
- Information Assurance (IA) Training.
- Systems and facility authentication processing.
- Special projects.
- Fort Detrick US Army Garrison liaison.
- Serves as the Information Management Officer (IMO) and Information Assurance Manager (IAM) for the Agency and conduit to USAMRMC Chief Information Officer (CIO).

3.8.3 MAJOR EFFORTS OF FY14

Each of the following ESD support areas describes the major efforts for FY14.

3.8.4 INFORMATION MANAGEMENT / INFORMATION TECHNOLOGY (IM/IT)

3.8.4.1 MISSION

Manage daily operations, IM/IT Infrastructure support, enhancements, and performance requirements supporting USAMMA's IM/IT Systems, Local Area Network (LAN) and communications, information assurance and IT security.

3.8.4.2 FUNCTIONS

- Maintain and monitor IM/IT Annual Budget.
- Life Cycle Management of Information and Information Technology Resources for the Agency-Desktop, Server Farm, Storage Area Networking, Remote Back-up and Restore.

- Configuration and Integration Management.
- Continuity of Operations and Business Continuity/Disaster Recovery.
- Cryptographic subsystem management.
- Information Assurance Policy, Planning, and Enforcement.
- Identification and Authentication subsystem management.
- Personnel Security processing.
- Physical and Environmental Controls.
- Remote Access Controls.
- Internal Auditing.
- Information Assurance Vulnerability Management and Reporting.
- Incident Response Planning and Execution.
- Application Development.
- Database Management and Database Management Systems Development.
- Web/Web Server development and Production.
- Tier I, II, and III User Support.
- Information Assurance Training.
- In/Out Processing.
- Forms Management.
- Print Management.
- Video Tele-Conference (VTC) Maintenance and VTC conference Set-up.
- Blackberry Management.
- Software License Management and Maintenance.
- Web Content Management.
- User Account Management and Administration.
- Patch Management and Implementation.
- Intrusion Detection, Investigation and Reporting.

3.8.4.3 MAJOR EFFORTS OF FY14

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
Server Ops	Completed server migration to Windows 2008 R2 Virtual Machines (VM). Completed COOP system.	100% conversion of physical-to-virtual systems including all Infrastructure (file, print, web and databases), COOP, and development servers. COOP system is now capable of supporting USAMMA public websites, including MMQC, Web MRE and MEDSILS in the event the Ft. Detrick NEC resources become unavailable.
User Support Branch	Tier II Help Desk Support.	USB Staff successfully responded to and resolved 788 incidents over the 2014 fiscal year. Responded and closed 400 IAVA taskers. Deployed Microsoft Office 2010 to the USAMMA achieving 100% compliance.
Inventory	Conducted quarterly hand receipt inventories.	Excess PB (W05J55) verified and signed in Feb '14. No physical equipment was moved, rather documentation was collected and PBUSE updated to reflect actual numbers.
Information Assurance	Incident Response.	Responded to X 5 IA incidents. Most incidents were minor in scope, no substantiated spillage incidents reported. One incident, a web server compromise was mitigated resulting in a complete redesign and rebuild of the public web and web app environments.
User Accounts Requests	Provide management and support for user accounts.	• IA Training: 373 • New User AD: 38 • Out Process AD: 28 • LOGSA: 17 • TEWLS: 26 • CCSS-F: 0 • FMS: 0 • VPN: 25 • MRE; 0 • EDMS: 0 • SANAR: 2 • LiveLink: 13 • SAAR: 34 **TOTAL: 556**

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
Certification and Accreditation	Certification and accreditation of systems.	Annual DIACAP Internal review completed. SAV-Mitigated. IA findings from 11/2012 SAV.
Acquisitions (approximately 50% reduction in expenditures from FY 12)	Credit card approved purchases:	Software: $33,499.58 Systems: $83,289.40 Peripherals: $41, 018.60 Consumables: $25, 191.85 Contracts: $528,308.89 Training: $5,000.00 Approx: $716,308.32
Network Enterprise Center/Command (NEC) Service Level Agreements (SLA)	NEC SLAIT.	$182K.

3.8.6 PROPERTY BOOK OFFICER (PBO)

3.8.6.1 MISSION

The PBO serves the USAMMA Commander as the focal point for the implementation, monitoring, and continually improving business results for property accountability. Exercises formal accountability for property assigned and loaned under the auspices of the command, including common property located within the DMLC and forward sites worldwide valued at over $7M. Has responsibility for assuring a comprehensive Command Supply Discipline Program (CSDP) including procurement, storage, distribution, inventory, inspection, classification, identification, and disposal of equipment.

3.8.6.2 FUNCTIONS

- Maintain property book account.
- Ensure timely submission of all required reports.
- Establishes and accountability for property not accounted for upon discovery.
- Conducts inventories of equipment and material. Coordinates and verifies the USAMMA equipment for the TDA.
- Delivers and picks up government furnishings and equipment to and from installation and USAMMA.
- Issue and maintain hand receipts.
- Conduct inspections and inventories.
- Ensure proper handling and accountability of Organizational Clothing and Individual Equipment.
- Assure proper handling and management of ammunition.
- Serve as reviewer and assign document numbers for all Reports of Survey.

3.8.6.3 MAJOR EFFORTS OF FY14

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
Property Management Officer transition	The Property Management section brought to record 4 million dollars of unaccounted for equipment.	The equipment is now accounted for and on army property records. Equipment if required will remain with in USAMMA or cross leveled to other organizations.
Excess Equipment	Turned in 500K of excess property/equipment.	The turn in of excess reduces the amount of unused equipment with in USAMMA as well as gives other army organizations the opportunity to acquire equipment free of charge which saves the army hundreds of thousands of dollars.

3.8.7 FACILITIES

3.8.7.1 MISSION

Facilitate and manage the plan, design, construct, repair, and maintain all real property facilities and utility plants. Provide housing and basic services (utilities, refuse, fire protection, custodial, etc.) for the staff and faculty in support of the USAMMA community.

3.8.7.2 FUNCTIONS

- **Work Orders.** Manages Work Orders by being the focal point for all Agency personnel to submit requests for repairs, personnel relocations within the facility, trouble calls for broken or failed material or systems within the facility.

- **Fire Inspections.** Manages Fire Inspection by maintaining liaison with the Fire Marshall to establish inspections and access to locked spaces, remediating deficiencies discovered during such inspections.

- **Grounds and Landscaping.** Maintains Grounds and Landscape by maintaining liaison with the Department of Public Works, Agency personnel, and other designated Garrison personnel to collect requirements from tenants, forward those requirements to the appropriate department, scheduling the work to be accomplished, and following up once the work is complete.

- **Evacuation Plan.** Maintains Building Evacuation Plan by maintaining liaison with Security, Fire Marshall, Operations, and facility points of contact to establish signs for evacuation, locations to muster, and signs to return to the building.

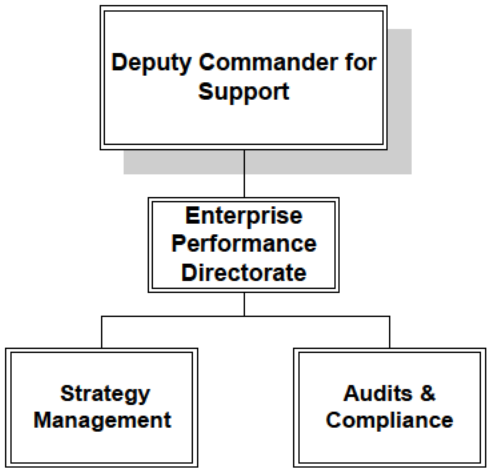
- **Building Access.** Manages Building Access by maintaining ensuring newly reporting personnel are directed to the badging office for electronic card identification badges. Ensures the facility is opened and locked at prescribed times.

- **Physical Security.** Physical Security by maintaining liaison with the Garrison Security and tenant Agencies to ensure spaces are only accessible to personnel with proper need, key control is maintained, visitors are appropriately escorted, and physical security program requirements are met.

- **Mail.** Manages Mail and Delivery by coordinating with tenants for personnel and department rosters, accepting deliveries on behalf of the Agencies, and delivering, or contacting the principles to pick up, packages that are brought into the building.

- **Conference Rooms.** Manages Conference Room utilization by ensuring the conference rooms are prepared at the beginning of the work day for the first scheduled use and facilitating the resolution of issues throughout the day, should they arise.

3.9 ENTERPRISE PERFORMANCE DIRECTORATE (EPD)



3.9.1 MISSION

The Enterprise Performance Directorate (EPD) is responsible for institutionalizing, monitoring, and continually improving business results while ensuring that proper internal controls are in place and reported. Additionally, conducts management studies affecting internal and external aspects of the organization.

3.9.2 FUNCTIONS

- **Strategy Management.** Strategic planning, Balanced Scorecard (BSC) management and Strategic Management System (SMS) Local Administrator.

- **Audits & Compliance.** Coordination of all external and internal audits, inspections, and evaluations.

- **Support Agreements**. Central repository for the management of all corporate level support agreements.

3.9.3 MAJOR EFFORTS OF FY14

Each of the following EPD support areas describes the major efforts for FY14.

3.9.4 OFFICE OF THE STRATEGY MANAGEMENT AND PERFORMANCE (OSM/P)

3.9.4.1 MISSION

The OSM/P is responsible for guiding the USAMMA organization in the management and implementation of its strategy process. The OSM/P ensures that the USAMMA strategy management process complies with the OTSG guidance that all Army Medical Department (AMEDD) organizations utilize the BSC as the methodology to develop and manage strategy, and the USAMMA strategy is in alignment with the AMEDD, USAMRMC, the AMLE, and the Defense Medical Logistics Enterprise (DMLE) strategies. In performing these roles, the OSM/P leads several strategy management processes while others it helps coordinate.

3.9.4.2 FUNCTIONS

- **Strategic Planning.** The OSM/P leads this process. The OSM/P guides USAMMA in the development of a mission and vision for USAMMA and then works with the Directorates and PMOs to establish overarching strategic goals. Performs assessments to identify shaping forces that USAMMA needs to be aware of and then formulates a case for change to identify the major functions, capabilities or processes USAMMA needs to change to in order to continue to meet the mission, vision and strategic goals that are impacted by the shaping forces. Additionally, represents the Commander in other strategic planning efforts such as the AMLE as well as inputs to other AMEDD strategies.

- **Scorecard Management.** The OSM/P leads the development and management of the USAMMA BSC. This includes developing a scorecard architecture (e.g. enterprise level scorecard that is then cascaded down to the Directorates, PMOs, establishing a process for scorecard development and management, establishing a project timeline for scorecard update/development, conducting and facilitating working sessions on the development of the scorecard and providing training on scorecard use and development. The OSM/P plays a critical role in the facilitation and synchronization of objectives, measures and targets across the themes. The OSM/P ensures the USAMMA scorecard reflects the needs of the USAMMA
enterprise and does not result in a stove piped strategy that does not achieve the mission and vision.

- **Organizational Alignment.** The OSM/P leads this process. The OSM/P facilitates and synchronizes the objectives, measures and targets. Ensures the USAMMA scorecard reflects the needs of the USAMMA enterprise and does not result in a stove piped strategy that does not achieve the mission and vision. Additionally, coordinates with other AMEDD scorecards to ensure effective cascading of objectives from higher level strategic guidance. This typically includes reviewing the OTSG AMEDD Enterprise scorecard; USAMRMC scorecard as well as working with the AMLE, DMLE, and maintenance community to ensure strategic goals from those functional areas is reflected in the USAMMA scorecard where appropriate. In this alignment function, the OSM/P plays a critical role in ensuring the USAMMA and higher level and cascaded scorecards all align in terms of complimentary objectives
measures and targets as well as initiatives. The OSM/P ensures that the USAMMA strategy is not in conflict with itself as well as with the enterprise goals of AMEDD and AMLE.

- **Planning and Budgeting.** The OSM/P supports this process and in this role integrates with the financial planning group. The financial planning group owns the budgeting and financial management process. The

OSM/P provides support to the financial group in helping to ensure the budget is driven by the strategy. This includes providing and interpreting the strategy for the financial team, providing the necessary performance data to justify budget submissions, ensuring project funding is aligned to strategic priorities and working with the budget office to rationalize investments and budget tradeoffs.

- **Human Capital (HC) Alignment.** The OSM/P supports this process and in this role integrates with the HC group. The human capital group owns the HC and workforce planning and management process. The OSM/P provides support to the HC organization in helping
translate the strategy into human capital needs. This entails the analysis and identification of strategic job families, core skills and competencies needed in those families and the development of action plans to fill those strategic job family positions. Collaborate with HC also to develop personal scorecards for the employees that are aligned to the overall USAMMA strategy. Finally, supports the HC organization in ensuring that recruiting and hiring actions are aligned with the strategic needs of USAMMA.

- **Strategic Communications.** The OSM/P leads this process. In this process, the OSM/P establishes the overall strategic communications plan. This plan is focused on communicating to the USAMMA workforce as well as external customers and stakeholders what the USAMMA strategy is and how performance against that strategy is proceeding. The OSM/P uses multiple communications mediums such as the USAMMAnet (Intranet), Town Halls, e-Mail newsletters and other mediums to share strategic information. The OSM/P actively analyzes performance data of USAMMA and broadcasts that information in the context of progress towards the strategic objectives of USAMMA.

- **Strategy Review Meetings (SRMs).** The OSM/P leads this process. In this process, the OSM/P leads the USAMMA leadership in reviewing the progress of the USAMMA strategy. To accomplish this the OSM/P focuses on establishing and implementing the strategic governance process, defining and help fill key roles and responsibilities for strategic reporting, formulating and getting approval on the meeting agendas, ensuring the objective leads report current progress, preparing meeting materials for strategic reviews, analyzing strategic performance data and tracking action items from strategy review meetings. The OSM/P has a pivotal role in the strategy review sessions in ensuring the leadership team stays focused on the agenda, discusses solutions to problems as opposed to placing blame and finally, drives the leadership team to make decisions when required.

- **Initiative Management.** The OSM/P leads this process. The OSM/P first establishes a process for the identification, ranking and selection of initiatives that support the strategy and will result in closing performance gaps. Once the process is established, the OSM/P executes it. This involves working with the USAMMA leaders to identify strategic projects (initiatives) needed for the strategy, align initiatives to strategy, evaluate initiatives across USAMMA to ensure no duplication of effort, aligning initiatives into portfolios' to ensure the greatest synergy, assist in structuring the description and intent of the initiatives and helping them present the initiatives to the Governance Council (GC). It facilitates the GC in the evaluation, scoring and final selection of initiatives. Once initiatives are approved, the OSM/P
provides project management support to the initiative sponsor. This includes preparing project charters, work breakdown structures, project plans, project teams, risk management tools and other project management controls and processes. The OSM/P works with the Initiative sponsors to ensure the progress on initiatives is reported on during the SRM process.

- **Best Practices.** The OSM/P leads and integrates in this process. The intent is to ensure that best practices in strategy as well as operations are shared across USAMMA. In this capacity, the OSM/P has responsibility for the establishment of knowledge management processes and supporting technology. Best practices may come from within USAMMA or external. The OSM/P actively researches and collects best practice data on strategy, supply chain, information technology, HC management and other critical topics.

3.9.4.3 MAJOR EFFORTS OF FY14

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
Managed and executed the Office of the Strategy Management and Performance (OSM/P).	The OSM/P is responsible for guiding the USAMMA organization in the management and implementation of its strategy process. In addition, the OSM/P provides assistance to USAMMA in advancing performance excellence by providing guidance on the various quality management approaches, methods, techniques, and tools.	Ensured the organization sustains its focus on strategy – from development to execution – by integrating Strategy - Focused concepts, principles, and best practices into the fabric, cadence, and processes of the organization.
Managed the Strategic Management System (SMS) automated system.	SMS is a web based software application that takes you step by step through both the construction of, and reporting on, Balanced Scorecards and strategy maps.	Integrated meeting management, enterprise alignment, performance, and initiative management functionality allows for real-time data entry during USAMMA's Strategy Management Reviews (SRM).
Conducted Agency's bi-annual strategy renewal.	Strategy Refresh or Renewal (evaluation) is conducted annually and bi-annually respectively to 'review the enterprise strategy progress toward planned strategic results and to review the balanced scorecard strategic planning and management system to determine where the system can be improved.'	Ensures USAMMA strategy is in alignment with the AMEDD, USAUSAMRMC, AMLE, and DMLE strategies.
Collaborated and participated in the USAUSAMRMC Quality Management Office (QMO) / Strategy Deployment and Automation (SDAT) Team.	The SDAT is composed of USAUSAMRMC sub-command representatives in their role as planning experts and consultants.	The focus is to improve the operational efficiency and effectiveness within the USAUSAMRMC Command, while leveraging customer requirements, by assuring quality strategic planning, and improvement activities.

3.9.5 AUDITS AND COMPLIANCE

3.9.5.1 MISSION

Ensures that proper internal controls are in place, reported, and in compliance with DoD, DA Directives and Federal Law. This oversight function assures the Commander that resources are being utilized efficiently.

3.9.5.2 FUNCTIONS

- **Army Managers' Internal Control Program (MICP).** Implementation, execution, and reporting of the Agency's MICP.

- **Internal and External Audits and Inspections.** Responsible for the coordination of external and internal audits to include all inspections activities with DoD entities, DA, and higher headquarters.

- **Organizational Inspection Program (OIP).** Responsible for the implementation, execution, and reporting of the Agency's OIP.

3.9.5.3 MAJOR EFFORTS OF FY14

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
Successfully met FY14 USAMMA's MICP Members Training Requirements.	Training is designed based on MICP member's roles and responsibilities.	Ensures the Agency has properly trained leaders and personnel to effectively perform their MICP duties.
Developed, coordinated, and published the USAMMA 10-1, Organizations and Functions regulation.	The USAMMA 10-1, Organizations and Functions provide information about the Agency's missions, principal functions, and core processes.	A comprehensive document that communicates the Agency's business processes, roles and responsibilities.
Management of Agency Support Agreements Program	Support agreements are written documents that are used to legally bind the Agency and other party(s) to cooperatively work together on an agreed service or other mission requirements.	Ensure all Agency support agreements are accounted, valid, and reviewed as directed by regulations.

3.10 MEDICAL LOGISTICS MANAGEMENT INTERNSHIP PROGRAM (MLMIP)

3.10.1 MISSION

The six-month program is designed to develop Army medical logisticians: officers, warrant officers, noncommissioned officers, and DA civilians. Graduates of the MLMIP are ready to assume greater responsibility at operational and strategic level assignments. The curriculum covers a wide-array of training, education, and on-site visits with academia, industry, and federal government institutions.

3.10.2 FUNCTIONS

- Develop logisticians for strategic-level programs emphasizing Joint and Army readiness.
- Provide experience and knowledge concerning leading-edge technology, organizational innovation, and defense acquisition.
- Combine the best of defense and commercial health care logistics business practices.

LEADERSHIP AND MAJOR CHANGES OF FY14

Deputy Commander for Support

LTC (b) (6)

Deputy DCS

(b) (6)

Director, Enterprise Performance

(b) (6)

Director, Enterprise Resources

(b) (6)

Director, Enterprise Services

(b) (6)

DEPUTY COMMANDER FOR OPERATIONS (DCO)

4.1 BUSINESS SUPPORT DIRECTORATE (BSD)

4.1.1 MISSION

The Business Support Office is comprised of two distinct sections; the Business Support Office (BSO) and the Army Data Synchronization Division (ADSD). The BSO collaborates both vertically (stakeholders, end users, and external business partners) and horizontally (BSO/TSO) to provide input to the Project Lead in support of new development and sustainment activities. The boundaries between these categories are fluid and highly influenced by program management decisions and dynamic mission needs.

4.1.2 FUNCTIONS

- **Business Support Office:** The BSO element provides functional expertise for enterprise-level business processes and related support to the management of the TEWLS application.

- **Army Data Synchronization Division (ADSD):** provides master medical data dissemination to the Defense Logistics Agency (DLA) and the Army.

4.1.3 BUSINESS SUPPORT OFFICE (BSO)

4.1.3.1 MISSION

The BSO provides functional expertise for the development and sustainment of the Theater Enterprise Wide Logistics System (TEWLS) application which supports USAMMA's mission of equipping and sustaining the Army's medical force. The ADSD also serves as the Secondary Inventory Control Activity for medical materiel, and provides continuous support to develop and maintain the Federal Logistics catalog system and Army cataloging operations.

4.1.3.2 FUNCTIONS

- **Blueprint and Development:** Through the Theater Enterprise Wide Logistics System (TEWLS) the BSO establishes enterprise business process and requirements. In addition, it develops the TEWLS' system environment, organizational structure, process definition, roles, and authorizations.

- **Realization:** Implement all TEWLS business process requirements based on the business blueprint; establish system configuration methodology in two packages—the Baseline (major scope) and Final Configuration (remaining scope).

- **Go Live and Sustainment:** Move TEWLS from a project-orientated, pre-production environment to a live-production operation; sustain production operation thru process management and issue resolution.

- **Documentation:** Develop and maintain functional documentation (e.g., requirements, specifications, testing, training), supporting the development and sustainment of TEWLS thru SAP Solution Manager.

- **Training:** Develop and maintain training materials for the functional users of TEWLS. Provide training directly to users and/or coordinate training by third parties.

- **Problem Solving:** Provide medical health services (MHS) and Help Desk support to users of TEWLS for all issue/problem resolution.

- **Coordination:** Coordinate efforts of system developers, operators, and users in sustaining TEWLS.

- **Exploration:** Maintain contact with other DOD and non-DOD ERP projects in order to stay abreast of new developments and opportunities that will benefit TEWLS.

4.1.3.3 MAJOR EFFORTS OF FY14

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
Army Enterprise System Integration Program (AESIP) interface.	Established bi-directional interface with the AESIP and TEWLS.	TEWLS sends NSN data to include component listing data for all medical Sets, Kits, and Outfits. This data allows access of all Army users to medical NSNs and images.
USAMMA Flu Vaccine Management	Development of a vaccine management system that handles the unique business requirements of the USAMMA Flu Manager.	Enables the USAMMA Flu Manager to gather flu vaccine forecast requirements from the total Army Force, report those requirements to DLA, and more efficiently process the flu vaccine orders received from customers.
Medical Master Catalog (MMC) interface	Established a searchable interface with the Enhanced Universal Data Repository.	Enables TEWLS users to search and pull in data from the Enhanced Universal Data Repository and the Medical Master Catalog. The capability gives users access to authoritative sourcing data which allows for less user searching and a higher catalog standardization compliance rate for New Item Requests.

4.1.4 ARMY DATA SYNCHRONIZATION DIVISION (ADSD)

4.1.4.1 MISSION

The Army Data Synchronization Division (ADSD) is a section of the Business Support Office (BSO) whose mission it is to provide master data support across the enterprise. The ADSD manages and maintains the Army's database for all medical NSNs and works directly with DLA to ensure accuracy and eliminate errors.

4.1.4.2 MAJOR FUNCTIONS

- **Secondary Inventory Control Activity (SICA) for all Army Medical NSNs:** manages and maintains the Army data for all medical NSNs

- **Works directly with DLA Troop Support and DLIS during the NSN cataloging process to ensure accuracy and to eliminate errors**

- **Executive Agent for Tri-Service Maintenance and Management of MEDSILS:** Standardizes medical NSNs for the Army

- **Data managers for all data entered into TEWLS database**

- **Medical Standard LINs:** Approval authority for and researches all medical standard LINs, coordinating directly with LOGSA

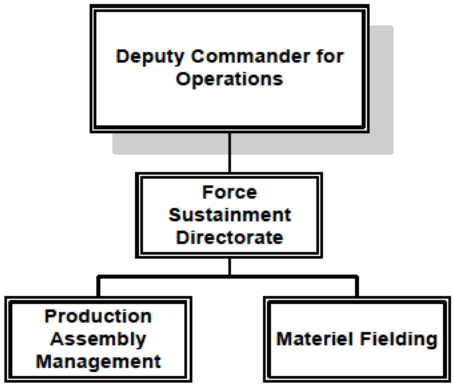
- **Medical Non-Standard LINs:** Approval authority for and researches medical non-standard LINs, coordinating directly with LOGSA

4.1.4.3 MAJOR EFFORTS OF FY14

- Processed over 100 new NSN requests.

- Completed over 253 NSN maintenance requests.

4.2 FORCE SUSTAINMENT DIRECTORATE (FSD)



4.2.1 MISSION

The Force Sustainment Directorate (MMO-S) provides medical materiel support to all Army components through Assemblage Production and Materiel Fielding facilitating optimal healthcare and worldwide medical readiness. As part of Army and AMEDD Force Management, the Directorate plans and executes a variety of medical materiel readiness missions, such as the Army Medical Department's Reset Program in support of the Active, Reserve, National Guard, and other contingencies, as required. This Directorate also collaborates with other USAMMA directorates during force projection and sustainment operations, and executes and supports initiatives under the USAMMA, the USAMRMC, and the USAMEDCOM and OTSG Strategic Plans.

The three main sections that support this mission are Office of the Director, Production/Assembly Management Division (AMD) and the Materiel Fielding Division (MFD).

4.2.2 FUNCTIONS

Major responsibilities focus on activities associated with programming, planning, budgeting, and executing [procuring (requisition/ordering), distributing, and supporting medical materiel, including the assembly of medical sets] for all of the Army's medical force structure requirements. Specifically, this Directorate assists the Deputy for Acquisition with the Agency's FL8D Program Objective Memorandum build, manages the year of execution MDEP FL8D OMA budget, along with the actions pertaining to the procurement, assembly, fielding, and follow-on logistics support for medical systems and equipment to facilitate combat ready forces. The MMO-S also supports other USAMMA organizations in discharging its duties within the arenas of force projection and force sustainment., Additionally, through the employment of Liaison Officers (LNOs) embedded in the Army Field Support Battalions located at the five Major Troop Posts, Fort Hood, Fort Bragg, Fort Carson, Fort Campbell, and Joint Base Lewis McCord, they directly support the Warfighter mission on a regional basis by providing early identification and resolution of logistics problems occurring within their respective regions. They manage the depot-level non-medical Associated Support Items of Equipment (ASIOE) program for select items, coordinate and provide management oversight for the medical materiel loan/lease agreement program and provide the Primary and Secondary Container Control Officers (CCO) for the Agency.

OFFICE OF THE DIRECTOR

In addition to the Director, the Deputy Director and two Nonmedical ASIOE Subject Matter Experts function at this level.

The Director is responsible for overall operation of the Directorate, providing vision and guidance, leading strategic planning, and establishing and monitoring performance measures.

The Deputy provides the following support:

- Assists the Director with overall program management and assumes Director role in his absence.
- Directorate point of contact for all support matters including Information Management Support and Personnel Actions.
- Liaison to the Support side of the house.
- Manages the FL8D OMA and Reset Budgets.
- Assists Deputy Commander for Acquisition in the FL8D POM Build.
- Provides Force Management and Integration Expertise.

The Two Nonmedical ASIOE Subject Matter Experts (SME) provide the following support:

- All USAMMA-provided nonmed ASIOE support to TO&E Units.
- Primary and Secondary Container Control Officer (CCO) functions for the Agency.
- Execute the Agency's Loan and Lease Agreement program.
- Lead Materiel Fielding Teams when OPTEMPO exceeds capabilities of our Regional Managers in the Materiel Fielding Division.
- Provides nonmedical ASIOE support to the Medical Logistics Support Team (MLST).
- Provides Nonmedical ASIOE support to the PJM, Medical Support Systems.
- Conducts QA/QC checks during medical materiel fieldings.

4.2.3 MAJOR EFFORTS OF FY14

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
Personnel: Military Director changed in Aug 13. Chief, Materiel Fielding Division retired 28 Feb 14	Chief, Materiel Fielding Division retired 28 Feb 14, and his backfill did not arrive until Aug 14.	Deputy Director assumed day-to-day operational management of the five civilian personnel aligned to this Division.
Managed FL8D OMA and Reset Budgets	Managed FL8D OMA and Reset Budgets.	FSD effectively executed $59M FL8D and Reset OMA in support of Army Contingency Forces (DCRF, C2CRE-A, C2CRE-B, etc), Deployers, Modernization, and Reset Units This resulted in 287 units being prepared for deployment, Reset and/or modernized.
Provided Directorate information for the MEDCOM/USAMAA On-Site Manpower Study	Refined, developed and managed the Directorate input to the MEDCOM/USAMAA Manpower On-site Study.	All incumbent positions workloads were fully justified, clearly articulated and deemed required.
Facilitated New Fielding and LNO Task Orders	Wrote new PWS, QASP and developed IGCEs, as well as sat on the SSEBs for both our fielding and LNO contracts.	Both task orders were awarded in time to preclude a break in service and mission achievement.
Coordinated with HQDA 3/5/7 FM reference the cked Master Force (MForce) and Objective Table of Organization & Equipment (OTOE)	Worked with HQDA 3/5/7 and obtained the Dec 13 Locked MForce which is still the most current and the most current consolidated TO&E update (CTU) OTOEs which are two of the three primary tables required for the PPBE Database to run POM data.	The Locked MForce and current OTOEs were provided and entered into the PPBE DB; thus, allowing us to run the FY17-21 FL8D POM data.
VCSA approved the Field Hospital Force Design Update 25 Jul 14. FSD determined the true medical implementation costs and worked with OTSG HCO FM to develop predecisional FY17-21 FL8D POM conversion timeline for all hospitals that will be equipped.	The VCSA approved medical equipping costs were approximately $69.8M based on requirements to requirements. Due to RCHD and FORSCOM 164-bed company disestablishments, the true implementation costs are closer to $165M across the EE PEG POM and SS PEG POM.	The more accurate implementation costs were included in the FL8D POM and funded along with modernization for the planned CSH conversions. This, also, required multiple GO and SES-level briefings for explanation.
Continued refinement of medical equipping FH FDU Implementation Strategies with OTSG HCO FM, HQDA 3/5/7 FM, FORSCOM and	Working with all principles to develop more cost effective means of FH FDU medical equipping implementation.	Multiple courses of action are being analyzed and researched for implementation in support of the first conversions in FY17.

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
DCDD		
Implemented precision fielding	Changed USAMMA's requirements determination process and execution process in order to garner efficiencies while maintaining or enhancing unit readiness. USAMMA	Modernization of units will cost less; thus, allowing us to modernize more units on our approved 1-N list.
Developed a PBUSE process to enable loading materiel into USAMMA's PBUSE DoDAAC prior to fielding; thus, facilitating accountability and adherence to Army ALARACT	Developed the PBUSE accountability workflow to insure a process is in place in order for materiel to be accounted for and properly issued and received by the Unit meeting requirements of AR 700-142.	The process is now in accordance with regulatory guidance and facilitates an increased level of accountability.
QA/QC Process and Logistics Assistance Program (Continued)	Formal process flows are being documented for major Directorate areas of execution and the QA/QC Process and Logistics Assistance Program are on their way to being fully developed and implemented.	Process flows will be used to develop quality assurance and quality controls throughout the Directorate and will assist in implementing business process improvements.
MILVAN and ISO Road-Ahead Process	Requested and managed the development of both MILVAN and ISO Courses of Action to facilitate better planning as we progress through the disestablishment of RCHD and the 164-bed hospital companies originally stored at SIAD.	We were able to turn back to AIDPMO, the MILVAN Commodity Manager, 246 MILVANS at a minimal cost allowing for more storage space at DDHU for RCHD disassembly and maximizing future use of the MILVANS. IPT is using data to determine COAs for new shelter system.
Materiel Readiness and Accountability	Provided accountability for 6,000 lines of Deployable Medical Systems (DEPMEDS) Nonmed ASIOE valued at $40M. Worked with SIAD and coordinated the turn-in and disposal of 116 Air Conditioners and 147 Heaters that were CC F/H. Procurement value totaling over $896,528. Developed Property Accountable Officer SOP, desktop reference and flow process for USAMMA	Equipment is readily available at SIAD to support the Medical Materiel Readiness Program (MMRP) hospitals or other missions as designated by the Army. Facilitates better management for ASIOE currently at SIAD.

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
	B69 Non-Med ASIOE to insure that over $66M worth of materiel is being accounted for and meeting the standards for AR 735-5. Compiled over 4 years of data totaling over 13,000 lines to write an information paper on the effectiveness of LTS in Japan.	
Conduct Convention for Safe Container (CSC) inspections	134 containers inspected for compliance with International laws for movement through the Defense Transportation System and International Maritime channels.	Maintain the ability to execute rapid deployment of the MLST, Army Prepositioned Hospital Supplies (APS) and effected units.
Depot Movement Directives to ship medical and non-medical ASIOE in support of medical units world-wide	Prepared 14 call forward messages for nonmedical equipment. Directed shipment of approximately $2,852,420 of non-medical equipment from SIAD in support of USAMMA, FORSCOM, and MEDCOM missions.	Equipment was provided to the units in CONUS and OCONUS in support of OUA/OIF/OEF, APS and Fielding support missions and special projects, to include, Loan Agreements.
Loan and Lease Agreements	Managed 7 Loan and Lease Agreements worth $3,999,203.	Enabled customers to execute requested missions. Ensured Loan & Lease Agreements were correct and in accordance with AR700-131.
Logistics Assistance Program	Developed flow charts and work flow processes incorporating the logistics assistance process in the fielding process.	Help units fill shortfalls and saved USAMMA money and man-hours by streamlining processes to be more effective at supporting the customer.
Led Non-Medical Materiel Assessment Team	Led 9 materiel fielding teams fielding $33,799,956 worth of materiel. Non-Med ASIOE subject matter experts for APS-4 RCDMH1 upgrade inventorying and capturing over $28,183,808 worth of materiel. Used newly created UAs T666, T662, T670 and T647 to inventory the 84- and 164-Bed Hospitals at APS-4 Japan saving the inventory teams countless hours from manually entering TEMPER components and inventories.	Ensured all mission requirements were accomplished on time during a high OPTEMPO period. Ensured unit shortages were filled increasing Unit Combat readiness. Provided guidance and ensured that the mission was successful. Allowed for multiple inventory teams to conduct the inventories, completing the 84 and 164-Bed TEMPER inventories of RCDMH1 and RCDMH4 to comply with TEMPER GPA.

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
	Inventoried 125 TEMPER Tents to comply with Ground Precautionary Action (GPA) issued by TACOM. Wrote and staffed SOWs for SIAD to perform work effort to support TEMPER GPA for multiple COAs.	825,000 lbs of TEMPER Tents were manually pulled, inspected and inventoried to capture known affected contract lot numbers. Defective contract lot numbers will be ordered and replaced.
Inter & Intra-agency/department collaboration	Worked with Assembly Management to have the Class VII and VIII data captured in TEWLS to reflect accurate inventory of all materiel at SIAD. Collaborated with SIAD Forward Site Manager (FSM) compiling the Reserve Component Hospital Decrement (RCHD) Non-Med ASIOE information. Provided staffing input, review, and comments in specialty areas for draft Army Regulations (AR) & Field Manuals (FM) as required, provided the expertise and technical support to the agencies published Supply Bulletin (SB) SB 8-75-S4, 4 chapters were provided for publication. Coordinated between MRMC, MEDCOM and FORSCOM to insure 30 Soldiers had all their requirements to travel to perform APS-4 upgrade to include mandatory training, forklift licenses, Form 55s, FPPs, finance and itineraries. Also insured that all flights arrived at or close to the same time to insure travel to and from the airport could be accomplished without event.	Provides a single database to assist USAMMA with both internal and external customer requests for Non-Med ASIOE. FPD now has an accurate inventory of TEMPER at the APS sites and can use TEWLS to identify and fill shortages, increasing the readiness at APS sites. Data was used to accurately plan for the RCHD disassembly and determine what containers were sent to Hill AFB for disassembly and what containers full of Non-Med ASIOE that would remain at SIAD. Allowed agency to meet all publication deadlines with appropriate and accurate information. Enabled mission execution within planned timelines.

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
Inter & Intra-agency/department collaboration (Continued)	Pulled and compiled ISO Shelter data from ACAMS, TEWLS and field notes to provide over 1700 lines of information to USAMMDA to help determine the overall costs associated with the rigid wall shelter modernization. Worked with USAMMDA to provide TEMPER testing in order to determine if warehouse stock at SIAD could be used to sustain FORSCOM Units until TEMPER air support is available.	Data will allow USAMMDA to provide accurate information to OTSG LOG to determine the road-ahead for modernization of our ISO shelters. Testing will determine what TEMPER stored in the warehouses at SIAD are still viable to be used to support future needs.
Primary & Alternate Container Control Officers (CCO) Primary & Alternate Container Control Officers (Continued) Team member on the US	Worked with Army Intermodal and Distribution Platform Management Office (AIDPMO) to pull all 'USAH' container data listed under USAMMA. Pulled all Medical Units authorized Office of the Surgeon General (OTSG) owned containers 'USAH' PBUSE data. Updated Army Container Asset Management System (ACAMS). Developed Excess ISO and MILVAN courses of actions for LINs S01291, S01359 and C13825 for the Command. Worked with Hill AFB and AIDPMO to transfer and ship 279 USAH MILVANs from DDHU to Tooele at no cost to USAMMA. Technical Representative on the MRMC/USAMMDA Integrated Product Team (IPT) for Shelter Systems Development. Provided insight, expertise and	Increased AIDPMOs visibility of 'USAH' containers and insured compliance with DoD and Army Regulations and aligns with USAMMA's commitment to property accountability. Allowed the Command to make an informed decision on how to better manage and sustain the large inventory of containers and expandable shelters generated as a result of the RCHD disassembly. Cleared PAD space at DDHU to make room for more containers arriving from SIAD for disassembly while providing AIDPMO containers to fill requirements throughout FORSCOM. Testing outcome will produce a Ground Precautionary Action (GPA) to be issued due to flame failure rates on fabric

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
Army Medical Research and Materiel Command (USAMRMC) Integrated Product Team (IPT) for Shelter Systems Development Effort	coordination on the ongoing soft wall shelter (tent) shelf life testing on TEMPER stored at SIAD and used throughout the medical community.	manufactured during specific contract years.

4.2.4 PRODUCTION ASSEMBLY MANAGEMENT DIVISION (PAMD)

4.2.4.1 MISSION

The Production Assembly Management Division serves as the Army Medical Department (AMEDD) Class VIII commodity manager for standard Sets, Kits and Outfits (SKOs).

4.2.4.2 FUNCTIONS

- **Assemblage Management:** Based on Army priorities, forecasts provided by USAMMA's FI&OD, funding and other Service funding, directs and coordinates the building of service-unique and multi-service medical sets, kits, and outfits (SKOs) with appropriate Defense Logistics Agency (DLA) supply and storage activities and contracted civilian corporations, to include:
  - ✓ Requisitioning/ordering all components (supplies and equipment) of SKOs.
  - ✓ Monitoring building, shipping, and maintaining records of materiel shortages and interim substitutes fielded.
  - ✓ Requisitioning, receiving, and backfilling primary items shortages and substitutes.
  - ✓ Providing DLA assembly sites projected workload forecasts.
- **Tailored UAs / BOM Management:** Manages UIC (unit) specific BOM master data to accommodate new sustainment methodology (providing only UA upgrades and replacements for damaged equipment and those items exceeding their life cycle rather than complete replacement).

- **Build Status and Follow-Up:** Monitors/manages assembly build process—see above.

- **Assembly Related Master Data:** Maintains acquisition sourcing data for Just-In-Time Prime Vendor and ECAT sources.

- **Disassembly:** Manages the process of bringing previously fielded sets back into the depot for disassembly and disposition.

- **Excess Materiel:** Manages the advertisement and disposition of excess materiel; handles inquiries and conducts research to satisfy customer needs.

4.2.4.3 MAJOR EFFORTS OF FY14

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
Set builds	Built new medical equipment sets and upgrade packages to support the following types of units: a. ONS: 1 set. b. Conversion: 319 sets. c. Modernization: 1,218 sets. d. Activations: 102 sets. e. APS: 442 sets. f. Army Contingency Force: 1,219 sets. g. Foreign Military Sales: 115 sets.	Using TEWLS and Indefinite Delivery, Indefinite Quantity (IDIQ) contracts for building SKOs, the PAMD quickly obligated funds to assemble sets for hospital and non-hospital units. SAP also provided the ability to surge its capability in producing SKOs while ensuring the highest possible percent of fill to facilitate gaining units' readiness.
Set build Roll-up	The Division built 3,416 sets assigned to Level I and II units, Hospitals, FSTs and FMS. Distribution of set builds were: 3,317 sets built within TEWLS and 99 sets built through contractor support via the Indefinite Delivery/Indefinite Quantity (IDIQ) contract.	Production Assembly Management Division directed and coordinated the building of service-unique and multi-service medical SKOs with appropriate supply and storage activities to ensure the highest percent of fill and facilitating gaining units' readiness.
Indefinite Delivery/ Indefinite Quantity Contract (IDIQ) Renewal	Implementation of the new IDIQ contract. Effective date of contract: July 2014. This is a supply contract valued at $225,000,000.	Awarded contract provides flexibility for assembly build surge requirements.
Class VIII Excess Program	The Division advertised $47,244,008.22 worth of excess medical equipment/materiel.	Redistributed $111,193.92 in excess medical equipment and materiel.

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
Obligations	Obligated approx $37.5M FL8D OMA and approx $1.3M Reset OMA.	Increased gaining units' readiness for mission requirements.

4.2.5 MATERIEL FIELDING DIVISION (MFD)

4.2.5.1 MISSION

The Materiel Fielding Division (MFD) provides continuous global medical materiel fielding support to all Army component forces with medical requirements in synchronization with ARFORGEN cycles (which are changing as the Sustainment Readiness Model (SRM) emerges) in order to facilitate the provision of healthcare and medical readiness across the operating force.

4.2.5.2 FUNCTIONS

- **Materiel Release, Fielding, and Transfer:** Executes those activities to ensure materiel is safe, suitable, and supportable prior to issuing equipment to gaining organization; ensures the orderly and effective deployment (fielding) and transfer (redistribution) of materiel IAW AR 700-142.

- **ARFORGEN:** Supports the Reset ARFORGEN tenet for the Army Medical Department which is transitioning to the Sustainment Readiness Model (SRM).

- **Materiel Enterprise** (ME): Communicates, coordinates and collaborates with the Materiel Enterprise (ME) as the medical materiel provider to the Army:

  ✓ Liaisons (LNOS): Incorporated five LNOs with Army Field Sustainment Brigades and Battalions (AFSB & AFSBn) to maximize Reset and all medical equipping support to the Army.
  ✓ Medical Equipping: Augments the medical equipping role of the Force Sustainment Directorate, as well as the Agency.

- **Fielding/Sustainment Action Coordinator:** Coordinates fielding or sustainment actions for the Commander, USAMMA.

- **Medical Equipping RESET:** Upon redeployment, return units to the highest level of readiness through Class VIII (equipment only) LIN and NIIN-level fieldings and simultaneously, inducting designated medical maintenance-significant equipment for recapitalization.

- **New Materiel Information Briefings:** Coordinates the introduction of new medical equipment and assemblages with PM offices and conducts New Materiel Introductory Briefs (NMIB) with the gaining unit.

- **Information Management:** Documents all equipment fielded to the force ensuring proper tracking and accountability of materiel fielding transactions within the TEWLS application:

  The following actions are executed:

  ✓ Configures set management within the TEWLS laptop fielding application; maintain program continuity and history.

- ✓ Analyzes, researches and documents business practices; documents program specifications to align set fielding with emerging business practices while garnering efficiencies and maintaining or increasing unit readiness.

- ✓ Maintains technical documents; provides input for TEWLS action items.

- ✓ Conducts QA/QC pre- and post-fielding documentation for Reset, sustainment/ modernization and direct shipments.

- **Property Book Unit Supply Enhanced (PBUSE) Process Management.** Manages and executes the process of ensuring all fielded data is electronically transferred from USAMMA's PBUSE account to the gaining unit facilitating a much greater level of fidelity for their property book. Ensures the data is accurate prior to transmission. Fulfills the requirement established in ALARACT 310-08, Worldwide Program Executive Office, Program Manager (PEO-PM) Equipment Fielding and Accountability using Property Book Unit Supply Enhanced (PBUSE), and ALARACT 092/2013, HQDA Update to Policy – Army Regulation (AR) 710-2.

4.2.5.3 MAJOR EFFORTS OF FY14

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
Materiel Fielding	Total units impacted by MFD in FY14: 287 Units by type of mission: Reset: 83 Modernization: 50 APS: 5 Shortage Closeout: 121 Unit MIPR: 28	287 units were ready to support their respective missions from a medical equipping perspective.
Documentation	Revised Fielding documentation to be more in accordance with AR 700-142 and disposition processes now managed by the Army Sustainment Command (ASC) Lead Materiel Integrator (LMI) Decision Support Tool (DST).	Documentation now meets formal regulatory guidelines and units are being informed of the ASC LMI DST process and how they will disposition instructions.
Personnel	MAJ (b) (6), Chief, retired 28 Feb 14, and MAJ (b) (6) backfilled the Chief Position 15 Aug 14. MILITARY: Three Military Healthcare Logistics Senior NCO positions and one Field Grade Officer position were not filled. CONTRACTORS: 37 Fielding contractors and 5 LNO contractors were on-site.	Deputy Director assumed day-to-day management and oversight of the five civilian personnel. Workload was much heavier for the three on-hand civilian Regional Managers and additional fielding support was provided by the two nonmedical ASIOE SMEs, as well as the PBUSE administrator to cover the gap.

LEADERSHIP AND MAJOR CHANGES OF FY14

Director
LTC (b) (6) (6 Aug 13 – 1 Dec 14)

Deputy Director
(b) (6)

Plans, Operations, and Programs Officer
(Position was vacant during FY14)

Depot Operations Officer
(Position was vacant during FY14)

Production Assembly Management Division
Chief, (b) (6)
Deputy Chief, (b) (6)

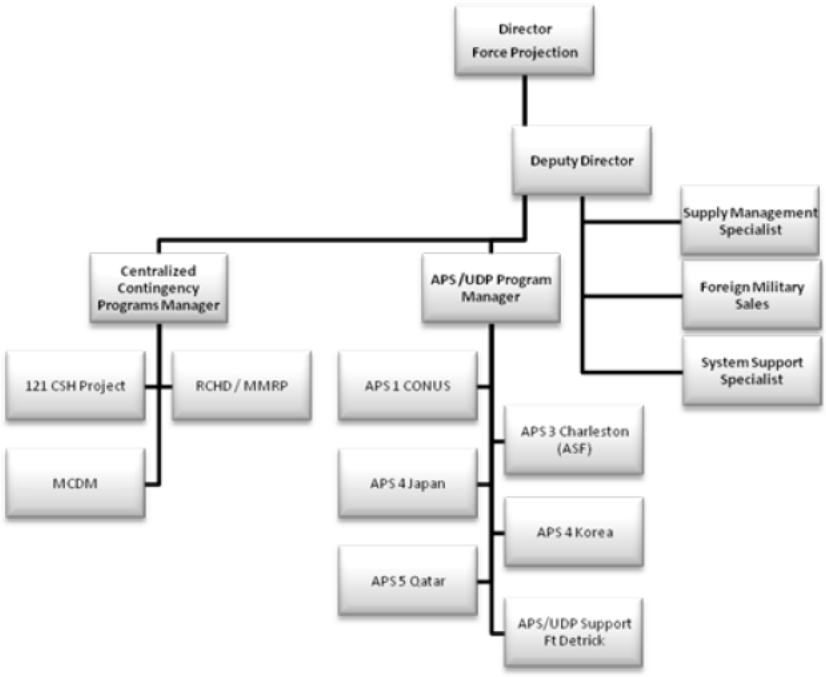
Materiel Fielding Division
Chief, Materiel Fielding Division and Commander of the Medical Logistics Support Team (MLST)
MAJ (b) (6): (16 Jul 12 – 28 Feb 14)

MAJ (b) (6): (15 Aug 14 – Present)

Fielding Operations Officer
(Position was vacant during FY14)

END of Force Sustainment Directorate (FSD)

4.3 FORCE PROJECTION DIRECTORATE (FPD)



4.3.1 MISSION

The FPD manages such programs as the Supply Class VIII portion of the Department of Army (DA), Army Prepositioned Stock (APS) Program [which consists of Brigade/Unit sets, Operational Projects, and Army War Reserve Sustainment (AWRS)].

This and other programs: Office of The Surgeon (OTSG)-designated contingency programs as listed below:

- Medical Chemical Biological Radiological Nuclear Defense Materiel (MCDM);
- Reserve Component Hospital Decrement (RCHD)/Medical Materiel Readiness Program (MMRP); and
- The centralized management of Potency and Dated (P&D) materiel for early deploying Echelon Above Brigade (EAB) medical units, Unit Deployment Packages (UDPs).
- 121st Combat Support Hospital

These programs provide this Agency with the strategic capabilities necessary to support deploying forces.

Responsibilities also include the full range of planning, programming, budgeting, and execution to include Care of Supplies in Storage (COSIS) and contractual obligations for materiel to support Army Operations and the Strategic Planning Guidance. Plans and coordinates with DoD, DA staff, OTSG, DLA, AMC, 121st CSH and other activities, on matters pertaining to functions performed by the Directorate. Additional responsibilities in this Directorate include coordinating the sale or transfer of medical materiel and services to foreign military governments via the foreign military sales portion of the Security Assistance Program.

4.3.2 FUNCTIONS

Managing several Army and Surgeon General readiness programs. These programs include the acquisition, storage, distribution and transfer of prepositioned stocks located ashore and afloat, as well as medical, chemical, biological, radiological, nuclear defense materiel (MCDM) packages and short shelf-life pharmaceuticals, and other materiel.

- **Operations and Planning:**

◇ Activities associated with supporting wartime and other contingency operations

◇ Requirements Determination and Army War Reserve Automated Process (AWRAP): Conducting analyses, determining requirements, and working with appropriate organizations to support the APS program.

- **OPLANS, CONPLANS, and LOGPLANS:** Participate in deliberate planning of Supply Class VIII (medical) full spectrum support for Army components of joint war plans and Army support of other contingencies.

- **Army Prepositioned Stocks (APS) / War Reserve**

◇ APS 1, 2 (new FY14), 3-5 Execution:

- Performing inventory management and COSIS
- Planning and coordinating sustainment and recapitalization

- Working with and providing guidance to forward site managers
- Coordinating with external agencies such as DA and AMC
- Reporting on program status

- **Care of Supplies In Storage (COSIS):** The in-storage inspection, minor repair, testing, exercising, preservation, and packing of materiel and all intra-depot materiel movement to perform those tasks. Does not include any action taken on materiel deficiencies discovered during receipt. (AR 740-3)

- **Program Status and Improvement:** Conducting all management functions and reporting the condition/status of the various projects and units (UICs).

- **Coordination with External Agencies:** Working with all appropriate organizations involved with APS to effectively manage the program.

- **Forward Site Manager Guidance:** Providing guidance and direction to persons physically located at the various APS sites.

Office of The Surgeon General (OTSG) Contingency Programs

- Medical, Chemical, Biological, Radiological, Nuclear, Defense Materiel (MCDM): Provides central management of the initial issue, Individual Service Member (ISM), of MCDM required for mobilization and supports the initial stages of a contingency while allowing the industrial base adequate time to move into full production. Also includes the potency and dated (P&Ds) for the Medical Equipment Set (MES) Chemical Agent Patient Treatment.

- Potency & Dated Materiel (P&D): This program gives USAMMA the ability to "push" Unit Deployment Packages (UDPs) to those initial Echelon Above Brigade (EAB) early deploying medical units that do not maintain on-hand stocks of P&D materiel during peacetime.

- The MMRP is an OTSG program that is planned and centrally managed by the United States Army Medical Materiel Agency (USAMMA) to improve support to the Warfighter. This initiative began in 2007 as part of the AMEDD Investment Strategy (AIS) to support the Army Force Generation Model (ARFORGEN). The program was designed to ensure MMRP Combat Hospitals (CSHs) were maintained in a maximum state of readiness as part of the entire life cycle management. Many lessons learned from the APS and other centralized programs allowed this program to maintain a distinctive advantage in management of the selected CSHs and to maximize resource efficiency. Additionally, MMRP inconjunction with unit home station equipment, assists in ensuring all compos CSHs receive the latest series MMSs and non-Medical ASIOE for contingency deployments whenever available.

- IAW HQDA EXORD 058-13 the CSH equipment sets maintained by MEDCOM at Sierra Army Depot in the Reserve Component Hospital Decrement (RCHD) program will lose association with numbered Reserve Component CSH units. CSH equipment sets maintained in the MMRP program will be available for MEDCOM as the medical Lead Materiel Integrator to align with units in the ARFORGEN trained/ready and available phases. Those sets that are maintained by MEDCOM in the MMRP will continue to be managed, funded, and maintained by MEDCOM and made available to CSH Commanders based on ARFORGEN requirements.

- Program Status and Improvement: Conducting all management functions and reporting the condition/status of the various programs.

- Coordination with External Agencies: Working with all appropriate organizations involved with OTSG contingency stocks to effectively manage the programs.

Security Assistance (Foreign Military Sales) – International Logistics Office (ILO)

The mission of the International Logistics Office is to administer the Foreign Military Sales (FMS) portion of the Security Assistance Program for Class VIII medical materiel and/or supplies, defense articles, services, training, disaster relief efforts and humanitarian assistance.

- Price and Availability (P&A): Develops P&A data provided to a foreign government for planning purposes only, and reflect estimated costs and projected availability of defense articles and services.
- Research and Product Integration: As part of the Total Package Approach, advises FMS customers on product design, capabilities, and compatibility with other USG equipment, installation, maintenance, and repair parts.
- Letters of Offer and Acceptance (LOA): Develops, coordinates, and monitors formal LOAs, which are contractually binding agreements between the United States Government (USG) and a foreign government.
- Case Management and Review: Performs case management to ensure compliance with contract terms, financial commitments, long lead times, and customer satisfaction. Prepares case-management reviews such as Program Management Reviews (PMRs), Financial Management Reviews (FMRs), and Security Assistance Reviews (SARs).

Related Activities: Provides policy and procedural guidance and coordinates the actions related to requests for disaster relief and/or humanitarian assistance.

4.3.3 MAJOR EFFORTS OF FY14

DESCRIPTION	EFFECT / RESULT
APS	
MDEP VWR1, 2 (new), 3-5 and VWSI POM FY16-20 Requirements Development. Initiated development of FY 17-21 Program Objective Memorandum (POM) for MDEP VWR-1-5 and VWSI requirements in preparation for January 2014 briefs.	Developed VWR1-5 and VWSI requirements based on approved APS Strategy .
Participated in DLA Medical Materiel Executive Agent (MMEA) Program Management and Requirements Readiness Team (RRT), formerly the Requirements Work Groups and provide information for all data calls for DLA MMEA to include participating in the MMEA Joint Integration Process Team meetings.	Ensured the Army requirements were included in any policy changes and the development of a tri-service requirements generation system.
Submitted the APS Sustainment Requirement shortages for to DLA-TS for the Medical Contingency File January and July 2014.	DLA-TS reviewed the Tri-Service shortages for potential sourcing on DLA-TS contingency contracts to ensure availability of stocks.
(b) (6) participated in the APS Strategy Workshop in March and (b) (6) particapited in Workshop September 2014.	Provided guidance regarding available CL VIII currently in APS and ensured the ASCCs considered CLVIII requirements when discussing overall APS

DESCRIPTION	EFFECT / RESULT
	requirements.
Executed MDEP VWSI funding.	Received and obligated 100% of funding received $20.1M.
APS-1 KELLYUSA/PERRY POINT	
Contract Number GS-10F-0528N, Order Number W81K04-13-F-0013 CLIN 1007 (ECMM-Support Services) was awarded to CACI to provide medical logistics support services at Kelly USA beginning on 1 October 2013.	Allows for continued logistics supports to provide management and perform COSIS for the APS materiel stored at this location.
Provided guidance regarding priorities of sets to sustain immediately based upon upcoming hurricane season for potential support to the homeland	Sets were prepared for potential issue to support the homeland.
Executed MDEP VWR-1 COSIS funding	Received and obligated 100% of funding received $1.0M.
National	
Army Strategic Flotilla (ASF) III Ship 1 downloaded in Jan and Ship 2 downloaded in May 2014 and and consisted of a 1 Forward Surgical Team (FST), 1 Preventive Medical (PM) Detachment, 1 Vet Service Support Team, 1 Vet Food, 1 Area Support Medical Company (ASMC), 1 Medical Logistics Company, 1 44 Bed Early Entry Hospital Element (EEHE), and 1 Food Procurement and Laboratory Team. . The sets in this units were upgraded to the latest unit assemblages, technical inspections were completed on the maintenance significant equipment. Ship 1 uploaded in May 2014, and ship 2 will upload in Dec 2014.	Performed inventory and maintenance service on MES/DES sets and components in preparation for future upload to ensure the best possible support to war fighter on the battlefield.
Contract Number GS-10F-0528N, Order Number W81K04-13-F-0013 CLIN 1014 (ECMM-Support Services) was awarded to CACI to provide medical logistics support services at Goose Creek beginning on 1 October 2013.	Allows for continued logistics supports to provide COSIS for the APS materiel stored.
Executed MDEP VWR-3 COSIS funding.	Received and obligated 100% of funding received, $1M.
APS-4 JAPAN	
With the assistance of the Medical Maintenance Management Directorate (M3D), All equipment in RCDMH1 – 4 was calibrated and technically inspected during the maintenance cycle in January – March 2014.	Ensured the all equipment is ready and available to meet the health care needs of the war fighter on the battlefield.
With the assistance of the MLST, MH1 was upgraded to the most current “P” series UAs in June 2014.	Ensured most current materiel was on hand and available to support the war fighter.
Received materiel to fill shortages and expiring materiel in 4 Combat Support Hospitals (RCDMH1-4), 8 Minimal Care Detachments (MCA-MCH), Trans Floating Craft, and Three Operational Projects.	Ensured most current materiel was on hand and available to support the war fighter.
Executed MDEP VWR-4 COSIS funding for Japan and Korea.	Received and obligated 100% of funding received for Japan and Korea, $1.8M.

DESCRIPTION	EFFECT / RESULT
APS-4 KOREA	
Procured and delivered materiel to fill shortages and expiring materiel for the Armour Brigade Combat Team (ABCT), the ABCT Authorized Stockage List (ASL), Combat Support Hospital, Three Operational Projects and the Sustainment Unit of Action (SUA).	Ensured materiel was on hand and available to support the war fighter on the battlefield
With the assistance of personnel from the Medical Maintenance Management Directorate (M3D) calibration and technical inspections were completed on all medical equipment on site in April/May 2014.	Ensured all equipment is at the highest readiness and available to support the war fighter.
Executed MDEP VWR-4 COSIS funding for Japan and Korea.	Received and obligated 100% of funding received for Japan and Korea, $1.8M.
APS-5 SWA	
Initiated the fourth option year on the ITT BOSS (CLIN) #4005 AA/AB/AC on contract W52P1J-10-C-0010. The option year expires 30 March 2015.	Ensured USAMMA has personnel onsite to manage the daily activities of the medical materiel to enable the materiel to be readily available to meet the health care needs of the war fighter.
Received materiel to fill shortages and expiring materiel for the Armour Brigade Combat Team (ABCT) and the ABCT Authorized Stockage List (ASL), the Infantry Brigade Combat Team (IBCT) and the ASL, the Fires Brigade, three Operational Projects and one Combat Support Hospital.	Ensured materiel was on hand and available to support the war fighter on the battlefield
With the assistance of personnel from the Medical Maintenance Management Directorate (M3D) all medical equipment was technically inspected and calibrated January/February 2014.	Ensured the medical equipment is available and ready to meet the needs of the war fighter.
Executed MDEP VWR-5 COSIS funding.	Received and obligated 100% of funding received, $1M.
MCDM	
October 2013: Inventory reconciliation being conducted for potential revision of FY14 program expenditure by OTSG. This is due to revised OTSG funding available for program. No issues.	All MCDM inventories were queried to identify the total on-hand inventory using the formula of the MCDM that is available for issue and use (12 months or greater dated materiel) both at the DFP and storage sites. Once identified (b) (6) commenced the task of requesting materiel shortages, all required MCDM were purchased as required. No issues.
January and July 2014, (b) (6) presented the FPD MCDM program to the USAMMA interns	Students were introduced to the MCDM program. This helped enhance the knowledge base of the logisticians most likely to be managing the MCDM Program or supervising personnel managing the MCDM and its requirements. No issues.
February, May and August 2014, SLEP Quarterly Meetings	(b) (6) attended the TMA Quarterly SLEP Meetings as the representative of

DESCRIPTION	EFFECT / RESULT
	not only the MCDM Program, but also as the POC for all ARMY SLEP inventories. (b) (6) submitted priority lists for the testing of MCDM, MEDCOM and Pandemic/Antivirals materials and most importantly for the ARMY ATNAA inventories. The ATNAA inventory that was under a remediation process, as result the extended ATNAA for Army wide programs was for 451,439 each for FY14 cost $7,349,426.92 No issues.
October 2013- September 2014: Attended Meeting for remediation of the ATNAA.	(b) (6) attended meetings and participated is teleconferences as the representative of the MCDM Program. (b) (6) submitted priority lists for the remediation of the ATNAA stocks. No issues.
July 2014: Finished 100% inventory of MCDM materiel within the Joint Medical Asset Repository (JMAR) and the Shelf Life Extension (SLEP) database.	(b) (6) conducted a 100% of the inventories in both the SLEP database and the JMAR database. Line by line the inventories were identified and checked, any discrepancies were noted and the DFP sites POC were made aware of the differences in inventory numbers. All issues were addressed and the Inventory was reconciled. Many issues; all resolved.
August 2014: FY 2014 MCDM Budget Management	(b) (6) actions during the year ensured that all MCDM required to support the Army Warfighters was purchased in its entirety and the budget of $20,396,630.78 was not only obligated but disbursed prior to year end.

UNIT DEPLOYMENT PACKAGES (UDPs)	
Sustained and replenished UDPs in five (5) geographical locations throughout the world (Health and Human Services Supply Service Center, HHS, Perry Point, MD; KellyUSA, San Antonio, TX; Camp Carroll Korea; Sagami Depot Japan; and Camp As Sayliah, Doha, Qatar) during Fiscal Year (FY) 2014.	$8.815M in funding, representing 44% of total annual requirements and 80% of $11.071M in critical and validated Management Decision Evaluation Package (MDEP) HSUK Program requirements was received throughout 2014 to support the Centrally Managed Medical Potency and Dated (P&D) Materiel Program (UDPs). Obligated 100% of the HSUK (APC HD2A) allocation. Total Program requirements for FY14 were $19.725M.

MDEP HSUK Program Objective Memorandum (POM) FY16-20 Process and Brief (November 2013). {Pacific requirements, Defense Chemical, Biological, Radiological, and Nuclear (CBRN) Response Force (DCRF) requirements and severe weather requirements were Critical Requirements.}	Completed MDEP HSUK POM FY16-20 requirements begun in November 2013 and briefed those requirements to Medical Research and Materiel Command (MRMC) medical logistics and PA&E personnel; (b) (6) [redacted] OTSG (DASG-LOZ); and later to the DA G4, Supply Sustainment Program Evaluation Group (SS PEG) Executive. MDEP HSUK requirements across POM years 2016-2020 submitted for funding totaled $82.182M of which $54.391M were critical requirements. The $26.771M projected FY16-20 funding would not support $55.411M in total requirements of which $27.620M were sustainment of critical Pacific, DCRF and severe weather requirements.
FY14 UDP Priorities 1-N list confirmed containing 51 UDPs.	The Pacific Area of Responsibility (AOR), DCRF, and severe weather UDP requirements remain the highest priorities for funding. Of the 51 UDP requirements, there were 29 identified as critical requirements (which were a combination of the highest number of a UDP type required for the Pacific, DCRF and severe weather) and 22 non-critical UDPs of which were seven (7) additional DCRF/severe weather requirements and 15 SWA UDP requirements.
Provide UDP Program presentations to the USAMMA Interns (January and July 2014).	Two intern classes, consisting of Medical Logistics Officers and Non-commissioned Officers received presentations pertaining to the Medical UDP Program. Information relative to the Program's purpose, Program requirements development, Program funding process, and UDP Readiness were provided during both sessions.
Upgraded various N and P Series unit assemblages (UA) to the latest Series UAs (either P or Q) in APS-5 (Qatar), APS-4 (Korea), APS-4 (Japan), and APS-1 (HHS and KellyUSA) (January - September 2014).	P and Q Series upgrades were initiated to specific N and P Series UAs within Priority Groups 1- 29, including Corps Combat Support Hospital (CSH) UDPs, EEHE (44 Bed) CSH UDPs, Forward Surgical Teams (FST) and Area Support Medical Company (ASMC) UDPs.

MDEP HSUK FY14 Execution Plan.	Reviewed FY14 UDP funding requirements based on receipt of $8.815M in HSUK funding (Functional Area HD2A) with the Deputy Director and Chief, ADP/UDP. Discussed anticipated funding allocations, Must Funds (labor and storage), new UDP builds, UDP upgrades, and other supply and equipment requirements.
US Army Medical Command (MEDCOM) Center of Health Care Contracting (CHCC) administered contract for Army UDP-ECMM Support Services (UDP management support at KellyUSA, San Antonio, TX).	Funds in the amount of $373,863.96 were provided to fund UDP CLIN 1008, Contract Nbr. GS-10F-0528N, Order Nbr. W81K04-13-F-0013 providing for three Med Matl Spec (Level I) and two Med Matl Spec (Level II) to manage UDPs at KellyUSA. MIPR0010438612, WBS D.0000186.2
USAF San Antonio Occupancy Agreement (OA) for storage of UDPs at KellyUSA. The previous KellyUSA OA with the Air Force Real Property Agency (AFRPA) expired April 2013 and management of the agreement was transferred to the Air Force Civil Engineering Center (AFCEC).	Funds in the amount of $215,971.70 were provided for FY14 storage of 22 UDPs under Tab 4, LTX16746 USAF San Antonio OA Nbr ATX07849. POP was 01Oct13 thru 30Sep14. MIPR0010455430, WBS D.0000186.3
Exercised Option 4, APS-5 ITT BOS Labor Contract W52P1J-10-C-0010. POP was 1 April 2014 through 31 March 2015.	$112,233.39 in funding was applied to ASG-QA WBS S.0002887.1.5.1 for the Lead Other Country National (Warehouse Supervisor) for CLINs 4005AA, AB and AC at APS-5 Qatar. Qatar WBS S.0002887.1.5.1
Funding for UDP materiel replacement at KellyUSA, San Antonio, TX.	Funding in the amount of $2,520,500.00 was provided for materiel replacement/replenishment of expired and shortage P&D UDP materiel maintained at KellyUSA, San Antonio, TX. (MOA btw USAMMA and AFLMO for Supply Support, dtd 23Mar12, signatories COL (b) (6) and COL (b) (6)). MIPR0010451523, WBS D.0000186.7
Funding for UDP upgrade at KellyUSA, San Antonio, TX.	Funding in the amount of $418,450.00 was provided to upgrade Area Support Medical Company (ASMC) UDP K457AI. (MOA btw USAMMA and AFLMO for Supply Support, dtd 23Mar12, signatories COL (b) (6) and COL (b) (6)). MIPR0010451523, WBS D.0000186.7
FY14 payroll funding provided for three (3) FTE Korean National (KN) employees at Camp Carroll, Korea.	Funds in the amount of $138,945.00 were provided for three KNs to manage one (1) Corps CSH and two (2) 44 Bed EEHE CSH UDPs at Camp Carroll, Korea. MIPR0010431403, WBS

	D.0000186.4.
Funds were provided to cover labor and storage costs associated with management of UDPs for FY14 at HHS Perry Point, MD	Under Agreement Nbr. 9966544, $245,982.14 and $237,168.00 were provided for labor and storage, respectively, to maintain and store UDPs. Total combined costs, $483,150.14. MIPR0010451395, WBS D.0000186.5 and MIPR0010451399, WBS D.0000186.6
UDP associated Shelf Life Extension Program (SLEP) Testing	Funds in the amount of $4,724.07 were provided for FY14 SLEP testing of UDP pharmaceuticals. MIPR0010454629, WBS D.0000186.8
Reimbursed for six (6) UDPs provided for Operation United Assurance (OUA)	Released two (2) ASMC UDPs, two (2) FST UDPs, one (1) Preventive Medicine UDP and specific assemblages of one (1) Veterinary Medicine UDP in support of healthcare operations within the AFRICOM AOR (OUA). Provided KellyUSA $1,024,858 in reimbursed OUA funding to rebuild the above UDPs. MIPR0010608358, WBS S.0030209.1
Reimbursement for 628th FST UDP Release	Funding in the amount of $111,000.00 was provided to USAMMA FPD as reimbursement for the FST UDP released to the 628th FST in support of Exercise Pathways. KellyUSA was tasked to rebuild the FST under MIPR0010589095, WBS D.0000186.12
Non-Tactical Vehicle (NTV) Support to UDP/APS-4 Korea	Funding in the amount of $7,500 was provided to Camp Carroll Korea to cover the cost associated with use of a TMP Vehicle. Korea WBS S.0018143.2.7.128
Leased Vehicle Support to UDP/APS mission requirements at APS-4 Japan	Funds in the amount of $4,699.56 were provided for CLIN 2001, Option Period 2 (17Jul14 thru 16Jul15) for the lease of one (1) 6-PAX Utility Van. Contract # FA5209-12-P-0107. Contract administered by 374CONS LGC. MIPR0010486850, WBS D.0000186.9

APS-4 Japan Site Visit, 25Jun14 thru 11Jul14	The UDP Program Manager conducted a site visit to APS-4 Sagami Japan and acted as Forward Site Manager in the absence of the assigned Forward Site Manager. Performed various site manager tasks, including but not limited to controlled substance accountability and storage and performed a general assessment of the operation.
Overall readiness of the Centrally Managed Medical P&D Materiel Program (UDP Readiness).	Overall UDP Program Readiness Rate (12 month average of monthly readiness) for the 51 UDPs during CY14 was Amber (82.17%).

121st CSH	
DESCRIPTION	**EFFECT / RESULT**
February 2014 LTC (b) (6) and MAJ (b) (6) conduct site visit to dispute a FLIPL against (b) (6) .	Inventory was conducted by USAMMA team that reduced the FLIPL value from $187.381 to $7,684. Upon receipt of the FLIPL, USAMMA proposed an change to the current MOA to discuss property accountability, responsibility, and maintenance
March 2014, Key Resolve Exercise.	Supported Key Resolve Exercise, by deploying B Co assets: OR, CMS, ICU, Lab Gen, Lab Blood, X-Ray.
June 2014, Staffing of draft Memorandum of Agreement for 121 CSH/USAMMA	Property accountability and maintenance has led to a COA to modify the current MOA with 121 CSH. In FEB 14 a FLIPL was initiated against Mr. Parry. Subsequently, 164 bed MTOE TIC "C" equipment items were utilized at Brian Allgood Army Community Hospital (BAACH) for patient care.
February-March 2014 Coordinated to obtain $851k of APS_4 Japan excess	(b) (6) coordinated with USAMMA Chief, APS/UDP and APS-4 Japan Forward Site Manager to obtain $851k of APS-4 Japan excess to fill shortages for the 121st CSH.
Minimal Care Ward Deactivation- July- October 2014	150th MCD receives inactivation orders for 15 OCT 14. USAMMA Forward Site team assisted with dispositions and redistribution 237 lines

	of materiel valued at $17,047.94.

RCHD/MMRP	
DESCRIPTION	**EFFECT / RESULT**
USAMMA FPD and M3D successfully completed the medical maintenance cycles for four MMRP's this FY.	In FY14, the requirement was for each MMRP to have the TIC "C" and TIC "E" items tested/calibrated yearly. The four hospitals were completed successfully and on schedule.
Three MMRP's worth of non-medical stock successfully went thru COSIS. • 39 100KW generators. • 42 M1022 dolly sets. • 48 Forklifts. • 6 Refrigerated containers.	USAMMA FPD Team, in conjunction with Sierra Army Depot (SIAD) successfully preformed Care of Supplies in Storage (COSIS) on Three MMRP's worth of non-medical stock.
510 containers of RCHD/HOSP excess, shipped to Hill AFB for disassembly based on January 2013, "HQDA EXORD 058-13 Disestablishment of the Reserve Component Hospital Decrement(RCHD) PROGRAM". .	In FY14, USAMMA FPD Team, successfully shipped 510 containers of RCHD/HOSP excess medical materiel sets to Hill AFB for disassembly. 206,319 Line Items have been processed for Disposition Services at Hill AFB at a value of $26,543,145.
September 14, FPD (SIAD Site) completed and updated the planograph of the DEPMEDS pad located at SIAD. • 393 MMRP containers. • 245 RCHD containers.	The FPD Forward Site Manager built a planograph for the containers locations of the MMRP and RCHD containers. Each container is provided a separate location for tracking and accountability purposes. Containers are inventoried yearly.
August 14, MAJ (b) (6), Force Projection Directorate, (b) (6) [redacted], Director Maintenance Operations Directorate and CPT (b) (6) [redacted] /Chief, OTSG Contingency Stocks (OTSG-SC) Branch , visit SIAD for an overview of the MMRP/RCHD/HOSP programs.	FPD/M3D Director/ Chief, OTSG-CS s visits the SIAD Forward Site for and overview and update of the MMRP/RCHD/HOSP programs.

DESCRIPTION	EFFECT / RESULT
USAMMA MMRP Support Service Contract March – July 2014	USAMMA contract management team worked with USAMMA technical POCs and USAMRAA to ensure all required documents were complete. Source Selection Board consisted of (b) (6), MMRP Forward Site manager, MAJ (b) (6), Deputy, FPD & Chief, OTSG-CS and (b) (6), Director, FPD completed and contract awarded. There was approximately a 30 day gap in service.
USAMMA FPD and SIAD worked to revise the Interservice Support Agreement (ISSA) for FY 15 for USAMMA to maintain presence at the SIAD site.	The revised Inter Service Support Agreement (ISSA) for MMRP/RCHD programs established clearly defined ground rules to be maintained.
Continued work goes into establishing and maintaining Standard Operating Procedures (SOP), Statements of Work (SOW) and Work Instructions (WI) for the MMRP/RCHD program.	Revised SOPs, SOWs and WIs will ensure continued stability for the program, maintain key partnerships with host site, and keep MMRP/RCHD relevant and cost effective. Once final disposition is received for the RCHD nonmedical ASIOE, work instructions will need to be revised tro transfer to Army activities for the Field Hospital Force Design Update or turn in to Army Material Command.

FMS– CASES
(b) (6) participates in weekly teleconference providing briefings and updates for Iraq, and Afghanistan. (b) (6) also participates in several teleconferences providing updates for Egypt and Georgia. (b) (6) provided briefing to the USARMC commander in preparation for briefing to the Deputy Assistance Secretary for Defense Exports and Cooperation (DASA DEC), during her visit to Fort Detrick. (b) (6) represented USAMMA at a pre-LOR meeting in Kuwait to discuss a proposed FMS case purchasing a new hospital and the medical equipment designated for case purchase.

FMS				
Country	**Designator**	**Case/Amendment/ Modification Amt**	**Total Case Value**	**Remarks**
Afghanistan	C5-B-UAA, A2	$ 1,311,870	$25,102,422	
Afghanistan	H5-B-UCE, A2	$ 276,486	$ 286,163	
Afghanistan	H5-B-UCG, A2	$ 402,651	$ 416,743	
Afghanistan	G5-B-UET, M2	$ (109,285)	$ 3,621,993	
Afghanistan	H9-B-UDR	$ 1,546,422	$ 1,546,422	
Afghanistan	H9-B-UDS	$ 1,268,910	$ 1,268,910	
Afghanistan	H9-B-UDS, M1	$ (91,390)	$1,177,520	
Afghanistan	H9-B-UDY	$ 2,849,614	$ 2,849,614	
Afghanistan	H9-B-UEI	$ 8,895,840	$ 8,895,840	
Afghanistan	H9-B-UEJ	$ 14,746,678	$ 14,746,678	
Azjerbijan	AJ-B-UAL	$ 92,061	$ 92,061	
Burkina Faso	H8-B-MAB			Cancelled
Burkina Faso	H8-B-MAC			Cancelled
Burundi	BU-B-UBH, A1			
Chad	H8-B-MAN	$ 70,365	$ 179,288	
Columbia	CO-B-MVK, M2	$ 223	$ 223	
Georgia	GG-B-UCD, M2	$ (878,084)	$ 157,997	
Israel	IS-B-MBD	$ (14,400)	$ 15,496	
Kenya	KE-B-MAB	$ 1,297,695	$ 1,29,695	
Kenya	KE-B-MAI	$ 10,166	$ 10,166	Line 029
Kyrgyzstan	KG-B-YAT, M1			Line 2
India	IN-B-UAH	$ (180,331)	$ 1,605,184	
	IQ-B-UCY	$ 9,959	$ 9,959	Cancelled

Iraq	C6-B-MLA PI-B-	$ 1,419,360	$ 1,419,360	
Libya		$ 1,775	$ 106,832	
	MTB, A4		$18,993,629	
Philippines	PI-B-MTB, A5	$ 1,775	$18,995,404	
Philippines	SR-B-UAZ	$ 23,184	$ 23,184	Line 017
Saudi Arabia	TW-B-ZAG, M2	$ 0		
Taiwan	TH-B-UAA	$ 238,728	$ 2,699,816	
Thailand			$ 238,728	

Case Closures		**Closed Value**
Country	**Case Designator**	
Afghanistan	E3-B-UDD	$1,689,231.93
Afghanistan	E5-B-UDS	$ 339,673.14
Afghanistan	G5-B-UET	$3,621,992.77
Israel	IS-B-MAU	$ 281,660.84
Israel	IS-B-MAU	$ 285,935.84
Jordan	JO-B-MAK	$ 986,580.00
Korea	KS-B-MZW	$ 47,199.00
Pakistan	G4-B-UOS	$8,994,549.15
Poland	H2-B-MAB	$ 78,816.72
Yemen	YE-B-UAM	$ 430,971.65

FMS – CASES	
(b) (6) prepared FMS Actions in support AFRICOM, EUCOM, SOUTHCOM, Tajikistan FY14 Section 1206 (CT BN Train/Equip) Synch Matrix,	
(b) (6) Participates in weekly teleconference providing briefings and updates for	

Ukraine Case UP-B-UBA, Presidential drawdown program.	

Country	**Designator**	**Case/Amendment/ Modification Amt**	**Total Case Value**	**Remarks**
Chad	C6-B-MLB	$32,308.00	$32,308.00	
Niger	C6-B-MLC	$37,891.00	$37,891.00	
Cameron	C6-B-MLD	$9,173.00	$9,173.00	
Nigeria	C6-B-MLF	$3,590.00	$3,590.00	
Chile	CI-B-UNB	$526,576.00	$526,576.00	
Burkina Faso	J1-B-MAA	$124,842.00	$124,842.00	
Croatia	J1-B-MAB	$267,733.00	$267,733.00	
Latvia	J1-B-MAC	$36,981.00	$36,981.00	
Romania	J1-B-MAD	$26,002.00	$26,002.00	
Burundi	J1-B-MAE	$124,842.00	$124,842.00	
Niger	J1-B-MAF	$127,023.00	$127,023.00	
Tunisia	J1-B-MAG	$44,767.00	$44,767.00	
Croatia	J1-B-UAS	$63,393.00	$63,393.00	
Burundi	J4-B-MAA	$50,008.00	$50,008.00	
Djibouti	J4-B-MAB	$37,230.00	$37,230.00	
Ethiopia	J4-B-MAC	$33,890.00	$33,890.00	
Uganda	J4-B-MAD	$85,099.00	$85,099.00	
UK	UK-B-MAA	$4,314.00	$4,314.00	
Ukraine	UP-B-UBA	$1,706,230.00	$2,072,132.00	
Uruguay	UY-B-MAG	$33,484.00	$33,484.00	
Congo	S4-B-VAK	$51,304.17	$51,304.17	
Bosnia	BK-B-UAC	$103,784.00		

Nigeria	S4-B-UEN	$1,427,049.00		
Croatia	J1-B-MAB	$44,475.00	$44,475.00	
Pricing & Availability (P&A)				
Hungary SOF		$123,606.55		
Y14 YJK		$293,262.08		
Burkina Faso		$191,093.01		
Tranche 2(Burkina Faso)		$97,320.00		
Burundi		$35,004.00		
Croatia		$375,316.30		
Ethiopia		$24,124.00		
Kenya		$94,099.00		
Latvia		$29,836.00		
Niger		$72,937.00		
Uganda		$42,575.00		
UG BY FY14 (Burundi)		$73,592.00		
Uganda		$44,417.00		
Ukraine		$3,806,573.00		
Australia		$6,366.00		Pending Item (On Hold)
Congo		$51,350.00		
Peru		$2,300.00		
Mexico		$41,607.00		
Africa partners		$6,348.00		
Ukraine		$16,000,000.00		IFAK Order
Bulgaria		$18,323.00		
Cameroon		$43,111.00		

Chad		$57,370.00		
Djibouti		$139,700.00		
Niger		$78,814.00		
Somalia		$181,955.00		
Tunisia		$91,059.00		
Uganda		$80,952.00		
Yemen		$70,585.00		
CTS BN LOR		$222,956.00		
Argentina		$697.00		

SYSTEMS	
October 2013 - September 2014 (b) (6) and (b) (6) participated in the various meetings and workshops for the Functional Executive Agent Medical Support (FEAMS). This model is to establish a single computation and management process for Class VIII's surge and sustainment requirements. Also consists of Medical Contingency Requirements Workflow (MCRW) model.	DLA-TS has invested funding to create an information and analytical tool necessary to implement an effective DoD Class VIII requirements management process.
October 2013 - September 2014 MAJ (b) (6) participated in the Readiness Requirements Team (RRT) a chartered group under the MLPC. Meeting minutes are produced at each meeting and are posted on DLA Executive Agent (EA) Planned Implementation/Actions collaborative workspace.	Assists with Tri-Service War Reserve planning computations process.
(b) (6) participated in the modeling sessions and requirements review with USAMMA BSO and SAP consultants for the Medical Assemblage Management Concept (MAMC) as part of an initiative for the AMLE.	MAMC will replace M3PT for Army Units and provide visibility of assets for higher headquarters. MAMC will also be an enhanced version of the TEWLS AMM. MAMC module was implemented Apr/May 2014 for FPD TEWLS sites.
(b) (6) participated in requiremenes review for Item Unique Identification (IUID) implementation for the TEWLS "C" Plants.	Tracking of individual items from acquisition through disposal of IUID relevant materiel to the National Registry.
October 2013 – September 2014 Participated in DLA-TS GENIV Pharmaceutical Business Process Review	(b) (6) participated in workgroup for DLA-TS GENIV Pharmaceutical Business Process Review to include Requirements doucments Review, User Story Review which resulted in the Pharmaceutical Prime Vendor Global Solicitation.

Converting all TEWLS "W" Plants (War Reserve Army Working Capital Funds - Stock Fund" to "C" Plants (Contingency Plants OMA Funds). (b) (6) and (b) (6) particapte in bi-weekly teleconferences with USAMMA Finance and BSO, OSTG, AMC, ABO, DFAS to provide status updates on progress to close "W" plants and decapitalize all Army Working Capital Fund (AWCF) Stock Fund assets. Assets were then captured in the OMA "C" plants. From FPD - (b) (6) and (b) (6) assisted with this effort.	Due to "Sunset" of the Army Materiel Command Commodity Command Standard System-Financial (CCSS-F), based on required funding to maintain this legacy system, USAMMA was approved to convert from the AWCF to OMA funding for the Army Prepositioned Stocks (APS) Program. Moving to OMA funding required USAMMA to decapitalize the APS materiel in the "W" plant and move materiel to the "C" plant for asset management. The last transactions submitted to CCSS-F for cleanup prior to the "Sunset" was 14 Feb 2014.

Leadership and Major Changes of FY14

Director
MAJ (P) (b) (6) (June 2014 – September 2014
(b) (6) (October 2013 – June 2014)

Chief, Logistics Support Coordinator/Deputy
(b) (6) (June 2014 – September 2014)
MAJ (b) (6) (October 2013 – June 2014)

Chief, OTSG Centralized Contingency Stocks
MAJ (b) (6) (October 2013 – June 2014)
CPT (b) (6) (July – September 2014)

END OF FORCE PROJECTION DIRECTORATE

4.4 MEDICAL MAINTENANCE MANAGEMENT DIRECTORATE (M3D)

4.4.1 MAINTENANCE OPERATIONS DIVISION (MOD)

4.4.1.1 MISSION

Provide depot-level maintenance support for standard and selected nonstandard medical materiel to Active Army, U.S. Army Reserve, Army National Guard, authorized Department of Defense (DOD) activities and other Federal agencies. Support is conducted on both a reimbursable and non-reimbursable basis under existing funding and support regulations and established support agreements.

4.4.1.2 FUNCTIONS

- Execution of the AMEDD Maintenance Sustainment Program to include POMing, planning, and execution.
- Wholesale medical materiel maintenance services for the AMEDD.
- Quality Control Management for serviced medical equipment (USAMMA Depots are ISO 9001 Certified organizations).
- Depot-level maintenance operations and support.
- Manage and provide sustainment and depot-level maintenance support services to medical units worldwide, other governmental agencies, and foreign countries under the security assistance program. (Includes RCHD, APS, MMRP, NGB, AC & RC).
- Manage the AMEDD TMDE program relative to stockage, assembly build and distribution, calibration, and repair of special-purpose TMDE.
- Automated Information System Management.
- Operate the Medical Equipment Standby Program (MEDSTEP) for Army TOE medical equipment, as well as a physical examination equipment refurbishment and loan program for MEPCOM.
- Maintain an FDA approved X-Ray tube head rebuild program.
- Provide forward deployed depot level medical maintenance expertise for the Medical Logistics Support Team (MLST) and the Forward Repair Activity - Medical (FRA-M).

4.4.1.3 MAJOR EFFORTS OF FY14

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
Overview of the Maintenance Operations Divisions workload	The Maintenance Operations Divisions supported new equipment fielding's, Army Prepositioned Stock (APS) maintenance cycle's, and sustained 51 National Guard (NG) States and Territories.	The Maintenance Operations Divisions continue to increase readiness of medical units worldwide. We are committed to delivering the highest quality products and services to our customers.
Overview of the Maintenance Operations Divisions workload - Continued	A total of 47,837 work orders were completed. The maintenance functions range from technical inspections to equipment repair and returns, services and calibrations, equipment rebuilds, refurbishments, and overhauls.	
Wholesale Support (includes equipment inspections and services)	Completed over 12,020 wholesale maintenance work orders supporting Army Medical Department (AMEDD) Assembly and Fielding as well as the Army's unit reset program	Provided medical readiness to the force.

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
ISO Recertification Surveillance Audit	The Medical Maintenance Management Directorate (M3D) completed a final annual Quality Management System (QMS) surveillance audit (performed by Orion Registrar, Inc.), in support of International Organization for Standardization (ISO) 9001:2008 recertification.	No post-audit QMS conformance findings (major or minor) were identified within the M3D organization. Successful audit completion highlighted the overall effectiveness of M3D QMS implementation and its organizational employment of best business practices. It further demonstrates the M3D's total awareness and dedicated commitment toward providing high-quality medical maintenance products and services that efficiently meet customer requirements/ expectations, focus on patient safety, and contribute to a tangible improvement in realized cost savings to the Army.
Refurbished recapitalized medical equipment items	Refurbished 1,485 medical equipment items with an acquisition value of $11,932,509 for a maintenance cost of $1,862,600.	Cost avoidance of $10,041,830.

4.4.2 AMEDD MAINTENANCE SUSTAINMENT PROGRAM

4.4.2.1 MISSION

optimize the total Army maintenance capability to support the war fighter's OPTEMPO requirements across the full spectrum.

4.4.2.2 FUNCTIONS

- Provide responsive, effective medical maintenance support to Army units thereby improving materiel readiness.
- Provide visibility of total Army medical maintenance requirements.
- Increase flexibility to meet un-programmed/surge requirements by balancing and reallocating medical equipment maintenance workload among maintenance support organizations.
- Achieve maximum cost effectiveness in accomplishing medical equipment maintenance operations by adopting a 'repair more, buy less' philosophy.
- Maximize synchronization between MTF/TDA and unit/TOE for maintenance support.

4.4.2.3 MAJOR EFFORTS OF FY14

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
Coordinate with FORSCOM to develop internal tasking capability	Internal tasking capability to supports integrating FORSCOM 68A repairers into program.	Utilize FORSCOM 68A medical equipment repairers to service FORSCOM equipment and provide mentorship training to the FORSCOM 68A. Provides 68A the opportunity to enhance their skills and increases confidence.
AMEDD Sustainment Maintenance National Guard Support	Provided sustainment maintenance for the National Guard units at 51 States and Territories. Tobyhanna completed its 20 States and 3 Territories. Hill completed all 18 States and Territories in their region. Tracy provided maintenance services to all 12 States in their region.	Performed complete preventive maintenance services and calibrations on all medical equipment at each National Guard installation visited. Provided customers with follow-on maintenance support information and guidance for services unable to be satisfied on site.

4.4.3 MAINTENANCE READINESS PROGRAM

4.4.3.1 MISSION

Provide management and oversight of medical maintenance requirements in support of prepositioned medical equipment.

4.4.3.2 FUNCTIONS

- Coordinate maintenance missions.
- Coordinate maintenance resources.
- Track and monitor equipment readiness

4.4.3.3 MAJOR EFFORTS OF FY14

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
Maintenance actions in support of Army Prepositioned (medical) Stocks	Successfully complete preventive maintenance services, calibrations, and electrical safety.	Provided medical maintenance support at Sagami Army Depot (Japan), Camp Carroll (Korea), and Qatar APS site. APS-3 Charleston: completed 292 items. APS-5 Qatar: completed 1,915 items in one CSH, two BCTs, and sustainment projects.

4.4.4 TOBYHANNA DEPOT CENTER OF EXCELLENCE

4.4.4.1 MISSION

MMOD-Tobyhanna is the center of excellence for audiometer calibration, optical equipment, dental hand-piece rebuild, Military Entrance Processing Station (MEPS) Direct Exchange (DX) program, TOE laboratory equipment, and the AMEDD X-Ray acceptance program.

4.4.4.2 FUNCTIONS

- Provide depot level medical maintenance support for Army TOE medical equipment.
- Support the AMEDD Maintenance Sustainment Program.
- Provide expertise to the FRA-M.

4.4.4.3 MAJOR EFFORTS OF FY14

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
Medical Equipment (R&R)	Tobyhanna completed 2950 work orders on a repair and return basis, of which 833 were dental Handpieces.	Provides Repair and Return services for Army TOE Units' medical equipment.
Dental Hand piece Repair	Tobyhanna provided in-house dental hand piece repair/rebuild services on 1,666 hand pieces at a cost of $97,529.	Estimated vendor cost for like services is $146,608. A cost savings of $49,079 resulted.
Support of MEPCOM equipment	Tobyhanna provided services on 690 items for the Military Entrance Processing Stations (MEPS).	Tobyhanna provides a cost savings to the AMEDD by performing this mail-in exchange service.
Annual Workload Summary	Tobyhanna generated 22,913 work orders for 23,746 items. TOE equipment serviced 84% TDA equipment serviced = 16%. Total man- hours expended was 41,684.	The highest quality equipment was provided for worldwide fieldings, special projects, and contingencies. Complete preventive maintenance services, calibrations, electrical safety, and repairs to both TOE and TDA customers.

4.4.5 HILL AFB DEPOT CENTER OF EXCELLENCE

4.4.5.1 MISSION

MMOD-Hill is the center of excellence for anesthesia, pulmonary, and field medical equipment.

4.4.5.23 FUNCTIONS

- Provide depot level medical maintenance support for Army TOE medical equipment.
- Support the AMEDD Maintenance Sustainment Program.
- Provide expertise to the FRA-M

4.4.5.3 MAJOR EFFORTS OF FY14

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
Annual Workload Summary	Hill generated 24,748 work orders on 26,052 equipment items. TOE equipment serviced (23,968) = 92%; TDA equipment serviced (2,084) = 8.0%. Total man hours expended 27,585.	The highest quality equipment was provided for worldwide fieldings, special projects, and contingencies. Complete preventive maintenance services, calibrations, electrical safety, and repairs to both TOE and TDA customers.
Continued to expand and improve critical repair parts support worldwide.	Received requests for Class VIII repair parts support which provided the customer with (9476) parts totaling approximately ($1,199,308); provided (18,60.94) repair parts totaling ($1,772,589.) for work orders for refurbishment/repair of critical medical equipment.	Allowed deployed/deploying medical maintenance personnel to quickly repair hundreds of critical medical equipment items to support the warfighter.
Introduction of DMLSS	Continue to improve utilization of Medical Maintenance Automation System DMLSS.	Although not fully realizing the full capability of DMLSS we are working through and have developed new processes to improve shop operations particularly the supply module resulting in consistent flow and availability repair parts.

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
GFEBS Activation	All Government Purchase Card purchases requirement creation of purchase request (PR) in GFEBS and approval prior to making any purchases.	This process ensure availability of funds prior to making purchases. Although the process provides better control of funds being spent it has added some delays (2 to 5 days) in purchasing repair parts, mainly waiting for the PR approval process.

TEWLS Implementation Nov 2014	TEWLS for equipment inventory and IUID tagging of equipment in compliance with DOD UID mandate.	In preparation for TEWLS implementation 100% conducted which went very well. Implementation of TEWLS is going well although working through learning process and developing various work instructions for each of the processes as equipment flows through TEWLS.

4.4.6 TRACY DEPOT CENTER OF EXCELLENCE

4.4.6.1 MISSION

MMOD-CA is the Center of Excellence for medical imaging equipment, special purpose, test, measurement & diagnostic equipment (TMDE-SP), and serves as a training platform.

4.4.6.2 FUNCTIONS

- Provide depot level medical equipment sustainment maintenance for Army Operational units.
- Manages 12 states of the USAMMA Medical Maintenance Management Directorate's National Guard Sustainment Maintenance Program.
- Provides expertise and staffing to the Forward Repair Activity-Medical, (FRA-M).
- Operates the TMDE-SP Service Center for all Army units.

4.4.6.3 MAJOR EFFORTS OF FY14

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
Annual Workload Summary	Completed 22,298 work orders.	The highest quality equipment was provided for worldwide fieldings, special projects, and contingencies. Complete preventive maintenance services, calibrations, electrical safety, and repairs to both TOE and TDA customers.
Test Measurement and Diagnostic Equipment (TMDE)	Tracy provided calibration and return services for 2,919 TMDE-SP equipment items.	Provides Calibration services for Army TOE Unit TMDE-SP.
Medical Equipment (R&R)	Tracy completed 584 work orders on a repair and return basis.	Provides Repair and Return services for Army TOE Unit medical equipment.

Technical Inspection for Issue, Medical Equipment (TI)	Completed 5,712 services for equipment fieldings.	Ensured the medical equipment issued was calibrated; this enabled MMO-S to successfully upgrade various medical units with new MES/MMS.
Technical Inspection for Issue, TMDE (CAL)	Completed 1,510 services for equipment fieldings.	Ensured the Special Purpose TMDE issued was calibrated; this enabled MMO-S to successfully upgrade various medical units with new TMDE sets.

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
Refurbished Medical Equipment Items for Issue	Recapitalized 227 equipment items by refurbishing for the wholesale mission.	Refurbished $4.5M worth of equipment for $606K, providing a cost avoidance of $3.9M. Items refurbished were; High capacity X-Ray systems, Computed Tomography Scanners, ISO Shelters, Computed Radiography Readers, Ventilators, Defibrillators, Patient Monitors, and Suction Apparatus.
Completed Inventory of all Medical Equipment assets on-site for inclusion to TEWLS and DMLLS	General Biomedical and Imaging equipment totals: A Stock 1080 units 22,119,418.00. K-Stock 1222 units $60,772,298.00. TMDE equipment totals. A Stock 621 units $3,024,153.23. K Stock units 386 $2,385,590.48.	Allow Depot Management to accurately assess ability to meet known customer requirements. Enable manpower staffing recommendations.
Implemented Fluke Automated Test equipment (ATE)	Enables automated calibration of ESA 612 Electrical safety Analyzer, Impulse 4000 Tester Defibrillator, Impulse 7000 Tester Defibrillator, MPS 450 Patient Simulator, 217A Patient Simulator.	Fluke ATE enabled an average of 42% reduction in Calibration and Verification man-hour requirements. Based on completed items in FY 14 a savings of 879 man-hours and $43,975.00 in labor cost were realized.

Conducted 100% Supply Inventory	Identified 1048 unique line items with a total of 33,021 parts on hand.	Enable Depot Management to properly plan and execute maintenance requirements.
Conducted Inventory of all ISO Shelters and Milvans	Identified 1801 equipment items that require Technical Evaluations for disposition.	Enable Government to Recapitalize equipment items or turn them into DRMO to reduce storage limitations.

4.4.7 SIERRA ARMY DEPOT MEDICAL MAINTENANCE ACTIVITY

4.4.7.1 MISSION

Provides medical maintenance services to the OTSG managed Reserve Component Hospital Decrements and the Medical Material Readiness Program Combat Support Hospitals

4.4.7.2 FUNCTIONS

- Maintain RCHD medical equipment to -10/20 standard.
- Maintain the MMRP CSH medical equipment to -10/20 standard.

4.4.7.3 MAJOR EFFORTS OF FY14

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
Annual Workload Summary	Sierra completed 4,325 work orders. Total man hours expended 11,446.	Complete preventive maintenance services, calibrations, electrical safety, and repairs for 4 MMRP Combat Support Hospitals.

4.4.8 JAPAN MEDICAL MAINTENANCE ACTIVITY

4.4.8.1 MISSION

Maintain four (4) Combat Support Hospital and eight (8) Minimal Care Detachment medical equipment -10/20 standard.

4.4.8.2 FUNCTIONS

Service field level equipment items to -10/20 standard.

4.4.8.3 MAJOR EFFORTS OF FY14

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
Medical equipment repairers on the ground at the APS-4 Japan site are able to maintain field level equipment cyclically	Repairers provide equipment maintenance service to ensure equipment is -10/20.	APS-4 Japan: Serviced 4,006 items in four CSHs and 8 minimal care detachments.

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
Medical equipment repairers on the ground at the APS-4 Japan site are able to maintain field level equipment cyclically (Continued)	Repairers stationed at Japan provide Field level services; Depot level repairers provide augmentation teams IOT service Sustainment level equipment.	
Maintained field level equipment to -10/20 standard	Total of three technicians maintained the equipment designated field level to -10/20 standard.	The four CSHs and eight MCD are maintained and ready.

4.4.9 KOREA MEDICAL MAINTENANCE ACTIVITY

4.4.9.1 MISSION

Maintain Combat Support Hospital, two (2) Brigade Combat Support Teams, and one sustainment package medical equipment to -10/20.

4.4.9.2 FUNCTIONS

Service field level equipment items to -10/20.

4.4.9.3 MAJOR EFFORTS OF FY14

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
Medical equipment repairer on the ground at the APS-4 Korea site is able to establish and maintain field level equipment cyclically	Repairers provide equipment maintenance service to ensure equipment is -10/20. Repairer stationed at Korea provide Field level services; Depot level repairers provide augmentation teams IOT service Sustainment level equipment.	APS-4 Korea: completed 1,716 items in one CSH and one BCT. Supported site in April with maintenance cycle of five depot technicians.

4.4.9 FORWARD REPAIR ACTIVITY - MEDICAL (FRA-M)

4.4.9.1 MISSION

The Forward Repair Activity-Medical (FRA-M) services the Iraq/Afghanistan theater of operations. During their rotational service, the team of technicians provide technical expertise in three unique specialties (Imaging, Laboratory, and Pulmonary) servicing and ensuring that the equipment is mission capable while simultaneously providing mentorship and technical assistance to the Biomedical Equipment Repairers (MOS 68A).

4.4.9.2 FUNCTIONS

- Provide maintenance expertise for TOE Medical Imaging Systems.
- Provide maintenance expertise for TOE Laboratory Equipment.
- Provide maintenance expertise for TOE Pulmonary Equipment.
- Provide maintenance expertise for TOE Oxygen Generation Equipment.
- Mentor and provide hands on training to deployed 68As.

4.4.9.3 MAJOR EFFORTS OF FY14

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
Deployed multiple FRA-M teams/rotations to support the theater	USAMMA provides the Army's only deployable depot level medical maintenance experts. FRA-M personnel include 68A (first ever enlisted soldier supporting the FRA-M) training with industry soldier.	Provided medical maintenance expertise to Afghanistan and Iraq.

4.4.10 NATIONAL MAINTENANCE PROGRAM (NMP)

4.4.10.1 MISSION

The National Maintenance Program (NMP) provides guidance and assistance to US Army Medical Materiel Agency (USAMMA) organizations, external commands, and deployed Biomedical Equipment Specialists (BES') through effective policy and strategic support in the area of maintenance during the development, acquisition, sustainment, and disposition of medical equipment. The NMP is committed to customer satisfaction as evidenced through implementation of its International Organization for Standardization (ISO) 9001:2008 registered Quality Management System (QMS).

4.4.10.2 FUNCTIONS

1. Develop, draft, review, update, publish, and integrate regulations, forms, policies, programs, and processes that delineate in detail how the Army Medical Department's (AMEDD's) medical maintenance operations will meet or exceed the Army's single maintenance standard requirements.

2. Provide enterprise-level maintenance analysis, utilizing institutional knowledge and multiple informational systems—including but not limited to ECRI, Property Book Unit Supply Enhanced (PBUSE), Logistics Information Warehouse (LIW), Integrated Logistics Analysis Program (ILAP), BI Discoverer, Theater Enterprise-Wide Logistics System (TEWLS) and Joint Medical Asset Repository (JMAR). Analyze, forecast and report the capabilities and capacities of sustainment maintenance operations and track their reported support activities and medical device readiness. Identify critical trends and/or opportunities for improvement. Develop effective solutions and propose course(s) of action. Following-up and coordinate maintenance support and implementation of solutions to assure improvement to existing and emerging issues.

3. Assess tactical medical units' maintenance operations and medical maintenance management processes, initial training and sustainment training programs, and over-all quality of maintenance programs. Identify gaps in capabilities, opportunities for improvement, and recommend changes to doctrine, strategic direction, business processes and policy to increase global medical equipment readiness.

4. Serve as the primary Army Medical Department (AMEDD) maintenance policy Subject Matter Experts (SME) resource in support of the medical and non-medical (Associated Support Items of Equipment (ASIOE)) Life Cycle Manager's Integrated Logistics Support processes. Review maintenance plans to assure compliance with established standards, ensure strategic and operational feasibility, determine implication to existing or emerging policies and training, assuring continuity between strategic maintenance plans while optimizing functional support, leveraging resources, and lowering life cycle costs.

5. Provide representation of tactical medical maintenance activities, coordinating medical maintenance data and metric requirements with logistics automation developers. Serve as the SMEs for Automation Information Systems (AIS) that are responsible for medical equipment accountability, medical maintenance and Class VIII repair parts support. Together these systems help tactical medical maintenance operations in garrison and in theater deliver quality, effective medical equipment preventative and sustainment maintenance operations.

6. Research, analyze and adjudicate maintenance related issues, as defined in existing, and newly revised and proposed Federal Regulations, Codes and Guidelines.

Respond to challenges to regulations, policies, and business processes elevated by the logistics and medical maintenance communities and/or resulting from after action reports and lessons learned. Represent those communities and coordinate change requirements with the Army Medical Logistics Enterprise (AMLE), the Defense Medical Logistics Enterprise (DMLE), USAMMA leadership and other Army commands.

7. Serves as the AMEDD's representative to the Army's Program Director for Test, Measurement and Diagnostic Equipment (TMDE), reviewing all AMEDD TMDE requests for compliance with existing policy. Provide representation at procurement and assessment meetings for the tactical medical units' TMDE emerging requirements and concerns. Monitor effectiveness of TMDE for accomplishing maintenance and make recommendations for TMDE upgrades to the USAMMA, Project Manager-Medical Devices (PM-MD); manage the Preferred Items List (PIL) on the USAMMA website and update the PIL with TMDE based upon current technology and increased capabilities.

8. Provide regulatory and technical oversight to the TMDE-Special Purpose (SP) calibration operations. Provide enterprise-level compilation, review and detailed analysis of TMDE Support Center (TSC)--Tracy Army Depot and United States Army Medical Materiel Center-Europe (USAMMCE)--monthly metrics. This analysis of TSC monthly metrics explains noncompliance factors, issues, failures and other deviations from published program performance standards for required completion rates, tolerance standard failure, calibration rework, and customer satisfaction.

9. Provide AMEDD enterprise-level data aggregation, review, and subject-matter detailed analysis in support of, and future planning of, numerous AIS' (i.e., Defense Medical Logistics Standard Support (DMLSS), Standard Army Maintenance System (SAMS), Global Combat Support System-Army (GCSS-ARMY), PBUSE, etc.). This detailed analysis provides Senior Leadership—Army Commands, Army Medical Logistics Enterprise Leadership, and 6th MLMC--with critical maintenance and resourcing data that aids their decision and planning process. This results in improved support of the operating and generating force, while maximizing repair support, assuring command level visibility of maintenance metrics and minimizing support costs.

10 Provide determination of maintenance significant medical devices and editorial review of maintenance significant content to the Medical Materiel Quality Control (MMQC), Field Change Order (FCO), and 'Safety of Use' message process. Provide oversight to those items deemed maintenance significant. This oversight includes researching maintenance implications, specific work to be performed, and what capabilities are available and required. Contacting the Original Equipment Manufacturer (OEM), and other sources (ECRI) validating the maintenance specifics, proposed processes and procedures. Researching various systems to determine the on-hand inventory of the specific items (often to serial number detail) to gauge the impact to patient-care. Maintaining an internet based (Common Access Card (CAC)- Required) site, that AMEDD activities use to report the status of this critical work. Aggregating all those data points to determine depot assistance requirements, or other means of assistance as required, and coordinating maintenance support requirements between equipment Life Cycle Managers, using units, depots and equipment manufacturers. Serve as the lead agent for coordinating MMQC, FCO and recall information support and tracking across the tri-services.

11 Serves as the AMEDD's Maintenance Master Data File (MMDF) proponent that coordinates with the US Army Materiel Command, Logistics Support Activity (USAMC, LOGSA) and the Headquarters, Department of the Army, Office, Deputy Chief of Staff (HQDA ODCS), G–4, to submit addition, correction, and deletion requests for medical devices to the LOGSA Quarterly MMDF Review Board.

Management includes the proactive identification of medical devices assuring accurate and complete cataloging and coding of reportable and pacing items from the Acquisition Life-Cycle Management Process to assure devices are properly and efficiently added, updated or dropped from the MMDF.

- Resourcing. The USAMMA NMP provides SMEs and models to support the Training Resource Model, Program Objective Memorandum (TRM, POM).

4.4.10.3 MAJOR EFFORTS OF FY14

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
Medical Materiel Quality Control (MMQC) message review, verification, and tracking	The National Maintenance Program (NMP) performed pre-release review and verification of 299 MMQC messages for maintenance significant item applicability and determination of equipment locations within the Army arsenal.	NMP participation contributed to patient/staff safety by ensuing appropriate actions were taken to communicate accurate MMQC messaging. The NMP additionally served to verify responsive repair of 165 impacted equipment items within the Army medical inventory.

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
Maintenance Master Data File (MMDF)	The National Maintenance Program (NMP) continued to manage the MMDF for medical equipment currently numbering over 600 total items and over 160 reportable items.	The NMP submitted 151 recommendations for change (including additions and deletions), and submitted a list of non-standard equipment to the US Army Medical Materiel Agency, Project Manager Medical Devices (USAMMA. PM-MD) for review. All 151 submissions were accepted at the Logistics Support Activity (LOGSA). The coordinated effort between NMP and PM-MD will lead to a more meaningful list of equipment on the MMDF stemming from the elimination of items that should not be carried on the MMDF and correct cataloging of equipment items designated to remain. 128 of 151 items were identified for removal.
Major revision of Technical Bulletin Medical (TB MED) 750-1	The National Maintenance Program (NMP) implemented a revision of TB MED 750-1.	This comprehensive TB revision involved incorporating medical maintenance guidance and policy from other publications.
Major revision of Technical Bulletin Medical (TB MED) 750-1 - Continued		The focus of this revision was to: • Establish a single point of guidance/policy reference for Biomedical Equipment Specialists. • Eliminate redundant/outdated guidance and policies. This revised TB MED 750-1 edition combines information content from currently issued TB MEDs 750-1 and 2 as well as from other TBs, including: TB MED 7, TB MED 521, and TB 38-750-2.
Support to US Army Forces Command (FORSCOM) Command Maintenance Discipline Program (CMDP)	The National Maintenance Program (NMP) provided ongoing technical and maintenance systems assistance in support of the FORSCOM CMDP.	Technical and maintenance systems support provided to the FORSCOM by the NMP involved the preparation of eight installation-level Command Supply Discipline Program (CSDP) analytics validating equipment maintenance and accountability. This effort encompassed over 1000 Modified Table of Organization and Equipment (MTOE)

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
		units with 89, 000 medical devices and sets valued at over $234 million dollars. Effective command maintenance program enforcement instilled by the FORSCOM CMDP validates medical maintenance compliance, enforces fiscal responsibility, identifies medical logistics challenges, and provides visibility to the medical maintenance community. This initiative led to a marked increase in the availability of medical equipment maintenance and reporting data.
National Maintenance Program (NMP) Quality Management System (QMS) and International Organization for Standardization (ISO) 9001:2008 Registration	Continually assess and document the NMP QMS goals and objectives focused on improving products and customer satisfaction.	The NMP successfully completed one QMS internal audit as well as two management reviews that were performed at six month intervals for continual and continuous process improvement. These were conducted in direct support of the annual US Army Medical Materiel Agency, Medical Maintenance Management Directorate (USAMMA, M3D) QMS external audit which will be performed by an independent certified ISO Registrar in January 2015. In anticipation of a successful external QMS audit outcome, the NMP expects to retain its ISO 9001:2008 certification status for calendar year 2015. Re-certification validates the NMP's focus on standardizing internal processes and performing at the highest level of quality to achieve customer satisfaction.
Department of Defense (DD) Form 2163 and Technical Bulletin (TB) 38-750-2 (review/ update/fielding)	The National Maintenance Program (NMP), in close collaboration with Air Force and Navy medical maintenance representatives, reviewed and improved DD Form 2163. The NMP facilitated development, staffing, and implementation of the new DD Form 2163 design while coordinating the revision,	The newly approved DD Form 2163 is smaller than the original it replaced making it easier to affix to the front of most medical equipment. This will allow equipment operators to easily identify the '*last serviced by*' date for equipment to be used on patients and will significantly improve patient safety.

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
	staffing, and publication of TB 38-750-2.	
Semiannual FOCUS newsletter	The National Maintenance Program (NMP) designed, drafted, developed, and published two editions of the Medical Maintenance Management Directorate FOCUS newsletter.	The FOCUS newsletter contains articles covering current, relevant issues impacting medical maintenance activities in both the Table of Distribution and Allowances (TDA) and Table of Organization and Equipment (TOE) environments. This communication tool is intended to keep all members of the biomedical maintenance community informed of key issues that contribute to improved management effectiveness and efficiency of their medical maintenance operation.
FY 2013 US Army Medical Materiel Agency (USAMMA) Historical Report	The National Maintenance Program (NMP) facilitated the update, formatting, and editorial review of the Fiscal Year (FY) 2013 USAMMA Historical Report.	NMP preparation of the FY 2013 USAMMA Historical Report included a comprehensive rollup of annual performance contributions across the entire agency.
US Army Medical Materiel Agency (USAMMA) Integrated Logistics Support (ILS) process implementation	The National Maintenance Program (NMP) furnished technical support for equipment centric USAMMA ILS process improvements.	The NMP reviewed and provided critical technical recommendations for improving AccuTemp AX56L Bio Refrigerator/Freezer, CP200 ECG, and portable coagulation analyzer maintenance plans.
Supply Bulletin (SB) updates	National Maintenance Program (NMP) Subject Matter Experts (SMEs) reviewed medical maintenance content applicable to existing SB publications and authored change recommendations for SBs 8-75-S1, 8-75-S6 and 8-	NMP review and technical change recommendations resulted in a number of medical maintenance related improvements designed to improve the accuracy, completeness, reliability, and usability of SBs 8-75-S1, 8-75-S6 and 8-75-S10 including updated guidance on the use and implementation of the Maintenance Master Data File (MMDF).

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
	75-S10.	
ECRI Institute Health Device Alert License and Health Devices (HD) Gold Suite of Services contract	The National Maintenance Program (NMP) successfully worked to obtain Army contract licensing for ECRI Alerts Tracker, BioMedical Benchmarking, and the HD Gold suite of services. Recognizing that these services were also procured under separate contract agreements administered by the departments of the Air Force and Navy, the NMP successfully collaborated with these services as well as the Defense Health Agency (DHA) to leverage the software needs of all three services by merging them into a single Department of Defense (DoD) contract.	The NMP worked in collaboration with the DHA to leverage the medical equipment hazard, alert, and recall communication needs of the Army, Air Force, and Navy. In doing so, a consolidated DoD contract it awarded. This contract met the needs of each service while reducing overall contract administration costs giving DoD a greater overall savings advantage.
Cooperative Unit Data Analysis (CUDA)	The National Maintenance Program (NMP) developed and implemented an enterprise-level Table of Organization and Equipment (TOE) data retrieval, analysis, and assistance process designed to: • Extract and analyze relevant unit-level maintenance data from the Logistics Information. Warehouse (LIW).	The CUDA program initially began as an effort to research and analyze unit-level medical equipment maintenance, accountability, and reporting data for the US Army Forces Command (FORSCOM). Since project inception, however, Active Army and US Army Reserve Command (USARC) units have requested supporting information derived from CUDA and have additionally requested both CUDA and LIW applications training from the NMP. The CUDA effort has since evolved into an important Global Combat Support System-Army (GCSS-Army) support effort.

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
Cooperative Unit Data Analysis (CUDA) - Continued	• Furnish analyzed data to unit-level Biomedical Equipment Specialist (BES) managers. • Provide technical assistance to unit-level BES managers, as requested. • Provide Major Commands (MACOMs) with a quarterly rollup of their unit-level maintenance status/posture. • Establish an annual medical maintenance award system. • Confirm and document both continuous and continual improvement in maintenance readiness to the Army Medical Logistics Enterprise (AMLE).	
Information Paper: Steam Operated Field Sterilizer	The National Maintenance Program (NMP) prepared a field sterilizer information paper addressing the root cause of an ongoing chamber collapse issue.	This information paper was prepared to convey potential causes of chamber collapse applicable to the Steam Operated Field Sterilizer (National Stock Number (NSN) 6515-01-926-2151, Line Item Number (LIN) S39122). Information provided will be used to avoid future steam operated field sterilizer chamber failures.

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
Global Combat Support System-Army (GCSS-Army) analysis	The National Maintenance Program (NMP) led US Army Medical Materiel Agency (USAMMA) and US Army Medical Command (MEDCOM) efforts to analyze GCSS-Army.	Analytical efforts introduced by the NMP brought GCSS-Army to the forefront of MEDCOM awareness and prompted the MEDCOM, Directorate of Combat and Doctrine Development (DCDD), and G 46 to begin sharing requirements information with the US Army Combined Arms Support Command (CASCOM). They additionally began preparing a strategy for operating forces that own medical equipment. The NMP continues to have an extensive involvement in the planning process including areas such as conversion and post-conversion support.
Life Cycle Equipment Record (LCER)	The National Maintenance Program (NMP) championed an effort to develop a customer-facing single portal for medical materiel information.	The LCER has become one of the US Army Medical Materiel Agency's (USAMMA's) principle development initiatives. Although the NMP is not a project lead for this effort, it continues to work with other directorates in order to foster continuing advancement of this initiative through its role as Subject Matter Expert (SME).
Correction of Test, Measurement, and Diagnostic Equipment (TMDE) cataloging inconsistencies	The National Maintenance Program (NMP), in collaboration with several Table of Organization and Equipment (TOE) medical units throughout the US Army Forces Command (FORSCOM), identified TMDE-Special Purpose (SP) cataloging problems in Technical Bulletin (TB) 43-180 and resultant TMDE Support Centers (TSCs) support services.	TMDE-SP has been assigned National Stock Numbers (NSNs) with incorrect Federal Supply Classes (FSCs) as well as incorrect calibration/repair and return service codes. Incorrect codes also contribute to problems with TMDE Integrated Maintenance Management System (TIMMs) accountability, identification of TMDE-SP support activities, and funding for TMDE shipping support.

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
Correction of Test, Measurement, and Diagnostic Equipment (TMDE) cataloging inconsistencies - Continued		The NMP contacted the US Army TMDE Activity (USATA) and worked with them to correct cataloging/ shipping issues and to provide proper equipment data entry into TIMMs. The NMP also worked in collaboration with the US Army Medical Materiel Agency, Project Manager-Medical Devices (USAMMA. PM-MD) to correct FSCs. Once resolved, these efforts will lead to improved equipment cataloging, heightened equipment data accuracy, and better support from USATA managed TSCs. Permanent solutions are expected in early Calendar Year (CY) 2015.
Medical maintenance milsuite/milbook	The National Maintenance Program (NMP) established a milsuite/milbook page, in order to improve and expand collaboration across the medical maintenance community.	The milsuite/milbook page allows medical maintainers to share ideas between units and commands outside of other more formal processes. This forum also provides a means for medical maintainers to stay up-to-date on medical maintenance issues and to voice comments/recommendations concerning NMP projects. The milsuite/milbook page has become a primary tool for informal medical maintenance communications and is used by representatives from the US Army Forces Command (FORSCOM), US Army Medical Command (MEDCOM), and US Army Medical Materiel Agency (USAMMA) as well as numerous Table of Distribution and Allowances (TDA) and Table of Organization and Equipment (TOE) organizations.
Medical maintenance community representative for maintenance centric issues.	The National Maintenance Program (NMP) has become the 'go to' organization for assistance in coordinating maintenance support between units at all levels; often across commands.	The NMP helped coordinate critical Army maintenance support for a Navy medical clinic in Djibouti and for Army activities at Fort Riley, Kansas, and Fort Bliss, Texas that didn't have Military Occupational Specialty (MOS) 68As and could not get support from their Installation Medical Supply Activity (IMSA).

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
AR 750-1: Operational Readiness Float-Medical (ORF-M) rapid revision	The National Maintenance Program (NMP) performed a rapid revision of Army Regulation (AR) 750-1 documenting regulatory guidance on the provision and maintenance of ORF-M, in response to a US Army Forces Command (FORSCOM) information assistance request.	Successfully published AR 750-1 regulatory guidance governing the provision and maintenance of ORF-M in support of garrison and operational missions.
Use of medical grade Liquid Oxygen (LOX) aboard Medical Evacuation (MEDEVAC) aircraft	The National Maintenance Program (NMP) provided Subject Matter Expert (SME) support of a Cooperative Research and Development Agreement (CRADA) with Essex Industries on the use of medical grade LOX aboard MEDEVAC aircraft. During this effort, the NMP provided Subject Matter Expert (SME) support on the logistics/ maintenance challenges and overall feasibility of integrating Liquid Oxygen (LOX) for aeromedical transport aboard MEDEVAC rotary wing aircraft. Benefits derived from the use of portable LOX systems include:	Information furnished by the NMP helped determine the prospective application of LOX in future MEDEVAC operations.
Use of medical grade Liquid Oxygen (LOX) aboard Medical Evacuation (MEDEVAC) aircraft - Continued	• Low Pressure - An operating pressure of less than 100 psi increases safety particularly under battlefield operating conditions. • Less physical space needed - A small amount of LOX expands 860 times following conversion to a gaseous state. • Reduced weight - Eliminates the need for heavy storage cylinders.	

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
Senior Medical Maintenance Teleconfrence (SMMT)	The National Maintenance Program (NMP) continued to host a monthly SMMT. This teleconference encourages senior leader discussion and collaborative involvement on current and future missions within the Table of Distribution and Allowances (TDA) and Table of Organization and Equipment (TOE) medical maintenance communities. Meeting minutes and related postings are captured and uploaded to milSuite for broad dissemination throughout the TDA and TOE medical maintenance communities.	SMMT continues to promote greater mission effectiveness and efficiency through collaborative communication among senior leaders with TDA and TOE mission responsibility.
Army Medical Department (AMEDD) pacing items (medical sets)	The National Maintenance Program (NMP) sought resolution to a problem in which units were unable to correctly determine the status of (or report) long-time designated pacing items (specifically medical sets). NMP staff collaborated with a designated Project Management Medical Devices (PjMMD) representative and the Logistics Support Activity (LOGSA) Readiness Directorate in order to investigate possible solutions.	LOGSA concluded that medical sets should not be designated as AMEDD pacing items. An effort to resolve this issue has become one of the US Army Medical Materiel Agency's (USAMMA's) leading project initiatives.
Developed a tri-service digital radiology acceptance procedure	The National Maintenance Program (NMP) collaborated with the Navy and Air Force to develop a tri-service digital radiology acceptance field test procedure. Defense Logistics Agency (DLA) approval was sought for use as a standardized acceptance test.	The NMP participated in joint tri-service testing and procedure submission to the DLA for inclusion in future DLA awarded digital radiography system procurement contracts.

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
Standardized tri-service C-Arm X-ray system acceptance test procedure	The National Maintenance Program (NMP) collaborated with the Navy and Air Force to develop a tri-service C-Arm X-ray system acceptance field test procedure. Defense Logistics Agency (DLA) approval was sought for use as a standardized acceptance test.	The NMP participated in joint tri-service testing and procedure submission to the DLA for inclusion in future DLA awarded C-Arm X-Ray system procurement contracts.
Biomedical Equipment Specialist (BES), Military Occupational Specialty (MOS) 68A handbook	The National Maintenance Program (NMP) developed a new publication intended to help a 'standalone' BES (MOS-68A) establish and run a fully functional medical equipment maintenance activity.	The BES handbook covers all areas required to provide medical maintenance support to organic and external customers and can be applied to both Table of Distribution and Allowances (TDA) and Table of Organization and Equipment (TOE) units. It additionally serves as a complimentary publication to Technical Bulletin Medical (TB MED) 750-1/2. Following staffing approval by the US Army Medical Materiel Agency (USAMMA), this handbook was staffed to the US Army Medical Command (MEDCOM) for final document approval and publication.
Provided medical maintenance specific data and analysis to the Defense Health Agency (DHA) in support of a Device Integration and Interoperability white paper.	Upon request from Captain Hung Trinh, US Public Health Service (USPHS) Department of Defense/Veteran's Administration (DoD/VA) Interagency Program Office, the National Maintenance Program (NMP) participated in meetings and teleconferences to review and (based on technical capabilities) provide a prioritized list of medical device candidates for integration and/or interoperability within the Military Health System (MHS).	Utilizing critical input from the NMP, the DHA provided a 13-page white paper report, entitled: *Medical Device Integration for the Military Health Service.* This paper outlines the MHS strategy for medical device integration and an approach for achieving an interoperable medical device system.

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
Medical device inventory for the US Army Medical Command (MEDCOM) Army Audit Agency (AAA) audit	The National Maintenance Program (NMP) collected, analyzed, and provided a comprehensive medical device inventory by device, component, Army Command (ACOM), and brigade level.	The NMP furnished inventory to MEDCOM as requested. Audit results are pending.
Field hospital X-ray and Computed Tomography (CT) power requirements	The National Maintenance Program (NMP) received an invitation from the Army Medical Department (AMEDD) Center & School to provide Subject Matter Expert (SME) input in support of a discussion on specific field hospital X-ray and CT power requirements.	The AMEDD Center & School, in collaboration with the US Army Central Command (CENTCOM), will consider the use of a Tactical Quiet Generator Set (TQG) 100 kilowatt (kW) generator set (or Uninterrupted Power Supply (UPS)) to operate at 480 Volts Alternating Current (VAC) for operation of field hospital X-ray and CT equipment. The Operational Requirements Document (ORD) may require a revision to specify the voltage change as well as inclusion of the UPS. AMEDD Center & School and CENTCOM will compile the total power requirement for the new Field hospital.
Army Techniques Publication (ATP) 4-02.1 revision	The National Maintenance Program (NMP) supported review of the program directive for ATP 4-02.1, Army Medical Logistics.	This publication revision addressed changes in Army medical logistics system capabilities and the role this system plays in sustaining the Army Health System mission. Revision changes were specifically implemented to support commanders and command staff, medical planners, medical logistics officers, and personnel at all levels.
Medical Maintenance Readiness Program (MMRP)	The National Maintenance Program (NMP) prepared comprehensive coordinating instructions in support of National Guard (NG), Army Prepositioned Stock (APS), and MMRP missions.	Information prepared by the NMP assisted the US Army Medical Materiel Agency, Medical Maintenance Management Directorate (USAMMA, M3D) in establishing comprehensive NG, APS, and MMRP mission coordinating instructions applicable to: • The National Guard • APS5-Qatar • APS4-Korea • APS4-Japan • Sierra Army Depot

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
Annual Request for Biomedical Equipment Specialist (BES) Support	In support of the US Army Medical Materiel Agency (USAMMA), the National Maintenance Program (NMP) prepared a comprehensive justification for contract maintenance personnel.	In support of the USAMMA, the NMP documented maintenance personnel justification, mission support requirements, and coordinating instructions for provision of ongoing BES, Military Occupational Specialty (MOS) 68A support from the US Army Forces Command (FORSCOM)/US Army Reserve Command (USARC).
ECRI Alerts Tracker Compliance	The National Maintenance Program (NMP) participated in a comprehensive review of the ECRI Alerts Tracker.	This review assessed the current level of ECRI Alerts Tracker compliance, the implementation status of each site, and efforts needed to establish an expected completion rate of 85% or higher.

LEADERSHIP AND MAJOR CHANGES OF FY14

Director
(b) (6)

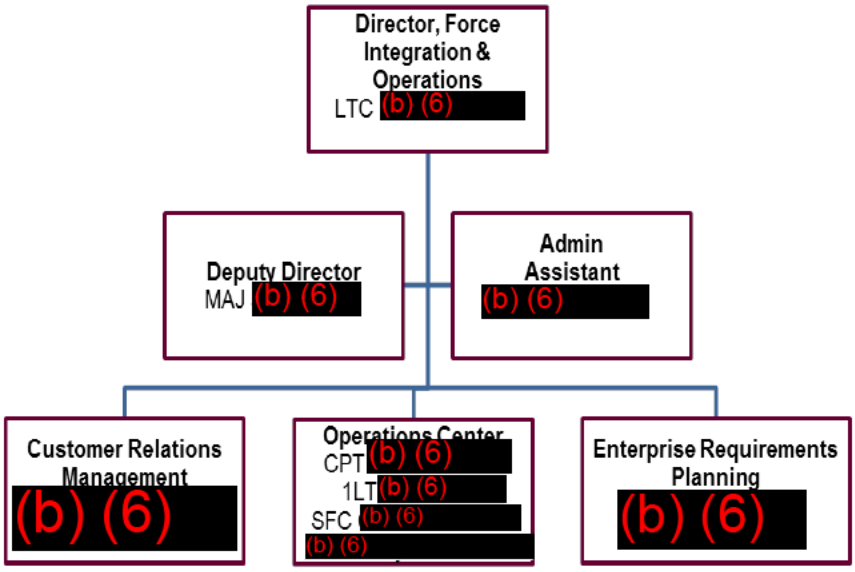
Deputy Director
(b) (6)

Chief, Medical Maintenance Operations Division
(b) (6)

Chief, National Maintenance Program
CW5 (b) (6)

END of Medical Maintenance Management Directorate

4.5 FORCE INTEGRATION AND OPERATIONS (FI&O) DIRECTORATE



4.5.1 MISSION

The US Army Medical Materiel Agency (USAMMA) Force Integration and Operations (FI&O) Directorate mission is to synchronize and optimize efforts across common areas within USAMMA core competencies in support of the agency's vision and mission.

- **Introduction**

The USAMMA FI&O Directorate supports the agency command group, directorates, and project managers by coordinating intra-agency workload and external communication with stakeholders.

As with any organization, USAMMA must understand and be prepared to take advantage of the opportunities ahead. The Current and Future Operations Division makes this happen by improving its capability to anticipate logistics requirements and forecast solutions across a broad spectrum of ever changing requirements.

Since USAMMA moved to the Defense Medical Logistics Center, our Current and Future Operations Division has evolved and increased its operational capability. This is due largely to the integration of the Air Force Medical Logistics Office, Naval Medical Logistics Command, USAMMA and the 6th Medical Logistics Management Center. These mission partners have collaborated on joint operations, processes and products that in turn, has enhanced situational awareness and improved interoperability.

Communication between USAMMA and its stakeholders is an integral part of USAMMA's core competencies. Communication is essential in maintaining strong, working relationships and informing stakeholders of relevant logistics and maintenance issues that arise during the year. Overall, effective strategic communication is critical in the Agency's ability to anticipate requirements and provide appropriate logistics solutions. The Current and Future Operations Division works daily to ensure that strategic communication is maintained.

Email/Suspense Management System is a web-based email/suspense tracking system to manage Stakeholder and customer email/phone inquiries. It is Capable of producing reports that identify the quantity of inquiries from stakeholders/customers and those action officers responding to the inquiry. System capability includes an ability to maintain and show historical trends and eliminate the need to maintain PST files and share drive folders. It is a web-based Oracle application that allows multiple users instant access to the same information simultaneously.

4.5.2 FUNCTIONS

Synchronizing and optimizing medical logistics coordination to synchronize USAMMA Directorates and Project Management Offices (PMOs) and to ensure that medical logistics solutions are available to support Department of Defense and Army operations.

The FI&O Directorate consists of the Emergency Operations Center (EOC), Customer Relations Management (CRM) Division, and the Enterprise Requirement Planning (ERP) Division:

- **EOC**

  - ✓ Stakeholder & Customer Communications (NIPR/SIPR).
  - ✓ Operational data generation.
  - ✓ Operational update/tracking and tasking tracker.
  - ✓ Security/force protection/personnel security.
  - ✓ USAMMA operational communication plan.
  - ✓ Logistics assistance representative management.
  - ✓ Deployment/Redeployment Time Phased Force Deployment Data.
  - ✓ Reset/Left behind equipment Unit & Line item number Planning.
  - ✓ Equipment common operating picture review.

- **CRM Division**

  - ✓ Customer Interaction, Education & Marketing.

  - ✓ Conference & Knowledge Management.
  - ✓ Interactive Customer Evaluation (ICE) Program Management.
  - ✓ Member of USAMMA Internet Website Committee.
  - ✓ Manage production of Supply Bulletins.

- **ERP Division**

  - ✓ Validate & integrate requirements for internal USAMMA activities from external stakeholder requirements.
  - ✓ Class VIII coordination with OTSG and other external Agencies.
  - ✓ Integrate requirements planning (all COMPOs).
  - ✓ Produce Enterprise-wide Centralized Production/Workload Schedule.

4.5.3 MAJOR EFFORTS OF FY14

Each functional area of the USAMMA FI&O Directorate below describes major efforts implemented throughout FY14. When combined, these efforts epitomize directorate contributions performed and documented in this historical report.

4.5.4 EMERGENCY OPERATIONS CENTER (EOC) - PLANS AND OPERATIONS DIVISION

4.5.4.1 MISSION

Develop and articulates a strategy of task methodology that translates the USAMMA Commander's guidance into operational objectives and tasks to ensure medical logistics solutions are available to support DoD and Army global operations and contingencies, and serves as principle staff consultant to the USAMMA Commander and key leaders in all aspects of future and current operational and contingency matters. Coordinates the central development, planning, and integration of the USAMMA Continuity of Operations Plan (COOP) and Operational Plan (OPLAN), engages the key leaders to create an optimal planning environment that supports and facilitates the achievement of mission goals and objectives, collaborates with enabling organizations to facilitate parallel planning and coordinates key aspects of joint and combined operations.

Maintain situational awareness of all ongoing operations, exercises and contingencies and translate the USAMMA Commander's strategic concepts and vision into operational objectives in order to facilitate the successful execution of current and future operations requirements to ensure medical logistics solutions are available to support the global Army and DOD healthcare mission.

4.5.4.2 FUNCTIONS

- Creates an optimal planning environment that supports the USAMMA Commander and key leaders in facilitating the achievement of mission goals and objectives.
- Serve as the principal integrator between higher headquarters and USAMMA Directors and PMOs in developing policy, guidance, plans, training, oversight, and exercises vital to the execution and sustainment of military operations.
- Conducts extensive independent examinations of open source and classified data sources to stay abreast of current events and the operational environment.
- Coordinates the central development, planning, and integration of the USAMMA COOP and OPLAN.
- Collaborates with enabling organizations to facilitate parallel planning and coordinate essential aspects of joint and combined operations.
- Plans, coordinates and de-conflicts scheduling and resource requirements for high-visibility events and activities for which the USAMMA serves as executive agent.
- USAMMA's focal point for all operational orders and administrative taskings received from higher headquarters.
- Establishes and operates the USAMMA OC as part of the DMLC Joint Operations Center (JOC) during emergency.
- Provide a comprehensive Common Operating Picture (COP) by monitoring and analyzing current force operations and the impact on USAMMA's sustainment capabilities.
- Serves as the focal point for developing plans and policy, publishing training circulars and materials, for Operational Security (OPSEC), Anti-terrorism, Force Protection, and Physical Security for the Agency.

4.5.4.3 MAJOR EFFORTS OF FY14

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
Revised internal OCONUS Travel SOP	The OC will manage the USAMMA OCONUS program. The program is to assist travelers with meeting packet submission timeline for OCONUS travel.	The OC revised the internal OCONUS Travel SOP and rectified the deficiencies noted in the MRMC Staff Assistance Visit (SAV).
Antiterrorism (AT) Plan	Antiterrorism (AT) Plans play a crucial role in ensuring that the risks associated with terrorism have been addressed and that mitigation strategies have been implemented by communicating a Commander's vision, intent, and decisions to his subordinates which focus on the results he expects to achieve in reacting to terrorists incidents in order to protect personnel, information, and physical assets by applying active and passive measures against the full threat spectrum.	Facilitated a complete revision of the USAMMA AT Plan by incorporating strategies outlined in Field Manual 3-37.2 (Antiterrorism), lessons learned from terrorist attacks, wartime engagements, and existing and developing AT strategies (military, federal, state, and local), policies, and doctrine. This has resulted in the most robust USAMMA AT Plan to date.

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
Antiterrorism (AT) Plan (Continued)		The plan assists the decision making process and is used to achieve objectives that deter terrorist incidents, employ countermeasures, mitigate effects, and conduct incident recovery by providing a context to develop situational awareness and a greater understanding of the terrorist threat, identification of terrorists risks, potential terrorist threats, reduces vulnerabilities to terrorist acts and attacks, and details effective strategies to react to terrorist incidents.

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
Army Disaster Personnel Accountability and Assessment System (ADPAAS)	U.S. Army Disaster Personnel Accountability and Assessment System (ADPAAS) standardizes a method for the Army to account, assess, manage, and monitor the recovery process for personnel and their families affected and/or scattered by a wide-spread catastrophic event. ADPAAS provides valuable information to all levels of the Army chain of command, allowing commanders to make strategic decisions which facilitate a return to stability.	USAMMA EOC will utilize the Emergency Alert Notification System (EANS) and Army Disaster Personnel Accountability and Assessment System (ADPAAS) after a disaster or upon an exercise-related event, military personnel must account for themselves and their Families by communicating their status to their supervisor. DA Civilians and government contractors can voluntarily account for themselves and their family members through ADPAAS. Additionally, if an ADPAAS event, account for themselves and their Families in ADPAAS, and complete the needs assessment survey in ADPAAS.

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
Army Disaster Personnel Accountability and Assessment System (ADPAAS) (Continued)		Military personnel will inform their supervisor of any devastation associated with the disaster to include loss of life of Family members, injury to self or Family members, and/or their home becoming uninhabitable. In the event communication with the supervisor is unattainable, accountability will be communicated directly to the USAMMA Operations Center.
Staff Assisted Visit	The OPS Center manages internal SOPs that are routinely inspected by higher headquarters. These include Emergency Operations, OCONUS travel, security, and COOP.	SOPs are continually updated to meet evolving threats. SOPs have been reviewed and approved IAW higher headquarter guidance.
Emergency Operations	The OPS Center manages the Emergency Operations SOP and the Emergency Alert Notification System (EANS).	Rapidly notified USAMMA personnel with emergency alerts pertaining to active shooters and weather alerts. The rapid dissemination of information enables commanders and personnel to make informed decisions in regards to

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
		manpower and asset management.

4.5.5 CUSTOMER RELATIONS MANAGEMENT (CRM) Division

4.5.5.1 MISSION

The CRM coordinates customer requests and feedback with the operational capabilities of USAMMA and also educates customers on the Agency's programs, products, and services. The division documents and manages all customer interactions which allows for improved trend analysis and a better understanding of the needs and requirements of our customer.

4.5.5.2 FUNCTIONS

- Performs Customer Relations Management and Support using a Centralized Inquiry Tracking and Automated-Response System.
- Develops Monthly Customer-focused Strategic Reports for the Agency in order to provide a Centralized view of customer requirements and feedback.
- Serves as the Agency Manager for the DA Medical Supply Bulletin 8-75 Series.
- Markets the Agency's capabilities and programs to customers and stakeholders through customer assistance and education and review and update of customer information published on the Agency website.
- Serves as the Agency ICE Program Manager.
- Serves as Print Control Officer (PCO) for the Agency.

4.5.5.3 MAJOR EFFORTS OF FY14

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
Customer Interaction, Knowledge and Retention Management and Trend Analysis	Provided a proactive approach to customer service through dialogue and customer interaction. Continued to manage all incoming communication (phone, email and in-person) in an effort to address customer requests for information (RFIs) and inquiries.	From Oct 2012 through Sep 2013, handled and tracked approximately 839 customer RFIs with a monthly average of 70 per month. CRM documented: 54 RFIs on fielding actions; 84 RFIs on Unit Assemblages (MES/Component Listings); 31 RFIs on MEDSILs; 30 RFIs on the SBs; 25 RFIs on Reset; 10 RFIs on the USAMMA website; and 35 RFIs on Vendor Day. All inquiries/responses were documented in the Inquiry Tracking and Automated Response System and retained for knowledge management.
Developed Customer-Focused Strategic Reports	Analyzed customer requests in the Inquiry Tracking and automated Response System and developed monthly reports for the Agency in order to provide a centralized view of customer requirements and feedback.	Reports provided insight to customer requirements; helped in determining whether Agency products and services are meeting customer needs; and assisted Agency leadership in determining the focus for personnel and resources.
Managed the Publication of the DA Medical Supply Bulletin 8-75 Series	Coordinated and performed technical and editorial reviews for seven (7) medical supply bulletins. Published one supply bulletin to the USAMMA website and AKO each month.	Performed as liaison between SB POCs from USAMMA Directorates; MEDCOM; ARNG; AMEDDC&S; DA Publishing, and AKO. Coordinated and performed technical and editorial reviews on seven (7) medical supply bulletins. Provided supply bulletins to APD for approval, and then published to USAMMA website and AKO. Participated in numerous informational telecons with the SB POCs and fielded all internal and external requests for information regarding the SB program. There were nine Supply Bulletins updated and published for the period Oct 2013 - Sep 2014.
Customer Education, Marketing, and Web Support	Educated customers on using various USAMMA products and services. Assisted with customer inquiries relating to Medical Logistics hosted Vendor Day events. Actively marketed the agency by facilitating and coordinating USAMMA	Educated 31 customers on using MEDSILs to locate Unit Assemblage listings and to export the reports to EXCEL. Instructed 35 customers on locating information for Medical Logistics hosted Vendor Day Events and facilitated interactions between private industry and government POCs for each event date. Coordinated review and updates for three

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
	brochure updates educating customers on available USAMMA products and services.	(3) DOC brochures published to the USAMMA website. Coordinated removal of outdated acquisition and Remote Diagnostic Access (RDA) brochures from the USAMMA website.
Customer Education, Marketing, and Web Support (Continued)	Performed technical and editorial reviews on the content of the Agency internet website so that customers had timely and accurate information. Provided new and updated program and product information, and posted material to the Agency AKO websites.	Generated FAQs to be published on USAMMA website (i.e. USAMMA Circular 40-1).CRM facilitated approximately 10 major improvements/changes to USAMMA products/services. Provided USAMMA marketing products for quarterly New Employee Orientations and to USAMMA visitors.
Managed the Agency Interactive Customer Evaluation (ICE) Program	Identified and tracked action items generated from the ICE surveys to ensure that Agency leadership was effective in providing timely guidance for improvement of short term (i.e., 36 hours or less) and long term (i.e., greater than 36 hours) targets. Understood the needs of external customers and as such, enabled the Agency to be more proactive in providing relevant information and educating the customer.	From Oct 2012 through Sep 2013, accumulated a total of 120 ICE customer comment cards. Analyzed ICE feedback from customers and provided monthly reports to USAMMA Leadership detailing customer responses. The breakout per Directorate was: FI&O – 64; FPD – 7; FSD – 30; and M3D – 19. CRM ensured that the appropriate Directorate responded in a timely manner and documented the response in ICE to all submissions that required a response from management. Assisted with setting up ICE cards for two new service providers (FSD LNOs and DOC). CRM requested ICE feedback from all customers.
Appointed Print Manager for te Agency	Ensured that Agency Publications met publishing guidance provided in DA policy.	Reviewed monthly medical SBs to ensure all published documents were in compliance with DA guidance. Maintained liaison with APD to assist with the coordination and removal of outdated medical Supply Catalogs (6545-series) for 255 equipment items from storage in St. Louis. Received and facilitated coordination of all communications from APD for PCOs.

1. 4.5.6 ENTERPRISE REQUIREMENTS PLANNING (ERP)

4.5.6.1 MISSION

The ERP coordinates USAMMA requirements planning within the AMEDD enterprise to synchronize Army medical logistics missions with USAMMA resources and capabilities in support of the Warfighter.

4.5.6.2 FUNCTIONS

- Validate and integrate requirements for internal USAMMA activities from external stakeholder requirements.
- Class VIII coordination with OTSG and other external Agencies.
- Integrate requirements planning (all COMPOs).
- Produce Enterprise-wide Centralized Production/Workload Schedule.

Medical Equipping Reset

Upon redeployment, return units to the highest level of readiness through Class VIII LIN-level fielding and simultaneous induction of medical maintenance-significant equipment designated for recapitalization.

- Provide disposition instructions within 72-hours of unit execution of Army Reset Management Tool (ARMT) plan.
- Work with units to identify projected return dates and lock in reset fielding dates.
- Reset medical LINs/NIINs via simultaneous equipment/set induction and Reset-Fielding/Direct Exchange (DX) at Home Station by Rtn+180 for Compo 1 and Rtn+360 for COMPO II & III unit.
- Resolve shipment discrepancies as necessary.
- Generate and submit Medical Sustainment Items (MSI).

4.5.6.3 MAJOR EFFORTS OF FY14

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
MEDB Database	The MEDB database maintained by ERP became the primary tool for forecasting and managing 98% of equipping actions within USAMMA and is used across all directorates.	This MEDB Database alleviated the inefficiencies experienced with the previous Forecasting Database in attempting to complete the annual Production Plan. Once granted access to this database, this centralized data such as fielding history, scheduled fielding's and costs, can be viewed and a query of reports can be generated across the agency to allow managers and employees of all Directorates nearly a real time reference of current data. This allows critical decisions to be made on the use of available resources which further streamlines the Production Plan. In addition, with this information centralized at the touch of a button, this saves on time management and allows employees to obtain information faster than old outdated methods of exchanging report data and holding various working group meetings to discuss these already documented reports

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
		and data.
Enterprise Requirements Planning Folder on Army Knowledge On-line	Maintained an ERP folder on AKO to post updated copies of the production plan, fielding schedules, Fielded LIN & NIIN Reports, replacement LIN reports and other pertinent data as required.	Effective in allowing designated representatives from MEDCOM, G8, USARC, FORSCOM, OTSG and the NGB access to view working documents such as fielding schedules, production plan, and replacement LIN reports. Several customers and stakeholders have expressed great satisfaction over the reference material available which continues to be posted to this AKO folder.
Monthly Staff Meeting for ERP, Assembly Management Division, Force Sustainment Directorate, & Customer Relations Management	Monthly Coordination Meetings with the Fielding Division, Assembly Division, Maintenance Division, Force Protection Directorate, Acquisition Directorate, and Customer Relations personnel.	Unforeseen circumstances and events produce unforecasted requirements and result in taskings from our Higher Headquarters. The result is possible additions or adjustments of units on the current Executive Level Fielding Schedule (ELFS) which needs to occur at a moment's notice. This weekly working group is able to discuss these challenges associated with both forecasted and un forecasted fielding requirements and resolve any issues.
Executive Fielding Schedule Tracking	Executive Fielding Schedule Unit Tracking and Review for Accuracy and Timeliness.	This involves a constant review/scrub and awareness to insure units scheduled are going to be fielded on time per their scheduled date(s) or have not been adjusted or removed from the schedule entirely. This also includes making sure this Agency has all required reporting data on-hand, which includes but not limited to a Request For Information (RFI) or Unit Checklist within the required suspense date so the Agency may continue to execute fielding actions efficiently and on schedule.
Quarterly Teleconferences	Along with HQDA-G8, continue to host separate Bi-weekly TELECONs with representative of the USARC, the NGB, ASC, and FORSCOM. In addition, introduced this TELECON communication concept to	This continues to improve communications with representatives of each Component (1, 2 and 3) issues and inquiries are continuing to be handled and resolved immediately at the lowest levels possible. This continues to foster an environment of open dialogue and communication between staffs and continues to

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
	USARPAC.	encourage and build a cohesive team environment approach to working together. More discussions continue to encourage confidence in our abilities to resolve issues in a timely manner.
Basis of Issue Plan Report	Basis of Issue Plan (BOIP) Documentation Report	This report has no ending date and is a documented review of all errors and inconsistencies discovered during consolidated reviews of the units on the Executive Fielding Schedule and along with their unit OTOEs and MTOEs. The result is a single place to note all errors and inconsistencies in Applied and Non-Applied BOIPs and begin a resolution process by reporting a status to stakeholders, and also continue to follow through until resolution. Once resolution occurs, record that resolution on this document.
Army Structure and Total Army Analysis Output	Army Structure Reports and Total Army Analysis Panel Data.	Translation of this data quickly on how it specifically impacts the medical equipment community and in the projection of the use of medical resources is critical. Identifying changes in structure is key to the USAMMA mission in order to insure the right equipment is in the right units at the right times.
Distribution Plan	Distribution Plan scheduled for 24 months data for the Decision Support Tool (DST) maintained at Army Sustainment Command (ASC)	Translation of this data quickly on USAMMA's Distribution Plan to incorporate in ASC's DST program for Army re-distribution purposes.

LEADERSHIP AND MAJOR CHANGES OF FY14

Director
LTC (b) (6)

Deputy Director
MAJ (b) (6)

Customer Relations Management
Division Chief, (b) (6)

Operations Center
CPT (b) (6)

Enterprise Requirements & Planning
(b) (6)

END of Force Integration and Operations (FI&O) Directorate
4.6 Distribution Operations Center (DOC)

4.6.1 Mission

The DOC serves as the DoD Executive Agent for the distribution of Anthrax and Smallpox vaccine. The DOC is responsible for coordination the distribution of biological Investigational New Drug (IND) agents owned by DoD and managed by the Army. The DOC serves as the Army's Inventory Control Point (ICP) for the Influenza Virus Vaccine by supervising the yearly Army-wide influenza vaccine distribution program. The DOC also maintains the public and secure websites which provide the customer with an accessible, expedient, and consistent method to order Adenovirus, Anthrax and/or Smallpox vaccine.

The DOC serves as the central quality assurance coordinating activity for medical materiel for the DoD by collecting medical quality control information from users and manufacturers. Additionally, the DOC develops and disseminates Medical Materiel Quality Control (MMQC) messages for DoD and Medical Materiel Information (MMI) messages for the Army and monitors and reports the results.

4.6.2 Functions

- The Distribution Operations Center continues to provide distribution management, coordination and execution of Anthrax vaccine, Smallpox vaccine, Influenza vaccine, Adenovirus vaccine, INDs, and other critical vaccines and temperature-sensitive products (TSMPs)
- The Distribution Operations Center continues to provide cold chain management consultation and training of customers and stakeholders, especially those involved in shipping and trans-shipping products
- The Distribution Operations Center continues to represent USAMMA in research working groups on Ft Detrick related to the transport of temperature-sensitive media, products and/or vaccines
- The Distribution Operations Center continues coordination of logistics management support for the storage and distribution of Adenovirus Vaccine on behalf of USAMMDA
- The Distribution Operations Center continues to pursue innovative ways to provide the most state-of-the-art equipment and procedures to support DoD's cold chain management initiatives
- The Distribution Operations Center continues to support the Defense Health Agency (DHA) Immunization Healthcare Branch (formerly Military Vaccine Agency [MILVAX]) and the Medical Countermeasures System (MCS) (formerly Chemical Biological Medical Systems [CBMS])
- The Distribution Operations Center provided Management of the Medical Materiel Quality Control (MMQC) & Medical Materiel Information (MMI) Messages

4.6.3 Major Efforts of CY14

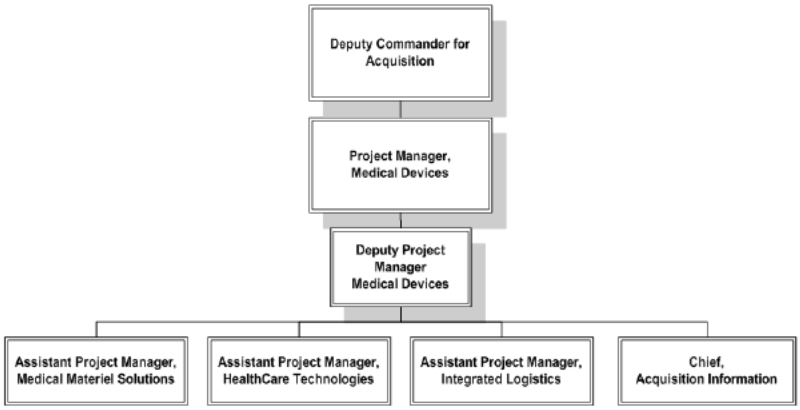
ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
Anthrax Vaccine Immunization Program (AVIP)	The DOC coordinated **1,323** shipments of Anthrax Vaccine to **315** locations and redistributed **1,049** vials to **8** locations.	**53,859** vials distributed **$15.1M**
Smallpox Vaccine Program (SVP) including diluent and needles	The DOC coordinated **548** shipments Smallpox Vaccine to **205** locations and redistributed **7** kits to **1** location.	**1,905** kits with diluents distributed. **$99K**
Army Influenza Program	The DOC managed the Army Influenza Program for Active Duty, National Guard and Reserve units through CONUS and OCONUS locations.	**1,695,020** doses of seasonal influenza vaccine were distributed. **$20.2M** Total of **12** locations required redistribution of vaccine for a total of **3,900** doses. Additional **23,780** doses were shipped to PACOM area; Humanitarian mission. Tracked over **2,000** shipments.
Investigational (IND)/Critical Vaccine Distribution	The DOC coordinated with USAMMRID to provide two emergency shipments of VIG IV to JBSA. The second shipment also included Tecovirimat (ST-246), an IND, and an antiviral for the treatment of smallpox infection.	**2** shipments of VIG IV for **14** Vials and **1** shipment of Tecovirimat (ST-246).
Medical Materiel Quality Control Messages (MMQCs)	**1119** MMQC messages were sent to DoD locations. **92** Messages disseminated as Class I recalls on medical materiel which may cause death, serious injury or illness.	Provided timely information to DoD customers on pharmaceuticals and equipment.
Medical Materiel Information Messages (MMIs)	**2** MMI messages were sent to Army locations.	Provided timely information to customers on their product complaints.
Medical/Dental Product Quality Deficiency Reports (PQDR)	**30** PQDR submissions were received	Provided timely feedback, as needed, to customers on product information.
Cold Chain Management (CCM)Training and Staff Assistance Visits	DOC personnel attended and/or briefed at **21** CONUS sites and **5** OCONUS sites on CCM practices and safe guarding TSMP's.	The safe guarding of TSMP's is a focal point in CCM and for all personnel who handle TSMP's.
On-line Cold Chain Management (CCM)Training	Launched monthly training opportunities via Defense Connect Online (DCO). Training is offered twice each month on first Thursday	There were **23** training opportunities (to include two after-hours events for Japan and Korea) for more than **250**

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
	at 0900 and 1400 Eastern Time.	personnel.
VaxiCool Refrigerator/Freezer unit and VaxiPaks	**16** VaxiCool units moved to **9** locations (4 OCONUS sites and 5 CONUS sites); **19** total VaxiPaks moved **7** locations (2 OCONUS sites and 5 CONUS sites); **87** PX6Ls shoulder carriers to **41** locations (4 OCONUS sites and 37 CONUS sites)	The shipment of VaxiCools and VaxiPaks ensures the safety and effectiveness of TSMP's and prevents waste.
Adenovirus Vaccine	The DOC coordinated **97** shipments of Adenovirus Vaccine to **9** locations. The DOC coordinated **2** trans-shipments on behalf of USAMMDA.	**4,986** bottles distributed (249,300 doses) IOT to reduce respiratory infections among new recruits/trainees and increase readiness. **$30.3M**
Vaccinia Immune Globulin Intravenous (VIG IV) for Smallpox	VIGIV Licensed by Cangene Corp provides a necessary complimentary capability to protect service member from rare adverse effects of smallpox vaccine.	USAMMA DOC provided distribution oversight for the purpose of pre-positioning, **240** vials that are due to expire 31 Jan 2016 (Lot# 10703691). Vials are available whenever smallpox vaccine is used, to treat the rare but potentially serious effects related to the vaccination.
New TSMP Technology	Initial testing conducted on the Triton insulated shipping container.	The container met initial "real world" testing requirements and is positioned for chamber testing at Telemedicine and Advanced Technology Research Center (TATRC).
DOC Website	Monthly schedule changes/updates were made to both the public and secure USAMMA DOC websites to include (Anthrax/Smallpox Vaccine order site, USAMMA/DOC Web Page).	Customer friendly improvements/updates to USAMMA Web Page.
MMQC Share Service Project	USAMMADOC is the co-lead on an initiative with DHA MEDLOG to improve the MMQC system. The working group created an As-Is process map, identified gaps (using DOTMLPF), determined requirements and created a To-Be model. IOT to meet determined requirements the co-leads are	The goal is to create an integrated hazard, alert and recall system that has a closed loop to include Patient Safety, Clinicians and integrates with the electronic health record.

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
	seeking a material solution and an IT solution.	

DEPUTY FOR ACQUISITION (DFA)

5.1 PROGRAM MANAGEMENT OFFICE, MEDICAL DEVICES (PMO, MD)



5.1.1 MISSION

The PMO, MD provides acquisition life cycle management of all tables of organization and equipment (TOE) devices and ancillary medical items supporting human and animal patient care. The mission of the PMO, MD is critical to the success of both the current and future missions of field medical treatment from Role I thru Role III. The advantages of an integrated staff are evident in technically superior equipment that is reliable and supportable in austere environments throughout the world. PMO, MD also provides internal support to the USAMMA to include assistance to other Directorates for Army Pre-positioned Stock (APS), Foreign Military Sales (FMS), and the Surgeon General's contingency programs. Integrates acquisition and logistics actions with Defense Logistics Agency-Troop Support (DLA-TS), and collaborates closely with the Directorate of Combat and Doctrine Development (DCDD), Army Medical Department (AMEDD) Center and School, AMEDD Board, and Service Laboratories. The PMO, MD also directly supports DoD Health Affairs research and development efforts as the advanced development consultant on Joint Program Committees (JPC's) and executes Defense Health Program (DHP)-Research Development Test and Evaluation (RDT&E) in support of Joint Service Research and Development programs that have the potential to support all Roles of Care (Roles I thru V). The products and innovations generated within this organization will enable the Army, as well as sister Services, with premier medical capabilities that front-line Soldiers depend on for medical treatment on the battlefield.

- **Introduction** - The Medical Devices Project Management Office (MDPMO) provides acquisition life cycle management of all advanced development and commercial medical devices supporting field medical organizations world-wide. This includes cost, schedule, and performance of all projects managed by MDPMO and includes financial management of multiple appropriations to include Other Procurement Army (OPA), Operations & Maintenance Army (OMA), Defense Health Program (DHP)-OM, Army Research, Development, Testing, & Evaluation (RDT&E) 6.4/6.5, DHP-RDT&E (6.4/6.5/6.7), Congressional Special Interest (CSI), and DoD RDT&E. Facilitates identification of products that fill recognized capability gaps and facilitates entry of products into USAMRMC Decision Gate process to ensure early visibility by the Executive Management Committee comprised of the Principal Assistant for Acquisition (PAA)/Milestone Decision Authority (MDA), Principal Assistant for Research and Technology (PAR&T), and Deputy Commander USAMRMC. Critical elements include: develop, evaluate, produce, modernize and deploy diagnostic and therapeutic medical devices supporting Combat Casualty Care, Military Operational Medicine, and Rehabilitative and Restorative Care to include detection and treatment of traumatic brain injury (TBI) (e.g. the Laboratory Assay for TBI and the Portable Neuro-stimulator); Burn Resuscitation Decision Support System; Noise Immune Stimulator; Oxygen Generator Field Portable (OGFP); Deployable Oxygen Generator System – Small (DOGS-S); Advanced Patient Monitoring; hemorrhage control and resuscitation products, Coliform Analyzer, and Hydration Status Monitor. Modernization of the Optical Fabrication System, Surgical Microscope, 120LPM Oxygen Generating System, and Filed Sterilizer. Evaluating Joint Product Solutions for Intravenous Pumps, Blood Warmers, Suction Apparatuses, and Patient Monitors. Execute expanded advanced development efforts supporting combat casualty care, rehabilitative medicine, and military operational medicine for the Defense Health Program. As part of a designated laboratory by the ASA(ALT), execute and manage Cooperative Research and Development Agreements with Industry Partners.

5.1.2 FUNCTIONS

- **APM, Medical Materiel Solutions**

✓ Primarily responsible for product management of advanced development efforts and new product ideas in support of both Army and Defense Health Program.

✓ Manages development of medical device solutions for combat casualty care, military operational medicine and rehabilitative and restorative care. Also houses the Office of Research and Technology Applications (ORTA) for the Agency in support of Cooperative Research and Development Agreements (CRADA's).

✓ APM-MMS provides oversight and management for technology, engineering, and manufacturing development efforts utilizing Army and Defense Health Program (DHP) Research, Development, Test & Evaluation (RDTE) funds utilizing 6.3, 6.4, and 6.5 program execution dollars.

✓ Facilitates and leads Integrated Product Teams (IPT's), represents the PM on Joint Program Committees (JPC's), reviews and responds to submissions through the USAMRMC New Product Ideas program, negotiates and manages Technology Transfer Agreements (TTA's), and manages pivotal/clinical trials with MEDCOM medical treatment facilities, USAMRMC research laboratories, and partnering Academic Institutions.

- **APM, HealthCare Technologies**

✓ Responsible for clinical and engineering oversight, management, and evaluation of commercial medical devices and associated support items for all Unit Assemblages (UAs) deployed in support of medical operations on the battlefield. This includes equipment and UAs ranging from the Tactical Combat Medical Care (TCMC) set to the core of the combat support hospital: the EMT, pharmacy, surgery, intensive care unit, and wards and clinics. Also includes ophthalmology and optometry services, dentistry, oxygen generation and supply systems, surgical subspecialties, laboratory and veterinary services, blood storage and delivery devices.

✓ APM-LS provides clinical and engineering oversight and management for technical and highly specialized medical assemblages that are deployed on the battlefield. Supports and collaborates closely with advanced development efforts as this is integral to the biomedical engineers' professional development. APM-LS Biomedical Engineers will take lead responsibility for selected advanced development efforts to maintain their proficiency in product development and support DoD 5000 processes.

✓ Provides internal support to the USAMMA to include assistance to other Directorates for Army Pre-positioned Stock (APS), Foreign Military Sales (FMS), and the Surgeon General's contingency programs.

✓ Integrates acquisition and logistics actions with Defense Logistics Agency-Troop Support (DLA-TS), and collaborates closely with the Capability Developer, AMEDD Center and School, AMEDD Test Board, and Service Laboratories. APM-LS also provides clinical consultation for development and modernization efforts.

✓ APM-LS is responsible for all medical devices and associated support items to include 220 major end items and 101 medical UA's.

- **Acquisition Information Division**

✓ The Acquisition Information Division assures that relevant information regarding medical devices is published or distributed so that CONUS and OCONUS units have the necessary critical information to perform their missions.

✓ Develops Interactive Electronic Technical Manuals (IETMs) and equipment literature for medical equipment compact discs (CDs), the Support and Consumables Handbooks, and provides configuration management processes for UAs and equipment start-up lists. The division also manages the PMO MD property book; provides technical writing/editorial support; and manages the PMO MD information on the USAMMA's internet and intranet.

- **APM, Integrated Logistics**

✓ Primarily responsible for all aspects of Integrated Logistics Support (ILS) for all clinical divisions within the PM office.

✓ APM-IL is responsible for the ILS of all clinical divisions within the PM office. This includes support within each one of the twelve ILS elements for new and existing equipment items and Sets/Kits and Outfits (SKOs). ILS is also responsible for the data management of all NIINs and LINs and any maintenance actions against those items, BOM management, configuration management, POM development, and acts as the financial OPA manager.

✓ Provides internal support to the USAMMA to include assistance to other Directorates for Army Pre-positioned Stock (APS), Foreign Military Sales (FMS), Medical Maintenance Directorate (M3D), Force Sustainment Directorate (FSD), Force Projection Directorate (FPD), Force Integration and Operations Directorate (FI&O), and the Surgeon General's contingency programs.

✓ Integrates acquisition and logistics actions with Defense Logistics Agency-Troop Support (DLA-TS) and collaborates closely with the Capability Developer, AMEDD Center and School, and AMEDD Test Board.

5.1.3 MAJOR EFFORTS OF FY14

Action Or Change	Description	Effect Or Result
Published 21 new handbooks, made 521 handbook revisions, archived 27 handbooks, published 24 new equipment start-up lists, made 798 start-up lists revisions, and added 38 new pictures to start-up records.	The handbooks provide a brief description of each piece of equipment, including color photographs and attributes, as well as a listing of authorized accessories and consumables. Included in each accessory and consumable chart is the NSN, nomenclature, part number, quantity, unit of issue, unit price, manufacturer, shelf life, refrigeration requirements, CONUS shipping times, and notes on pertinent information about each item. To date 157 handbooks and 594 start-up lists have been developed.	The handbooks will ensure USAMMA's TOE customers have access to information needed to ensure equipment readiness and cost-effective, timely supply management. Annual reviews of handbooks are done to maintain and update the latest in published content.
Developed 58 interactive electronic technical manuals.	Manuals were developed using Interactive Authoring and Development Software and printed on CDs.	CDs are now distributed to both TOE and TDA units and contain set-up procedures, repair procedures, 10/20 standards, and repair parts information.
Published 50 operators and service literature manuals.	Published in PDF on AKO website and on CDs.	Critical equipment information is now readily available to soldiers
Requested and received an Air Force Liaison within PMO to work as a Product Manager on Joint initiatives.	This will provide synergy between the Army and Air Force Advanced Developers. We are planning on receiving at least one more Air Force employee to support Advanced Development efforts	Looking for successful integration with the wound care portfolio and vascular care products currently being developed by AF.
Neurocognitive Assessment - MDD Brief	Participated as the PLRC and IPT member.	DANA received FDA clearance and IPT will looks at TBI indication.
Deployable Oxygen Generator System-Small - IPR Brief	Participated as the PLRC and IPT member.	Ongoing IPT
Oxygen Generator Field Portable - IPR Brief	Participated as the PLRC and IPT member. Soros selected to move forward into SKO. In April 2011, the Army procured 100 Saros oxygen generators (containing 1 battery each) for field evaluation at 12 different locations. Before this procurement was executed, we had identified a potential issue with electromagnetic interference and approved the manufacturer's solution of shielding the battery. In 2014, the Army was alerted that some, if not all, of the batteries in the 100 devices procured did not have the approved EMI shielding and could pose a	The overall status of the Saros batteries remains unchanged: unshielded batteries of all 66 units that stayed in CONUS have been removed from service; 4 of the units sent to Afghanistan have been located and the unshielded batteries removed from service;

	potential issue when used on rotary-wing aircraft. To identify the systems with the unshielded batteries, and remove them for shipment back to the depots, US Army Medical Materiel Agency (USAMMA) issued a Medical Materiel Quality Control (MMQC) message and posted a link on the Air Warrior Forum. In addition, the Medical Devices Project Management Office (MD PMO) directly contacted all of the points of contact that originally received the Saros	and the remaining 30 units sent to Afghanistan have not been located.
Compartment Pressure Relief - IPR	Participated as the PLRC and IPT member. Was placed in tech watch by the MDA. Contract issues with the manufacturer.	Ongoing tech watch
Junctional Noncompressible Hemorrhage Control - MDD Brief	This effort has not yet entered into MDD and AF is assisting with manufacturing efforts.	Ongoing IPT
Non-Invasive Neuro-Assessment Device - Brief	Participated as the PLRC and IPT member.	Ongoing IPT
Laboratory Assay Traumatic Brain Injury (LATBI)-Project Milestone B	Milestone B for laboratory assay traumatic brain injury (LATBI) received in July 2014.	Contract award pending
MHSRS Posters	Sterilizer modernization, CRADA with Essex Industries Inc. Liquid Oxygen, and Procellera study.	Honorable mention for the CRADA with Essex Industries Inc. Liquid Oxygen poster.
Junctional Tourniquet	Fielded Junctional tourniquets to the theater of operation.	Pending assessment from users with source selection in FY15.
Negative Pressure Wound Therapy Modernization	6.7 DHP funds awarded for T&E for a Negative Pressure Wound Therapy suction downselection and source selection.	Pending FY15
Manual Suction Modernization	6.7 DHP funds awarded for T&E for a manual suction downselection and source selection.	Pending FY15
Monitor Modernization	6.7 DHP funds awarded for T&E for a monitor downselection and source selection.	Pending FY15
Ventilator Modernization	6.7 DHP funds awarded for T&E for a ventilator downselection and source selection.	Pending FY15
Defibrillator Modernization	6.7 DHP funds awarded for T&E for a Defibrillator downselection and source selection.	Pending FY15
LIN/NIIN Management	Conducted a major cleanup against our LIN/NIINs processing over 730 maintenance actions.	Allows for divestiture and disposition of equipment reducing footprint along with DEPOT inventory. Also

		prevents unneeded purchases due to current stock inventory.
Urology Modernization	Met directly with urology consultant and manufacturer of the telepack to modernize the urology UA. No updates or modernization have been done in over 20 years with this UA. A face to face meeting is needed because we (USAMMA) have not had hands on the equipment and it is in excess of $50,000 per unit. Although the equipment is being used in the TDA the unit has a monitor and other accessories that are not currently being used in the field. Discuss maintenance issues with the manufacturer and the medical maintenance staff at SAMMC as well as review the equipment.	
Medical Equipment Set Medical Service Clinic 84 Bed	Complete review of the LIN items in set as per the AR 40-60 and AR 71-32.	The Panel review accomplished the recommendations to change, add or delete items from the assemblages based on professional military judgment, deployed experience and the capabilities of the user. The panel eliminated redundancies, modernized the assemblages, and included the materiel necessary for health care providers to utilize all of their skills based on current standards of care.
Medical Equipment Set Medical Service Clinic 164 Bed	Complete review of the LIN items in set as per the AR 40-60 and AR 71-32.	The Panel review accomplished the recommendations to change, add or delete items from the assemblages based on professional military judgment, deployed experience and the capabilities of the user. The panel eliminated redundancies, modernized the assemblages, and

		included the materiel necessary for health care providers to utilize all of their skills based on current standards of care.
Optometry Equipment Se	Provides initial diagnosis and management of eye injuries on the battlefield. Provides examination to prevent, detect, triage, diagnose, treat, and manage visual dysfunctions ocular injuries and pathology	Successful review of the LIN and non Lin items. All recommended changes and additions were made from the assemblages based on professional military judgment, deployed experience and the capabilities of the user.
Optical Fabrication Unit Portable Filed	Provide single vision optical fabrication capabilities to support all levels of care. This set contains equipment, durable and consumable supplies to sustain operation for 72 hours.	Successful review of the LIN and non Lin items. All recommended changes and additions were made from the assemblages based on professional military judgment, deployed experience and the capabilities of the user.
Optical Equipment Set Multivision Augmentation	Provide multivision optical fabrication capabilities to support all levels of care. This contains the equipment and consumable materiel required to provide for the fabrication of multivision and limited single vision lenses. This assemblage augments the OES Optical Fabrication Unit Portable Field.	Successful review of the LIN and non Lin items. All recommended changes and additions were made from the assemblages based on professional military judgment, deployed experience and the capabilities of the user.

Leadership and Major Changes of FY14

Project Manager, Medical Devices
(b) (6) transitioned July

Deputy Project Manager, Medical Devices
MAJ (b) (6)

APM, Medical Materiel Solutions
(b) (6)

APM, HealthCare Technologies
MAJ (b) (6) transition to MAJ (b) (6)

Chief, Acquisition Information Division
(b) (6)

APM, Integrated Logistics
(b) (6)

A. Healthcare Delivery

1) CH-47 Surgical Suite. Collaborated with USAMMDA to develop the genesis of a CH-47 Surgical Suite. Worked to secure the necessary equipment and supplies for a senior level demonstration of what "could be" for the future surgical suite in the air.

2) Supported Foreign Military Sales (FMS)

B. Veterinary Services

1) Projected FY15 set review

C. Training and Education

1) Defense Acquisition University:

a. 5- Level III - PM (1 Certification)

b. 1- Level II - PM

c. 2- Level I – PM

d. 1- Level II- SPRDE

e. 1- Level II – LCL

f. 7- On the Spot Cash Awards/Time Off awards

2) Continuing Education

a. One employee obtained an MBA from Mount St. Mary's

b. One employee obtained a Masters in Program Management from Penn State

D. Research and Development

1) Milestone B for laboratory assay traumatic brain injury (LATBI) project. Worked with USAMRAA on a new pay for performance contract with Abbott Industries on the TBI Biomarker effort. This effort will total over $19M (Reduced through negotiation and better understanding of objectives from an initial proposal of $50M) and will be based on a payment for performance contract. This should improve disbursement rates and also motivate the contractor to meet agreed upon milestones. In addition, successfully completed enrollment to Banyan LATBI pivotal study and secured Philips as a subcontractor to Banyan for feasibility on a new point of care device.

2) Support setup of PoNS Level 1 study at the University of Wisconsin. Statistical analysis of data will be utilized to compute number of subjects needed for Level 3 study; IPT selected 3 clinical sites to conduct the level 3 clinical studies utilizing the PoNS v4.0 device; Development of the training material, manuals, post-test and training strategy for the PoNS device to be used in Level 3 study.

3) Cooperative Research Agreement Development Agreement (CRADA) between Essex Industries, LLC and USAMMA regarding maintenance, sustainability and Customer Assessment of Liquid Oxygen for MEDEVAC and battlefield scenarios. Maintenance, sustainability and customer assessment have been completed.

4) Paved the way for the implementation of a Phase I and II process for the enterprise testing, evaluation, and selection of joint service medical equipment. Successfully competed for Defense Health Program

(DHP) 6.7 funds in excess of over $2,000,000 in support of environmental, operational, user, and air worthy certification testing and evaluations. Major equipment items included patient blood and fluid warmers, IV pumps, ventilators, suction, and patient monitors.

5) Submitted one Small Business Technology Transfer (STTR) and three new Small Business Innovative Research (SBIR) topics and all of them being approved and funded for a total of $1.35 million
   a. Cricothyrotomy (2 contracts awarded)
   b. Multiplex Biomarker Assay (4 contracts awarded)
   c. Evoked potential for TBI (2 contracts awarded)
   d. Development of novel wound dressing technology combining advanced hydrogel and perfusion enhancement technologies

E. Resource management and Budget
   1) FY14 funds managed:
   2) FL8D RDTE ($6.3 million)
   3) DHP RDTE ($14.7 million)
   4) OPA ($20.3 million)

F. Information Management
   1) N/A

G. Operations
   1) N/A

H. Modernization
   1) Completed Initial procurements for the following new capabilities.
      a. AVCC - Analyzer Vet Clinical Chemistry
      b. DLLM - Diode Laser Light Meter
      c. MESPT - Medical Equipment Set: Physical Therapy USUDV - Ultrasonic Unit Diagnostic Veterinary VESCCB - Veterinary Equipment Set, Canine Care Basic XRAPDR - X-Ray Portable Digital Radiography

I. Logistics
   1) Fielded 7,683 items to deployable medical units
   2) Initiated 68 LIN obsolescence directives
   3) In order to clean up the logistics trail on our LINs, we have completed over 730 maintenance actions against the assigned NSN's allowing for divestiture and disposition of equipment.
   4) Completed 80 disposition instructions and loaded them to the ARMD website.
   5) Completed Maintenance Plan initiative resulting in a more robust and improved Maintenance Plan for Life Cycle Support Plans
   6) Completed 3 Maintenance Plans within the new format
   7) Worked with Maintenance Depots and Force Sustainment Directorate on improving recapitalization process for medical equipment
   8) Secured 8 training classes for the DEPOTS and for our maintainers on current Army TOE Equipment.

9) Managed 113 UAs/SKOs

10) Managed 89 pieces of equipment

11) Processed 9 ZLINs with 24 more items that were initiated for ZLIN processing

12) Participated as IPT members on 28 IPTs

J. Construction

1) N/A

K. Health and Environment

1) 3 Standing Desk and 1 alternative seating for better ergonomics

L. Other

1) Presented awards

a. 1- Superior Civilian Service Award

b. 2- Commander's Award for Civilian Service

c. 2- Achievement Medal for Civilian Service

d. 1- Presented first ever Honey Badger Award by the USAMMA Commander for resilience and tenacity in achieving results (steam sterilizer effort)

e. 1- Certificate of Appreciation

M. Appendices

1) See Electronic Data Management System for Advanced Development official documentation

2) See USAMMA Shared drive

END of Project Manager, Medical Devices (PJM, MD)

5.2 PROJECT MANAGER, INTEGRATED CLINICAL SYSTEMS (PJM, ICS)

5.2.1 MISSION

The mission of the Integrated Clinical Systems (ICS) Program Management Office (PMO) is to execute a patient-centric, system of systems approach to ensure timely delivery of affordable, sustainable, interoperable, and information assurance compliant capabilities in support of clinical requirements for fixed and deployed medical treatment facilities. Specific responsibilities include managing Picture Archiving and Communication Systems (PACS), imaging, and teleradiology program initiatives; executing the Technology Assessment and Requirements Analysis (TARA) program, and managing Information Assurance (IA) requirements for designated medical devices.

- **Introduction -** PJM, ICS is the materiel developer (MATDEV) and lifecycle manager for all imaging, image management, and major clinical systems that integrate with the DOD Electronic Medical Record (EMR). PJM, ICS is actively engaged in the following task activities:

✓ Establishing a fully capable imaging enterprise architecture managing all medical images. This effort includes integration of other medical images such as pathology slides, captured surgical images, and ophthalmic images.

✓ Federating all regional image repositories into a vendor-neutral architecture.

✓ Providing imaging related Subject Matter Expert (SME) input in support of the MHS Electronic Healthcare Record (iEHR) DOD/VA initiative.

✓ Completing deployment of the ARMD system

✓ Beginning deployment of the Integrated OR and Pharmacy RFID systems for the entire AMEDD.

✓ Beginning conversion from CR-to-DR on all our imaging modalities.

✓ Developing and providing long-term support to telehealth initiatives.

✓ Supporting the Army standardization effort.

5.2.2 FUNCTIONS

ICS is the Army Medical Department (AMEDD) focal point for managing all imaging, image management, and major clinical systems that integrate with the DOD EMR. Responsibilities include managing PACS, imaging, and teleradiology program initiatives, executing the TARA program, and managing IA requirements for all medical devices.

- **The Product Manager for Image Management Systems** (PM IMS) - Assists in the TARA Program and provides lifecycle management of PACS, teleradiology, and other image management capabilities.

- **The Product Manager for Clinical Technologies** (PM CT) - Executes the TARA program and provides lifecycle management of all medical devices/clinical systems.

- **Director/Coordinator**

✓ TARA Site Visits: Completed 7 TARA site visits including the medical treatment facilities (MTFs) at the following sites: Fort Bragg, Fort Huachuca, Fort Sill, Fort Leavenworth, Fort Leonard Wood, Fort Meade/Detrick/Meyer, Site R, and Fort Sam Houston & Wilford Hall. Completed 2 mini-TARA visits at the command request to review certain imaging modalities including the medical treatment facilities (MTFs) at the following sites: Fort Drum and Fort Knox. More than $14.5 million in savings was identified during these visits. Prepared 30- to 100-page reports for each facility outlining 3-5 year replacement plans for each of the modalities found in the MTF.

✓ Capital Investment Medical Systems: Performed group buys of capital/investment medical systems for integrated operating rooms (IORs), plasma sterilizers, anesthesia devices, and pharmacy equipment saving the AMEDD more than $7.45 million.

✓ Integrated Operating Room (IOR): Secured $55M in funding for the IOR modernization across the AMEDD. Using civilian facility IOR models, a standard equipment template was formulated by ICS staff. Each of the 21 MTFs identified for upgraded IORs will be customized based on caseload, workflow, cost, and future renovations. IA protocols are required for the vendors entering the installation project. In addition, proper DIACAP (DOD Information Assurance and Accreditation Process) and CoN (Certificate of Networthiness) forms have been sent to vendors for completion prior to installation. ICS is working closely with DLA-Troop Support in Philadelphia to complete an Indefinite Delivery/Indefinite Quantity contract in order to establish baseline costs before complete contracts are awarded; this will ultimately expedite the acquisition process and delivery timelines to each MTF.

✓ Anesthesia Recording & Monitoring Device (ARMD): The system brings the Anesthesia Care documentation into the digital age by interfacing with the anesthesia machine (to record agent delivery data), the physiological monitor (to record vital signs) and the Surgical Scheduling System (S3) for patient demographics. The outcome is a digital medical record that is easy to read (analog records were sometimes illegible) and can be used for anesthesia care quality management, both locally and across the DoD. This is a tri-service proliferation in conjunction with the Navy and Air Force which was pushed by TMA.

✓ Pharmacy RFID: The system will automate the retrieval of refill pickup utilizing RFID technology to monitor stored prescriptions within the system. This system will provide more accuracy, reduce errors and increase efficiency involved with retrieval of refill prescriptions. MEDCOM was able to set aside $5.8 million to execute this project across 9 MTF's which saves over $900 thousand by making this a group buy and executing on one contract with the assistance of USAMRAA.

✓ Medical Care Support Equipment (MEDCASE)/Super Capital Equipment Expense Program (SuperCEEP) Funds: Executed more than $134 million of FY 2014 MEDCASE program mission funds. Executed $17 million of SuperCEEP program mission funds. Major equipment acquisition areas included diagnostic imaging, medicine, laboratory, surgical, nursing, and PACS program.

✓ Requirements Review: Conducted a complete review of all requirements identified for procurement to support AMEDD MTFs. The TARA team reviewed 103 SuperCEEP requirements totaling more than $23.5 million and 90 MEDCASE requirements valued over $93 million. Factors discussed for consideration in the prioritization process included clinical acceptability (standard of care), supportability, system effectiveness, workload, criticality of need, and life expectancy.

✓ Enterprise Clinical Image Archive (ECIA): Deployment has was initiated for the ECIA, a joint Army/Navy vendor neutral archive which will provide access to all Army and Navy medical image data across the enterprise.

✓ Southern Regional Medical Command (SRMC) PACS Replacement: Source selection and award were completed for the replacement of the PACS at ten sites within the SRMC.

✓ Support to Chief Information Officer (CIO) and MEDCOM: Continued to work closely with the to support the ICS mission and portfolio of products with significant emphasis on the Integrated Operating Room and the Enterprise Clinical Imaging Archives. Areas of collaboration and support include IM/IT governance, stakeholder functional coordination, and IA policy development. To lessen the impact of IA resource limitations, ICS conducted re-engineering efforts to optimize the IA certification processes and to increase involvement of IA personnel in development of contract solicitations for vendor proposals or quotes. The new contracting language is designed to allow for development of an enforceable schedule and for better evaluation of a vendor's capability to achieve IA certifications.

✓ Advanced Development Programs: Responsible for three advanced development programs: the portable ultrasound, deployable dental X-Ray system, field X-Ray Bucky, portable digital X-Ray system, field C-Arm, and field, CT initiatives.

5.2.3 MAJOR EFFORTS OF FY14

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
Update Supply Bulletin DA SB 8-75-S5	Ensure Supply Bulletin is current.	Supply bulletin helps to disseminate information on ICS and its functions and guidance on acquisition processes.
Support to Diagnostic Imaging and Radiotherapy Subcommittee (DIRS)	Manage twice yearly meetings and provide data management support in DIRS decision making process.	DIRS functions efficiently and clinicians do not lose valuable clinical and staff time.

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
Update and Manage WebMRE	Designing a prioritization module for the annual Strategic Technology & Clinical Policies Council (STCPC).	This module allows for the real-time web review and prioritization by the STCPC for all medical systems throughout the AMEDD. This tool is used to budget the execution of over $100 million. The task included creating approximately 100 new pages/reports.
Support for OTSG Clinical Consultants	Provide data collection and decision-making support for senior clinicians.	Senior clinicians can provide feedback and management insight to community hospitals.
Management of MEDCASE and SuperCeep Requirements	About $151 million of program funds were managed.	Fixed facilities have appropriate medical technology to meet needs of Warfighters, families, and retirees.
Implementation of Information Assurance Strategy	Developed IA for networked medical devices in support of the MEDCOM.	Network security is enhanced and clinical operations can have confidence of network continuity.
Information Assurance Certification Process Re-engineering	Developed optimize Information Assurance Certification Processes to maximize the use of limited Information Assurance Resources.	Enable for implementation of processes designed to increase throughput. Optimized processes will reduce but not overcome the backlog of Information Assurance Certification projects.

5.3 PROJECT MANAGER, MEDICAL EVACUATION – MISSION EQUIPMENT PACKAGE (PJM, MEDVAC (MEP))

5.3.1 MISSION

PjM, MEDVAC is responsible for management of the MEP (a group of subsystems and equipment) undergoing installation on UH-60A/L Black Hawk helicopters participating in the UH-60 Recapitalization Program. MEDEVAC (MEP) is involved in the conversion of some of these helicopters into MEDEVAC aircraft. The final product shall have the same medical capabilities as the HH-60M Black Hawk MEDEVAC helicopter that is currently being fielded for rapid evacuation of the wounded warfighter.

5.3.2 FUNCTIONS

In 2010, the Office of the Surgeon General (OTSG) of the Army directed the Medical Research and Materiel Command (MRMC) to become the funding source for a Project Management Office dedicated to management of the mission equipment package for MEDEVAC. In response to this new directive, USAMMA created PMO MEDEVAC (MEP) to provide oversight and management of MRMC's involvement with this project. PMO MEDEVAC (MEP) works directly with the office of the Product Director (PD) MEDEVAC within the Office of the Project Manager - Utility Helicopters at Redstone Arsenal in Huntsville, Alabama. This combined team is dedicated to providing the World's finest MEDEVAC aircraft to meet the ground commander's requirement. Specific products include:

- Interim MEDEVAC Mission Support System (IMMSS) - This patient handling system includes seat pallets, seats, interior components, and a litter lift system.

- MEDEVAC Mission Sensor (MMS) - This subsystem is a Forward Looking Infra-Red (FLIR) sensor that will be used as a patient location device. MMS is critical in providing a continuous patient search capability during night and limited visibilirthweather operations.

5.3.3 MAJOR EFFORTS OF FY14

ACTION OR CHANGE	DESCRIPTION	EFFECT OR RESULT
Procurement of 62 Interim MEDEVAC Mission Support Systems (IMMSS)	Teamed with the LSFMA Contract Shop (Redstone Arsenal, AL) under an IDIQ contract to procure 62 Interim MEDEVAC Mission Support Systems (IMMSS)	This brings the total of IMMSS in the MEDEVAC fleet to 216
Procured 39 Medical Mission Sensor (MMS) Forward Looking Infra-Red (FLIR)	Procured 39 MMS FLIR	Despite a FY14 program funding decrement of over $3M, teaming with PD MEDEVAC and tiered pricing allowed this program to procure the target quantity of 39
Aeromedical Evacuation En Route Critical Care Validation Study (AE2C2VS)	Executed validation study of Black Hawk MEDEVAC helicopter's usable space for medical treatment and crew activities	Data from this study will influence changes to the Black Hawk MEDEVAC helicopter's medical treatment spaces to facilitate advanced Army Flight Medic (68W) training to the EMT - Paramedic level
Prototype Transport Telemedicine (T2) System Demonstrative Flight	Executed flight of prototype T2 System with C/1-168th MEDEVAC, in Stead, NV at the Nevada Telemedicine Conference	Orchestrated inter-agency, inter-governmental organizations to demonstrate cutting edge telemedicine technologies to a wider audience
Cooperative Research and Development Agreement (CRADA) with Essex Industries, Incorporated	Successful Customer Assessment, environmental test and maintenance evaluation of liquid oxygen (LOX) system with C/1-168th MEDEVAC, in Stead, NV for patient oxygen delivery at altitude	Operational, Environmental and Maintenance/Sustainment Testing results reported in August 2014 poster presentation at Military Health System Research Symposium (MHSRS) in Fort Lauderdale, FL – received Honorable Mention

END OF DEPUTY FOR ACQUISITION SUPPORT (DFA)

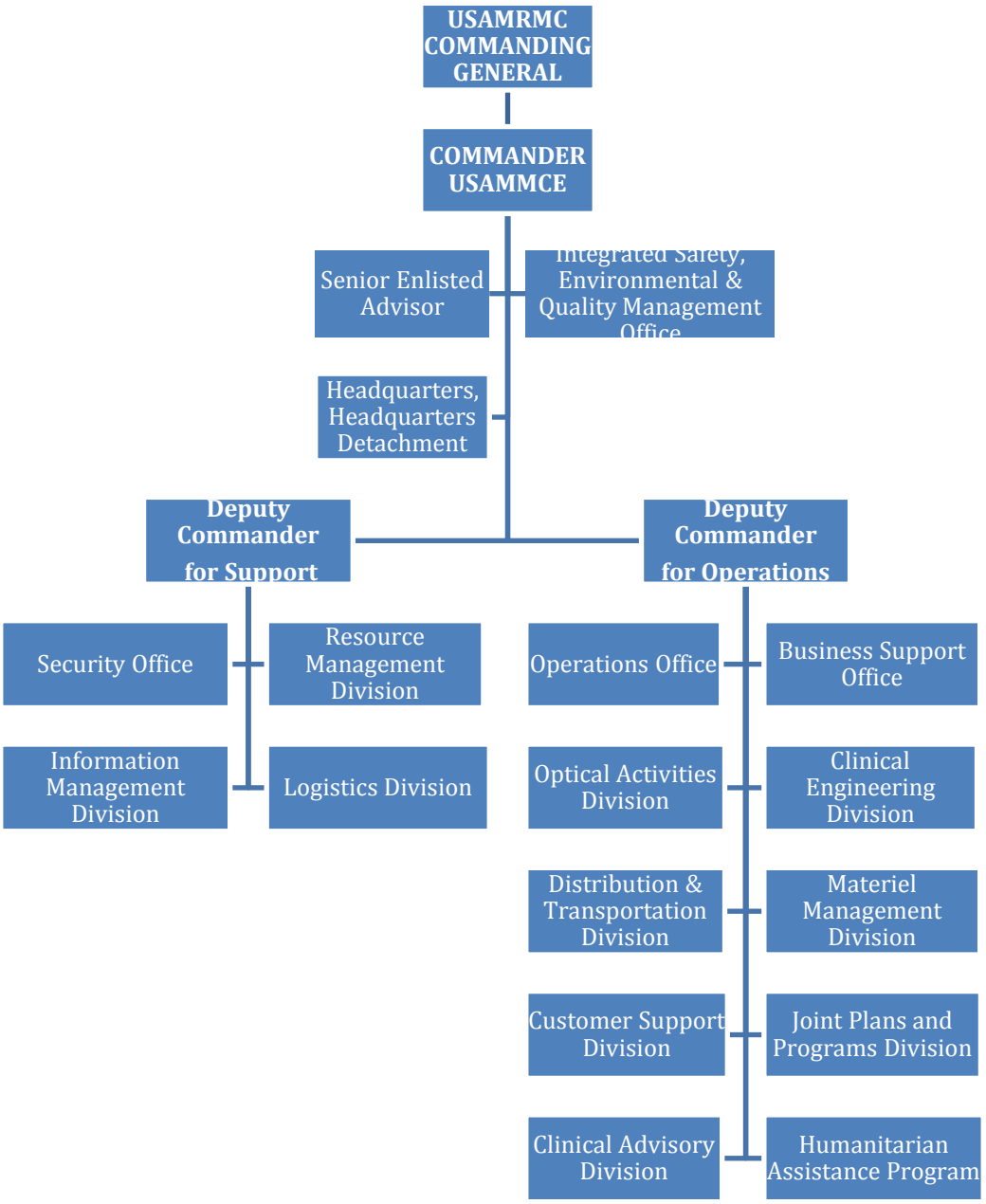
Section 29

Fiscal Year 2014
Annual Historical Report

U.S. Army Medical Materiel Center - Europe

ORGANIZATION

1-1. ORGANIZATIONAL CHART.

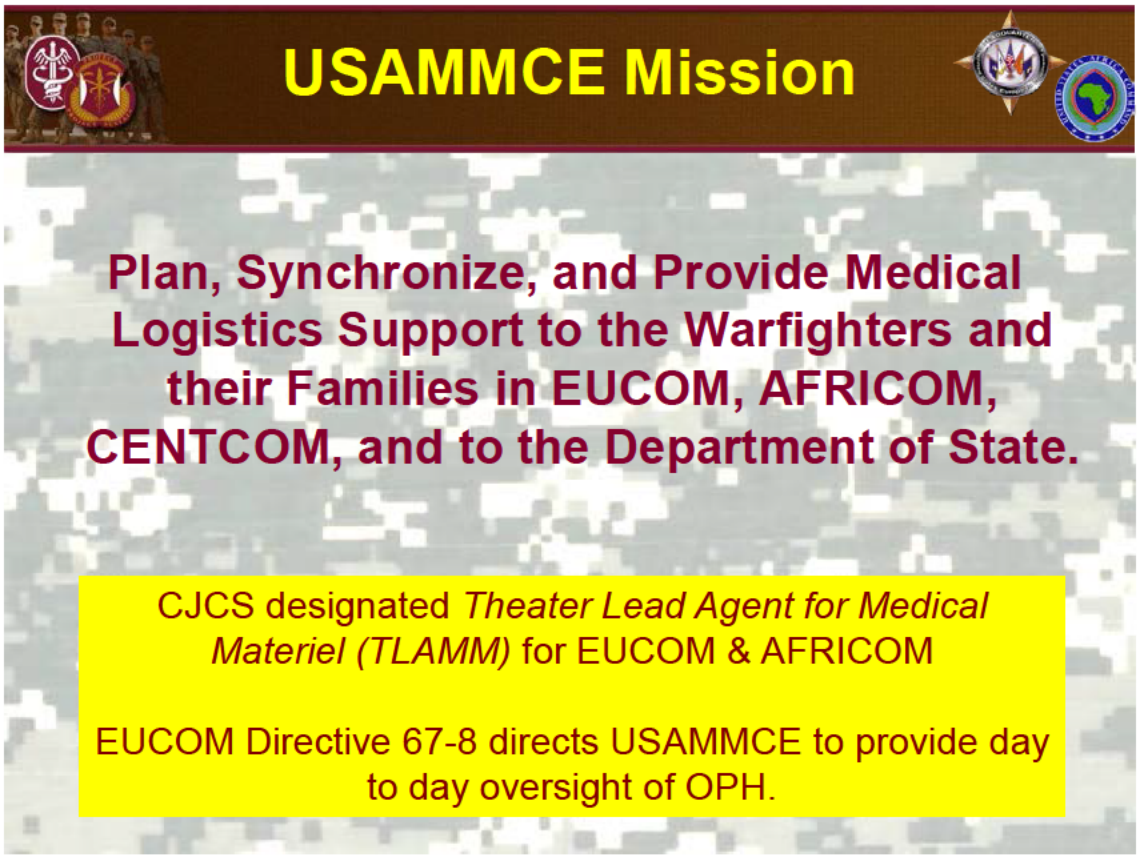


A. **GENERAL.**

1) Internal. USAMMCE is internally organized into two distinct but interdependent directorates: Operations and Support. Each of these directorates is headed by a deputy commander who answers directly to the USAMMCE Commander.
2) Operations. The USAMMCE Operations directorate is focused on external customer support and includes the following Divisions: Business Support Office (BSO), Clinical Advisory Division (CAD), Clinical Engineering Division (CED), Customer Support Division (CSD), Distribution and Transportation Division (D&T), Humanitarian Assistance Program (HAP), Joint Plans and Programs Division (JPPD), Materiel Management Division (MMD), Optical Activities Division (OAD), and Headquarters and Headquarters Detachment (HHD)/ Operations (OPS) Office.
3) Support. The USAMMCE Support directorate is focused on internal customer support (i.e. employees of USAMMCE), and includes the following Divisions: Information Management (IMD), Logistics Division (LOG), Resource Management Division (RMD), Integrated Safety, Environmental and Organizational Quality Management Office (ISEOQM), and the Security Office.
4) Military Branches. Although not officially defined as a joint organization, USAMMCE has permanent military representation from the U.S. Navy (within CSD), the U.S. Air Force (within CSD), and the U.S. Army (approximately 34 officers and enlisted Soldiers, permanently assigned to the Headquarters and Headquarters Detachment).

MISSION

USAMMCE MISSION STATEMENT.



FOCUS AREAS

A. USAMMCE VISION. The USAMMCE Vision is to provide value and inspire trust through innovative and responsive medical logistics solutions. To achieve this vision we are committed to:
   1) Providing superior medical logistics support to ensure our customers have what they need to provide the best medical care possible.
   2) Aggressively supporting the development, implementation, and sustainment of the Theater Enterprise-Wide Logistics System (TEWLS).

B. USAMMCE FOCUS. USAMMCE focused on the following goals to achieve our Mission and Vision.
   1) Achieve excellence in supply chain integration.
   2) Integrated and supportive internal systems pertaining to transformation, International Organization for Standardization (ISO), Voluntary Protection Program (VPP).
   3) Medical Logistics Training Center of Excellence.
   4) Strategic Communications

C. MISSION ESSENTIAL TASKS.
   1) GMETS. USAMMCE General Mission Essential Tasks:
      a. Conduct Command and Control.
      b. Protect the Force.
      c. Provide Sustainment.
   2) CCMETS. USAMMCE Core Capabilities Mission Essential Tasks:
      a. Life cycle management of Class VIII materiel.
      b. Clinical engineering support.
      c. Clinical advice and consultation.
      d. Optical fabrication.
      e. Assembly, reconstitution, disassembly of Medical Equipment Sets, Kits, and Outfits (MESKO'S), also known as Kitting.
      f. Training logisticians.

D. USAMMCE STAFF. As of 30 September 2014, the USAMMCE Staff consists of approximately 34 officer and enlisted U.S. Soldiers, one U.S. Air Force and three U.S. Navy employees, 36 Department of the Army Civilian (DAC) employees, one Defense Logistics Agency (DLA) employee, and 275 Local National employees.

E. USAMMCE TRANSFORMATION. This fiscal year USAMMCE continued to evaluate relocation options:
   1) October 2013, coordinated with the Little Rock District U.S. Corps of Engineers (USACE), to initiate an Initial Outfitting and Transition contract for USAMMCE's relocation to KAD. Attended initial design meeting for the HAZMAT packing building (2238) at KAD. Provided input to the European Infrastructure Consolidated (EIC) review with special emphasis on determining USAMMCE relocation requirements for Germersheim, Germany.

   2) November 2013, Continued negotiations with the Little Rock USACE; refined HAZMAT packing requirements for KAD relocation; provided USAMMCE's KAD security requirements to IMCOM-E, USAREUR, and the Garrison; coordinated ERMC Commander & staff visit to KAD; answered data call for the 0% design contract for USAMMCE KAD buildings (2213, 2217, 2219, 2222, and 2264); refined USAMMCE's KAD building requirements; coordinated with Supersavers for proposed contingency racking system; began negotiations with Intralogistics for design/capacity study of the main KAD Distribution & Transportation building (2369).

   3) December 2013, attended meeting with IMCOM-Europe and Europe District USACE-for updates on the KAD project development. Coordinated with DPW Kaiserslautern for USAMMCE KAD parking requirements & location; continued to refine USAMMCE's KAD building requirements for input to

Europe District USACE- and the Garrison Department of Public Works (DPW); provided input to the KAD road and utilities requirements; continued coordination with Little Rock District USACE.

4) January through April 2014, continued coordination with Intralogistik to analyze USAMMCE's Distribution and Transportation materiel processing in order to recommend the specifications for a suitable racking/conveyor system. Continued coordination with Supersavers for proposed contingency racking system; continued refinement of facility requirements for relocation to KAD with the Garrison DPW, A/E contractor, and Europe District USACE. Conducted several KAD on-site tours to articulate USAMMCE's requirements. Attended a meeting with IMCOM-E, 21st TLSC-E, and USAMMCE, chaired by Europe District USACE, to determine the facility bill payers.

5) May through June 2014 continued coordination with Intralogistik to analyze USAMMCE's Distribution and Transportation materiel processing in order to recommend specifications for a suitable racking/conveyor system by 31 July 14. Spacesavers submitted their proposal for contingency racking system. Submitted USAMMCE's comments to the 10% final submittal for the KAD relocation. Coordinated a $2.2M fund transfer to the USACE, European District for USAMMCE/MEDCOM. Continued coordination with USACE, Little Rock, on the IO&T schedule. Currently conducting USAMMCE's relocation inventory to determine what materiel must be replaced, relocated, and/or disposed of by February 2017. Coordinating USAMMCE's design/build HAZMAT packing KAD building requirements (which is at the 35% design/build threshold).

6) July 2013, initiated coordination Initial Outfitting and Transition (IO&T) with MEDCOM and Health Facility Planning Agency (HFPA) for the development of a Scope of Work. Continued coordination with Intralogistik on USAMMCE's Distribution and Transportation proposed racking/converyor system for KAD building 2369. Hosted meeting with Wayss & Freytag (W&F) on the HAZARD packing operational requirements for KAD building 2238.

7) August through September 2013, participated and updated the USAMMCE Transition Group on relocation efforts. Hosted a Reduction-In-Force information meeting with local Civilian Personnel representative. Conducted several KAD tours for USAMMCE personnel to familiarize them on the relocation efforts to KAD. Initiated and conducted a coordination meeting with the 21st TLSC-E to gain insights into the 21st TLSC-E operation with the idea of obtaining future TLSC-E support. Continued to participate in weekly KAD building 2238 designer meeting with W&F, USACE, and 21st TLSC-E. Coordinated telecom meeting with USACE, Little Rock and the continued development of USAMMCE's IO&T SOW. Met with INCOM-E on potential sites for USAMMCE's BDE HQs.

BUSINESS SUPPORT OFFICE (BSO)

GENERAL.

The Business Support Office (BSO) staff consists of three Department of the Army Civilian (DAC) employees and 16 Local National employees.
This fiscal year, the USAMMCE BSO staff made significant contributions to the TEWLS project where TEWLS was selected for the AMSUS 2014 Medical Logistics Award.

MISSION.

The Theater Enterprise-Wide Logistics System (TEWLS) BSO provides comprehensive business support by sustaining, improving and expanding the business enterprise through analysis of supply and logistics policies, procedures, and practices. Specifics include support in areas such as business and information technology integration and collaboration between the functional subject matter experts and Joint Medical Logistics Functional Development Center (SAP/JMLFDC) technical staff, SAP expertise in assigned areas, TEWLS troubleshooting, functional integration testing, functional development and documentation, TEWLS End User training, and Tier 1 and 2 help desk support. The BSO articulates changes for the TEWLS application that will support new business

processes, submits the changes, participates in the actual design and development of the changes required, and tests the changes to the application. The BSO designs, develops, and implements statistical reports in Business Intelligence/Business Warehouse (BI/BW) to assist management in gathering information for analysis and/or improvement. The BSO also provides direct support to USAMMCE, USAMMC-K and USAMMC-SWA. Following are the specifics functions the BSO performs:

A. Managing and assigning trouble call/issues with resolution severity I, II, & III from Tier I & II support; managing action items and issues; and coordinating with stakeholder and enterprise level organizations.
B. Providing training, including initial end-user training, recurring and sustainment training, new policy or business process change implementation training, and developing training documentation, including work instructions and computer-based training products.
C. Providing module-specific sustainment support to all SAP modules used in TEWLS, to include development of specifications for needed enhancements or improvements, functional testing, troubleshooting, and application support.
D. Monitoring Exchange Infrastructure/Message Queue (PI/MQ) interfaces ensuring traffic flow with Defense Logistics Agency–Transaction Services (DLA-TS) and Source of Supply.
E. Implementing solutions for TEWLS system corrections.
F. Preparing presentations to Configuration Control Board (CCB) on TEWLS system end-user problem reports and enhancement requests by evaluating level of impact on user community, assigning a priority, and estimating human, financial and time resources on those Action and or Issue items impacting Cost, Resource, and business processes as requested.
G. Monitoring testing and transport processes.
H. Managing enhancement or corrective actions requiring SAP involvement.
I. Managing business process changes needed to adapt to future SAP releases.
J. Managing transport approvals in accordance with Standard Operating Procedures.
K. Providing database support administration from a data perspective through members matrixed to the Technical Support Office (TSO).
L. During conversion phases, creating core SAP Legacy System Migration Workbench (LSMW) tools to allow data migration from legacy to ERP systems.
M. Performing system research and handling/managing process and system change requests for approval.
N. Participating in future phase blueprinting and realization/configuration activities.
O. Providing reporting support to include: Business Intelligence/Business Warehouse (BI/BW) and Issue Resolution Database (IRDB) management.
P. Defining and testing role, authorization and configuration requirements that the Technical Support Office (TSO) creates.
Q. Providing oversight and guidance to data managers within the Army MEDLOG Enterprise and its components.
R. Directing and supervising the collection, integration, and analysis of specific data management information to support the Objective Enterprise Medical Materiel Activity (OEMMA), the ERP Central Component/Executive Steering Committee (EEC/ESC), and the TCC deliberations and decisions as they relate to items in Solution Manager (SOLMAN), as well as prioritization of Army system requirements.

S. Ensuring that the audit Quality Assurance (QA) functions required by the OEMMA and TCC are performed.

T. Reviewing the Data Management support provided to specifically identified DoD organizations to verify compliance with reference Federal Cataloging Committee guidelines and Army policy.

U. Extracting, gathering, and analyzing data to support Enterprise-Wide business decisions and performance tracking (in coordination with OEMMA), to include providing data in support of Balanced Score Card strategy management.
V. Developing and maintaining work instructions for assigned master data areas.
W. Assisting the OEMMA with metrics in coordination with the AMLE organizations to determine the quality of master data. Based on metrics results, develop performance improvement initiatives to reinforce or update master data policy.
X. Enterprise lead agent and principal contact for cataloging non-National Item Identification Number (non-NIIN) materiel/items, and the authority over non-NSN material master data.

FOCUS AREAS.

A. Military Health Systems (MHS) Tickets. The BSO continued to provide TEWLS Release II (Version 2.01.10.00) sustainment activities affecting users across the Enterprise. In this period the BSO staff created and resolved 5,789 Military Health System (MHS) Help Desk tickets affecting all modules. These tickets resolved user problems, corrected errors, identified and implemented system improvements, and supported users worldwide. 28% of these MHS Help tickets were in support of users not assigned to USAMMCE (USAMMC-K in Korea and USAMMC-SWA in Qatar). Many of the Help tickets were the basis for Systems Applications Programs (SAP) Solution Manager Action Items leading to system enhancements or corrections.
B. Balanced Score Card. In FY14, the USAMMCE Balance Scorecard initiative 3.1 (owned by BSO) changed from a subjective "tracking customer satisfaction for TEWLS training delivered in a classroom environment" to an objective "Percent Improvement after Training" which measures improvement in knowledge. The difference in scores is calculated to demonstrate the percent of learning that took place during the training. FY 2014 student improvement in test scores has ranged from 22% to 41%. A third assessment was added 3 months after training using the same questions. Generally, about 90% of these post-post tests scored the same or better than the end of course test. The remaining 10% scored worse in the post-post test than the end of course test.
C. Training Material Development. End user training is a critical element in TEWLS sustainment. The USAMMCE BSO has been the key force behind the continuing development and updating of training materials and course curriculum. A total of 67 roles-based courses are now available to the end user community through three learning platforms: TEWLS University, the Education Portal, and Army Training Requirements and Resources System (ATTRS). The training team transitioned from primarily classroom based training to primarily computer-based training supplemented by classroom and OJT (on-the-job). Training materials continue to be updated and developed as changes and improvements are incorporated into TEWLS. USAMMCE has six employees who each spent at least 50% of their time dedicated to training development and training updates.

D. Training Provided. Between 1 October 2013 and 30 September 2014, 211 classes were taught by SMEs and BSO functional experts either in a classroom (at USAMMCE or SWA) or via Defense Connect Online (DCO) Connect. These classes were a combination of refresher training, initial end-user roles-based training, and training based on changes and upgrades to TEWLS where transactions were added and/or business processes revised. These classes ranged from one hour to multi-day trainings. A total of 1009 students were educated. Currently, the entire USAMMCE Training team is Army Basic Instructor Course (ABIC) qualified.
E. USAMMC-SWA and USAMMC-K Support. The BSO provides ongoing support to both of these locations. This support consists of two main areas. The first area is rotation support where military personnel rotate into and out of the CENTCOM location. The BSO provides extensive support to teach new staff TEWLS fundamentals in respective roles as well as in entire job functions, such as Chief, Material Management and Accountable Officer. Three personnel (two WM and one SD) went TDY to SWA once in November 2013 and again in July 2014. One team of two (WM and BSO Chief) went TDY to Korea in January 2014 to train the new accountable officer, C/Material Management and Outbound Manager. All of these TDYs provided new training to rotating personnel and sustainment

training for existing staff. The BSO also uses DCO Connect teleconferencing capability to provide sustainment and knowledge transfer on both new and existing TEWLS roles and processes. During FY14, numerous DCO connect sessions were conducted with personnel at Korea and at SWA. As an example six DCO sessions were held for new WEB Portal reports and New Item Request (NIR) processes.

F. Developmental Integration Testing (DIT) of the TMIP Intermediate Medical Logistics System (TIMLS). The TMIP Intermediate Medical Logistics System (TIMLS) supports the capabilities required by medical logistics companies (MLC) to provide theater intermediate medical supply support to operating forces conducting expeditionary operations as identified in the Functional Capability requirements for TMIP Intermediate Medical Logistics (TIML) Medical Logistics Company (MLC) Supply Support (S2). The primary purpose of the Developmental Integration Testing (DIT) was to validate that the Theater Enterprise Wide Logistics System (TEWLS), as the information technology solution, supports the capabilities required by medical logistics companies (MLC) to provide theater intermediate medical supply support to operating forces conducting expeditionary operations. In the very near future a full-blown test on M3 functionality will be conducted. The USAMMCE BSO team designed and executed test scenarios that offered an opportunity to test multiple requirements as the scenarios unfolded. The results of these tests where then used by the Project team to fix bugs and to enhance the TIMLS capability.

G. XI to PI Upgrade. The upgrade from XI 3.0 to PI 7.3 was successfully finalized in this fiscal year which offers new features to the end-users such as Application Interface Framework (AIF). This allows monitoring data exchange in the ECC systems and enables end-users to correct and resend transactions which had errors. With the implementation of Web Services it is possible to easily establish synchronous interfaces allowing the retrieval of data from the remote business partner and to use it in the current transaction in the ECC system. Sample interfaces are IUID, Price Verification and the enhanced UDR.

H. Security. In FY 2014 the USAMMCE BSO security resource resolved 1517 customer assistance tickets in the Defense Health Systems (DHA – BMC Remedy) in the following categories of assistance: unlocking TEWLS accounts, locking TEWLS accounts, password resets, deleting user master records, resolving single sign-on issues, researching role problems/questions, submitting user access/modification request forms, resolving other questions, modifying user accounts, creating new user accounts, resolving workflow problems, resolving Customer Portal problems, resolving screen sequence issues, creating new test IDs, creating/modifying roles, creating LiveLink documentation, performing Separation Of Duty (SOD) analysis, submitting transaction SU53error results, and completing user traces. USAMMCE BSO performed 45 weeks of System monitoring for the AMLE.

I. Master Data Management. During FY14 the Master Data Management Team (MDM) completed 5065 external new item requests; completed 2465 internal new item requests; created 189 new customer master records; deleted 415 customer master records; added 98 new vendor master records: and deleted 5 existing vendor master records.

   A new transaction was developed, tested and transported to the production system that identifies materials that have not been used within the last 24 months. These materials can then be removed from the system. As a result 21,800 materials were flagged for deletion. This leaves 51,000 active materials in the USAMMCE catalog and 37,900 active for the Korea plant.

   The checks and balances reporting on Master Data (started last FY) for plants USAMMCE, USAMMC-SWA, and USAMMC-K resulted in 6 weekly single checks for a total of 900 runs; 15 monthly single checks for a total of 540 runs; and 3 quarterly checks for a total of 36 runs. This process significantly improves the synchronization of Master Data across the Enterprise and all 3 enterprise TLAMM locations. Accurate master data is a TEWLS key performance indicator (KPI) that was absent in all previous DOD legacy medical logistics programs. This accuracy is critical in maintaining successful MDM strategies.

   The MDM team functioned as core team members in blueprinting and testing the new NIR (New Item Request) process with extended Universal Deposit Repository (UDR) search. This required a week TDY in February 2014. 17 new test scripts were developed and executed to test the full functionality

of the new NIR process with extended UDR search capability. This test phase lasted 2 months. In conjunction with this new process it was required creation of a new table that holds vendor and manufacturer names with an associated 3 digit code. The table is accessible via a drop down within the material master and the New Item Request form. Having the manufacturers/vendors loaded in a table will ensure data accuracy in comparison to manually entered information. To maintain the table, a cleansing of already used vendors/manufacturers in the system was required and the 3 digit code had to be assigned. The cleansing was performed together with the BSO

USAMMA MM Team and BSO USAMMCE MM Team. A new entry to this table and the assignment of the respective 3 digit code is the MDM team's responsibility. A total of 84 new entries were created through the end of FY14. Transaction SCOV Testing: This testing coverage analyzer tracks how much of the testing code was exercised in testing or even in the course of normal production use. The Coverage Analyzer reports on code coverage at the procedure, branch, and statement levels. It also tracks the frequency with which code is executed and the occurrence of runtime errors.

SCOV testing was exclusively done for custom Z transactions of each module. This included 5 test scripts for MDM and MRP.

J. Production Planning (PP) Accomplishments. Created, revised, and updated 83 business process test scenarios for developmental and system integration testing of newly customized processes; conducted 5 weeks of Remediation/Regression testing; conducted 8 weeks of TEWLS UDR/MMC Developmental and System Integration testing; conducted 6 weeks of Developmental and System Integration testing for Single Line of Accounting (SLOA) in TEWLS; conducted 4 weeks of Developmental and System Integration testing for SCOV Code Clean up in TEWLS; created and revised 20 transactional work instructions for end user training. Created, documented, tested, and implemented 5 Production Planning System Change Requests (SCRs) for process enhancements, role changes, reports, and bug fixes.

Army Prepositioned Stocks (APS) APS-2/Germany European Activity Set (EAS): In March 2014 USAMMCE Kitting was appointed as the lead agent for the Management of Army Prepositioned Stocks (APS) Germany European Activity Sets (EAS). This includes the packing, inventory, hand off to using units, replenishment, storing, and shipping of these Medical Equipment Sets. The USAMMCE BSO Production Planning (PP) team supported this new requirement by providing training to the end users, revising current business processes to accommodate the new MAMC functionality, and monitoring system transactions to identify potential problems.

USAMMCE Kitting re-organization: In April 2014 the USAMMCE Joint Plans and Programs Division (JPPD) was re-organized into USAMMCE Kitting. This re-organization mainly consisted of consolidating JPPD assets and resources within other USAMMCE divisions. The USAMMCE BSO Production Planning (PP) team supported this re-organization by establishing procedures and responsibilities for planning, coordinating, producing, and managing the assembly, reconstitution, and disassembly of medical Sets, Kits, and Outfits (SKOs). In addition, extensive testing by the PP team on roles and authorizations was conducted to ensure that no Segregation of Duty (SOD) existed with the required role combinations.

325 Ground Ambulances: USAMMCE Produced and shipped 325 Ground Ambulance Medical Equipment Sets to the Afghanistan Army and Police. This requirement normally takes four to six months to fulfill, but due to the urgency of need, USAMME completed the task in less than eight weeks. The USAMMCE BSO supported this effort by providing training to the end users, revising current business processes to accommodate the short lead time, and monitoring system transactions to identify potential problems.

K. Sales and Distribution (SD) Accomplishments

The SD team participated in testing of new processes and regression testing of existent functionality during various system change events such as the implementation of SLOA (Single line of accounting), MMC, (Material Master Catalog), Medical Assemblage Management Capability (MAMC), for TEWLS release 2.01.10.00, as well as the remaining testing and changes for Item Unique Identification (IUID) , TIMLS-S, and remediation in 2013. Changes to the TEWLS production environment to benefit users are customers began with the implementation of reports to the TEWLS customer WEB portal that allows customers **to run these reports for procurement research on their own. The reports implemented were:**

- Transaction Register
- Due-out report
- Controlled substance report
- Turn-in Report
- Free Issue Report

The increased use of materials with alternate units of measure, where the purchase unit as represented by the base unit of measure in TEWLS is issued out of TEWLS in multiples of the base unit of measure (sales unit), the price in the B7 MILSTRIP supply price change status was incorrect. The price was the base unit of measure price but didn't represent the actual value of the material as sold and a correction was made to the status message to reflect the correct price. The correct price, by sales unit if an alternate unit existed, was already displayed on the customer Web Portal material master query correctly. The correct pricing was also applied to the new customer reports on the TEWLS customer portal. The logic behind this functionality was quite complex to get correctly functioning in all TEWLS modules.

Accountable Officers requested the Maximum Release Quantity (MRQ) be increased for the USAMMCE (SFV1) and USAMMC-SWA (SR2L) plants, to insure that stock levels in TEWLS more accurately reflected customer demands while reducing work load for sales managers.

The NIR (New Item Request) program was modified adding new user requested fields and enlarging the point of contact e-mail address fields to accommodate the longer mail.mil addresses.

A new statistical report, ZSDNIR_STATS, was created to allow material management divisions to better gauge performance and react to problems within the new item request processing. Changes and additions were also requested for the main transaction that is used to process NIRs. Additions to the ZSDNIR transaction included:

- Shelf life code added to ZSDNIR
- Added a free text PSR field to NIR
- Added a HAZMAT code field to NIR
- Added rule on customer portal to make the manufacturer name and manufacturer catalog number mandatory on type item ID 'M' entries.
- Increased the length of the nomenclature field to allow longer entries
- Added the vendor and manufacturer information to the NIR completion e-mails sent to customers.

SD personnel participated in two trips to Qatar to support the unit rotations with training**.**

L. TEWLS Warehouse Management (WM) Accomplishments.
FY 2014 Test Cycles:

MAMC SIT TEST 10 March 2014	UDR/MMC DIT Test: Jun 17 until 10 July
UDR/MMC SIT Test: 5-28 Aug	SLOA DIT Test: 21 July until 1 Aug

SLOA SIT Test: 5-28 Aug SCOV Code clean up: 5-28 Aug

The WM Team created and executed 28 test scripts for use in above test cycles. An additional 7 test scripts were created and executed during System Integration testing (SIT). Although most test scripts were successfully tested to completion, some corrections and refinements are still ongoing. TIML-S regression testing involved one negative testing result.

1) Item Unique Identification (IUID)
IUID cutover phase and implementation occurred in November 2013. WM-Team supported warehouse users in USAMMCE, USAMMC-SWA and USAMMC-K in capturing IUID material stock numbers of relevant materials. This included new cutover and labeling actions. After IUID was implemented the WM-Team assisted in correcting incorrect or duplicate equipment records.

2) Low Unit of Measure (LUM)
Prior to mission and force strength reductions in CENTCOM and EUCOM, USAMMCE was able to purchase materials in the same unit of measure as the selling unit of measure. With current force drawdown this requirement changed. During Supply Chain Meetings the solution in Low Unit of Measure sales LUM was introduced. This new process allows the splitting the purchasing unit of measure, adjust purchase price, and allows the sale at a lower unit of measure (LUM) to a customer. System checks implemented prevent a receiver from inaccurately receiving material at a wrong Order Purchase Unit (OPU). This change benefits all enterprise locations and allows the customer to purchase in smaller quantities than the purchased quantity.

To implement the LUM process for a designated material, a new material number was created for the LUM material (Target Material) with the lower unit of measure specified in the Material Master Data record. The original material (Source Material) number stays the same. The high-level LUM process is:

a. A material is identified as a possible LUM candidate.
b. The Accountable Officer makes the decision to designate a material as LUM.
c. The MRP Planner notifies the MRP Controller.
d. The MRP Controller submits an Internal New Item Request (INIR) for the material.
e. The BSO Master Data Manager creates a Material Master Record for the LUM material with a new material number.
f. The MRP Planner notifies the WM Inbound Manager Replenishment to ‘break down’ a specific quantity of source material to the target (LUM) material.
g. The Inbound Manager Replenishment manages ‘break down and movement of LUM materials both in TEWLS and physically within the warehouse.
h. As customers purchase LUM material, on-hand stock of LUM is depleted.

The MRP Planner monitors availability of LUM material using a report and notifies the Inbound Manager when to replenish a LUM material.
This LUM process affects the Material Management Division (MMD), the Business Support Office (BSO), and Distribution and Transportation Division (D&T). Identifying LUM material can also involve the Customer Support Division (CSD) and other sources as needed.
Transaction ZMM_MATL_BREAKDOWN was created for the LUM Process and is performed by the Inbound Manager Replenishment.
Tasks for the Inbound Manager Replenishment in LUM Process:
a. Checks stock situation in the warehouse for requested source material before executing ‘breakdown’ of source material to target material. This includes checking open put away, different expiration dates, and storage units.
b. Executes the appropriate TEWLS transactions to breakdown requested source material quantities to target material quantities.

c. Instructs a warehouse clerk to physically remove source material from the storage bin and move to Inbound Manager Replenishment work area.
d. Creates NSN-labels which identify the 'new' unit of measure for the target material and attach labels to the target material.
e. Adjusts expiration date of target material.

LUM Process was implemented in July 2014.

3) Future LUM Process Improvements:

In the future the LUM Process will change to work with full system support in the same way we currently order our regular material. The difference is that USAMMCE is both the vendor and also the receiving plant. Requirements for LUM material will need to trigger a sales order for the source material to be picked within a regular pick-wave and at the same time create a purchase order for the LUM material to be received. Transaction ZWM_MIGO_GR update for order price unit vs. the order unit should also allow for a smoother transition in this scenario.

Advantages in the new Process include:
- Automated re-order based on system reorder point and maximum stock level (insuring stock ratio).
- no need for special LUM material area in the warehouse, WM master data can be maintained one time and the same way as regular material.
- receiving section will mark the item with new small identification labels
- process requires less manual intervention or dependencies on employees.

4) ZWM_MIGO_GR update. Two significant changes were made to transaction ZWM_MIGO_GR.
a. 1. For the TIMLS application a new transaction was created, named ZWM_MIGO_MLC, to allow a receipt by handling unit. ZWM_MIGO_MLC was consolidated with ZWM_MIGO_GR. The Initial screen was extended by one additional Input field for receipt by handling unit.
b. 2. In the past fragmented receipts issues resulted with warehouse receivers and these different handling units.

This problem related to material where the order price unit is different from the order unit and caused receipt errors. Changes to transaction ZWM_MIGO_GR were made so the receiver enters the QTY of the OPU, which is on the invoice. TEWLS then converts the received QTY of Order Price Unit (OPU) into correct Order Unit (OU). Cross Dock Decisions are blocked for these kinds of materials. Receiving is not possible if necessary entries in material master record and in the contract are not correct.

Support D&T Warehouse Storage Section in rearrangement of the BIN Section
D&T Bin Section identified a problem where picking and put-away workload time was abnormally high in two specific rows. To correct this problem the WM team created several new Material Movement Reports allowing the rearrangement of storage types and materials in the BIN Section. These Reports classified materials into fast movers, medium movers, and slow mover categories. These reports showed that most materials in these two rows were incorrectly placed. Based on this, materials were rearranged to more suitable storage bin locations. Materials with shelf life code "0" in these two rows were moved to storage type 303.
Effort of this material re-arrangement:
Workload is evenly split in BIN Storage Section.
Pick-waves can be worked off faster.
Drive distances for the stock selector are shortened with correct material location assignment.
Picking and put away process was speeded up.

M. TEWLS Workflow (WF). Processes are in place to notify various users when a user specific action is required. These process actions are sequential and can involve many different people in differing departments. The BSO WF Administrator provides system oversight on the WF processes and resolves WF issues as they occur.
Generally at least once per week overdue WF tasks are evaluated and reported for correction as needed. Issues that cannot be resolved locally are forwarded to a developer for resolution.
With the recent change in transaction ZWM_MIGO_GR WF no longer process a receipt for a PO item where the Price Order Unit is different from the Order Unit and the alternate unit of measure is not loaded in material master. This problem causes a manual intervention where purchasing agents must inform the MDM team about the change. This causes the receivers to stop working and report the issue when the material is already in the warehouse. A new system improvement WF task is identified to create a new workflow message triggered whenever an Order Price Unit is entered into a contract that is different from the Order Unit. When approved and programmed this new WF task will be fully tested.

N. TEWLS BI/BW. Two Statistical Reports were implemented for warehouse Distribution and Transportation (D&T) division and Resource Management Division (RMD) which drastically reduced work load of personnel. In spite of running several transactions in EP1 and combining the results manually, the BI reports allow retrieving the data with a few mouse clicks. In addition, the basic definitions have been standardized to ensure that every user who runs the report gets the same results.

O. Infrastructure / BASIS Team. The USAMMCE BASIS team has two members co-located within the BSO.
The infrastructure team moved 32 servers, most of which were running Windows Server2003, from physical hardware to virtual machines. Almost all of them were upgraded to Windows Server 2008 in the process.

The Basis and Infrastructure teams developed an Excel application written in Visual Basic for Applications that allows users to submit a firewall request by selecting from drop-down menus and entering text in fields that are automatically validated, for example email addresses and IP addresses. The Basis team also developed a comprehensive guide for troubleshooting DCAM connectivity problems. The Basis and Security teams also developed a comprehensive guide for troubleshooting TEWLS website connectivity problems. The Infrastructure team worked with Information Assurance and Medical Network Operations Center managers at USAMITC to streamline the firewall implementation process. We now expect firewall rules to be implemented in three days instead of at least two weeks.

The Basis team developed a new web server to support future versions of DCAM. The new version supports both certificate and basic (username and password) authentication and MILSTRIP and XML file formats. Root certificates and Certificate Revocation Lists are downloaded, formatted, and incorporated into the web server automatically. It also has more detailed and improved logging and automatically generates and emails reports to system administrations on user activity and account status.

The Basis team resolved a serious printing issue when the TEWLS printers in Korea were reconfigured with private IP addresses instead of public IP addresses, and the TEWLS print server could no longer connect to the printers. The Basis team worked with network managers in Korea and the Medical Network Operations Center along with local IT support personnel in Korea. The Basis team identified the problem and provided troubleshooting support for the network managers until the problem was resolved.

CLINICAL ADVISORY DIVISION (CAD)

GENERAL.

The Clinical Advisory Division (CAD) staff consisted of one military personnel and two Department of the Army Civilian (DAC) employees. The division was incorporated into the Material Management and D & T Divisions in April 2014.

MISSION.

The mission of the CAD was to advise the Commander on all clinical matters pertaining to management and distribution of medical supplies, develop systematic processes to evaluate all clinical issues related to medical materiel, ensure availability of medical supplies by identifying proper substitutions for permanently/temporarily unavailable products, establish procedures to identify cost-effective substitutions for medical supplies whenever possible, identify the most convenient sources of supply to improve the procurement of materiel, provide assistance to customers with specialty specific issues, improve communication and to assist with the New Item Request process while managing all specialty specific programs and/or projects.

FOCUS AREAS.

A. CAD continued to provide exceptional clinical support to customers in all environments while improving its internal processes and procedures as they pertained to the ongoing implementation of the Theater Enterprise Wide Logistics System (TEWLS).

B. CAD assisted with the receipt and redistribution of 259,830 doses of seasonal influenza valued at over $2.39 million to three Geographic Combatant Commands (GCCs) without the loss of a single dose due to cold chain failure.

C. CAD continues to review and standardize USAMMCE catalog records and is an integral part of the Medical Material Enterprise Standardization Office (MMESO) (formerly the European Tri -Service Regional Business Office (TRBO The Standardization effort is ongoing by the MMESO with CAD assistance in the form of identifying products needing standardization and having eyes-on/hands-on review of standardized product lines that pass through USAMMCE on their way to USAMMCE's customers. CAD members also attend the annual MMESO conference and provide insight and review of the MMESO's standardization efforts based on their medical specialty and the Medical Materiel Depot point of view.

D. CAD worked towards increasing the Brand to Generic compliance providing USAMMCE Pharmaceutical customers with less expensive alternatives to high priced Brand Name Medications.

E. CAD processed over 5,000 New Item Requests from customers of USAMMCE, USAMMC-SWA and USAMMC-K ensuring that items the customer was in need of that were not catalogued were procured and delivered. Assisting MMD in NIR turnaround time, currently stepping items from 10 queues as needed. With Pharmacy and Dental lines stepping NIR's through to cataloging, step 40, again to assist with lowering NIR time for USAMMCE customers.

CLINICAL ENGINEERING DIVISION (CED)

GENERAL.

The Clinical Engineering Division (CED) staff consists of seven military personnel, one Department of the Army Civilian (DAC) employee, eight Local National employees, and one contractor.

MISSION.

The CED is the command's technical advisor concerning all medical equipment support issues. Plans and coordinates Sustainment Support level medical maintenance. Coordinates medical maintenance support with HQ, USAMRMC, the U.S. Army Medical Materiel Agency (USAMMA) and supported activities; Plans and coordinates equipment replacement and modernization of Test, Measurement, and Diagnostic Equipment (TMDE) used in mission accomplishment; Manages the requisitioning, receipt, storage, and issue of supplies and equipment required for the maintenance mission; Maintains sustainment and pre-deployment training.

FOCUS AREAS.

A. United States Army Medical Material Center-Europe (USAMMC-E) has six TMDE-SP test stations in their Clinical Engineering Division (CED) and maintain a Fluke Biomedical Authorized Laboratory to calibrate and verify calibration for several types of TMDE-SP devices with NIST traceability. The TMDE-SP test stations are equipped with the most comprehensive calibration automation solution available. The automated calibration environment for the test stations allow USAMMCE's technicians to perform automated calibration on most TMDE-SP devices and provides consistent, fast calibration across the entire TMDE-SP lab. The automated calibration software provides calibration procedures for the technician and collects test data during the calibration process so calibration reports and certificates can be provided to the customer.
   Before USAMMCE established the new test stations, all TMDE-SP had to be sent annually or semi-annually to the Original Equipment Manufacturer (OEM) or other certified lab to be repaired or calibrated. This created an extended wait time for customers who need their TMDE-SP returned in a timely manner. The new test stations equipped with the latest, state of the art technology will reduce customer turn-around-time significantly because most TMDE-SP devices will no longer have to be returned to the OEM for calibration, thus saving time and money on shipping.
B. CED Turn Around Time (TAT) as of September 2014 = 32.80 down from 42.17 days in FY13.
C. CED Total Backlog Days for work orders as of September 2014 = 12.8 days, down from 18 days in FY13. CED goal is 5 days.
D. Completed work orders for FY14 = 4,232 slightly down from 4,262 in FY13
E. Work orders for medical equipment in support of the Theater Provided Equipment (TPE) retrograde program. The contractors received 889 pieces of medical equipment, inspected 2,268 and shipped 2,523 items which were recapitalized into Army inventory. Completed 97% of all medical equipment and TMDE received from Iraq and Afghanistan for the TPE program.
F. TPE program identified, inspected and shipped 51 pieces of medical equipment valued at $391,000 to Kosovo to fill much needed medical equipment shortages. This equipment reduced equipment down time to improve patient care.
G. CED continued to provide Medical Maintenance Sustainment Training to the 68As throughout Europe, including the Soldiers of the 8th Medical Logistics Company. This training allows the 68As to maintain their skills and increases their ability to work on different types of medical equipment.
H. In CEDs expanding role as a TLAMM for AFRICOM, we sent three medical devices from our Medical Equipment Standby (MEDSTEP) program to limit interruption to patient care.
I. CED coordinated the delivery of parts and supplies for two Soldiers to perform preventive maintenance and calibration services for three anesthesia units and 6 ventilators for Expeditionary Medical Facility (EMF) Camp, Lemonnier, Djibouti Africa. Additionally, the two Soldiers calibrated and inspected 45

pieces of medical equipment worth $220K for other units providing life-saving medical evacuation support from Camp Lemonnier.

J. SSG (b) (6) trained three personnel in through the ATRRS based Expeditionary Deployable Oxygen Concentration System (EDOCS) to prepare technicians for deployment.

K. CED established temporary work stations used to perform technical inspections for 325 medical devices; met urgent suspense requirements for a highly visible kitting mission for the organization.

L. Saved the Army $480K in new equipment acquisition costs by identifying 63 pieces of excess medical equipment which was calibrated and sent to units in FORSCOM.

M. Completed 274 technical inspections of excess medical equipment and TMDE worth $1.4M located in CED to reduce excess inventory by 75%.

CUSTOMER SUPPORT DIVISION (CSD)

GENERAL.

The Customer Support Division (CSD) staff consists of five military personnel, two Department of the Army Civilian (DAC) employees, and seven Local National employees. The CSD incorporated the former JJPD leadership into its division in 2014 creating an Assemblage Management section.

MISSION.

The CSD serves as the central point of contact, liaison, and advisor for Class VIII supply readiness issues to the U.S. Department of State and all DoD Forces within U.S. European Command (EUCOM), U.S. Africa Command (AFRICOM), U.S. Central Command (CENTCOM), Special Operation Command Europe (SOCEUR), U.S. Army Medical Research and Materiel Command (MRMC), and Europe Regional Medical Command (ERMC) Areas of Responsibility (AOR). It provides superior customer-focused education, and continuously identifies resolves, improves, and monitors USAMMCE's customer interactions. CSD also plans, coordinates, tracks and manages medical logistics requirements and medical logistics training requirements in support of joint operations within the three AORs. CSD division serves as the single operational link between USAMMCE-held and maintained contingency medical supplies and the supply owners (Office of the Surgeon General (OTSG), Department of Defense (DoD), Health Affairs (HA), U.S. Army Medical Command's (MEDCOM), EUCOM, AFRICOM)). The CSD serves as the conduit to provide support to Emergency Operations and State Department coordinated support to natural and manmade disasters within the responsible AORs. CSD also provides advisory guidance and coordination for the assembly, reconstitution and disassembly program at USAMMCE. Customer Support coordinates medical Sets, Kits and Outfits (SKO) requirements in support of deployments throughout the three AORs. CSD synchronizes all USAMMCE support to the U.S. Central Command (CENTCOM) TLAMM (USAMMC-SWA) as their sole source of supply.

The Assemblage Management section of the CSD is responsible for providing customer-focused planning and guidance as it relates to the assembly of non-standard assemblages that range in size from a general-purpose first aid kits to various hospital configurations.

FOCUS AREAS.

A. CSD conducted numerous Customer Assistance Visits. The Customer Support Chief went directly to senior leadership of each command within the European footprint to see how USAMMCE could best support the customer. The goal was to understand demands and future requirements of each enterprise and to find the best support opportunities between leadership and future mission. CSD sent 198 customer surveys to customers via email and placed over 1,500 customer surveys in every tri-wall leaving the transportation section.

B. CSD processed 328 High Priority (HIPRI) requisitions on behalf of USAMMCE customers via telephone, fax, email, and web tools categorized as urgent/emergent requests (HIPRI 02) "work stoppage, affecting patient care, or impairing mission accomplishment", Life or Death (HIPRI 03) requests are processed to "save life, limb, or eyesight" as determined by the attending physician in writing.

C. CSD planned (ongoing) and synchronized the OEF retrograde support requirements between USAMMCE. U.S. Forces-Afghanistan (USAFOR-A), CENTCOM and Army Central Command (ARCENT). CSD coordinated the AFRICOM/EUCOM special mission planning exercise. CSD worked as a conduit for information though the Class VIII planning and tracking process ISO many natural disasters on a global scale, ranging from earthquakes to flash floods. Planned and supported visit, and training for the Task Force MED Kosovo Force (KFOR) 18 in preparation for their upcoming deployment to Kosovo. Customer Support coordinates daily with the DLA liaison on the specific critical concerns affecting USAMMCE in relation to acquiring and shipping medical materiel by DLA Troop Support for USAMMCE.

D. CSD visits have interacted with several organizations and have included all three branches of the military services. On these visits USAMMCE was able to identify areas of improvement. Since the services conduct different missions, USAMMCE was able to identify with the customer and clarify the ways USAMMCE business practices impact the customer's mission. Some of the areas customers stressed concern with Blanket Purchase Agreement use, and having USAMMCE create a program to view items customers can order directly from USAMMCE instead of going through local purchase. This will result in cost savings to the customer as some local purchased items were found to be more expensive than items carried by USAMMCE. This will allow both the customer and USAMMCE to stock the items close to where they are needed and save time and money. Another issue was the modification to the delivery schedule to several customers throughout USAMMCE's area of responsibility. CSD was able to speak with the customer face-to-face and direct feedback as to what days of the week worked best for delivery of supplies, and explain to the customer procedures for the future as transportation becomes more expense. USAMMCE was able to achieve a reduction in routes to some areas while increasing them to other; this was all achieved by working in concert with the customer. The enterprise was also able to arrange Theater Enterprise Wide Logistics System (TEWLS) training for several customers allowing them to obtain a wider base of knowledge on how the TEWLS system works. During the visit USAMMCE was able to invite the customers to visit the Distribution Center, after their visit they had a great understanding and grasp of our overall mission and additional way we could help support their mission in the future.

E. The Chief of CSD has scheduled weekly Supply Chain Meetings as a direct result of information received during the site visits with Unit Commanders. Due to an increase involvement from senior leadership, these meetings have proven extremely beneficial and results oriented. The weekly meetings result in each division within USAMMCE to be able to speak directly to each other about issues at hand. The meeting focuses on issues that arise during the duty week and from direct customer feedback. They also spotlight issues and changes occurring throughout the services due to budget cuts and organizations downsizing or deactivating. During these meetings several issues brought up by customers and employees have been resolved and are now providing better results to the customer. New Standard Operating Procedures were established for incoming equipment, making the process much smoother and providing a better product to the end customer. High priority requests were also brought up as an internal issue. After several meetings a better process was achieved resulting in fewer customer high priority requests. Another issue addressed is Low Unit of Measure (LUM); many customers have requested that USAMMCE sell items in smaller packaging. This is still in progress, 24 items have been reviewed and four approved to be broken down. During the visits Leadership expressed that they were happy with the support received and that they had a better avenue to address issues if additional concerns come up in the future. USAMMCE continues to meet the customer needs.

F. The Assemblage Management section is currently managing a Consequence Management Set for use by USAREUR and funded by MEDCOM's Office of the Surgeon General (OTSG). This set consists of one Tactical Combat Medical Care Sets for, Medical Equipment Set (MES) Chemical Patient, two each (MES) Chemical Treatments, 10 each MES Ground Ambulances, three each MES Tactical Combat Sets, and 18 each MES Combat MEDIC Kits for United States Army Medical Materiel Agency (USAMMA) Army Preposition Stock (APS), European Activity Set (EAS) Program. Assemblage Management manages the Contingency/Medical Chemical Defense Materiel (MCDM) Relabeling Stocks valued at $7.5M. Also Assemblage Management manages the storage, readiness,

and issue of 5 each Sound Proof Booths for LRMC. Assemblage Management assembled and reconstituted 35,929 medical assemblages consisting of 693,985 lines, with a total dollar value of $12M plus. In addition, there is a Memorandum of Agreement (MOA) between USAMMCE/USAMMA/Directorate of Combat and Doctrine Development (DCDD) AMEDD Center and School where Assemblage Management has the lead to build standard sets in newer configurations. In FY14 four sets were built. Examples of these sets: (1). UA N403, MMS (Medical Material Set) Microbiological Augmentation. (2). UA N703 MMS Lab General 164 Bed. (3). 262A MES X-Ray Field Lightweight. (4). UA P312 MMS Physical Occupational Therapy.

G. Assemblage Management 's biggest customer during FY14 was the CENTCOM FMS case for the Afghanistan National Army and Police. This requirement consisted of 325 MES Ground Ambulances with a total value of $6M. The second biggest customer was the CENTCOM FMS case for the Afghanistan National Army and Police. This requirement consisted of 1 Vaccine Set with a total value of $1.3M. The third biggest customer was the OPM-SANG (Office of the Program Manager Saudi Arabia National Guard) FMS case. This requirement consisted of 22 Medical Training Sets with a total value of $700K.

H. Assemblage Management also supported AFRICOM, AFMOA, MEDCOM, USAMMA, USAREUR, and other DOD agencies in FY14.

I. Assemblage Management continued to support the development of the Theater Enterprise Wide Logistics System (TEWLS). As Assemblage Management has been using TEWLS Release 1.2 since July 2006 we now are live with TEWLS Release 2.01.10.00.

DISTRIBUTION & TRANSPORTATION DIVISION (D&T)

GENERAL.

Distribution & Transportation Division (D&T) staff consists of eleven military personnel, seven Department of the Army Civilian (DAC) employees, and 150 Local National employees.

MISSION.

The mission of the D&T is to provide medical logistics support across the full spectrum of joint military operation for over 700 DoD, interagency and coalition customers throughout European Command (EUCOM), Central Command (CENTCOM), African Command (AFRICOM), and State Department. Additionally, D&T coordinates and executes movement of supplies via multiple transportation tenders and ensures cold chain integrity during transit to over 100 customers daily.

FOCUS AREAS

A. Warehouse personnel maintained over 5,700 stocked lines valued at $11 million. Over the past year we filled 298,214 customer orders and processed 171,152 receipts. The Transportation Branch shipped over 14,025 pieces of material to over 200 different locations. Shipments are conducted through many channels to include the EUCOM Tenders, CAT-A Contract, AMC, local 6966th Truck Company, USAMMCE depot drivers, regular and registered mail. Our movement section manifested over 7,972 shipments by ground and air throughout the past year and over three million pounds were transported to three continents. Support to CENTCOM was a significant portion of D&T's efforts last year as well as this year. We have a shared customer base with USAMMC-SWA in Qatar and ship directly to the combat support hospitals in Kandahar and Bagram. D&T also shipped over 315,487 pounds directly to bases throughout Afghanistan and Qatar. We also significantly increased support to AFRICOM this year by shipping over 218,241 pounds. Our In-Transit Visibility monitored over 7,972 shipments to ensure materiel was delivered correctly and in a timely manner to all customers throughout the past 12 months. Our Turn-In section accepted, inspected and distributed 6,184 lines, worth approximately $12 million of surplus materiel from supported customers.

B. D&T provided direct support to Operation United Assistance. This operation provides a global response to the deadly Ebola epidemic that is ravaging West Africa.

The division personnel reacted quickly to numerous requests for support and then expedited the receipt, segregation, storage and distribution of over $5 million worth of personal protective equipment for troops and medical workers in Liberia. D&T will continue to support this mission until the epidemic is under control.

C. 2014 was a year with a lot of changes, process improvements and streamlining for D&T. Over this past year we have been working to integrate the former Joint Plans & Programs Division (JPPD) and the former Clinical Advisory Division (CAD) into the D&T Division. These changes are part of continuing steps to implement a "One Warehouse Concept" where all customer related functions and responsibilities find their conclusion. The goal is to improve and streamline in-house processes to react faster and more flexible to customer requests, to improve information flow and to provide our customer the product they need when they need it. The former JPPD Division is now part of the D&T Division as "Kitting Operations" which is a component of the Storage Branch. "Kitting Operations" assembles, reconstitutes and disassembles medical sets, kits and outfits for our customers.

D. The former CAD is now integrated into the Special Handling Branch and works with our Reefer section to assist customers in getting information from "TempTale" devices that are part of every Reefer shipment that leaves USAMMCE. The Clinical Advisory Team provides also clinical insight, expertise, support and assistance to our customers on all clinical matters. The Clinical Advisory Team assisted with the receipt and re-distribution of 259,830 doses of seasonal influenza valued at over $2.4 million to three Geographic Combatant Commands (GCC's) without the loss of a single dose due to cold chain failure. The Clinical Advisory Team also processed over 5,000 New Item Requests (NIR's) from customers of USAMMCE, USAMMC-SWA and USAMMC-K, ensuring that items that were not catalogued were procured and delivered.

E. Another change was the integration of the Supply Discrepancy Team from the Materiel Management Division (MMD) into D&T. The SDR team operates now within the Quality Assurance and Inventory section which allows D&T to react faster to all customer requests concerning SDR's. We also continued our efforts to consolidate smaller warehouses into our main warehouse in building 4171 to streamline all warehouse operations.

F. We continued to improve our safety and environmental measures within our main warehouse in building 4171 by installing windshields for the employees that are working in the packing section to protect them from cold draft during loading operations. Another improvement was to install plastic stripe curtains that help to reduce the cold draft as well as keeping the temperature in the heated warehouse which safes energy and money. In addition to those contributions we also replaced the aged reefers in the Special Handling Branch in building 4136 and installed a set of new ones to reduce energy consumption and repair cost, and to increase reliability.

HUMANITARIAN ASSISTANCE PROGRAM (HAP)

GENERAL.

The Humanitarian Assistance Program (HAP) staff consists of eight Department of the Army Civilian (DAC) employees, and one Local National employee.

MISSION.

The mission of the HAP is to manage and execute all Operation Provide Hope (OPH) medical humanitarian assistance missions for the State Department. HAP stores, consolidates, packs, and releases materiel upon request for HAP missions. This division serves as Executive Agent for the State Department for medical humanitarian assistance and disaster relief missions to the newly Independent States of the Former Soviet Union. The program was phased out and closed on 30 September 2014.

FOCUS AREAS.

A. Completed an initial Operation Provide Hope (OPH) Mission supporting seven medical facilities in Tbilisi, Georgia, providing $11,961,872.36 of medical equipment and supplies.

B. Completed 15 special aid missions to the countries of Armenia (2), Georgia (10), Moldova (2), and Tajikistan (1), providing $6,649,280.00 of medical equipment and supplies.

C. Executed the appropriate disposition/turn in of $24.3 million dollars of program materiel assets to complete program closure.

D. Vacated all program warehouses in accordance with drawdown of program and turned them back into USAMMCE.

INFORMATION MANAGEMENT DIVISION (IMD)

GENERAL

The Information Management Division (IMD) staff consists of one military personnel, and 16 Department of the Army Civilian (DAC)/Local National employees.

MISSION

IMD team advises, recommends, and acts for the Commander on all matters pertaining to the Information Mission Area as follows: Information Assurance (IA), Automation, Customer Assistance, Telecommunications, Records Management, Printing and Publications and Visual Information. The IMD Chief Information Officer oversees strategic planning, procurement actions and budget execution; oversees the Telecommunications Control Officer (TCO); and oversees the provision of Self-Service Supply Center (SSSC). The TCO procures, manages, and maintains Blackberry smart phones, cellular telephone and facsimile equipment for local users. The Customer Assistance Branch (CAB) corrects/resolves trouble tickets, conducts Lifecycle Management and schedules/maintains Video Teleconferencing (VTC) equipment. The Information Assurance Manager oversees the Cybersecurity program and Cybersecurity Awareness training. The Networking Branch oversees networking infrastructure and user account access. The IMD team also prepares and maintains accreditation documents for all computer hardware and software systems within the organization.

FOCUS AREAS

A. IMD Networking personnel maintained a 99.667% uptime rate on 21 servers along with a 99% Security Content Automation Protocol (SCAP) compliance and 100% IAVA compliance on assigned servers.

B. IMD Networking personnel tracked and assisted over 100 employees in updating their milConnect profiles. Ensuring DISA Enterprise Email (DEE) accounts accurately reflect their owners and proper departments being charged for this service. Staff added this item to the IMD in-processing procedures to maintain continuity and accuracy of DEE accounts.

C. USAMMCE activated their new 50Mbs NIPR circuit in July 2014 eliminating mission essential bandwidth congestion.

D. IMD Networking personnel doubled the available resources for the VMware virtual infrastructure by adding a third host server and upgrading the hard drives of the other servers.

E. IMD CAB moved 37 computer systems in support of the JPPD drawdown, and moved an additional 30 systems in order to accommodate resultant office reorganizations. The team gathered and turned in

or reutilized over 150 items of equipment including printers, monitors, and computers. Over 70 computers were turned in to log after sanitization and thorough documentation.

F. The CAB Team managed and coordinated the protection of USAMMCEs sensitive data by ensuring the team removed and destroyed over 200 hard drives from Life-Cycled and broken computers. They worked with, assisted, and documented the destruction of those sensitive hard drives with the 21st TSC in Kaiserslautern.

G. USAMMCE CAB life-cycled 30 classroom computers to make sure both TEWLS and office training environments were up to the USAMMCE standard.

H. The CAB team conducted over 60 additional lifecycle computer replacements.

I. Severe weather and bad power fluctuations shorted out another 10 computer systems while another eight out of warranty failed due to deteriorating motherboard problems. All computers were repaired or replaced through contingency funding and team's repair efforts.

J. The team also set up special VTC training sessions that enabled several IMD personnel to secure additional Continuing Professional Education units (CPEs) in order to maintain Security+ certifications. All CAB personnel completed requirements and started their second three year cycle. The VTC method of conference participation saved several hours of travel time, saved the government money, and improved the skill set of all participants.

K. In support of the EBOLA crisis, the team supported weekly and now daily DLA, Navy, and Air Force team meetings with Direct Connect Online sessions with AFRICOM and other key organizations. CAB provided VTC support for an ever increasing VTC schedule, now averaging more than five VTCs per week.

L. Within hours of notification, set up two mobile workstations to support warehouse management of EBOLA stocks in an alternate warehouse. Team ensured mobile printers, hand scanners, charging capability, and network access were configured correctly . Unfamiliar personnel were trained in proper SAP and equipment operation. Everything was in place and operational ahead of all expectations.

M. Completed more than 840 help desk tickets with 99% customer satisfaction. 91% of all tickets were closed within service level agreement standards. Delays with parts deliveries and awaiting the customer accounted for most of the remaining 9%.

N. The CAB team maintained 25 SIPR accounts, removed five users and added another five new employees by establishing accounts, requesting tokens, and modifying user accounts. Updated TACLANE firefly for another year of operation. Supported monthly Secure VTCs ensuring security standards were met, cleared personnel access, and controlled the system for proper shut-down and room security at conclusion.

O. The team migrated unique German language-based electrician computer software to latest ISO standardized testing system. Worked with contractor to ensure database was repaired and a good backup was created for baseline. Validated that efforts safely migrated several years of certification data. Ensured Electricians got training needed and that Logistics branch worked with the contractor to secure an additional training day since so much time was spent on equipment repair.

P. The CAB team coordinated a special VTC with the surgeon general, MRMC, USAREUR and other support staffs to support the impending Entrance Conference: AAA Audit - Army Medical Stocks in Europe. Team worked with Aspen Corporation, Director of support Ops, and electrician shop to scrub relocation plans for space and power requirements to ensure present and future CAB requirements are covered. Validated equipment on hand with hand receipt holders and identified future mission needs during the transition phase.

Q. For the Distribution and Transportation Division, the IMD CAB Team standardized the installation of the TIPS software and setup of the new ISO 18000-7 RF Tag. Retired the SAVI software and hardware formerly used for tagging shipments.

R. The IMD team participated in all Assured Compliance Assessment Solution (ACAS) upgrade planning to ensure USAMMCE input was considered. Set up scan criteria to optimize and streamline program execution to identify and remedy problems thoroughly and efficiently. Upon live implementation, USAMMCE transitioned away from scanning resources with Retina software which will no longer be used.

S. IMD Cyber Security successfully managed accountability for all IAVM activities, including remediation and reporting; teamed with IMD CAB to achieve 100% compliance on over 300 relevant IA alerts and bulletins for over 500 workstations and server systems. Met or exceeded all mandated suspense dates for DA/MEDCOM/ERMC IA IAVM OPORDS and initiatives.
T. IMD CAB and Cyber Security teamed up to successfully migrate 500+ workstations and servers to Microsoft Internet Explorer 9, and 450+ workstations to Microsoft Office 2010, both well before a MEDCOM-mandated suspense date of 15 January 2014.
U. IMD chaired a four member board to interview and select a new USAMMCE hire for the customer assistance branch. We worked through 37 candidates and interviewed the 10 most qualified to ultimately select and hire the superior candidate.
V. The Team successfully provided AKO sponsorship of 295 local national employees. Advised affected personnel and assisted dozens of local nationals with resetting logins, adjusting permissions, and authorizing access to a variety of Army sites through the AKO portal while working through language barriers.
W. IMD TEWLS Administrators facilitated high priority support for DCAM users involved in Operation United Assistance. Approximately 25 users in areas such as Burkina Faso, Liberia, South Sudan, and Uganda had major difficulties ordering Class VIII supplies and we were able to successfully provide the support which allowed the users to place successful orders.
X. IMD TEWLS Administrators were able to create a successful solution for Business Intelligence and Business Warehouse users to use the BEx Analyzer interface accessing the Excel program after a Microsoft Office 2010 upgrade. This is necessary for management to utilize online analytical processing, data mining, process mining, business performance management, benchmarking, predictive analytics, and other analytical reporting.
Y. IMD TEWLS Administrators established a process to reconnect Central User Administration following a SAP system refresh which saves time and decreases errors associated with more than 20 reconnection steps.
Z. IMD TEWLS Administrators created a 178 page step-by-step installation guide for installing Oracle and SAP ERP 6.0 EHP5 on a Windows 2008 Enterprise Server running on VMware. This provides much needed continuity for TEWLS Administrators and can be used to install the SAP ERP 6.0 system as a new build, for refreshes, and system copies.
AA. The Visual Illustration (VI) team provided outstanding audio visual and presentation support for over 60 promotion, award, training, and social activities and ceremonies.

JOINT PLANS & PROGRAMS DIVISION (JPPD)

GENERAL.

The Joint Plans & Programs Division (JPPD) staff consisted of three Branches, (Assembly Branch, Project Management Branch, and Production Storage Branch). JPPD was disbanded and the personnel were reorganized into different Divisions within USAMMCE on April/May 2014. The majority of the former JPPD personnel are now part of D&T (Distribution and Transportation Division). One Expeditor was incorporated into MMD as a Purchasing Agent, one of the Production Managers was incorporated into Support Ops, one Expeditor and one Managers Assistance was incorporated into RMD, one Managers Assistance was incorporated into the Logistics Division and two Production Managers are now working in CSD (Customer Support Division).

MISSION.

The mission of the JPPD is to plan, coordinate, and manage builds of standard nonstandard, and nonmedical Sets, Kits, and Outfits (SKO's) ranging in size from a general-purpose first aid kit to various hospital configurations through reimbursable funding. The vision of JPPD operations was to manage and identify the customer's needs and provide them with the highest quality of medical assemblage at the right time, place, and configuration at a lowest cost with a high readiness status.

FOCUS AREAS.

A. JPPD managed the Consequence Management Set (CQM) which consist of four separate sets for MEDCOM Office of the Surgeon General (OTSG), four each Tactical Combat Medical Care (TCMC) Sets for USAREUR, one each Medical Equipment Set (MES) Chemical Patient, two each (MES) Chemical Treatments, 10 each MES Ground Ambulances, three each MES Tactical Combat Sets, and 18 each MES Combat MEDIC Kits for United States Army Medical Materiel Agency (USAMMA) Army Preposition Stock (APS), European Activity Set (EAS) Program. JPPD managed the Contingency/Medical Chemical Defense Materiel (MCDM) Relabeling Stocks valued at $7.5M. Also JPPD managed the storage, readiness, and issue of 5 each Sound Proof Booths for LRMC. JPPD assembled and reconstituted 35,929 medical assemblages consisting of 693,985 lines, with a total dollar value of $12M plus. In addition, there is a Memorandum of Agreement (MOA) between USAMMCE/USAMMA/Directorate of Combat and Doctrine Development (DCDD) AMEDD Center and School where JPPD had the lead to build standard sets in newer configurations. In FY14 four sets were built: (1). UA N403, MMS (Medical Material Set) Microbiological Augmentation. (2). UA N703 MMS Lab General 164 Bed. (3). 262A MES X-Ray Field Lightweight. (4). UA P312 MMS Physical Occupational Therapy.

B. JPPD's biggest customers during FY14 was the CENTCOM FMS case for the Afghanistan National Army and Police. This requirement consisted of 325 MES Ground Ambulances with a total value of $6M. The second biggest customer was the CENTCOM FMS case for the Afghanistan National Army and Police. This requirement consisted of 1 Vaccine Set with a total value of $1.3M. The third biggest customer was the OPM-SANG (Office of the Program Manager Saudi Arabia National Guard) FMS case. This requirement consisted of 22 Medical Training Sets with a total value of $700K. JPPD also supported AFRICOM, AFMOA, MEDCOM, USAMMA, USAREUR, and other DOD agencies in FY14.

C. JPPD continued to support the development of the Theater Enterprise Wide Logistics System (TEWLS). As JPPD had been an advent user of TEWLS Release 1.2 since July 2006, JPPD was using the current version of TEWLS Release 2.01.10.00.

LOGISTICS (LOG)

GENERAL.

The Logistics Division (LOG) staff consists of 33 Local National employees.

MISSION.

The mission of the LOG is to provide Base Support to the Center. Plans, directs, supervises, and coordinates the activities of the Property Management Branch, Service Branch, and Motor Pool Branch. Advises the Commander on matters pertaining to supply, equipment, and repair of facilities for the Center and its subordinate units. Acts as the Commander's representative in matters pertaining to the role of a Site Manager. Coordinates the activities of the Logistics Division with the other Center elements and with U.S. Army Garrison Rheinland-Pfalz. Initiates and processes all medical and non-class VIII purchasing contracts and the majority of non-class VIII Government Purchase Card purchases for the Center. Responsible for the inspection, maintenance and repair of all equipment in the Center. Administers all non-medical hazardous materiel supplies from purchase to destruction and coordinates all regulated and non-regulated hazardous waste.

FOCUS AREAS.

A. LOG processed 19 contracts in the amount of $1.355M. Equipment in the amount of $1.8M was turned into Defense Reutilization Management Office (DRMO). 482 Government Purchase Card purchase requests in the amount of $1.185M were processed. 190 General Fund Enterprise Business Systems (GFEBS) Purchase Requests have been processed. Maintenance and repair for equipment in the amount of $50K has been conducted. Accountability for all Medical Stand-by-Equipment (MEDSTEP) and accountability for all durable items was completed. Property in the total amount of

$13M was maintained and controlled on 74 Hand Receipts. 16 Command Supply Discipline Program (CSDP) evaluations were conducted on all USAMMCE divisions and special staff. All equipment was reconciled with USAMMCE's Table of Distribution and Allowances (TDA) without any discrepancies.

B. LOG initiated and coordinated the completion of the following projects:

1) October 2013: A server was moved from building 4173(HAP) to building 4155 (BSO) by a contracting company. This was funded by USAMMCE via Government Purchase Card in the amount of $3,624.

2) October 2013: LAN drops and an I3MP cabinet were installed in building 4171 (D&T) by 2nd Signal Battalion. This was funded by USAMMCE in the amount of $12,760.

3) February 2014: Eleven windows were replaced in room 138, 140 and 141 in building 4108 (CSD). This DPW project was funded by USAMMCE in the amount of $22,183.

4) March 2014: A plastic curtain has been mounted at the transportation gate of building 4171 (D&T). This project has been performed by a contractor funded by USAMMCE in the amount of $6,363.

5) March 2014: Building 4158 (open shed) has been returned to DPW.

6) March 2014: Six windows in the IDS area of building 4107(Security) have been exchanged with bullet proof glass. This DPW project was funded by USAMMCE in the amount of $28,830.

7) May 2014: Building 4143 (HAP) has been returned to DPW.

8) June 2014: Building 4173 (HAP) has been returned to DPW.

9) July 2014: The Nasatka barriers at the main gate have been exchanged. This was performed and funded by the Security Command.

C. LOG Services Branch

1) Built 1,020 wooden pallets and 51 wooden crates in support of USAMMCE'S storage and shipping function.

2) Completed 561 internal work orders.

D. LOG Motor Pool

1) Provided transportation support for medical and non-medical supplies, and for personnel attending mission related training classes, meetings, conferences, CAC card issue and BAD examinations.
2) Provided basic and re-fresher drivers training for all USAMMCE personnel requiring driver's licenses. All automotive mechanics received on the job training.
3) Took over 12 General Services Administration (GSA) vehicles from TMP 6 in Kaiserslautern on 1 August 2014. A total of 151,693 miles were driven during this fiscal year.
4) Conducted 1094 Material Handling Equipment (MHE) inspections, 543 repairs of MHE, and 225 Unfallverhuetungsvorschrift (UVV) accident prevention inspections.

MATERIEL MANAGEMENT DIVISION (MMD)

GENERAL.

The Materiel Management Division (MMD) staff consists of two military personnel, three Department of the Army Civilians (DACs) and 28 Local National employees.

MISSION.

The mission of the MMD is to be responsible for all medical supply and equipment purchases, materiel breadth management, materiel line item/depth management, product standardization, and product catalog management/clinical advice for USAMMCE's 653 supported customers as well as arising kitting needs required by numerous stakeholders. MMD executes materiel line item management, standardization and procurement within the Theater Enterprise Wide Logistics System (TEWLS); an SAP based Enterprise Resource Planning (ERP) application. To the procurement mission, MMD utilizes multiple procurement methods such as Prime Vendor, Electronic Catalog (ECAT), DLA Troop Support (SMS), Local Purchase, Blanket Purchase Agreements (BPAs) and contracts. Materiel comes in from these various sources via commercial and military transportation. Materiel is both cross-docked for immediate redistribution and/or placed into storage to meet forecasted requirements. Customer orders come into USAMMCE from various means (TEWLS, DMLSS, DCAM, USAMMCE webpage, Service legacy systems, phone, fax or email) and the requested items are picked, packed, consolidated, and shipped by either commercial or military transportation assets to fixed medical facilities or operational Joint, Inter-service or multi-national customers located throughout the EUCOM, CENTCOM and AFRICOM areas of responsibility (AOR) as well as Department of State embassies.

Besides managing USAMMCE's stocked lines, MMD's enterprise responsibilities include materiel management for 1,500 lines stocked at USAMMC-SWA and enterprise wide catalog management for non-stocked lines spanning all TEWLS users.

FOCUS AREAS.

A. USAMMCE's total sales for FY14 exceeded $135 million. USAMMCE maintained an average of 75,600 cataloged records for our location as well as 81,400 lines cataloged records for USAMMC-SWA. Of these cataloged records, USAMMCE stocked approximately 5,600 items in FY14. Additionally, MMD processed an average of 720 New Item Requests (NIR) monthly for both USAMMCE and other enterprise partners around the globe, mostly attributed to the Generation IV Prime Vendor contract. MMD interfaced with over 1,700 vendors using DLA's Prime Vendor Program, ECAT, and Depot systems.

B. MMD supported customer requirements in support of the Overseas Contingency Operations across multiple theaters; 653 supported customers, including those customers in direct support of Operation Enduring Freedom in Afghanistan and Operation United Assistance in West Africa.

C. USAMMCE MMD focused heavily on improving the health of the organization by maintaining the fundamental measures of a healthy materiel operation. During this FY, MMD maintained relatively stable account metrics, focusing on maintaining Demand Accommodation, minimizing zero balance lines, and focusing on increased stockage of high-demand lines. In addition, excess creation was a focus, shrinking the inventory value from $22M to $13M.

D. During the same period, USAMMCE continued to reduce its stocked lines by 1,000 lines; down to 5,600 from 6,600. This effort occurred while maintaining an 85% Demand Accommodation rate and a 90% Demand Satisfaction Rate.

E. USAMMCE's MMD also provided technical expertise for two audits this FY. The U.S. Army Audit Agency as well as the Defense Logistics Agency focused on numerous areas relating to materiel management to include e-commerce compliance, inventory management metrics, and customer satisfaction requirements. Both audits received no findings for actions to be executed by USAMMCE.

F. Through coordination with DLA, MEDCOM and OTSG, USAMMCE was an enterprise leader of standardization efforts. With the assistance of two data research programs, Product Data Bank (PDB) and eZSAVe, MMD continued to implement strategies to improve acquisition methods for migrated product lines. This process of standardization made it possible for the TSG to re-baseline standardization from an 85% to a 90% standard.

OPTICAL ACTIVITIES DIVISION (OAD)

GENERAL.
The Optical Activities Division (OAD) staff consists of four military personnel and 13 Local National employees.

MISSION.
The mission of the OAD is to advise the Commander on all matters pertaining to optical activities. Renders technical assistance to the joint services of the United States European Command (EUCOM) and the United States Central Command (CENTCOM). Performs management activities related to the production and repair of spectacles. Edits, processes, and files spectacle orders. Coordinates inventory and accounting for optical supplies and repair parts. Coordinates budgetary and productivity matters with the Resource Management Division. Requisitions/Receives/Replenishes optical and general supply. Packs and releases inspected spectacles. Performs final acceptance inspection of all spectacles/lenses manufactured at USAMMCE prior to shipment, and the optical processing time verification. Coordinates with the DOD Optical Enterprise for new equipment.

FOCUS AREAS.
A. The OAD produced 46,640 pairs of eyewear during FY14, to include standard issue spectacles, protective mask inserts, ballistic protective eyewear, and Frame of Choice spectacles. This program continues to offer Soldiers a new standard issue frame (R5A, unisex), nine spectacle Frames of Choice in several sizes, colors, temple length and three additional protective mask inserts (ESS Oakley, Smith, Wiley X and UPLC). OAD has the capability to create any lens in both single and multi-vision using CR-39 from clear to tinted N-15, N-31, UV400 or Soflite (light pink for Computer glasses) and Polycarbonate material in single vision. OAD continued to improve the production timeline for single-vision eyewear from a three-day to a two-day process thus exceeding the civilian spectacle production standards and significantly lowered the laboratory's work order backlog. OAD maintained a three-day production for multi-vision lenses.

B. OAD provided support to over 25 clinics within EUCOM, CENTCOM, AFRICOM and the State Department as well as to ships at sea, and continued to acquire new customers because of troop rotations in Afghanistan. The lab continues to support all deployment missions on short term notice and during fourth Quarter of FY14, we supported Kuwait with over 250 optical devices. OAD produced prescription eyewear for active duty Soldiers, Sailors, Airmen, and Marines, as well as for U.S. military retirees and personnel detained by the U.S. military.

C. OAD leadership planned and coordinated purchase and installation of spectacle manufacturing equipment, that significantly increased the quality of spectacles produced and decreased the risk of accident to the fabricators. To keep fabricators at newest standard of eyeglass fabrication, OAD purchased new edgers, blockers and frame warmer which reduce time of production. OAD implemented a spectacle inspection report that captured productivity and efficiency data. As shown by the report when taking a look at FY13, the reject rate dropped to 1.02% which is way below the Army standard of 5%.

RESOURCE MANAGEMENT DIVISION (RMD)

GENERAL.
The Resource Management Division (RMD) staff consists of one military personnel, three Department of the Army Civilian (DAC) employees, and 19 Local National employees.

MISSION.
The mission of the RMD is to implement the Resource Management Program of the command. Advises, recommends, and acts for the Commander on resource matters pertaining to the Center. Serves as the

Commander's principal staff advisor on resource utilization, manpower, productivity, organization, and functions. Serves as liaison with external organizations and higher headquarters on resource matters. Responsible for financial reporting to external organizations. Acts as the Agency Program coordinator for the Government Purchase Card program. Serves as the Commander's principal to manage and implement the Strategic Business Plan, including the Balanced Score Card (BSC), the Activity Based Costing (ABC) Model and the Continuous Improvement Program (CIP) through Lean Six Sigma (LSS) Program and Projects. Supervises the functions of subordinate branches within the RMD.

FOCUS AREAS.

A. Human Resources/Manpower, Postal Operations and Adjutant: The branch processed 141 requests for personnel action, with 63 requests out of those personnel actions being for awards. The decrease of processing personnel actions compared to prior FYs is a result of the hiring freeze which still was in place at the beginning of the fiscal year, as well as the restriction of the monetary and time-off award programs. A total of 145 various furlough letters were issued to the U.S. civilians prior to, during, and after the time of furlough. During this period 57 USAMMCE/ Husterhoeh Installation Procedures, 45 Command Policy Letters/HHD Command Policy Letters, 148 Additional Duty/Assumption of Command Memos were published, 29 Ration Cards were issued, 31 Notary Documents as well as 5 Financial Liability Investigation of Property Loss (FLIPL), and 12 Financial Liability Investigation of Property Loss (FLIPL) Monthly Reports to MRMC were processed. Postal Operations has 150 mail boxes and services the customers with parcels, letters, etc. accordingly.

B. Strategic Planning & Performance (SPP): Completed 6 Performance Audits for the center to determine manpower requirements and assess operations and functions. One other comprehensive Performance Audit was initiated in FY14 and will be completed in FY15.

   Completed unscheduled taskers/special surveys and participated in projects in reference to future shaping of USAMMCE, such as divisional reorganization, workload forecasts and manpower requirements determinations. Maintained the USAMMCE Space Utilization Program to include COOP space planning and space adjustments resulting of the reorganization performed. Provided support to Deputy Chief of Staff and Contractors in reference to the planned move to Kaiserslautern Army Depot. This included data collection for space and space utilization, verification of inventory data, and updates of floor plans. Started an initiative for collaboration with partnering units to prepare for the planned move. In coordination with Human Resources, established and maintained a data base to provide manpower data for requirements and assigned personnel. Administered and monitored 25 agreements for the center. Monitored the center's Strategic Management Program to include the Balanced Scorecard. Manages the center's Continuous Process Inprovement Program (CPI) to include LSS deployment, administration and belt support. Achieved 1 Black Belt certification and 2 Green Belt certifications. Started a comprehensive CPI survey to identify improvement opportunities (ongoing). Revised and automated the internal USAMMCE Suggestion Program.

C. Finance. Budget Execution: For FY13 USAMMCE obligated $30,740,300 on the Defense Health Program (DHP) account and $7,739,093 on reimbursements and $488,695 on Direct Charge Customers. From the DHP obligated funds, $1,973,884 was in support of Overseas Contingency Operations (OCO). The reimbursements primarily consisted of set builds in support of deployed units. Other sources of reimbursements were from Department of State (DoS) in support of Humanitarian Missions ($804,162) and Non-Appropriated Funds (NAF) in support of the Veterinary clinics ($446,934). Reimbursable business for the veterinary clinics and unit support for optical mask inserts, equated to a lesser dollar value, but comprised of multiple external customers. Additional funds were received and obligated for the USAMMCE Relocation to KAD for Corps of Engineer Projects ($2,946,984) including (188,000) for Security and ($35,411) were spend on GPC purchases related to the move. Operations & Maintenance Funds, Army were received and obligated ($26,740) to relocate contractor personnel for Medical Equipment Field Level Reset requirements to restore re-deploying units' readiness to meet operational demands. General Funds Enterprise Business System (GFEBS)

implementation was completed in July 2012, as the replacement for the legacy Standard Financial System (STANFINS). Two systems, STANFINS and GFEBS, continue to be maintained until STANFINS will be retired.

1) Implementation of Global Combat Supply System, Army (GCSS-Army): Due to the implementation of GCSS-Army, the financial system for non-medical supply purchases, a significant number of individual TEWLS customer accounts have been adjusted including financial updates in the financial system.

2) Standard Financial Information Structure (SFIS) compliance of Theater Enterprise Wide Logistics System (TEWLS): In reference to the preparation of TEWLS to be SFIS compliant entire master data have been reviewed and adjusted in conjunction with Joint Medical Logistics Functional Development Center (JMLFDC). Even if the Go-live date – originally programmed for the end of this CY 2014 for the new method of providing SFIS compliant data to the appropriate interfaces was postponed, the infrastructure was researched and analyzed.
3) Implementation of new TEWLS transaction code to reduce the number of Interface IDOCs and UMDs in the financial system (GFEBS), caused by TEWLS: During FY14 a system modification was developed and implemented in order to reduce the number of fiscal abnormities caused by system deficiencies regarding the production of accurate financial records. After the test phase started at the beginning of FY the modification was implemented in TEWLS in February FY14. Since that time 2415 records have been identified, reviewed and corrected with a total dollar amount of $1,214,962.41. This resulted in a drastic reduction of failed financial transaction and especially at the end of the FY in the lowest number of not resolved transactions since ever, as stated by MEDCOM.
4) Audit Readiness requirements were applied in appropriate areas and procedures adjusted accordingly to accommodate prerequisites for auditing purposes.
5) Acting as the Resource Manager for SWA Credit Card program resolved numerous issues in line with the rotation of personnel, clarification of issues regarding newly implemented programs (Single Charge Card Solution, AXOL, updates on training requirements). Managing the Government Purchase Program including coordination with responsible contracting offices in EUCOM and CENTCOM region.
6) Acting as FI/FM representative for TEWLS BSO provided support to customers and TLAMM personnel regarding financial requirements throughout the entire spectrum. That included coordination, analysis and development of methods to comply with additional reporting requirements set by DLA and MEDCOM, e.g. in reference to Command Management Reporting (CMR). Established the financial environment in TEWLS during Fiscal Year End (FYE) process for all three Medical Centers regarding funding and account set-up in TEWLS especially in the field of Prime Vendor Credit monitoring and compliance with given Obligation Authority from MEDCOM.

Integrated Safety, Environmental & Organizational Quality Management Office (ISEOQM)

GENERAL.

The Integrated Safety, Environmental & Organizational Quality Management Office (ISEOQM) staff consists of one Department of the Army Civilian (DAC) employees and one Local National employee.

MISSION.

The mission of the ISEOQM is to establish and coordinate a program of occupational health services for all military personnel, DACs, and Local Nationals to ensure that each employee receives legally mandated occupational health services as specified in AR 40-5. Manages the safety program using the guidelines specified in AR 385-10, and develops safety policies, standards, and procedures for accident prevention (motor vehicle safety, fire prevention, electrical hazards, etc.). Provides assistance in accident investigation, reporting, counter measures, and maintains accident records and statistics. Encourages and promotes safety and training. Provides and interprets for the

command Occupational Safety & Health Administration (OSHA) standards, Army safety policies, and host nation safety requirements. Initiates, coordinates, and monitors USAMMCE's Medical Surveillance Program in accordance with USAREUR contract and host nation standard. Liaisons with host nation OSHA agencies in order to promote integration of host nation occupational safety and health legislation. Monitors and identifies responsibilities and requirements of the Environmental Protection Program in accordance with host nation directives, laws and regulations. Investigates environmental violations, such as spills, and hazardous material releases, and monitors the Materiel Waste Program (including hazardous material). To eliminate hazardous conditions provides technical assistance and necessary coordination. Reviews Safety and Quality management processes during International Standards Organization (ISO) audits. Ensures that USAMMCE adheres to the ISO certification requirements, hence continuously monitors work processes.

FOCUS AREAS.

In March of 2013 USAMMCE received Star recognition in the OSHA Voluntary Protection Program (VPP). In 2014 moving forward the focus is centered on maintaining the recognition status achieved and transitioning the elements comprised in the Voluntary Protection Program into the Army Safety and Health Management System while continuing to provide effective integrated safety, environmental, and organizational quality management. The command completed 2014 Summer Safety training with a 91%, and the 2014 Fall/Winter Safety participation rate with an 89% participation rate. The office followed up on 11 accidents with ten reportable during FY14. ISEOQM is reviewing and providing input to all Hazardous Material (HAZMAT) and safety issues involving the possible move of USAMMCE to the Kaiserslautern Army Depot (KAD). Seventeen Quality Management (QM) and thirteen Safety Management audits were completed in FY14. For FY14 a total of 76 findings were identified. In addition, this office conducted one ergonomics study, one occupational health study, and one environmental assessment during FY14.

SECURITY OFFICE (SEC)

GENERAL.

The Security Office (SEC) staff consists of one Department of the Army Civilian (DAC) employees and one Local National employee.

MISSION.

The mission of the SEC is to advise, recommend, and act for the Deputy Commander for Support on all matters pertaining to Security Operations, including Force Protection as directed by the U.S. Army Garrison Kaiserslautern, operational planning and military training. Administers the USAMMCE alert systems emergency action procedures, readiness tests, and command and control evaluation for the commander. Manages the Security Clearance Program and all classified documents for USAMMCE. Manages the Background Investigation program for the Local National Employees of USAMMCE.

FOCUS AREAS.

A. September 2014 - Participated in the U.S. Army Garrison Force Protection exercise. The exercise tested the installation security efforts, with outstanding results.

B. Tested the emergency evacuation system to insure that it functions properly testing every building throughout the entire year, scheduling two to three buildings per month.

C. Coordinated and hosted the Threat Awareness and Reporting Program (TARP) briefings for the entire organization with 371 participants (with a 95% attendance) in November 2013.

D. Initiated and reestablished the key control program for the entire installation. Each exterior door to the building is being labeled and accounted for in accordance with AR 190-51.

E. Set up security for the USAMMCE Change of Command in July 2014.

F. Input all of the Local National Employees into the Local National Screening Program so that they will receive a completed Background Investigation.

G. Working on the security requirements and program for the unit transition to Kaiserslautern Army Depot.

HEADQUARTERS AND HEADQUARTERS DETACHEMENT/OPERATIONS OFFICE (HHD/OPS)

GENERAL.

Headquarters and Headquarters Detachment/Operations Office (HHD/OPS) staff consist of three military personnel, one Department of the Army Civilian (DAC), and one Local National employee.

A. Operations Chief and HHD Commander: CPT (b) (6) . CPT (b) (6) served previously in this position from July 2013 to May 2014. CPT (b) (6) served as the Chief of Support Operations (SPO) from March 2013 until July 2013, when the HHD and SPO was combined to form HHD/OPS. MAJ (b) (6) served as the Chief of SPO from August 2012 until March 2013.

B. HHD Detachment Sergeant: SSG (b) (6) is the new HHD Detachment Sergeant beginning on Dec 2014. SFC (b) (6) assumed the role of HHD Detachment Sergeant in June 2013 until Dec 2014, after completing his time as HHD/OPS NCOIC. SFC (b) (6) previously served as the HHD Detachment Sergeant, from April 2012 until June 2013, when he assumed the role of the SPO NCOIC.

C. OPS NCOIC: SSG (b) (6) is also serving as the Operations NCOIC beginning on Dec 2014. SFC (b) (6) assumed the role of NCOIC in June 2013 after completing his time as the HHD Detachment Sergeant. SFC (b) (6) previously served as the SPO NCOIC from September 2012 until June 2013 when he assumed the role of the HHD Detachment Sergeant.

D. Training NCO: SSG (b) (6) assumed the role as Center Training NCO on June 2014. SGT (b) (6) assumed the role as the Center Training NCO upon the departure of (b) (6) in May 2013 until June 2014. SGT (b) (6) previously served as an SPO NCO within the HHD/OPS section from October 2012 until she assumed her current role. (b) (6) performed in the role of the Center Training Coordinator from 2009 until her PCS in June 2013.

E. Military Personnel Specialist: (b) (6) serves as the Military Personnel Specialist and handle all matters pertaining to military personnel actions. She moved to the HHD/OPS office from Resources Management Division (RMD) in July 2013.

F. Military Operations Specialist: (b) (6) serves as the Military Operations Specialist and handles areas pertaining to Operation Orders, Task Orders, future operational planning, current operational tracking, and training.

MISSION.

The mission of HHD/OPS is to perform future operational planning, current operational tracking and synchronization across the nine functional divisions of the O6 level Command. As the Theater Lead Agent for Medical Materiel (TLAMM) for two Combatant Commands (COCOMs), the HHD/OPS section integrates the USAMMCE operational and contingency planning functions with operational and logistical planners of U.S. European Command (EUCOM), U.S. Africa Command (AFRICOM), U.S. Army Medical Research and Materiel Command (MRMC), and Europe Regional Medical Command (ERMC). The HHD/OPS office synchronizes USAMMCE support to the U.S. Central Command (CENTCOM) TLAMM (USAMMC-SWA) as their sole source of supply. HHD/OPS serves as the single operational link between USAMMCE and the supply owners: Office of the Surgeon General (OTSG), Department of Defense (DoD), Health Affairs (HA), U.S. Army Medical Command's (MEDCOM), EUCOM, and AFRICOM.

Supports the Commander's goal of becoming a training center of excellence for medical logisticians by planning and executing Overseas Deployment Training (ODT) to reserve units, Pre-Deployment Training (PDT) to deploying units, and Medical Skills Readiness (MSR) Training for EUCOM medical units. HHD/OPS serves as the conduit to provide support to Emergency Operations and State Department coordinated support to natural and manmade disasters within the responsible AORs. While Division Chiefs focus on executing current operations under the guidance of the Deputy Commander for Operations, HHD/OPS coordinates the efforts between Divisions. HHD/OPS focuses on the future support requirements through the deliberate planning process, develops these requirements, communicates plans, and monitors execution across the multiple functional divisions, while remaining in synch with our external partners and informing the Commander's decision making. HHD/OPS provide oversight to all matters related to the health, welfare and discipline of 34 assigned and one attached military personnel. This includes but is not limited to Army Physical Fitness Test administration, Uniform Code of Military Justice, barracks maintenance, Force Protection, weapons maintenance, Nuclear, Biological, and Chemical readiness, Soldier Medical Readiness, and Soldier Safety.

FOCUS AREA.

A. Operational. Coordinates tasking and operational activities for USAMMCE. Produces internal plans and documents such as OPORDs, Command Briefings, and Concept Plans/Briefing. Coordinates mission support requirements with all divisions within USAMMCE. Manages multiple requirements within Medical Operational Data System (MODS), Medical Protection System (MEDPROS), and the Defense *Readiness Reporting System*-Army (DRSS-A). Compiles and submits training and readiness reports to both ERMC and MRMC.

B. Training. Training NCO: Serves as the Center Training NCO and central point of contact for all training policies, procedures, and regulations governing the training of 34 military personnel, 43 Department of the Army Civilian (DAC) employees, and 287 Local National (LN) employees. Operator and manager of multiple training and readiness systems, to include Digital Training Management System (DTMS), Army Training requirements and Resources System (ATRSS), Range Facility Management Support System (RFMSS), Training Share Point link, the center-wide training database. Responsible for the continual development, maintenance and communication of a central training calendar for USAMMCE. Schedules and leads monthly training meetings, at both the divisional and center level, designed to ensure that each of the military, DAC, and LN training requirements are met on an ongoing and timely basis. Communicates training statistics to, and solicits training support from, both ERMC and MRMC on a continual basis. Prepares all command briefings. Assist the Chief, Operations Division in planning and receiving units to USAMMCE for pre-deployment training and overseas deployment training.

C. Military Personnel: Serves as the Military Personnel Specialist (S1) and is the central point of contact for all military personnel actions. Updates and maintains enlisted and officer records, NCO promotion packets, the Electronic Military Personnel Office (*eMILPO*), and Officer and NCO rating schemes. Prepares and processes Personnel Actions (DA Form 4187), leave and pass forms, awards, flags, and other personnel related actions.

SIGNIFICANT ACCOMPLISHMENTS.

A. Operational-External. Planned (ongoing) and synchronized the OEF retrograde support requirements between USAMMCE. U.S. Forces-Afghanistan (USAFOR-A), CENTCOM and Army Central Command (ARCENT). SPO coordinated the AFRICOM/EUCOM special mission planning exercise. SPO managed MEDCOM, OTSG, HA, EUCOM, and AFRICOM contingency stock. Worked as a conduit for information though the Class VIII planning and tracking process of many natural disasters on a global scale, ranging from earthquakes and flash floods. HHD/OPS managed a centralized tasking monitoring process for tracking external taskings for Deputy Commander USAMMCE. HHD/OPS monitors the Secret Internet Protocol Router Network (SIPRNET) operational information for USAMMCE. HHD/OPS operates the Emergency Operation Center (EOC) for USAMMCE during Force Protection exercises.

B. In order to better meet our customers' needs and to streamline the customer support process, Support Operations (SPO) was reconfigured to an internal operations and detachment headquarters element. The DLA Troop Planner was aligned with the Customer Support Division in order to work more closely with COCOM MEDLOG Planners.

C. Training. The training NCO updated the USAMMCE Training SOP that defines how training is planned conducted and reported. He managed the USAMMCE ATRRS account for,

Maintenance Management and Expeditionary Deployable Oxygen Concentration System (EDOCS) classes. The training NCO established a training matrix to track USAMMCE military and department of civilian personnel in their required training. The Training NCO coordinated Arbinger Leadership training for internal supervisors which trained 50 of USAMMCE's key leaders increasing their ability to successfully communicate and accomplish the Center's mission. The training NCO managed and updated personnel in the Digital Training Management System (DTMS) daily. Planned and coordinated multiple training contracts with external trainers or outside agencies such as, Combined Arms Training Center (CATC), and local training companies. She managed all levels of training throughout the Center for FY13 resulting in better than 97% completion of mandatory training requirements as directed by DA, MEDCOM, MRMC and USAREUR. This training resulted in a more productive work environment, increased morale, and a healthy climate of employer-employee relationships.

INTERNAL OPERATIONS.

Established a scheduled rotation of daily checks for the USAMMCE SIPR account. Ensured that the incoming Staff Duty Officer of the week had an active SIPR account and was familiar with the procedures to access the SIPR room allowing for seamless 24/7 coverage of USAMMCE critical information. Maintains the USAMMCE open access tracking matrix, which allows each division to monitor and update their respective tasks. Coordinated key recurring events for USAMMCE including Command and Staff, Production Meeting, TEWLS Meeting, special guest occurrences, Weekly Commander's Situational Updates, and other critical events as assigned (created, updated, conducted briefing for all of these events). OPS operated the Emergency Operation Center for USAMMCE during Force Protection exercises. Ensured that all high priority telecoms and VTC's were scheduled and linked in on time with the requesting commands. Executed two semi-annual APFTs in April and October 2013. Coordinated with external organizations to qualify assigned Soldiers with M16 and M9 ranges at Landstuhl Regional Medical Center and Baumholder Ranges. Planned and conducted training for four Soldiers to attend the Expert Field Medical Badge in Grafenwoehr, Germany.

Section 30

Fiscal Year 2014
Annual Historical Report

U.S. Army Medical Materiel Center - Korea

Mission.

Provide medical supplies, medical maintenance, and optical fabrication support to units operating in Korea while preparing to Fight Tonight.

A. Vision: Customer-centered in all we do in order to consistently deliver the best service experience to our supported units.

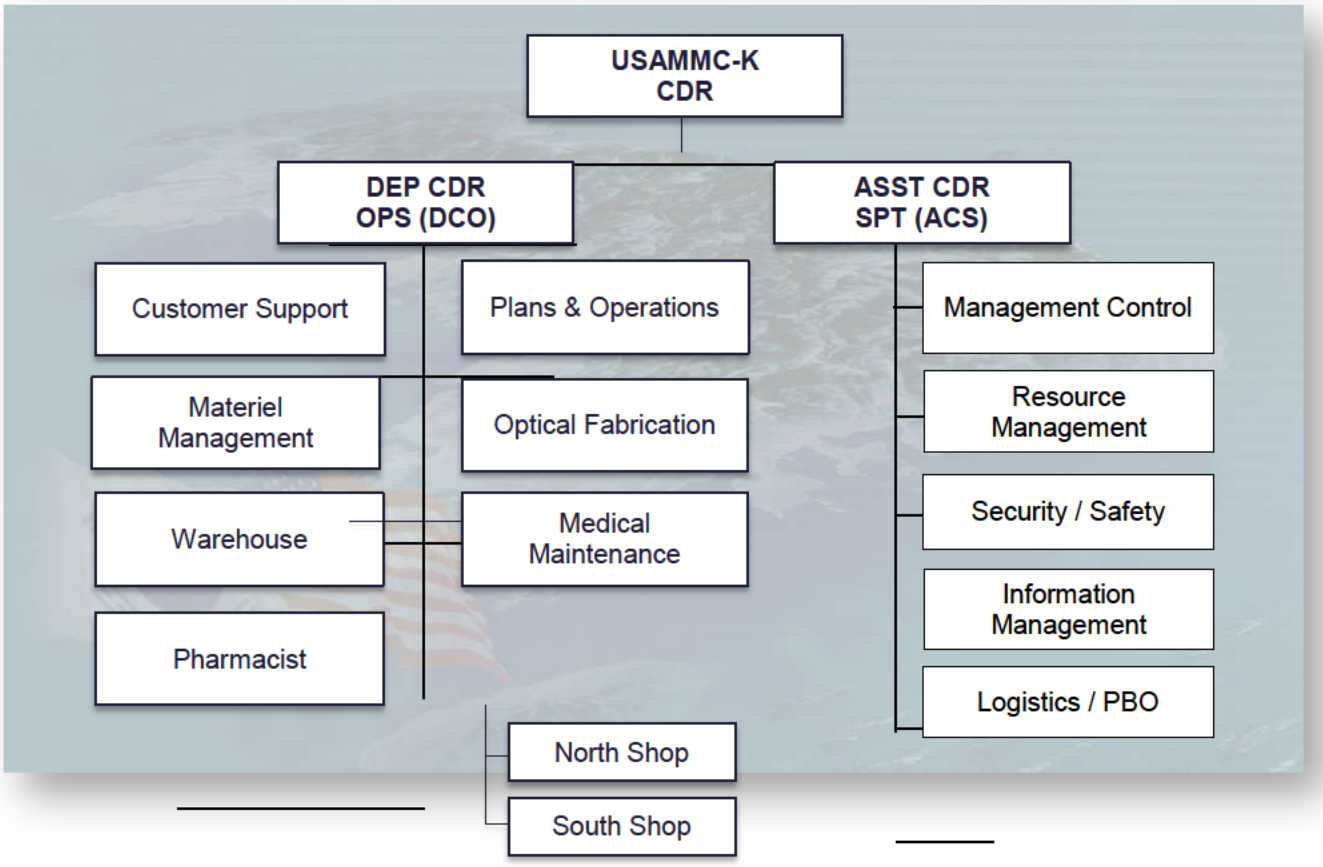
B. Unique Features of USAMMC-K:

1) The only Army MEDLOG unit with both peacetime and wartime missions. It is designated as the Theater Lead Agent for Medical Materiel (TLAMM) for the United States Forces Korea (USFK) and executes the Single Integrated Medical Logistics Manager (SIMLM) for the 8th Army in accordance with OPLAN 50XX.

2) Partners with the 65th Medical Brigade and the Korean Service Corps (KSC) Battalion to execute its mission. The staff is comprised of US Soldiers, Korean Augmentation to the US Army (KATUSA) Soldiers, US civilians, local national civilians, and paramilitary (KSC) civilians.

Organization and Personnel.

A. Organizational Chart:



B. Key Personnel (October 2013 to September 2014):

Commander
LTC Kevin Cooper (departed in June 2014)
LTC Jonathan Butler (reported in June 2014)

Deputy Commander for Operations
MAJ (b) (6) (departed in May 2014)
MAJ (b) (6) . (reported in June 2014)

Assistant Commander for Support
(b) (6)

Accountable Officer
CPT (b) (6) (reported in November 2013)

Customer Support Chief / Pharmacist
CPT (b) (6)

Warehouse Chief
(b) (6) (departed July 2014)
CPT Michael Baisa (reported in June 2014)

Logistics Chief
(b) (6)

Plans & Operations Chief
(b) (6)

Resource Management Chief
(b) (6)

Information Management Division Chief
(b) (6)

Security Chief
(b) (6) (departed in October 2013)
(b) (6) (arrived in January 2014)

Medical Maintenance OIC
CW3 (b) (6) (departed in July 2014)
CW2 (b) (6) (reported in August 2014)

Optical Fabrication NCOIC
SFC (b) (6) (departed in July 2014)
SFC (b) (6) (reported in July 2014)

Management Control
(b) (6) (departed May 2014)
(b) (6) (reported in August 2014)

Statistical Data.

A. Medical Maintenance: Provides scheduled and unscheduled services support to 43 outlying health, dental, and veterinary clinics as well as MTOE units at 36 locations across the peninsula.

B. TDA Medical Equipment: completed 2827 scheduled and 1342 unscheduled services.

C. MTOE Medical Equipment: completed 3719 scheduled and 127 unscheduled services.

D. Total Services Completed: 8015.

E. Optical Fabrication: Produces standard issue frames including 2 styles of aviation frames, 10 frames of choice with 3 varying colors, single and multi-vision spectacles, protective mask inserts, and ballistic eyewear. The section supports all USFK personnel including KATUSAs, emergency essential employees, and retirees.

1) Spectacles: produced 23,357 pairs.

2) M50 inserts: produced 6,934 pairs.

F. Medical Supply:

3) FY14 Sales: $23,884,014.

4) Stocked Items: average 2,211 stocked line items.

5) Contingency Stock Items: There were $11.9M worth of contingency stocked items including Pandemic Influenza, Medical Chemical Defense Materiel, and Investigational New Drugs.

6) Materiel Received: 1,416 pallets/ 3,205 boxes received from various vendors.

7) Materiel Processed: 74,636 sales order from customers.

8) Materiel Shipped: 917 pallets and 7262 boxes weighing 1,086,747 lbs.

9) Zero Losses in Temperature Sensitive Medical Products (TSMP): There were zero losses in TSMP including the receipt and handling of over 42K influenza vaccines. Also, there was a 78% decrease in expired and unused influenza vaccines from the previous year.

Healthcare Delivery.

N/A

Veterinary Services.

N/A

Training and Education.

A. Mandatory Annual Training: The training was conducted online or face-to-face and the type of training needed was based on targeted audience of US military, DA civilians (e.g., GS), or local nationals (e.g.,

KGS). Note: Soldiers not assigned to USAMMC-K were tracked and managed by their respective chain of commands.

Total Training Topics: 29
Online training: 17
F2F training: 12

B. Internal Training: Each section conducted internal training requirements to meet their respective needs. This included individual training that was essential for the mission or task required. The following skill sets were examples of ongoing internal training: MOS level I/II skills, forklift operator, hazmat handler, shipping material equipment processor, logistics automation system (e.g., TEWLS, DCAM, DMLSS, and SAMS-E).

C. External Training & Certification: Most of the training and certification were provided in Yongsan Base, Continental US, on-line, or DCO. Some known trainings requirements were Digital Training Management System (DTMS), Command Post of the Future (CPOF), TEWLS, DCAM, ISO 9001, Safety Officer, and Hazmat Training.

D. Career and MOS progression training courses (IDP): Individuals and supervisors assessed Soldiers/employees IDP to ensure required course were completed or planned for completion. Note: Soldiers not assigned to USAMMC-K were tracked and managed by their respective chain of commands.

1) General Civilian Career Requirement: Foundation (1st year in the job), Basic (GS 7-9), Intermediate (GS 9-12), and Advance (GS 13 and above) Courses.

2) General Military Career requirement: BOLIC, Captains Career Course/Advance Officer Course, and Command and General Staff College.

3) US Civilian Career Fields at USAMMC-K: 0301 Series Plans and Operations Officer, 0341 Series Administrative Officer, 0080 Series Security Manager, 2001 Series General Supply Manager, and 2200 Series IT Specialist.

4) Korean Civilian Carrier Fields at USAMMC-K: 0303 Series Office Support Assistant, 0318 Series Secretary, 2210 Series IT Support, 0343/0344 Series Management Analyst, 2001 Series General Supply Specialist, 2005 Series Supply Technician, 1910 Series QA/QI Technician, 2030 Series Storage Specialist, 2003 Series Supply Systems Analyst, 2010 Series Inventory Management Specialist, 0640 Series Optical Technician, and 5704 Series Forklift Operator.

Research and Development.

N/A

Resource Management and Budget.

A. The USAMMC-K executed $3,522K in Defense Health Program (DHP) programmed dollars. The expenditure was required to support the MEDLOG mission in Korea.

B. In September 2014, the USAMMC-K launched initial procedures to use the Global Combat Support System Army (GCSS-A) to acquire non-medical supplies from Supply Point 60 by establishing GCSS-A DODAACs (WT4GCR for PBO, W8120U for S-2/4, and W81K8C for Repair Parts) and Cost Centers.

C. In September 2014, the Korean National payroll processed through Standard Army Finance Information System (STANFINS) was deactivated in order to convert and process thru the General Fund Enterprise Business System (GFEBS).

D. The Business Support Office (BSO) provided ongoing feedback and necessary guidance to respective stakeholders in order to maintain compliance with DLA and MEDCOM Defense Working Capital Fund (DWCF) requirements including obligation authority (OA) and Government Purchase Card (GPC) program.

Information Management.

A. Submitting Heat Tickets: Internal customers were referred to the Enterprise Service Center for basic computer related issues. This helped the Information Management Division (IMD) to maintain its focus on IMD related work. The IMD will continue to educate (enforce) the use of the ESC for non-emergency, basic computer problems.

B. Access to 8th Army NIPR Network: The USAMMC-K utilizes the MEDCOM network to gain access to NIPR internet sites. The lack of access to 8th Army Korean network made it difficult to request Local Service Request (LSR), Cargo Movement Request (CMR), and Requirement Change Request (RCR). The Network Team at 65th MED BDE was working with representatives from the Korea domain to resolve these issues by providing network drops and Landwarnet access.

C. Support to DCAM Customers: The DCAM users are located at various locations throughout South Korea. This required the IMD staff to travel numerous hours to assist users. DCAM users that utilize the MEDCOM NIPR network can in most cases be assisted via remote access. External units and other Major Subordinate Command (MSC) to include the Navy and Marines are not currently able to be assisted by real-time access.

Operations.

A. Key Resolve (KR) 2014 Exercise: The USAMMC-K participated in the Combined/Joint KR Exercise from 18 February to 7 March 2014. This annual computer assisted exercise (CAX) focused on transition to hostilities (TTH) operations and the associated support requirements. The USAMMC-K provided 24/7 Tactical Operations Center (TOC) staffing, MEDLOG concepts of support briefs/products as well as collaborated with Joint MEDLOG stakeholders. Of note, the 563rd Medical Logistics Company (MLC), in partnership with USAMMC-K, validated logistics automation ordering procedures through DCAM/VSAT system during their field exercise. Medical supplies were requisitioned electronically from the field, processed by USAMMC-K, and supplies delivered to the supported unit within 24 hours. Also, the 563rd MLC's Medical Maintenance Section completed numerous work orders in support of 2nd Infantry Division to gain proficiency on tactical medical maintenance operations.

B. Ulchi Freedom Guardian (UFG) 2014 Exercise: The USAMMC-K participated in the Combined/Joint UFG Exercise from 13-29 August 2014 which was very similar to the KR exercise. The focus for this exercise was to better understand USFK/8th Army OPLAN 50XX briefs and products as well as develop (update) USAMMC-K briefs and products including CLVIIIA theater flow, personnel availability analysis, medical set breakdowns, and TOC battle drills. The analysis and products developed during this exercise assisted in the identification of numerous MEDLOG gaps in theater. The products will be used as a basis for the KR Exercise in March 2015.

Modernization.

A. The Medical Maintenance Section acquired new test, measurement, and diagnostic equipment (TMDE) for the calibration of audiometers used for hearing tests. The new equipment allows USAMMC-K to calibrate audiometers on-site instead of sending them back to the U.S. for calibration. The equipment turnaround time for audiometers was reduced from several weeks to virtually nothing, and customer satisfaction has increased. Also, new TMDE for vital sign monitors were acquired. This equipment is very compact and functions as four pieces of TMDE in one. It allows technicians to travel lighter and work more efficiently by eliminating the need to switch TMDE while calibrating vital signs monitors.

B. The Information Management Division acquired a new CSS-VSAT and CAISI system. The new system located at USAMMC-K will enable the 563rd MLC to employ a Forward Distribution Team with their CSS-VSAT and CAISI system and electronically order medical supplies from the field to USAMMC-K.

C. The Plans and Operations Section relocated the Tactical Operations Center (TOC) into Building 710 Annex. This relocation allowed a more updated and secured TOC with upgraded ADVANTOR, XO90 security systems, and sound proofing for secure briefings. The new TOC provides USAMMC-K the advantage and capabilities to work independently without relying on the 65th MED BDE TOC for SIPR, CENTRIX, VOIP, CPOF, and VTC.

Logistics.

A. Department of State (DoS) Support: The USAMMC-K established Memorandums of Agreement with the U.S. Embassies in Korea, Mongolia, and Thailand to fulfill their CLVIIIA requirements.

B. In October 2013, the Army mandated the use of the Standard Army Maintenance System-Enhanced (SAMS-E) for maintaining and reporting medical equipment. The medical maintenance staff conducted Customer Assistance Visits (CAVs) and assisted customers with entering equipment into SAMS-E as well as trained them on how to create, send, and receive work orders.

Construction.

Completed 17 work orders totaling $266,206.

PROJECT NUMBER	TASK DESCRIPTION	START	COMPLETE	TOTAL
H6-00549-2J	Install wall light above rear-door on bldg. 710	01/17/2012	10/01/2013	$6,468.99
H6-00536-2J	Repaint/install waterproof for roof at bldg. 713 to 716	12/09/2011	10/29/2013	$104,494.34
H6-00597-2J	Improve on the top of server room and carpenter room in building 709	05/03/2012	10/29/2013	$18,834.00
H6-00559-3J	Replace to new three heads of eyewash station at maintenance and warehouse	04/10/2013	11/07/2013	$2,392.82
H6-00587-2J	Install the grated ditch in front of building 710 from mail room to gate	04/25/2011	11/12/2013	$24,570.00
H6-00531-2J	Reposition air conditioning plant in front of bldg. 711	08/27/2012	11/20/2013	$2,416.76
H6-00589-3J	Install gutters at building 713 to 717	08/27/2012	11/20/2013	$26,081.99

H6-00554-3J	Install three detectors and relocate eight detectors in building 718	03/11/2013	11/21/2013	$2,981.59
H6-00657-2J	Install steel grating around new building next to bldg. 710	09/04/2012	12/03/2013	$17,447.41
H6-00534-3J	Install metal grate ditch and RCP behind bldg. 709	12/17/2012	12/03/2013	$18,325.57
H6-00549-2J	Installing guard rail across side-walker near motor pool and optical	01/17/2012	12/03/2013	$6,468.99
H6-00566-3J	Install removable poles and chains to protect men and vehicles on the docks in warehouse, bldg. 709	05/20/2013	12/09/2013	$4,395.36
H6-00514-4J	Install acrylic type wall on stairs near building 712,710	10/31/2013	12/15/2013	$9,942.00
H6-00509-4J	Install a faucet at exterior wall from mechanical room in building 710	10/23/2013	06/15/2014	$70.00
H6-00510-4J	Install a faucet at exterior wall from mechanical room in building 712	10/23/2013	06/15/2014	$50.00
H6-00527-2J	Install a shed to protect a ATS panel box for back-up generator at building 711	12/06/2011	08/15/2014	$1,997.00
H6-00501-4J	Install metal grate ditch/RCP in front of bldg. 709	09/27/2013	9/22/2014	$19,270.00

Health and Environment.

A. The USAMMC-K was evaluated and maintained its Army Safety and Health Management System (ASHMS) Star status on 21 March 2014.

B. The USAMMC-K received its 4th Certificate of Achievement for Safety from the 65th Medical Brigade Commander for maintaining its accident free record in FY14.

Other.

The USAMMC-K conducted International Standards Organization (ISO) 9001 and Occupational Health and Safety Management System (OHSAS) 18001 Surveillance Audit on 18 Dec 2013 and was recertified for ISO 9001 and OHSAS 18001, which reflects USAMMC-K's operation has been standardized and its quality management has been improved.

Section 31

Fiscal Year 2014
Annual Historical Report

U.S. Army Medical Research Acquisition Activity

Mission:

Provide quality, timely and cost effective business advice and solutions for our customers.

Organization and Personnel:

In 2014, contracting leadership changed in that the Head of the Contracting Activity (HCA) was moved from the USAMRMC to the Office of the Surgeon General. Currently, the Principal Assistant Responsible for Contracting (PARC) and the Director, USAMRAA positions are combined. Below Figures 1 and 2 show the change in the organizational structure during the past year.

As of 31 December 2014:

212 Department of Army Civilians
8 STEP Employees
1 Military
9 IMO Contractors

FIGURE 1: The USAMRAA Organizational Chart (2013 Historical Report)

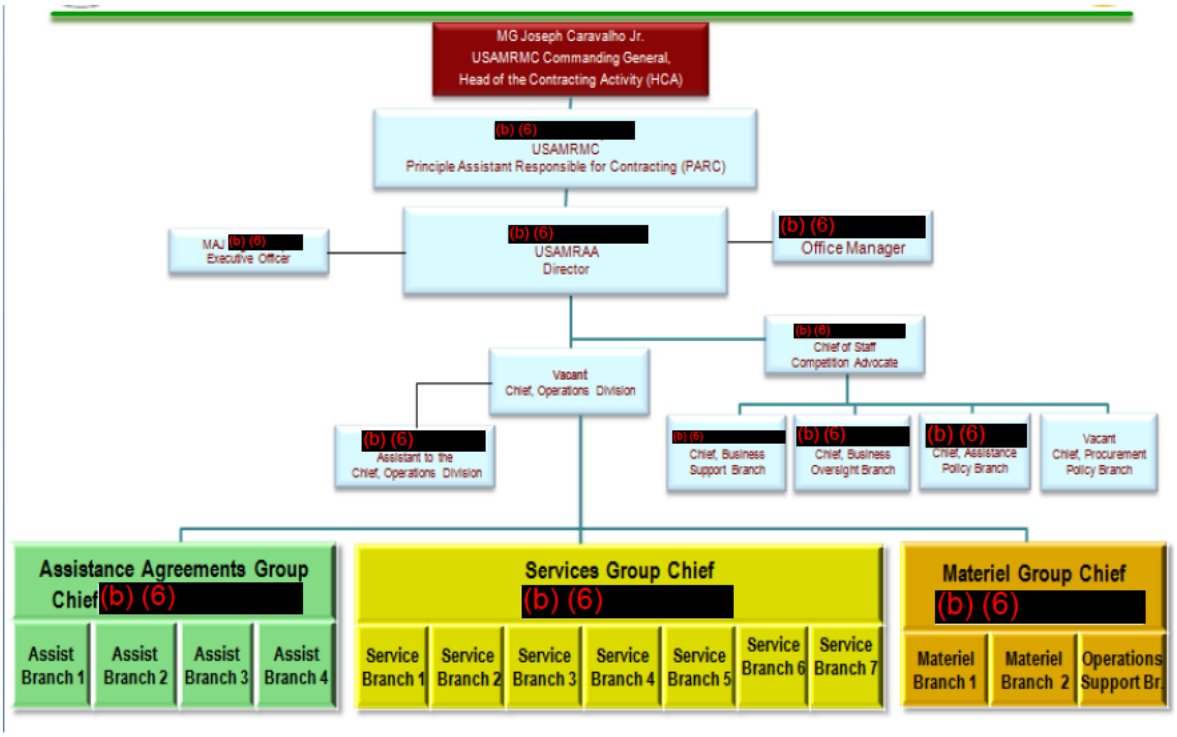
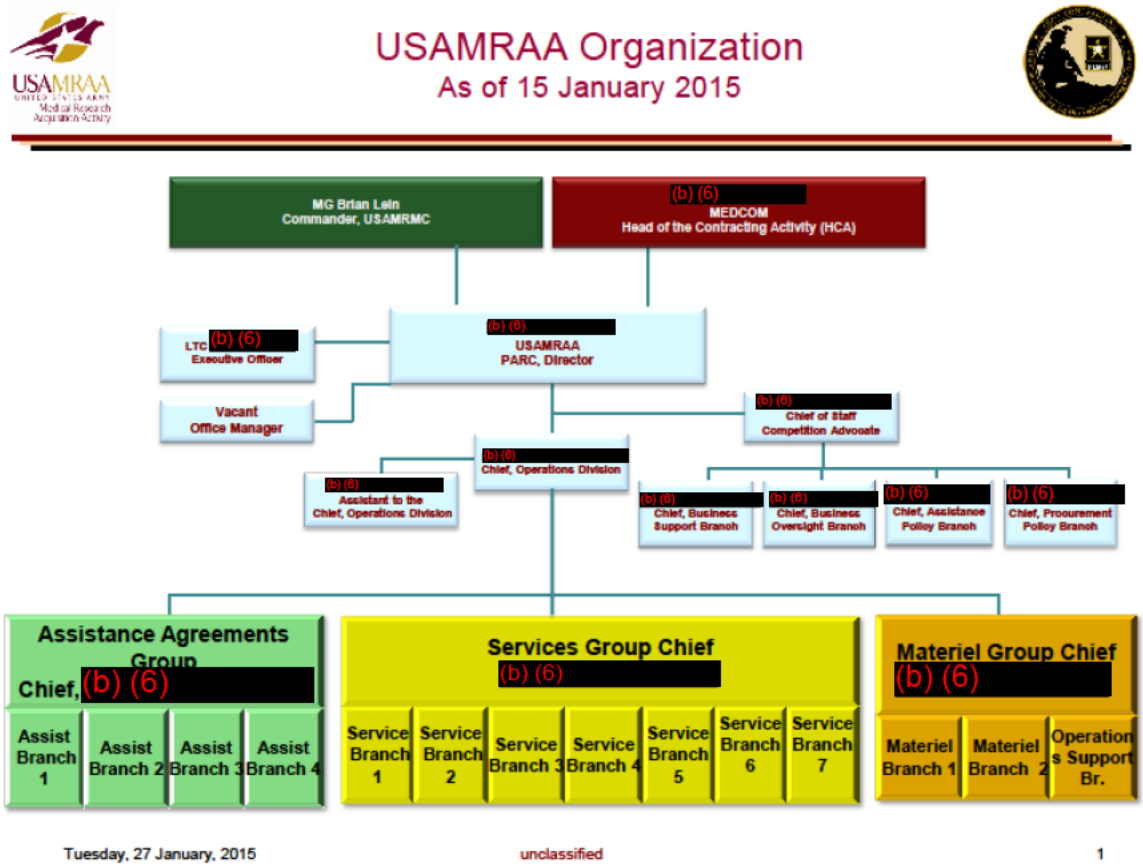


FIGURE 2: The USAMRAA Organizational Chart (2014 to Present)



Statistical Data:

	Quantity	Dollar Value of Awards
Assistance Agreements	2504	$.8B
Contracts	5236	$1.3B
Total	7740	$2.1B

Statistical Data obtained from IMO "R12 Comparison FY06 to Date by Month" Excel report.

Healthcare Delivery:

N/A

Veterinary Services:
N/A

Training and Education:

Numerous training seminars and events supporting professional development, certification, and job growth continue to attract Activity staff and promote close cooperation with the National Contract Management Association and the Defense Acquisition University. The USAMRAA spent $230K over the past calendar year in support of personnel training, education, and professional development. The USAMRAA's Stand Down Training days and Town Hall meetings provide additional training opportunities for specific and targeted training for staff members.

Research and Development:
N/A

Resource Management and Budget:

U.S. Army Medical Research Acquisition Activity

$ in (000)s

	FY13 - Actuals	FY14 - Actuals	FY15 - Advance Billing Estimate
Payroll	$22,788	$23,469	$25,121
Expenses	$2,947	$2,488	$2,987
Total Reimbursable Cost	$25,735	$25,957	$28,108

Starting FY13, under the direction of USAMRMC, USAMRAA is under a cost reimbursable environment. For each FY, and advance billing amount is issued at the start of the fiscal year with adjustments being made for actual cost each quarter.

For FY16, with significant adjustments anticipated, our budget will be issued in June 2015 with an overall estimated advance billing rate for RM budgetary purposes. A tasker will go out in September requesting FY16 workload in order to calculate the customers' requirements in establishing an FTE. In November 2015, we will issue the advance billing amount forecasted for each activity for cost reimbursement purposes.

Out cost reimbursement environment takes the DOD FMR, the DOD instructions, and a subsequent legal review into guidance. With FY15 being our 3rd year, our cost reimbursable billing process is now an established business practice.

Information Management:
No new systems were deployed.

Operations:

The USAMRAA participates in the monthly USAMRMC Continuation of Operations Plan (COOP) exercise.

Modernization:
N/A

Logistics:
N/A

Construction:
N/A

Health and Environment:
N/A

Section 32

Fiscal Year 2014
Annual Historical Report

The National Museum of Health and Medicine

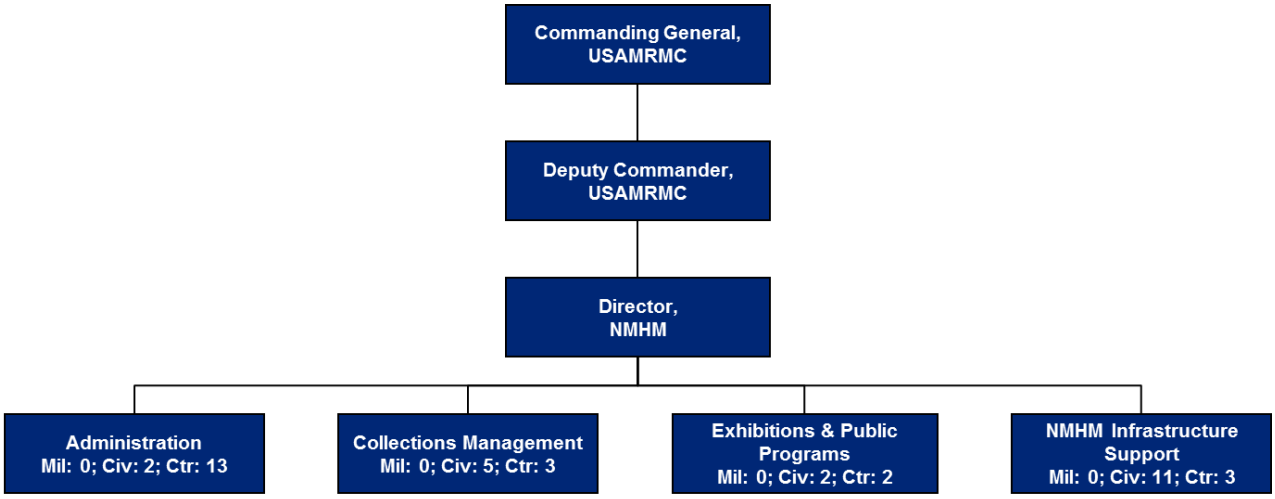
Mission

A. The National Museum of Health and Medicine (NMHM) is a Department of Defense museum that inspires interest in the understanding of medicine—past, present, and future—with a special emphasis on tri-service American military medicine. It's national medical collection is recognized as a National Historic Landmark for its ongoing value to the health of the military and to the nation.

Organization and Personnel

A. NMHM is a DoD joint entity, according to Directive-Type Memorandum 12-001, and DoD designated the Secretary of the Army, and further the Army Medical Command, as the DoD Executive Agent for the NMHM. MEDCOM further designated the executive agency function to the U.S. Army Medical Research and Materiel Command (USAMRMC) in 2011, as a result of BRAC 2005, and NMHM is administered as an element of USAMRMC Headquarters.

B. NMHM is headed by the Museum Director and maintains four major subordinate areas: Administration, Collections Management, Exhibitions and Public Programs, and NMHM Infrastructure Support.



Statistical Data

N/A

Healthcare Delivery

N/A

Veterinary Services

N/A

Training and Evaluation

N/A

Research and Development

A. The roll-out of publications from a National Institute of Justice research and development grant continued in 2014. The research projects, conducted by NMHM anatomical collections staff, explored the microbial ecology and bacterial community succession that takes place during human decomposition. The products of this research directly impact the medico-legal community by developing new methods for estimating postmortem interval and locating clandestine graves.

Resource Management and Budget

A. As a result of prior-year decisions, the budgeting, processing and accounting of NMHM funding remains with the MRMC HQ Resource Management Directorate. As the assigned missions, functions and personnel of the NMHM did not change significantly during FY14, the funding did not change significantly. The funding expended per element of resource (the internal allocation of resources) has been very similar from one year to the next. As of the end of FY14, no decrements to future funding had been identified which allows the NMHM to continue performing all assigned missions without reduction or degradation of functions. The development of the FY16 budget along with planning for future years' budgets continues to be an ongoing process with the desired result being properly funded and meticulously prepared budgets capable of sustaining NMHM activities in the current and future years.

Information Management

A. NMHM Information Management reported the following achievement during fiscal year 2014: IM/IT successfully completed the import of hundreds of thousands of records into the museum's integrated collections database, as one element of the conclusion of the BRAC relocation effort.

Operations

A. NMHM full mission is ongoing, with exhibitions, programs and research activities. Collections housed in the new facility are accessible for use in exhibitions, research, and public programs.

Modernization

N/A

Logistics

A. NMHM Logistics diligently worked in concert with key staff at USAMRMC Contracting during FY14 culminating in contract awards exceeding $3 million that sustained fundamental operational necessities such as technical and administrative support as well as establishing contracts tailored to meet the unique mission in maintaining historical artifacts and specimens and preserving them in a clean and safe environment to the public.

B. NMHM successfully established two new contract services in FY14: one continues a long-term process to digitize NMHM object accession records for preservation and better utilization in a collections database; the second contract facilitates the digitization of at-risk media (films, videos, slides) for preservation purposes.

Construction

A. A design-build sustainment, restoration, and modernization (SRM) funded project to renovate a former medical supply warehouse (Building 178), located adjacent to the NMHM, was completed during FY14. An additional 70,000 SF of environmentally-controlled space is now available to house the NMHM collection and provide management workspace for approximately 20 permanent staff.

Health and Environment

N/A

Other:

A. NMHM collections continued apace in FY2014, including accessions from the following agencies, among others: the U.S. Army Medical Research and Materiel Command (USAMRMC); the Telemedicine & Advanced Technology Research Center (an element of the USAMRMC); the Walter Reed National Military Medical Center; the Val G. Hemming Simulation Center of the Uniformed Services University of the Health Sciences; and the Armed Forces Medical Examiner System.

B. NMHM conducted official visits and professional development tours throughout FY14, including to groups and agencies such as:

    1) Association of Military Surgeons of the United States
    2) Surgeon General and staff, Republic of Korea
    3) Armed Forces Pest Management Board
    4) Armed Forces Medical Examiner
    5) Surgeon General and staff, Royal Thai Army

C. NMHM hosted a series of informative community engagements during FY2014, including:

1) 15th Annual Brain Awareness Week: Hundreds of DC-area middle-school students engaged with leading TBI researchers and clinicians at this STEM-focused program. Partner agencies included: Walter Reed National Military Medical Center; Uniformed Services University of the Health Sciences; Defense and Veterans Brain Injury Center.
2) Monthly “Medical Museum Science Cafes” featuring speakers from DoD entities such as the Naval Medical Research Command; Walter Reed Army Institute of Research; Defense and Veterans Brain Injury Center.
3) Public programs for general audiences, including: Scout Day (May); Anatomy of Sports (Aug.); Teddy Bear Clinic (Sept.); Halloween at the Museum (Oct.).

Appendices

N/A

Section 33

Fiscal Year 2014
Annual Historical Report

Armed Forces Medical Examiner System

Mission:

The mission of the Armed Forces Medical Examiner System (AFMES) is to provide comprehensive and innovative medicolegal services worldwide.

Organization and Personnel:

A. Organizational diagram: The AFMES organizational diagram, together with core mission and function comments are provided at Appendix A.
B. Organizational Strength as of 1 Oct. 13/30 Sep. 14:
Civilians: 55/59
Military: 42/38
Contractors: 191/184

Statistical Data:

The following represents the workload statistics and activities performed in FY14 by the AFMES Divisions/Offices listed:

A. Armed Forces Repository of Specimen Samples for the Identification of Remains

1) (AFRSSIR) Section:

Total number of reference cards in storage as of 30 Sept. 2013: 6,994,032
Total number of reference cards processed in FY13: 273,333
New Accessioned Cards: 260,212
No DEERS: 1,817
Duplicates: 11,304
Total number of reference cards destroyed: 6 (all donor destruction requests)

DNA Reference Cards Released:

To AFDIL: 303
To other Federal Agencies: 15
To Non-Federal Agencies: 16
AFRSSIR references: 379
Non-AFRSSIR references: 22
OAFME cases: 455
Total OAFME specimens: 659
Average STAT turnaround time: 30 hours
Average Turnaround time: 28 days
Non-AFMES cases: 46
Law enforcement: 43
Other DoD medical: 3

Average outside casework turnaround time: 28 days
Additional cases reviewed: 958

B. Armed Forces DNA Identification Laboratory

1) Nuclear DNA Section:

Total Number of OAFME Cases Received (FY 14): 390

Total Number of OAFME Specimens Received:	506
- Autopsy Specimens:	462
- Dis-associated Specimens:	44
Average STAT Case Turn-Around Time in Days:	2
Average Case Turn-Around Time in Days:	17.4
Total Number of OAFME Reports:	438
- Identification Reports:	326
- Exclusion Reports:	102
- No Results:	10
Total Number of Additional Cases Reviewed for MtDNA:	516
Total Number of USACIL Case Requests:	20
Total Number of DoD Law Enforcement Case Requests:	7
Total Number of Other Law Enforcement	

2) Mitochondrial DNA (mtDNA) Section:

Total cases received (FY 14):	278
Total specimens received:	987
- From JBPHH Lab:	958
- From Offutt Lab:	29
Average Number of Samples/Case:	3.6
Total Analyses Reported:	1,300
Non-human specimens Reported:	51
Total Comparison Reports Completed:	183
- First Time Named Comparison Reports:	75
- Subsequent Named Comparison Reports:	57
- “No Name” Comparison Reports:	51
MtDNA Success Rate (reportable data):	88%
Y-STR Success Rate (Reportable Data):	52%
Autosomal-STR Success Rate (Reportable Data):	51%
Average Sample Turn-Around Time (Duty Days):	83
Family Reference Specimens Collected:	1,283
- References Collected At Family Updates:	285
- References from Service Casualty Offices:	998
- Family References Reported Out:	4,351
- MtDNA:	3,151
- Autosomal DNA:	607
- Y-Chromosome Analysis:	593

3) Laboratory Automation Section:

Samples Processed:	39, 839

4) Laboratory Support Section:

Non-DMLSS Supply Orders:	112
DMLSS Supply Orders:	60
Order Tracking & Follow-up:	660
Reconcile of Non-DMLSS Items Purchased:	265
Management of Inventory Stock Items:	698
Manage and Fill Laboratory Requests:	616
Data Entry and Report Generation via LISA:	615
Work Orders for Repair or Maintenance:	460
Equipment Maintenance Follow-up Requests:	425
Maintenance of PM Records on Critical Items:	237
Water Testing Collections:	96
Facility Maintenance Issue Resolutions:	146

5) Quality Management Section:

Proficiency Tests Completed:	136
Training & Education:	
- New Hires In-Processed:	18
- Individual Training Programs Developed:	63
- Personnel in Training Programs:	89
- Lectures/Demonstrations Given:	123
- Written/Verbal Exams Given:	178
- Trainee Laboratory Demonstrations Presented:	55
Quality Control - Validation:	
- Total Instrument QCs Performed:	2,103
- Primer QC Folders Completed:	12
Reagents QCd:	
- MtDNA reagents QCd:	13
- NucDNA STR kits QCd:	41
Reagents Prepared:	105
Standard reference NIST Folders Completed:	9
Staff Profiles Processed:	1,507
Instrument Performance Checks:	78
Validation Projects Completed:	8

Administrative Support Section:

Family Reference Specimens Up-Loaded:	1,283
Report, Sequence, & Received Letters Completed:	3,832
Admin Case Review of Folders Completed:	2,932
Personnel Actions:	245

C. Division of Forensic Toxicology:

1) Overall statistics
Aircraft Incidents – 2,457 (1.7 day average turnaround)
Air Fatalities – 21 (5.8-day average turnaround)
Criminal/Investigative – 2,604 (4.4-day turnaround)
Postmortem – 399 (6.7-day average turnaround)
Special Request Batch Testing – 50 (18-day average turnaround)

Quality Controls – 291 (3.3-day average turnaround)
Surveys – 44 (12.7-day average turnaround)
Total for Standard Toxicology Cases – 5816 (4.3-day average turnaround)
Total Number of Cases Reported – 5,866

Legal Support:

Certified Reports/Summary Reports – 11
Discovery Requests – 10
Litigation Packages – 112
Total – 103

Accomplishments:

A. **Research:**
The Division developed several new methods for toxicological analyses and assisted with several significant projects:

1) Continued research and development of assays for detecting emerging drugs of abuse, such as synthetic cannabinoids; synthetic cathinone's; amphetamines; opioids; and several other classes of psychoactive compounds. The DFT continually monitors those compounds identified in seized evidentiary materials and adjusts the testing methodology to maximize detection and deterrence.

2) DFT procured a high throughput mass spectrometer system (Rapid Fire) instrument (Agilent Technologies) to evaluate its potential as an alternative sample delivery system in an effort to find technologies to replace some, if not all of the immunoassay based drug screens. This technology offers impressive initial screening throughput, and when coupled to a tandem mass spectrometer, results in significant advantages relative to analytic specificity. The added capability of this technology may permit screening for current drugs of abuse and emerging drugs concurrently.

3) Efforts have been ongoing to develop and deploy LC-MS/MS (Liquid Chromatography Tandem Mass Spectrometry) to DDRP laboratories in an effort to replace and/or augment drug testing confirmation currently performed by GC/MS (Gas Chromatography Mass Spectrometry). The benefits achieved by this technology are meant to address analytical challenges posed by "difficult to detect" compounds such as: benzodiazepines, opiates, and amphetamines.

4) The laboratory has continued its drug surveillance efforts and has added a novel technology to its analytical inventory: an LC-QToF (liquid chromatography time of flight mass spectrophotometer). The QToF technology was acquired in FY13 and will permit the lab to conduct surveillance of DoD members and hundreds of compounds (broad spectrum of drugs) of interest to the DDRP. This technology allows for the mass data files to be re-analyzed at any time in the future, as spectrophotometric information of novel compounds become available.

5) The Division continued to research amphetamines "immunoassay positive/confirmation negative" specimens submitted from the DoD drug testing laboratories for emerging drugs that exhibit some structural similarity to other sympathomimetic amines, and therefore are suspected of triggering a presumptive positive screen for amphetamines at the DDRP drug testing labs.

B. **Proficiency Testing/inspections:**

1) Managed the DoD Quality Assurance Open and Blind Drug Testing Proficiency Program

Worldwide, with a total of 21,163 Quality Control (QC) specimens prepared, sent to and analyzed by the DoD drug testing laboratories in 2014: 3,226 military open proficiency specimens and 17,856 military blind proficiency specimens. A total of 832 specimens were tested internally by DFT as a quality assessment measure.

2) Participated in College of American Pathology (CAP) proficiency testing: CAP T (toxicology-3x per year); CAP UDC (urine drug toxicology-4x per year); CAP AL1 (whole blood alcohol/volatiles-3x per year); and CAP FTC (whole blood forensic toxicology-2x per year).

3) The Division of Forensic Toxicology had five on-site inspections in 2014: Health West inspection of DoD QA (March 2014 - DOD QA), the Health West Inspections of the Special Toxicology Forensic Drug Testing Laboratory (Jan 2014, May 2014, and September 2014), and the Divisions ABFT on-site inspection (September 2014). It was determined that the DoD QA Laboratory met all of the DDRP requirements and continues to provide Quality Assurance oversight of the Drug Testing Laboratories. The inspection of the Special Toxicology Forensic Drug Testing Laboratory revealed the laboratory met scientific and administrative requirements for DDRP certification and will maintain its certification. ABFT determined the Division continues to meet all ABFT requirements and was granted re-accreditation for two years.

C. **Diagnostic Consultation:**

5,816 cases were reported in FY-2014. The average turnaround times for these cases were 5.7 days for routine toxicology submissions and 18 days for special request batch testing.

D. **Legal Support:**

Military and civilian toxicologists are often asked to provide expert witness testimony in military and other federal court proceedings. The Quality Assurance section of the Division of Forensic Toxicology is responsible for fulfilling requests for laboratory business records, Freedom of Information Act (FOIA) requests, discovery requests, and other special data requests (*e.g.*, DoD Quality Assurance Laboratory (DoDQA) records).

E. **Operations:**

F. **Expert Witness Testimony/Support/Consultation:**

Forensic toxicology. Due to understaffing, the DFT had to restrict its litigation support to trials that involved predominantly testing from the AFMES. Requests for trial support involving DFT testing has declined however there has been a significant increase in requests to DFT to provide expert support when testing was performed at other forensic laboratories, or where there was no testing performed. Even with these limitations, it was a significant
challenge to sponsor requests the DFT has traditionally supported. On average, division experts provided testimonial support to 2-3 legal proceedings per month and fielded nearly 200 phone consultations for the year.

G. **DoD Drug Detection Quality Assurance Laboratory Inspections/other inspections:**

The DFT administered the DDRP inspections for the 6 DoD drug testing laboratories, providing on average 2 inspectors for each of the 18 inspections conducted. Twelve of these inspections were in assistance to the contracted Health West inspection teams; six of these inspections however involved the DoD personnel only. In these cases DFT inspectors served as leads for the inspection team.

H. **National/International Consultations/Collaborations:**

1) USACIL collaboration concerning emerging drugs of abuse in evidentiary materials.

2) NMS Laboratories, ongoing collaboration on synthetic cannabinoid R&D.

3) LGC Laboratory, United Kingdom, ongoing collaboration on emerging drug threats, and prevalence in UK and Europe.

4) The laboratory started collaboration with the Center for Substance Abuse Research (CESAR). This collaboration will involve analytical testing of samples collected in response to regional incidents concerning suspected use of an emerging synthetic drug. Additionally, the collaboration allows for Division personnel to influence National drug control policy in an effort to affect changes in the DoD.

I. **Education:**

J. **Faculty Appointments:**

Clinical Associate Professor, University of Maryland School of Medicine, Department of Pathology, B Levine

K. **Workshops/other training:**

January 2014 - American Academy of Forensic Sciences, Seattle, WA, (b) (6) and Lt Col (b) (6) attended this conference.

June 2014 – DDRP Joint Service Drugs Testing Meeting, Great Lakes, IL, CDR (b) (6), Lt Col G. (b) (6) attended this conference.

August 2014- USN Justice School, Newport RI, workshop on Prosecuting Sexual Assault, (b) (6) taught at this course.

April 2014- USA, TCAP - Justice School, San Antonio TX, workshop on Prosecuting Sexual Assault, CDR (b) (6) taught at this course.
August 2014- USN Justice School, Plano, TX, workshop on Defending Sexual Assault Cases, Lt Col (b) (6) taught at this course.

October 2014 - Society of Forensic Toxicology Annual Meeting, CDR (b) (6), Lt Col (b) (6) attended this conference.

Nov 2014 - Borkenstein Drug Course, Lt Col (b) (6), attended 5 day training.

Dec 2014 -Borkenstein Alcohol Course, (b) (6), attended 5 day training

Dec 2014 – Sexual Assault Medical Forensic Examiner Training, Lt Col (b) (6) taught at this course.

June 2014 - Sexual Assault Nurse Examiners (SANE) Kit, VTC training for 60 Navy Echelon II & III Command Sexual Assault Prevention and Response officers, CDR (b) (6) taught this course.

OTHER ACCOMPLISHMENTS:

Presentations: 5

Publications: 5
Certifications: 2
Editorial Boards: 1
Manuscripts/Research Proposals Reviewed: 5
National Panels: 1

Healthcare Delivery:

Does not apply to AFMES.

Veterinary Services:

Does not apply to AFMES.

Research and Development:

Resource Management:

a. Defense Health Plan (DHP) O&M: $21,233,400
b. Counter Narcotics Program (CNP): $,550,000
c. VREM: $11,018,000
d. Reimbursable Funding: $4,268,965
e. OPA: $316,893
f. Total Funding: $41,034,644

Information Management:

Throughout the year Information Management/Information Technology (IM/IT) continued its mission support of all aspects of AFMES operations with the focus for the year remaining on key projects such as the continued Information Technology (IT) hardware lifecycle replacement plan. The team life-cycled over 200 work stations consolidated and upgraded 23 servers to 17 2008R2 servers. Privacy Impact Assessments (PIA) was awarded for LISA, SMS and AFMETS. We also transitioned from Retina to ACAS with 100% IAVM compliance. Provided IAVM, patching, software upgrades and other on-demand technical support to National Museum of Health and Medicine. Installed and configured PSSC HPC cluster for genomics and next-generation sequencing applications. Other achievements included development of remote autopsy photography camera stations in support of the AFMES Mortuary Affairs Contaminated Remains Mitigation Site (MACRMS) Operation; spear-heading the AFMES Temperature Sensitive Medical Product (TSMP) program; completing the annual review of Department of Defense Information Assurance Certification and Accreditation Process (DIACAP) and Federal Information Security Management Act (FISMA); successfully completing MICP, JCSIVA, 436/CCRI inspections; developing telecommuting software solution with DISA to support AFMES COOP; and organizing deploying the Government Emergency Telecommunications Service (GETS) in support of the COOP. Successfully stood up Forms/Pubs and Records Management program. The AFMES Application Development Support Services contract went out for rebid and FTI received that contract.

Operations and Security:

a. During FY 14, the Operations and Security section continued to build and resource its operations and security function. OPS and Security developed its Continuity of Operations Plan (COOP) OPLAN and increased efforts to resource and test the plan. Major improvements to the COOP were gained in the area of continuity of communications. Additionally, the AFMES participated in its second Dover Air Force Base (DAFB) wide Vulnerability Assessment, as well as the Air Mobility Command's Emergency Management Site Assistance

Visits. Operations and Security also received commendable ratings following the DAFB Information Protection and Secret Internet Protocol Router (SIPR) certification inspections.

b. AFMES continues to partner with Delaware State University to offer the Gain In the Education of Mathematics and Sciences (GEMS) Program, an educational program for7th and 8th grade children of military, civilian and contractor employees. S2 supported this program by closely working with MRMC's Strategic Partnerships Office and conducting thorough, in-depth background investigation checks with Dover AFB military police, Criminal Investigative Division and Dover AFB medical staff for the volunteer instructors who were in contact with the students.

c. The AFMES participated in the following Emergency Management and Anti- Terrorism Force Protection (AT/FP) exercises and Real World Events:

AFMES COOP Tabletop exercise(s)
DAFB Wing Full Scale Force Protection exercise
DAFB Active Shooter Exercise
AFMES Shelter in Place Exercise
AFMES Evacuation Exercise(s)

d. AFMES increased its security posture by installing an Intrusion Detection System (IDS) which is linked into the DAFB security network. Additionally, S2 procured and installed electronic fingerprinting equipment via Secure Web Fingerprint Transmission (SWFT) to be utilized during the submission of background investigations and clearance submissions.

Logistics:

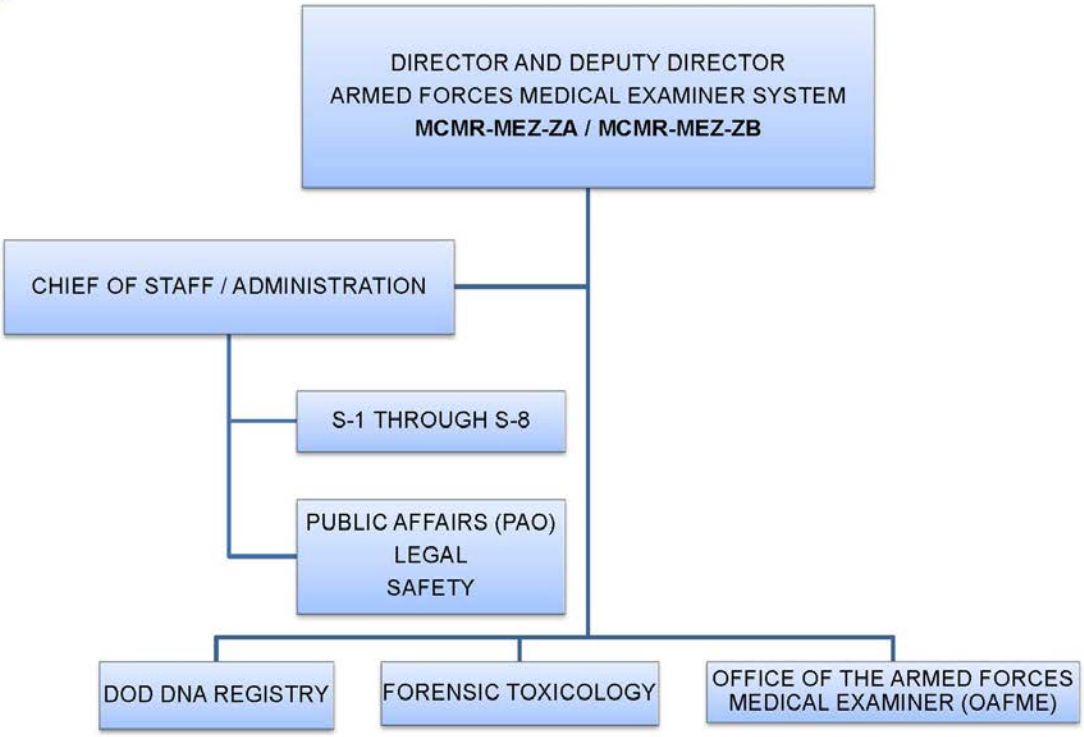
a. AFMES Logistics continues to refine the Logistics process to ensure enhanced interoperability between the General Fund Enterprise Business System (GFEBS) and the Defense Medical Logistics Standard Support (DMLSS). The Inventory Management section made more than 2,000 credit card purchases with a value in excess five million dollars. These purchases were made with a 98 percent error free processing rate, exceeding MEDCOM's error free rate of 92 percent. Additionally, Logistics is coordinating the evaluation of a Temperature Sensitive Monitoring Program capability that will allow it to monitor the temperature of all refrigerated material within AFMES' refrigeration units.

Construction:

a. Design and award for construction of an additional bathroom was completed in FY14. Design for a new warehouse was also completed. Award for construction is expected in 4th QTR FY15.

Appendices:

The Armed Forces Medical Examiner System



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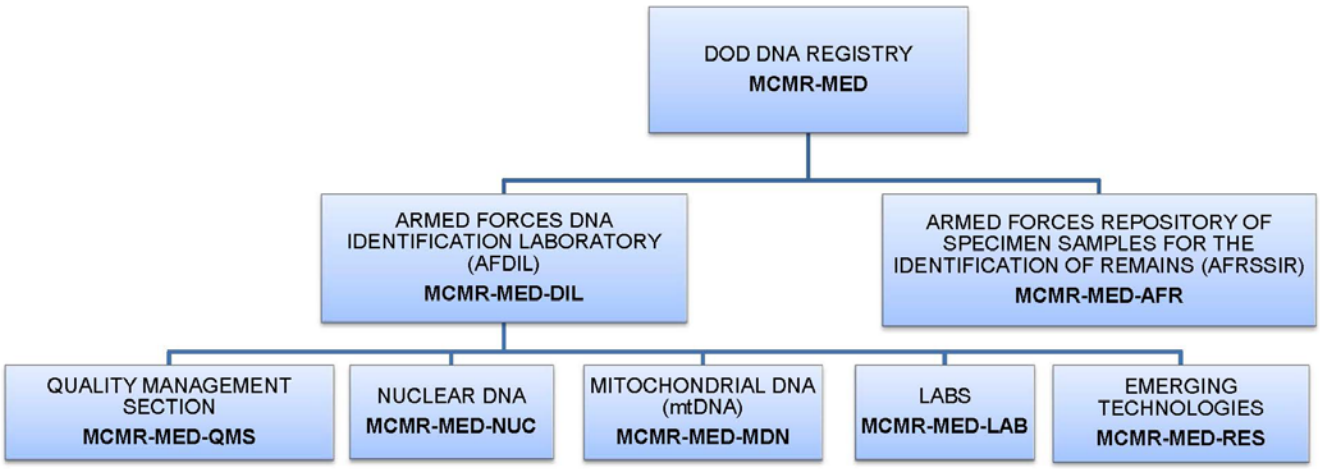

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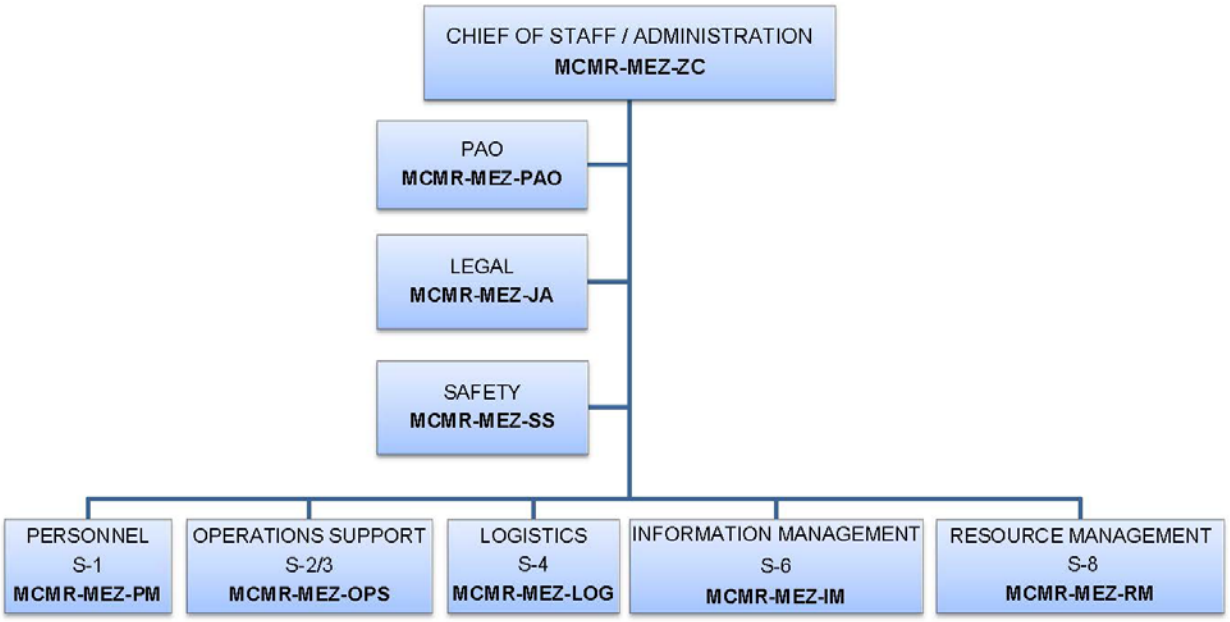

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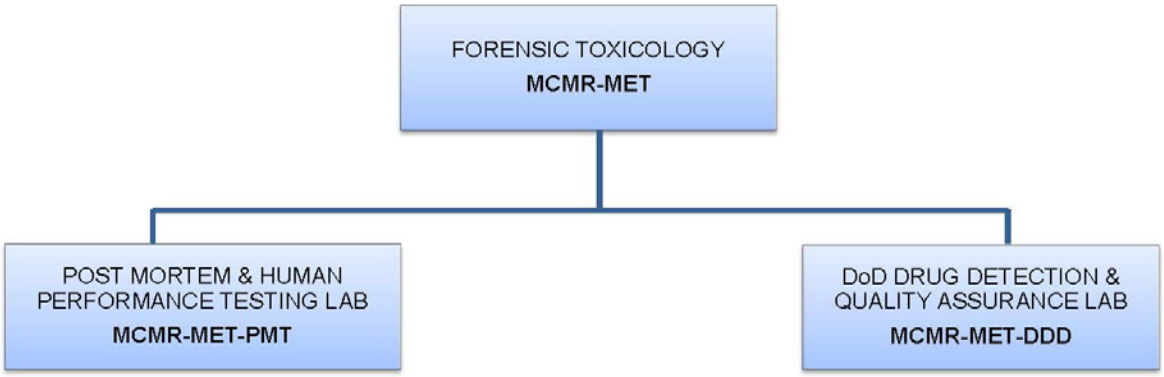

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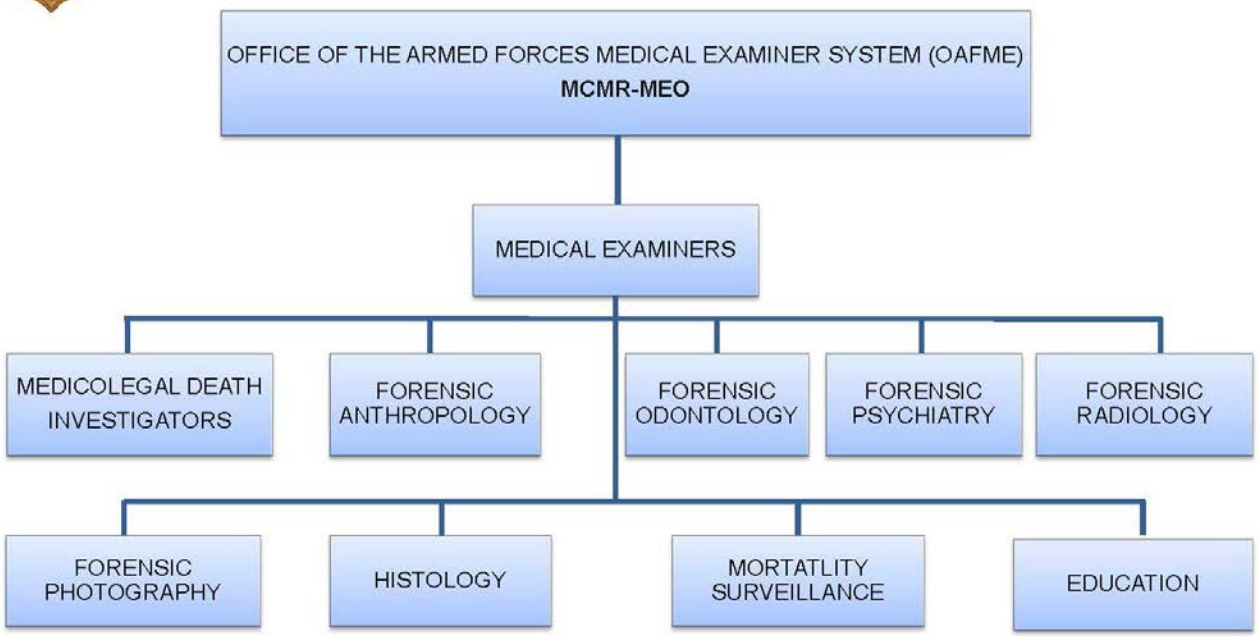


Appendix A

AFMES Organizational Diagram and Core Mission Comments:

Office of the Armed Forces Medical Examiner:

Office of the Armed Forces Medical Examiner (OAFME) - OAFME is the center of medicolegal death investigations for the AFMES. Working closely with investigative arms of all the branches of the military, forensic investigation of crime scenes are conducted upon request. The AFMES also has memorandums of understanding/agreement to support a variety of additional federal agencies. Operational deployment can be accomplished worldwide in 4 to 48 hours, depending on location. OAFME personnel include board certified forensic pathologists, forensic anthropologists, medicolegal death investigators, photographers, histology technicians and administrative support staff.

The Department of Defense DNA (DOD DNA) Registry:

The DOD DNA Registry is composed of two subdivisions, the Armed Forces Repository of Specimen Samples for the Identification of Remains (AFRSSIR) and the Armed Forces DNA Identification Laboratory (AFDIL).

AFRSSIR:

The AFRSSIR is responsible for managing, coordinating and maintain the collection of DNA reference specimens of all military service members with collections taking place at over 1200 DOD personnel collection sites worldwide. They maintain the DNA reference repository for all active duty, reserve, and National Guard service members, deployable DOD civilians, Coast Guard and select Department of State and contractor personnel.

AFDIL:

AFDIL is the sole DOD DNA laboratory tasked with human ID efforts, for both current and past conflicts. AFDIL adheres to the Scientific Working Group for DNA Analysis Methods (SWGDAM) guidelines and the Federal Bureau of Investigation (FBI) Quality Assurance Standards (QAS) and is accredited by the American Board of Crime Laboratory Directors-Laboratory Accreditation Board (ASCLD-LAB). AFDIL is comprised of the following sections:

Nuclear DNA (NucDNA) Section:

The NucDNA section is responsible for supporting the Office of the Armed Forces Medical Examiner (OAFME) for current medicolegal death investigation identification requirements, supporting other DOD human identification efforts, and assisting other Federal agencies in human identification endeavors according to established MOAs/MOUs. Analyses focus primarily on nuclear DNA methodologies (autosomal and Y short tandem repeat (Y-STR)) but the staff are proficient in mitochondrial DNA techniques, should the requirement arise for current casework. With the withdrawal of US forces from Iraq and continued reduction of military forces in Afghanistan, workload for the section has decreased to pre-war levels, however due to increased workload within the mtDNA section for use of autosomal and Y-STR analysis, the section has been actively involved in the review of casework data.

Mitochondrial DNA (mtDNA) Section:

The mtDNA section is responsible for providing DNA testing and consultative services to the Joint Prisoner of War/Missing in Action Accounting Agency (DPAA), used in certification of identifications (ID) for past conflict accounting efforts. Duties include casework and reference processing as well as the maintenance of the Family Reference Database, which is essential to the ID process. At present, approximately 85% of the past conflict identifications are based on DNA comparison results. The mtDNA section mainly utilizes mtDNA methods for the analysis of unknown specimens, although in certain cases, nuclear (autosomal & Y-STR) DNA analyses are now

being performed. AFDIL has increased throughput by 30% utilizing existing budget and personnel. This was accomplished through internal efficiency enhancements in an effort to build capacity for the road to 200 identifications per year.

Laboratory Automation Section (LABS):

The Laboratory Automation Section is responsible for providing DNA testing and services to the DoD and other Federal Agencies. Duties include casework and reference processing using the latest high thru- put instrumentation and methods for mtDNA and autosomal DNA analysis.

Laboratory Support Section (LSS):

The mission of the Laboratory Support Section is to provide logistical services to the AFDIL and their key function is to keep the laboratory stocked with critical reagents, coordinate the purchase of reagents and instrumentation and, facilitate the repair and service of all instrumentation.

Admin Support:

The mission of the Administrative Support Unit provides administrative and casework support services to the AFDIL and AFRSSIR. Their key functions include handling of personnel actions for the 134 contract staff, identify critical administrative supplies, coordination of family reference collections with the Service Casualty Offices, and the maintenance and final review of all cases going to file.

Quality Management Section (QMS):

The Quality Management section works behind the scenes to ensure all personnel are trained and proficient, equipment is validated, laboratory is stocked with reagents, and all accreditation requirements are met. Without continuing efforts of the Quality Management section, all laboratory operations would cease. In addition, 8 new validation projects were completed to allow AFDIL to utilize

Major Milestone:

12 August 2014 - The American Society of Crime laboratory Directors Laboratory Accreditation Board accessed and found the AFDIL to conform with the ISO/IEC 17025:2005, the ASCLD/LAB- International Supplemental Requirements for Testing Laboratories (2011) in the field of Forensic Science Testing under the discipline of Biology for Nuclear and Mitochondrial DNA testing.

Research and Development:

The mission of the Emerging Technology Section (ETS) is to provide the Armed Forces DNA Identification Laboratory (AFDIL) and the broader forensic community with technological advancements in the use of DNA methods for human identification. Currently the Emerging Technologies Section of the AFDIL is actively engaged in several research projects tied to three funding lines:

G1-Funded Projects:

<u>The Next Generation Sequencing of Degraded Skeletal Remains/Punchbowl Specimens using Illumina Instrumentation</u>:

Project Description: This project entails the development of an mtDNA sequence generation from highly degraded skeletal remains using Illumina instrumentation (HiSeq, GAIIx, and MiSeq). The protocol is now being applied to

Punchbowl specimens in order to establish the feasibility of recovering endogenous DNA sequence from these recalcitrant specimens. Sequencing occurs either via contract with Eureka Genomics, Inc. (HiSeq, GAIIx) or in-house on the MiSeq. Future work will compare the Illumina instruments for sequence generation with this specific sample type/preparation method.

Rapid Extraction Evaluation:
Project description: Typical extraction methods are time consuming, prone to contamination due to many steps with open tubes, and may yield limited quantities of DNA. Recently, manufacturers have developed robust extraction buffers that are able to lyse cells and tolerate inhibitors. Amplification can then be performed directly from the lysate without the need for purification. These single step extraction methods are rapid and easily amenable to automation, thus having the potential to drastically reduce the time needed for reference sample processing from both swabs and storage cards (buccal and blood). The resulting extract will be evaluated according to its compatibility with multiple forensic STR kits using standard procedures (non-direct) as well as mtDNA sequencing, potential for sufficient volume for several amplifications, and stability for long term storage.

Post-Amplification and Post-Sequencing SPRI Cleanup Optimization:
Project description: Current protocols used at AFDIL for post-amplification and post-sequencing cleanup are not easily amenable to automation, which is critical to reducing both time and money spent processing samples in a high-throughput manner. To address this shortcoming, an alternative, automatable post-amplification cleanup procedure and two alternative, automatable post-sequencing purification procedures are being compared and optimized, with the goal of eventual automation and incorporation into casework processing as well as ETS data basing or NGS sample preparation.

Tailed Amplification Primers for Streamlined, Automatable Casework Processing**:**
Project description: In an effort to both simplify and automate the sequencing of casework samples M13 tails will be added to validate casework amplification primer sets (HV, PS, MPS).

RRTO-Funded Projects:

RRTO Funding Management, Project Implementation and Technical Representation:
Project description: Outside funding has been awarded to explore the use of next generation sequencing (NGS) technologies for personnel accounting. The goals of this project focus on higher quality casework and reference-type samples and simplified enrichment techniques compared to those covered in Project 3, and will explore not only mitochondrial DNA sequencing, but sequencing of various nuclear targets as well in order to increase the discrimination of the genetic information obtained from each sample.

National Institute of Justice -Funded Projects:

Entire Mitochondrial Genome Data basing (NIJ Grant 2011-MU-MU-K402):

Project description: Project goals and deliverables center on establishing the long-term data foundation required to expand mtDNA-based capabilities in forensics to the entire mitochondrial genome. These include: the development and dissemination of mtGenome reference data which meet quality standards established for the control region; various analyses of the data, including examination of population group composition and position/lineage-specific substitution rates; development of information technology infrastructure to support storage, search and analysis of mtGenome data; and initial efforts toward the use of next generation sequencing for the development of mtGenome reference data.

Manuscripts and Presentations:

Species Identification Manuscript:
Description: This manuscript describes the validation of the 12S species identification assay for use with compromised skeletal remains with the purpose of determining human or non-human origin in cases when standard

human mtDNA testing fails. The article also discusses the first few cases tested and the overall impact of implementation of the assay into casework since 2010.

NGS High-Quality Population Samples Manuscript:
Description: This manuscript will discuss the generation of 96 whole mtGenomes with NexteraXT library preparation and sequencing performed on the Illumina MiSeq. The paper will emphasize concordance checks with the highly characterized Sanger sequencing data generated on theses samples (NIJ project). Intra- and inter-laboratory studies will be discussed.

African American Population Announcement:
Description: This manuscript will present 2563 African American control region haplotypes generated by Sanger sequencing. Twenty-two datasets across twenty states are included in this population sample.

Caribbean/Central American Population Announcement:
Description: This manuscript will present 897 control region haplotypes generated by Sanger sequencing. The countries of Jamaica, the Dominican Republic, Haiti, Honduras, and Guatemala are represented in this population sample.

Control Region Data basing: Post-Award Efforts (NIJ Grant 2005-DN-R-08, 2005-2010):
Description: Continuing efforts in this area focus on the public release of the large amount of data generated as part of this grant work, including publication, EMPOP concordance and coordination/release, distribution to external agencies (FBI and others), and collaborator permissions. Internally, the transition of the ~24,000 available haplotypes into LISA (and eventually LSAM) with associated metadata for use by casework is underway.

Division of Forensic Toxicology:

The Division of Forensic Toxicology is organized into 4 Departments:

1. Postmortem and Human Performance Testing Laboratory
2. Technical Services: DoD Drug Detection Quality Assurance Laboratory and the Division Quality Assurance Section
3. Special Forensic Toxicology Drug Testing Laboratory (SFTDTL)
4. Military Working Dog Training Aid Program

The Division of Forensic Toxicology and its personnel play a key role in establishing the role that toxicological agents play in military readiness relative to illness, accident, or death. The scope of operations for the Division of Forensic Toxicology is large and wide-ranging; the division provides toxicological services to over 1,700 military, federal, state, local, and non-governmental agencies worldwide.

The Postmortem and Human Performance Testing Laboratory offers a full-service toxicological capability for the Armed Forces Medical Examiner System; all Armed Forces air, ground, and sea-based mishap investigations; Armed Forces criminal investigations; Armed Forces fitness for duty investigations; and Armed Forces medicolegal death determinations. Toxicological consultations have been provided to hundreds of military and federal agencies in support of Operations Enduring Freedom (OEF) and Iraqi Freedom (OIF).

Technical Services includes the Quality Assurance (QA) section, whose staff members prepare and certify all internal standards and controls for forensic analysis; write and revise all Division Standard Operating Procedures (SOPs); conduct all internal QA investigations; oversee all external proficiency testing (College of American Pathologists (CAP) proficiency program);, produce monthly Quality Assurance Reports; and manage all external accreditation requirements by the American Board of Forensic Toxicology (ABFT) programs. The Division is one of only 34 forensic toxicology laboratories certified by ABFT and is the only DoD laboratory with this elite distinction.

The other Technical Services section, the DoD Drug Detection Quality Assurance Laboratory, is integrally linked to the DoD Drug Demand Reduction Program and manages the laboratory certification process for the six (1 Air Force, 2 Army, and 3 Navy) DoD Forensic Drug Testing Laboratories through proficiency testing and laboratory inspections. Annually, more than 20,000 open and blind proficiency specimens are prepared and sent to the military laboratories to ensure that the over 4.6 million drug test results are reported with 100% accuracy. Continued laboratory certification for each Military Forensic Drug Testing Laboratory is maintained through vigorous triennial inspections conducted by teams of division personnel and civilian forensic toxicologists. Division personnel contribute immeasurably to the continuing success of the DoD Drug Testing Program by maintaining a credible deterrent to drug use by military personnel. This is accomplished by development of new procedures to identify emerging drugs of abuse (*e.g*., synthetic cannabinoids; synthetic cathinone's; substituted phenethylamines, tryptamines and piperazines; *Salvia divinorum* ;and opiate analogs) and conducting periodic prevalence tests for abused drug threats DoD-wide, to include synthetic cannabinoids and cathinone's benzodiazepines (*e.g*., valium); methadone; heroin; and hydrocodone. The division also conducts special testing for drugs of abuse that are not tested for by the military drug testing laboratories (*e.g*. synthetic cathinone's; LSD; barbiturates; psilocin; ketamine; OTC supplements (diethylphenethylamine- N-alpha-DEPEA); methadone; mescaline; *Salvia divinorum;* BZP; DMAA; and various drugs associated with drug facilitated sexual assault cases, including ethanol; gamma-hydroxybutyrate (GHB); fast acting benzodiazepines (rohypnol); dextromethorphan; and sedative/hypnotics like zolpidem.

The Special Forensic Toxicology Drug Testing Laboratory (SFTDTL) was established in September 2012 and was fully operational in December 2012. This laboratory was funded by the U.S .Navy and was tasked to provide probable cause testing, for synthetic cannabinoids (Spice) and cathinone's (Bath Salts) at a rate of 2,500 specimens per month. In Sept 2013 the SFTDTL became part of the Drug Demand and Reduction Program (DDRP). In this capacity, the SFTDTL was instrumental in rolling out the DoD-wide synthetic cannabinoid testing initiative which was initiated at the 6 DoD drug labs in Dec of 2013. The SFTDTL has provided confirmation testing to all DoD drug labs for presumptive positives synthetic cannabinoid samples. Additionally, this laboratory has the added emerging drug surveillance mission for the DDRP. To this end it must be dynamic, and capable of developing and adjusting its processes and methods to address an ever changing drug threat. To accomplish this, the SFTDTL employs the most technologically advanced staff and instrumentation available.

The Division also provides expert witness testimony at military courts-martial, federal court proceedings and administrative separation boards. DFT experts also provide in-depth consultation services for commands and law enforcement agencies worldwide. Forensic

Toxicology personnel continue to support other aspects of the military drug testing program as determined by DDRP program manager.

The DFT continues to promote external educational initiatives by working with the Navy, USMC and Army Trial Counsel Assistance Programs (TCAP) by providing subject matter experts for lectures in their Prosecuting Sexual Assault cases and Deployed Lawyer courses around the world. The Division also helped focus the training curriculums for courses offered to Service's investigative agents, pathology fellows, and students. Division personnel continued to lecture on drug facilitated sexual assault at national and international sexual assault prevention conferences.

During this year, the Military Working Dog Program continued to prepare and distribute training aids to Service kennels throughout the world. The division also received and destroyed expired training aid materials for over 200 DoD Military Working Dog units worldwide. Staff also traveled to review processes at several sites and presented information briefings to Security Forces' leadership. The precise preparation of these training aids is paramount to the effectiveness of dog training and significantly

Section 34

Fiscal Year 2014
Annual Historical Report

The Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury

History

Due to the nature of recent conflicts, as well as greater scientific knowledge and public awareness of mind and brain sciences, U.S. service members report posttraumatic stress disorder (PTSD) and traumatic brain injury (TBI) as common injuries. Since 2000, more than 170,000 service members have been diagnosed with PTSD and more than 320,000 have sustained a traumatic brain injury. These injuries, and the people dedicated to the recovery of U.S. service members and veterans ignited significant research and advancement of clinical care and prevention strategies.

Congress called for the establishment of Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury (DCoE) in 2007 as the lead Defense Department agency responsible for the advancement of psychological health and TBI prevention and care in the Military Health System (MHS). The DoD/VA Wounded, Ill, and Injured Senior Oversight Committee chaired by the Deputy Secretary of Defense and the Deputy Secretary of Veterans Affairs officially established (DCoE) in a memorandum dated 31 August 2007. DCoE evaluates, integrates and promotes psychological health and TBI practices and policies across the services.

On 23 January 2009, under the authority of the Deputy Secretary of Defense, the Under Secretary of Defense for Personnel and Readiness directed the establishment of DCoE as an operating entity in the TRICARE Management Activity (TMA).

In an April 2011 report to Congress, the MHS Center of Excellence (CoE) Oversight Board was established. The CoE Oversight Board is responsible for providing policy guidance and oversight of all MHS CoEs, including DCoE. The report also directed the transfer of support responsibility for DCoE from TMA to U.S. Army Medical Command, specifically the U.S. Army Medical Research and Materiel Command.

Department of Defense Directive, Number 6000.17E, dated 2 January 2013, designated the Secretary of the Army as the DoD Executive Agency for DCoE in accordance with DoD Directive 5101.1 and transferred control and organizational support for DCoE from the Director, TMA, to the Secretary of the Army. The transfer included three component centers under the DCoE headquarters: Defense and Veterans Brain Injury Center, Deployment Health Clinical Center and National Center for Telehealth and Technology.

On March 26, 2014, DCoE completed the first ever wiring diagram as part of the MEDCOM Concept Plan Staff Assistance Visit. DCoE received and addressed all MEDCOM concerns with the Concept Plan and completed modifications of the Concept Plan in FY 2014. MEDCOM endorsed the modifications. DCoE began discussions with the Defense Health Agency (DHA) Manpower team to facilitate the transition of DCoE from MEDCOM to DHA. DCoE began coordinating the transfer from MEDCOM to DHA.

Mission

The mission of DCoE is to improve the lives of our nation's service members, veterans, and their Families by advancing excellence in psychological health and traumatic brain injury prevention and care.

Vision

To be the leader of profound improvements in psychological health and traumatic brain injury prevention and care.

Strategy Map

The Balanced Scorecard methodology was recently adopted by DCoE. This widely-recognized approach to communicating organizational priorities and monitoring strategic performance has not only supported enterprise-wide decision-making, but also increased transparency across all levels of the organization. The DCoE Strategy

Map is a key component of the Balanced Scorecard methodology. It outlines the ways, means, and ends necessary for the DCoE strategy to be successful.

During FY 2014, DCoE completed its pilot year of execution against its strategy and, leveraging best practices and lessons learned, began the process of assessing its strategic components (e.g., objectives, metrics, initiatives). The DCoE Strategy Map (see Appendix A) reflects the current priorities of the organization. The 17 objectives on the strategy map will drive transformation across four key areas: Stakeholder Value, Internal Processes, Organizational Readiness, and Resource Management. DCoE leadership took careful thought to develop meaningful metrics and initiatives that effectively assess and drive objective performance. The ongoing management of these strategic components will not only enable organizational success, but also position DCoE toward its vision to be the leader of profound improvements in psychological health and traumatic brain injury prevention and care.

About DCoE

DCoE oversees three centers: Defense and Veterans Brain Injury Center (DVBIC), Deployment Health Clinical Center (DHCC) and National Center for Telehealth and Technology (T2). As an enterprise, DCoE serves as DoD's single point of accountability for psychological health and TBI prevention and care. DCoE is uniquely positioned to collaborate across DoD, Department of Veterans Affairs (VA), and other agencies to provide leadership and expertise, drive policy, and achieve improvements in outcomes.

Specifically, DCoE provides value to its stakeholders by embodying the following tenets of the DCoE Value Proposition:

A. Quality: Identifies, prioritizes, and translates evidence-based practices and research into clinical standards thereby improving quality and increasing efficiency in healthcare delivery across the continuum of care

B. Treatment and Outcomes: Develops MHS psychological health and TBI metrics, pathways of care, clinical tools, and other products that benefit providers, service members, veterans, and Families to improve understanding and treatment

C. Research and Evaluation: Provides MHS leaders with focused analyses, research, and program evaluations to achieve the greatest return on investment. DCoE is responsible for creating, evaluating and integrating psychological health and traumatic brain injury practices and policies across the services

Deployment Health Clinical Center

A. Mission: To advance excellence in psychological health care across the MHS by enhancing care quality, effectiveness and efficiencies; facilitating the translation of research to practice; and providing leadership, advocacy and implementation support

B. Since 1995, DHCC has worked to improve deployment-related health care. Initially delivering tertiary clinical care for deployment-related health concerns, DHCC grew to deliver clinical care for psychological trauma spectrum symptoms, to conduct a portfolio of deployment-related and psychological health clinical and health system research, and to transform military health care delivery systems from a disease management model to a more effective and efficient population-based collaborative model of care. In FY 2013, DHCC pivoted from providing direct clinical care and from its focus on deployment health to consolidating DCoE's psychological health mission and incorporating the staff and projects of DCoE's Resilience and Prevention and Psychological Health Clinical Standards of Care directorates

C. DHCC develops, implements, manages, and coordinates programs delivered in MHS primary care and specialty behavioral health care settings to ensure that evidence-based treatments are adopted in these settings, measures are embedded into the care system, and quality and access to care are improved. DHCC

designs and implements measurement and reporting methodologies that allows MHS leaders to survey the psychological health of the force and assist psychological health program leaders to evaluate, manage, and where indicated, expand their programs. DHCC's research programs adopt a translational research paradigm and develop processes to evaluate the strength and quality of key findings to minimize the science-to-service delivery gap and expedite knowledge translation into clinical practice

D. DHCC's vision is to drive system change to enhance clinical and health outcomes related to psychological health and optimize service delivery mechanisms across the Defense Department

E. The center is comprised of six directorates with distinct areas of responsibility:
   1. Primary Care Behavioral Health directorate supports DoD behavioral health programs in primary care to improve early identification, treatment and access to care for psychological health.
   2. Psychological Health Promotion directorate identifies early intervention and psychological health advocacy practices for MHS providers, leaders and clinics and translates evidence-based practices into programs and policy.
   3. Psychological Health Clinical Care directorate supports MHS providers, leaders and clinics through development and implementation of evidence-based practices, tools and programs to enhance clinical care delivery of psychological health specialty care treatments and improve health outcomes.
   4. Evaluation and Measurement directorate collects, evaluates, analyzes and interprets psychological health and program data to best understand population health, clinical outcomes, program/system performance, quality, effectiveness and cost efficiencies.
   5. Research directorate initiates, conducts and manages a portfolio of innovative programmatic and externally-funded psychological health research and leads research priority setting and knowledge dissemination, translation and integration efforts to close the science to service delivery gap.

Defense and Veterans Brain Injury Center

A. Mission: To serve our nation's service members, veterans, and their Families with traumatic brain injuries through state-of-the-art clinical care, innovative clinical research, and educational programs.

B. DVBIC was founded in 1992 in response to the first Persian Gulf War, under the name Defense and Veterans Head Injury Program. At the time, its goal was to integrate specialized TBI care, research, and education across military and veteran medical care systems. Twenty years later DVBIC is a network of 16 centers, operating out of 11 military treatment facilities and five VA polytrauma centers. The specific activities vary at each site and include research; helping service members, veterans and their Families find and use the right services for their needs; providing education in military and civilian settings; providing direct care to service members; and assessing TBI injury data.

C. DVBIC treats, supports, trains, educates, studies and monitors service members, veterans, Families and providers who have been, or care for those who are, affected by TBI.

D. DVBIC assists the military health system by performing pre-deployment provider training and provider training at military treatment facilities, gathering data mandated by Congress and DoD, and overseeing research programs. The center treats service members and veterans with mild, moderate or severe TBI, and helps them from the moment of injury to their return to duty or reintegration into the community. DVBIC develops, provides and distributes educational materials for both military and civilian providers, Families, service members and veterans.

E. The DoD has further solidified DVBIC's role by naming it the office of responsibility for these tasks:

   1) Creation and maintenance of a TBI surveillance database to describe the scope of the TBI issue

2) Chair of the chartered Neurocognitive Assessment Implementation Working Group

3) Design and execution of a 15-year longitudinal study of the effects of TBI in Operations Iraqi and Enduring Freedom for service members and their Families

4) Design and completion of an independent head-to-head study to evaluate the reliability and validity of computerized neurocognitive tests

5) Design and execution of a study of the effectiveness of cognitive rehabilitation for mild traumatic brain injury (mTBI)

National Center for Telehealth and Technology

A. Mission: To lead the innovation of health technology solutions to deliver tested, valued solutions that improve the lives of our nation's service members, veterans, and their Families.

B. T2's vision is world-class health care and optimized health in the Defense Department through effective leveraging of behavioral science and technology.

C. The advanced health technology solutions of T2 are user-friendly, valued by our U.S. service members and cost-effective. These qualities align with the MHS Quadruple Aim to ensure readiness, population health, experience of care, and responsible management of the total cost of health care. T2 also supports the Defense Department's goals of increasing access to care, establishing best practices and quality standards for health technology and telehealth, and reducing both military suicide rates and the prevalence of stigma associated with seeking behavioral health services.

D. T2 leads DoD in applying existing and emerging technologies for delivering psychological health care options to the military community. As the benefits of these services grow, the need will continue.

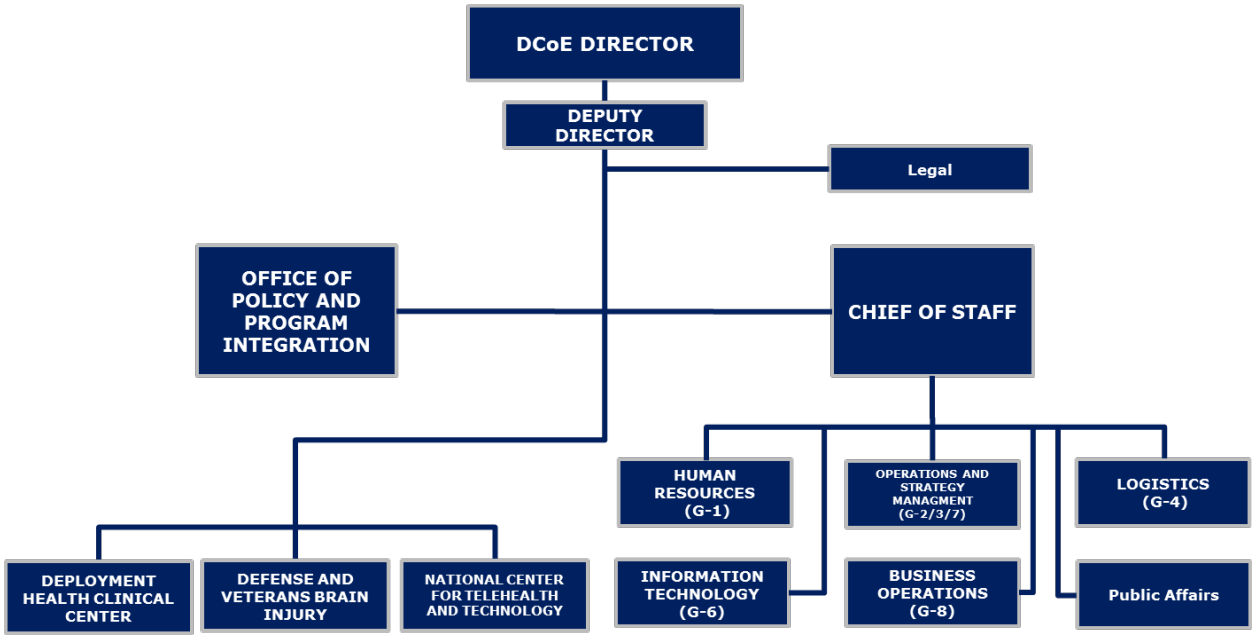
E. T2 is organized into mobile health; telehealth; and emerging technology programs, which are supported by the divisions of Technology Operations; National Capital Region; and Research, Outcomes and Investigations.

DCoE recognizes that advancement cannot happen without the help and knowledge of others. To get the best care possible for U.S. service members, veterans, and their Families, DCoE partners with military, government and academic organizations to identify gaps, eliminate redundancies, and prioritize needs in psychological health and TBI research. DCoE plays an active role in DoD working groups for psychological health and TBI. Additionally, the organization receives guidance from various sources which include, but are not limited to:

National Defense Authorization Acts
Defense Department Task Force on Mental Health
Defense Department Suicide Prevention Task Force recommendations
Defense Department and Department of Veterans Affairs Integrated Mental Health Strategy
Senior Military Medical Advisory Council
Health Executive Council
Joint Executive Council
Formal research programs

Organization and Personnel

Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury Command Organization



Key Personnel (1 October 2013 to 30 September 2014)

DCoE Director
Navy CAPT (b) (6) (15 May 2013 to 30 September 2014)

DCoE Deputy Director
(b) (6) (21 June 2010 to 30 September 2014)
Department of Veterans Affairs

DCoE Chief of Staff
(b) (6) (2 September 2008 to 30 September 2014)

DHCC Director
Navy CAPT (b) (6) (15 July 2013 to 30 September 2014)

DHCC Deputy Director
(b) (6) (15 August 2011 to 30 September 2014)
Department of Veterans Affairs
U.S. Public Health Service CDR (b) (6) (15 September 2011 to 29 June 2014)

DHCC Chief of Staff
(b) (6) (21 April 2009 to 30 September 2014)

DVBIC Director
Army COL (b) (6) (1 July 2013 to 30 September 2014)

DVBIC Deputy Director
(b) (6), MS, CRNP, ANP-BC, CNRN (5 January 2009 to 30 September 2014)

DVBIC Chief of Staff
(b) (6) (2 March 2009 to 30 September 2014)

T2 Director
Air Force COL (b) (6) (3 March 2014 to 30 September 2014)
(b) (6) (2 June 2008 to 2 March 2014)

T2 Deputy Director
(b) (6) (11 May 2008 to 30 September 2014)

T2 Chief of Staff
(b) (6) (14 June 2010 to 30 September 2014)

G1
U.S. Public Health Service CAPT John Golden (Acting, 11 August 2014 to 30 September 2014)
(b) (6) (22 November 2010 to 8 August 2014)

G2/G3
(b) (6) (3 August 2009 to 30 September 2014)
Chief of Operations

G4
U.S. Public Health Service LCDR (b) (6) (17 December 2012 to 30 September 2014)
Chief Logistics

G6
(b) (6) (19 November 2012 to 30 September 2014)
Chief Information Officer

G8
(b) (6) (17 August 2009 to 30 September 2014)
Chief of Business Operations

Public Affairs
(b) (6) (10 May 2010 to 30 September 2014)
Chief of Public Affairs

Office of Policy and Program Integration/ Office of Shared Services Support
(b) (6) (15 October 2009 to 30 September 2014)
Chief of Integration

Statistical Data

DCoE Headquarters

DCoE completed the first ever wiring diagram as part of the MEDCOM Concept Plan Staff Assistance Visit on March 26, 2014. DCoE received and addressed all MEDCOM concerns with the Concept Plan and completed modifications of the Concept Plan in FY 2014. MEDCOM endorsed the modifications. DCoE began discussions with the Defense Health Agency (DHA) Manpower team to facilitate the transition of DCoE from MEDCOM to DHA.

In August 2014, DCoE changed the name of the headquarters staff element known as Office of Policy and Program Integration to Office of Shared Services Support to more accurately reflect its purpose and capabilities. Among other capabilities, the Office of Shared Services Support plays an integral role in knowledge translation, which is a systematic and iterative process intended to identify and close the gaps between scientific knowledge and practice across MHS by accelerating the adoption of targeted knowledge products to enhance clinical care. The Office of Shared Services Support facilitates knowledge translation by collecting, collating, and analyzing knowledge in which stakeholder needs are systematically identified, validated, and prioritized. This knowledge is weighted to inform determinations regarding a) research prioritization and b) development of knowledge products.

DCoE worked with MRMC to develop a collaborative approach to knowledge translation for use in the MHS and held a meeting with other federal agencies (DHA, VA, National Institute on Disability Research and Rehabilitation, etc.) to begin strategic collaboration on the knowledge translation initiative. DCoE drafted a written knowledge translation process and launched two pilots of the process.

The Office of Shared Services Support engaged in a variety of activities to provide enterprise-wide visibility of products and to support DCoE's product lifecycle management process:

A. Quarterly production of the DCoE Resource Catalog and DCoE Communications Guide
B. Maintained a dynamic database of 1,864 product records, with more than 50 meta-data fields
C. Produced bi-weekly Product Pipeline Reports to provide visibility into products being designed
D. Created looping slides that promoted products for 28 webinars that reached a clinical population of more than 8,500
E. Supported the centers and the Product Configuration Control Board in review of 53 Concept Approval Forms, five Business Case Analyses and 45 Business Case Analysis Addendums
F. Implemented process controls to minimize expenditures that could result from unnecessary expedited shipping
G. Created a supplemental tool, the Product Launch Checklist, for tactical use by the centers when launching a product to market
H. Established the DCoE Product Slide Library as a one-stop-shop for PAO approved product advertisements and organizational slides

DCoE's Program and Product Evaluation and Improvement (PPEI) capability supports a critical mission: to enhance the effectiveness of psychological health and traumatic brain injury programs that provide care to an estimated 4.4 million service members and their Families through systematic, evidence-based evaluation activities. DCoE's PPEI effort provides a foundation to improve program evaluation standards and metrics across DoD psychological health and TBI programs to establish a culture that values continuous improvement through evaluation activities.

In Fiscal Year 2014, the PPEI capability was extended beyond the sole focus on psychological health programs to include the identification, validation, and assessment of over 150 psychological health and TBI programs. A

scientific panel comprised of non-DoD federal experts in program evaluation and related fields was conducted for identified DoD-funded TBI programs, identical to the FY 2013 panel review of psychological health programs. A rapid evaluation process was employed for identified programs and the analysis of programmatic data informed the development of a plan to eliminate gaps and redundancies services and treatment as mandated by Section 739 of FY 2013 National Defense Authorization Act. Individualized program feedback reports were distributed to each program detailing strengths and opportunities for development based on the initial evaluation.

Other products developed during FY 2014 to support the PPEI capability include:

A. Development and airing of monthly DCoE program evaluation and improvement webinars designed to familiarize program managers with universal program evaluation concepts

B. Continued design of three modules of the Program Evaluation Guide, designed to instill principles of best practices in program evaluation to a broader audience of DoD program administrators

C. Stand-up of an operational database solution to serve as a central repository of collected program information. Following the FY 2014 information collection, all programmatic data was uploaded into the database platform

The PPEI staff engaged in several externally-facing meetings and planning sessions with key stakeholders on a routine as well as ad hoc basis. At the beginning of the fiscal year, DCoE hosted information sessions for points of contact from each Service's Office of Manpower and Reserve Affairs and Public Health Command to present planned activities with identified programs. DCoE also hosted a quarterly in-progress review with external stakeholders, including senior leadership from the aforementioned offices. These meetings provided progress updates and reviewed upcoming plans regarding program evaluation and training and change management activities. In addition, PPEI staff engaged with Service-level stakeholders at their request to address ongoing concerns or to provide relevant updates regarding program evaluation activities planned for programs within their purview.

On November 17, 2013, PPEI presented at the 142nd American Public Health Association (APHA) Annual Meeting and Exposition. This meeting is the largest gathering of public health professionals in the world, and provided a valuable opportunity for PPEI to demonstrate DoD's program evaluation efforts through the co-authorship and presentation of three scientific abstracts. Each of PPEI's abstracts was selected among thousands of entries to present a panel entitled, "A Novel Approach to Program Evaluation: Experience from Designing and Conducting Rapid Evaluations for approximately 200 Psychological Health and Traumatic Brain Injury Programs in the Defense Department."

DCoE offered 45 webinars to provide information and facilitate discussion on a variety of topics related to psychological health and traumatic brain injury. Webinars were targeted to health care providers and most offered continuing education credit. Attendees for the year totaled 12,586 people and DCoE issued 3,009 continuing education certificates.

The inTransition program is a collaborative effort between the Defense Department and VA that bridges the gap for service members with psychological health concerns who are transitioning between behavioral health care systems. It also connects health care providers with licensed behavioral health care specialists trained in military culture. The inTransition team conducted 33 provider trainings through video teleconferences, conference calls or site visits that were attended by more than 550 participants over the course of the year. Program staff also conducted exhibits and briefs at eight Yellow Ribbon Reintegration Program events and 17 military conferences. As a result, the program received 14,191 calls; 2,943 of these calls became intake calls and 99 percent of those resulted in service members accepting program services.

In August 2014 the inTransition program was part of the Presidential Executive Action to change the enrollment process from voluntary to automatic. This required the identification of service member profiles and then developing

a staffing plan to cover the proposed increase in utilization. DCoE developed a cost proposal to cover the staffing expansion needed to reach out to a projected list of more than 76,000 eligible service members who will be separating from service each year and who have seen a behavioral health provider within twelve months of their separation date.

The DCoE Outreach Center provided information and resources regarding psychological health and traumatic brain injury through almost 4,400 calls, e-mails, and chat sessions touching more than 2,000 service members, veterans, military Families, health care providers, researchers and the public. As the only Defense Department resource center dedicated exclusively to psychological health and traumatic brain injury concerns, the DCoE Outreach Center has collaborative agreements with other DoD and VA hotlines and resource centers to ensure that service members, veterans and Families get a warm hand-off to the agency or program that can best address their needs.

On 28 August 2015, (b) (6), a German psychologist, joined DCoE for a one year tour as part of the Engineer and Scientist Exchange Program.

DHCC

DHCC developed clinical support tools that align with the 2013 VA/DoD Clinical Practice Guideline for the Assessment and Management of Patients at Risk for Suicide. The suite of tools for providers, U.S. service members and Families includes recommendations on suicide warning signs, protective factors, safety planning, and effective treatments.

DHCC developed new clinical recommendations and a suite of clinical support tools to assist all DoD health care providers with the management of patients who disclose a sexual assault or sexual harassment during health care encounters.

DHCC completed the 5-year, randomized effectiveness trial Stepped Enhancement of PTSD and Depression Services Using Primary Care, which tests a system of care for posttraumatic stress disorder and depression that integrates case management with evidence-based pharmacological, web, telephone and in-person therapies within primary care.

DHCC hosted the DCoE Psychological Health and Resilience Summit in September 2014. More than 800 participants from around the world joined the hybrid, cross-service training on the prevention and treatment of psychological health concerns and evolving best practices to enhance resilience and readiness.

DHCC completed working group participation and final reports for six Integrated Mental Health Strategy (IMHS) Strategic Actions (SAs). The SAs were among 28 developed in 2010 as part of a joint DoD/VA strategy to promote early recognition of mental health conditions; delivery of effective, evidence-based treatments; implementation and expansion of preventive services; and education, outreach and external partnerships.

DHCC also initiated three DoD/VA Joint Incentive Fund (JIF) projects which continue the work of IMHS SAs related to chaplains' roles, resilience programs and translation of research into practice. JIF 1 addresses improved integration of chaplains with mental health care, JIF 7 focuses on providing Problem Solving Training for behavioral health clinicians and JIF 26 creates a DoD/VA Practice Based Implementation Network to speed the translation of mental health research into innovative practice.

The Real Warriors Campaign is a multimedia public health awareness campaign to encourage service members, veterans and military Families to seek care for psychological health concerns and to promote psychological health. The campaign employs websites, social media, video profiles, public service announcements, and mobile applications to encourage help-seeking behavior and to share psychological health resources with service members, veterans, and military Families. The campaign aims to:

A. Educate service members, veterans, and military Families, and reduce misperceptions regarding psychological health

B. Foster a culture of psychological health

C. Restore faith in the Military Health System

D. Improve service members, veterans, and military Families' support system

E. Empower behavior change within service members, veterans, and military Families

The campaign was created in response to the 2007 DoD Mental Health Task Force recommendation to develop and execute a public awareness campaign to dispel the stigma of seeking psychological health care and to encourage service members to seek appropriate care.

Key campaign highlights include:

A. Produced 11 new articles and eight article updates, and five print products (mini-brochures, event materials)

B. Received 270,533 unique visitors, 318,354 visits and 847,730 page views to the website, www.realwarriors.net

C. Directly interacted with 1,610 individuals and distributed 23,247 materials at 15 events

D. Engaged 53,783 Facebook fans and 31,541 Twitter followers through the campaign's social media channels, averaging 996 interactions daily

E. Campaign video and radio public service announcements aired more than 14,284 times to American Forces Radio and Television Service potential audiences of more than 2 million service members in 177 countries each week, including Afghanistan and Iraq

F. Produced two new video profiles of a U.S. Marine Corps and U.S. Army First Sergeant

G. Launched the Real Warriors photo-sharing app – for iPhone, iPad and iPod touch – and a complementary website that offers peer support for U.S. service members, veterans, and military Families, garnering 599 downloads

H. Achieved a campaign milestone of disseminating more than 1.5 million pieces of material through free online ordering to service members, veterans and military Families

I. Launched the "7 Tools for Active Duty" mini-brochure in Oct. 2013. Distributed more than 60,000 mini-brochures in the first month of launch

J. Aired campaign's video PSAs 78 times on the Jumbo-Tron during the Indianapolis 500 in May 2014, reaching more than 1.2 million viewers

From November 2013 to September 2014, DCoE conducted six educational sessions for military chaplains for the purpose of providing current information on psychological health conditions and associated resources for service members and their Families. Topics included promoting recovery from sexual trauma, several sessions promoting PTSD information awareness and coping mechanisms, and an overview of DCoE tools and resources for military chaplains. Over the course of the six sessions, the Chaplain's Working Group accrued a total of 569 attendees.

DVBIC

The DVBIC website provides worldwide numbers (updated quarterly) representing active duty medical diagnoses of TBI since 2000 that occur anywhere U.S. forces are located, listed in total and identified by service and injury severity. With 18,564 new medical diagnoses of TBI by third quarter of calendar year 2014, the total of all severities

diagnosed since 2000 had risen to 313,816; 82.5% of these were classified as mild TBI, or concussion. In 2014, DVBIC broadened data source partnerships with Joint Trauma Analysis and Prevention of Injury in Combat and Armed Forces Health Surveillance Center, expanded surveillance capabilities with internal and external stakeholders and developed major reports to guide and influence staffing and policy, to include the Event Monitoring Summaries, Medical Encounters Report, TBI Worldwide Numbers report and others.

In 2014, DVBIC partnered with the Joint Program Committee-6 (JPC-6) to provide "translation potential" information on completed TBI studies funded by DoD/JPC6 in 2007. This information can be shared with the DVBIC clinical and education divisions during the development of new or revised DVBIC products. Thus, results from DoD's research are used to ensure the most up to date research findings are used during the development of state-of-the-science clinical and education products. Also, the translation potential can inform what research should be done next to advance the state of the science to impact clinical practice.

DVBIC released two clinical recommendations on "Progressive Return to Activity (PRA) Following Acute Concussion/Mild Traumatic Brain Injury" in January 2014. These first of their kind clinical recommendations offer primary care managers and rehabilitation providers standardized guidance on how and when service members should return to activity following a concussion. DVBIC provides a PRA suite of products that include the clinical recommendations, clinical support tools, a provider training guide, a patient education brochure to be distributed by primary care managers, and a patient education tear-off tablet for rehabilitation providers.

To assist health care providers in the identification of sleep disturbances and provide recommendations for its initial treatment, *DVBIC launched the "*Management of Sleep Disturbances Following Acute Concussion/Mild TBI" product suite *in June 2014. The suite consists of a clinical recommendation and companion support tool, as well as a training guide, a fact sheet and a warfighter sleep kit.*

DVBIC released the "Concussion/Mild Traumatic Brain Injury and Posttraumatic Stress Disorder Fact Sheet" in September 2014. The fact sheet provides the definitions of concussion/mild TBI and PTSD, lists overlapping symptoms, and includes guidance for the recovery process. DVBIC Regional Education Coordinators reported positive feedback on the new fact sheet and noted that it addressed the requests from service members and their families.

DVBIC's Regional Education Coordinators provided 1,881 outreach briefs and educational presentations related to TBI, more than doubling the 2013 efforts, and reached over 205,443 service members, veterans, Families and community-based organization members.

T2

Three T2 programs designed to address psychological health and traumatic brain injury needs were ranked in the top quartile (with two in the top 10) in a comprehensive review of all Military Health System psychological health program assessments of evaluation readiness (a total of 115 programs were reviewed).

T2 was awarded a $165,000 grant in collaboration with TATRC to test the integration of two separate IT systems: the secure TATRC Mobile Health Care Environment Research System and the T2 Mood Tracker smartphone application. Going forward, this will result in a wholly unique product within the DoD--a mobile app that can transmit data from patient to provider within a completely secure environment to securely hold a patient's information from their mobile device into their clinician's existing records.

T2 released Virtual Hope Box (VHB), an app designed for use by patients and their behavioral health providers as an accessory to treatment. The VHB contains simple tools to help patients with coping, relaxation, distraction, and positive thinking. Patients and providers can work together to personalize the VHB content on the patient's own smartphone according to the patient's specific needs. The patient can then use the VHB away from the clinic, continuing to add or change content as needed. T2 released the Virtual Hope Box mobile application for use with

face-to-face treatment to help patients who are struggling with coping and negative thoughts. This app contains simple customizable tools to help with relaxation, distraction, and positive thinking.

In 2014, T2 authored DoD's Report to Congress on "Use of Telemedicine to Improve the Diagnosis and Treatment of Posttraumatic Stress Disorder, Traumatic Brain Injuries, and Mental Health Conditions", as mandated by Section 702 of the National Defense Authorization Act for Fiscal Year 2014.

A major activity in 2014 was bringing T2's systems into alignment due to T2 being reorganized under the Army. Part of this task involved migrating all the hosting for T2 websites over from commercial servers to military servers at Fort Detrick's Network Engineering Center in Maryland. In addition, a mobile encryption module was developed to better ensure the security of data stored on end users' mobile devices.

The Software Development Life Cycle Plan was also established in 2014, which includes software engineering best practices and greatly improved the process for producing information management and information technology solutions. This should ensure even better-quality products and improves predictability for future software development.

T2 worked in partnership with Sesame Workshop, the non-profit educational organization behind Sesame Street, to develop The Big Moving Adventure. This app was created for preschool children of military Families to help them cope with the stress of frequent moves, and includes a section for parents.

T2 created the Navy Leaders Guide for Managing Sailors in Distress mobile app, based on the Navy & Marine Corps Public Health Center website of the same name. This app gives leaders the resources needed to respond to almost any issue affecting sailors.

T2 created two mobile apps in partnership with the VA's Office of Mental Health Services as part of the DoD/VA Integrated Mental Health Strategy:

A. Moving Forward, a companion app to T2's Moving Forward online course, features problem-solving therapy tools designed to teach skills for overcoming life problems

B. Parenting2Go, a companion app to T2's Parenting for Service Members online course, helps parents reconnect with their families after a deployment and build closer relationships with their children

T2 also created five mobile apps in partnership with the VA's National Center for PTSD:

A. ACT Coach – designed for use with face-to-face treatment in Acceptance and Commitment Therapy. This app incorporates mindfulness and acceptance strategies to help cope with unpleasant emotions and symptoms of mental health conditions

B. Concussion Coach – designed for use with face-to-face treatment for those with symptoms of a concussion or mild-to-moderate traumatic brain injury. This app provides tools for people to assess symptoms and cope with TBI-related problems

C. CPT Coach – designed for those participating in cognitive processing therapy (CPT), which is used for posttraumatic stress disorder. This app is designed to improve engagement and participation in CPT and to help CPT providers better adhere to the treatment protocol

D. Mindfulness Coach – designed to reduce tension and worry and improve coping by helping people focus on present experiences and away from potentially distressing thoughts about the past or future

E. PFA Mobile – designed to supplement the training of responders who provide psychological first aid (PFA) following a disaster or emergency. This app allows responders to review PFA guidelines and learn tips on putting PFA into practice in the field

Healthcare Delivery

DVBIC's TBI Recovery Support Program (RSP), formerly known as the Recovery Care Coordination program, expanded its focus and outreach during 2014. Based on recommendations from external and internal reviews, the following measures were adopted: expansion of RSP service mandate to include coordinating care for TBI and co-occurring psychological health conditions; expansion of client services to include caregivers and family members of service members and veterans impacted by TBI; and development and expansion of marketing of program resources to increase the referral network and expand knowledge of and client access to available services regionally and nationally. The program adapted and now uses a customized version of the Wounded Ill and Injured Registry database to better track and facilitate coordination of care as well as assess client outcomes and satisfaction with the RSP.

In 2014, DVBIC's TBI Recovery Support Specialists (RSSs) provided support services to more than 788 active duty service members and veterans who experienced TBIs while serving in support of Operations Enduring Freedom, Iraqi Freedom, and New Dawn. RSSs completed 570 intakes and 1106 follow-ups to ensure that patients stay on the path to recovery by providing TBI education, and connecting them to appropriate resources as they transition from treatment settings, back to duty or to civilian life.

A.	3-month follow-ups	316
B.	6-month follow-ups	196
C.	9-month follow-ups	117
D.	12-month follow-ups	149
E.	18-month follow-ups	94
F.	24-month follow-ups	106
G.	Non-standard follow-ups	128

Veterinary Services

N/A

Training and Education

Employee Professional Development

DCoE's professional development, education, and training program was enhanced to bring it into in alignment with the organizational readiness perspective of DCoE's Strategic Plan. This perspective contains objectives focused on developing and enhancing DCoE's most valued assets – its people and their talents. DCoE strives to have a high performing organization through a positive, continuous learning culture.

The DCoE Professional Development, Education, and Training Plan aligns with the following organizational readiness strategies:

A. Retain a high-performing workforce

B. Build a culture of trust, innovation and productivity

C. Improve organizational agility

DCoE offered its staff an array of professional development opportunities such as courses related to program/project management, government writing, congressional affairs, acquisition and procurement, contracting, information technology, web development, and leadership development.

DCoE's strives to ensure its staff has the necessary relevant skills and competencies to build or join teams that can swiftly and thoroughly create and execute plans in a fast paced work environment. Proper and timely training of individuals is the cornerstone of readiness and the key to the accomplishment of DCoE's mission. DCoE strove to meet all standard USAMRMC training requirements, as well as additional training requirements directed by DCoE leaders. DCoE staff members continued to strive towards MEDCOM standards and were 61% compliant.

DCoE continued to utilize a training manager position and training liaisons to all of the staff elements to assist with training awareness and reporting. DCoE continued to reserve Wednesdays as training days across the Centers, offering mandatory face-to-face courses such as: Equal Opportunity, Army Substance Abuse Policy, Ethics, Sexual Harassment/Assault Response and Prevention, Army Fraternization Policy Awareness, and Resiliency Skills.

External Professional Development

DCoE Webinar Series

DHCC offered 11 monthly webinars to provide information and facilitate discussion on a variety of topics related to psychological health. Webinars were targeted to health care providers, but attendance was open to the public. Many webinars offered continuing education credit.

A. Mean webinar attendance in FY2014: 363 (a mean decrease of 395 from FY2013)
B. Total webinar attendance in FY2014: 3,997 (a decrease of 4,343 participants from FY2013)
C. Total continuing education (CE) certificates issued in FY2014: 1,156 (a decrease of 1,528 CEs from FY2013)
D. Total certificates of attendance issued in FY2014: 229 (a decrease of 755 CAs from FY2013)

DVBIC conducted 10 webinars to provide information and facilitate discussion on a variety of topics related to traumatic brain injury. Webinars were targeted to health care providers, but attendance was open to the public.

A. Mean webinar attendance in FY2014: 337 (a mean decrease of 81 from FY2013)
B. Total webinar attendance in FY2014: 3,374 (a decrease of 389 participants from FY2013)
C. Total continuing education (CE) certificates issued in FY2014: 768 (a decrease of 761 CEs from FY2013)
D. Total certificates of attendance issued in FY2014: 117 (a decrease of 283 CAs from FY2013)

Psychological Health and Resilience Summit

From 17-19 September 2014, DCoE hosted the Psychological Health and Resilience Summit. A hybrid format was utilized, which was composed of both a virtual and live on-site component. The virtual component of the conference was hosted through Adobe Connect and allowed individuals from locations around the world including Australia, Canada, Chile, Guam, Japan, Malaysia, and New Zealand to participate. The on-site conference took place at Defense Health Headquarters in Falls Church, Virginia. The conference focused on the prevention and treatment of psychological health concerns and the evolution of best practices to enhance resilience and readiness.

A. Total attendance FY2014: 812 (an increase of 317 (39%) participants from FY2013
B. Total CE certificates issued: 306 (an increase of 157 CEs)

C. Total certificate of attendance issued: 20 (an increase of 2 CAs)

Traumatic Brain Injury Global Synapse

From 15-17 September 2014, DCoE hosted the Traumatic Brain Injury Global Synapse. The same format was utilized as for the FY2014 Psychological Health and Resilience Summit. The conference focused on the deliverance of evidence-based care that is timely, thorough, compassionate, and appropriate to each family and patient. Discussions ranged from current trends in TBI research to treatment of sports-related concussions, co-occurring psychological health conditions, hearing problems, substance use and intimacy, chronic pain management, visual dysfunction, dizziness, cognitive treatment, concussion management, and assistive technology.

A. Total attendance: 1041 (an increase of 248 participants from FY2013)
B. Total CE certificates issued for conference attendance: 359 (a decrease of 187 CEs)
C. Total certificates of attendance issued for conference attendance: 14 (a decrease of 34 CAs)
D. Total CE certificates issued for on-demand content (enduring material): 334 (an increase of 232 CEs)
E. Total certificate of attendance issued for on-demand content: 12 (a decrease of 9 CAs)

Internal Behavioral Health Consultant (IBHC) Sustainment Training

DHCC began conducting training in April 2013 for members of the Patient-Centered Medical Home (PCMH) – Behavioral Health team who serve as internal behavioral health consultants or IBHCs. In FY 2014, 11 webinars offered training to improve brief assessment and intervention for health conditions, behavioral health problems, and populations commonly seen in Military Health System PCMH settings. Half of these training events offered continuing education credit.

A. Mean training attendance in FY2014: 147 (a mean increase of 16)
B. Total training attendance in FY2014: 1618 (an increase of 1,335 participants)
C. Total CE certificates issued in FY2014: 230 (an increase of 105 CEs)
D. Total certificate of attendance issued in FY2014: 20 (total number of CAs in FY2013 not available)

Regional Education Coordinators

DVBIC's Regional Education Coordinators provided 1,881 outreach briefs and educational presentations related to TBI, more than doubling the 2013 efforts, and reached over 205,443 service members, veterans, Families and community-based organization members.

T2 Technology Training Workshops

T2 conducted technology training workshops for 2,329 health care providers to help them integrate technology solutions into their practice.

Research and Development

Publication information for DHCC, DVBIC, and T2 is listed below. For a comprehensive listing of research projects, see appendices B and C.

DHCC Publications

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Resource Management and Budget

Unlike 2013, there were no issues with regards to the level or timing of DHP O&M funding within DCoE. DCoE utilized its comprehensive FY14 Spend Plan to request and receive the appropriate amount of DHP O&M funding within each quarter. The timely receipt of funding allowed DCoE to fund and submit its contracts to USAMRAA prior to the stipulated contracting close-out dates. As a result, all DCoE contracts were awarded and obligated well

before the 30 September year-end close. The longer-term impact of sequestration (from FY13) and restrictive travel approval requirements still had an impact on overall travel execution within FY14. DCoE obligated only $115K out of its approved FY14 travel plan of $400K. However, restrictive travel policies began to ease somewhat towards the end of FY14.

A. FY14 Budget
   1) $156,728,000 DHP O&M budget plan; $135,463,163 in final allotment; $134,888,083 in total expenditures (99.6% expenditure to final allotment rate)
   2) $1,214,000 DHP RDTE budget plan; $1,214,000 in final allotment; $1,132,060 in total expenditures (93.3% expenditure to final allotment rate)

B. Changes to budget plan from FY13
   1) Increase of $3,786,000 DHP O&M, from FY13 to FY14
   2) Full use of $1,214,000 in FY14 DHP RDTE in comparison to $0 in FY13 DHP RDTE due to sequestration (RDTE is a 2-year appropriation)

C. Projections for FY15 budget year
   1) $161,230,000 in DHP O&M
   2) $1,323,000 in DHP RDTE

Information Management

A. Set groundwork for implementation of a DoD approved technology solution for T2's Technology Enhancement Center.
B. Closed all CAT 1 findings on DCoE network
C. Implemented Data at Rest and Data in Transit policies to ensure FIPS 140-2 requirements were satisfied to further protect DCoE data
D. Qualified for and received our first Authority to Operate
E. Implemented DCoE security policies to ensure DCoE data is protected

Information Management:

A. New IP networking structure developed and implemented
B. Setup and configured new Xerox copiers/printers in the Silver Spring location to include CAC enabled email scanning and secure printing
C. Designed and built a new file/print high availability cluster in Silver Spring to replace multiple old and failing file/print servers in two separate locations. Data migration was completed with minimal down time
D. Identified and worked with vendors to replace, repair, and rebuild the electrical and HVAC equipment on the new 3rd floor and roof in preparation for the new build out
E. Implemented a Juniper fix to allow automatic updating of VPN clients without IT intervention for each user

F. Login via TACACs server implemented on all DCoE network devices

G. Latest IOS upgrades preformed on all DCoE network devices

Modernization:

A. G6 identified the need for a 508 Compliance Program. Created and staffed the position and started our 508 Compliance Program

B. SAN migration and replacement in Crystal City and Silver Spring. The new SAN units are a fraction of the physical size and therefore reduce the cooling and electrical loads resulting in a monetary savings for the client

Other Items of Significance:

A. G6 took responsibility for the consolidated print service management function for DCoE.

Operations

DCoE conducted a Continuity of Operations (COOP) exercise on 27 March 2014 in order to test the Emergency Alert Notification System (EANS), familiarize DCoE emergency response staff with the COOP Facility, and test remote access operations and communications capabilities. Overall the exercise was a success with an 83% response rate to the EANS test and an 88% achievement rate in completing required tasks as identified in the exercise checklist.

In FY14, DCoE facilitated answering 439 taskers from external partners. Over 85% of external taskers came from MRMC, DHA, and the Office of the Surgeon General. DCoE coordinated the response for 226 reports or updates, 86 comment matrices, 37 information papers, 25 briefings, and 23 Questions for the Congressional Record during FY2014. Four Reports to Congress were guided through the approval process in FY2014.

Modernization

DCoE has prioritized ergonomic and health interests in its equipment modernization, particularly on the build-out floors, where it procured 48 height-adjustable desks for distribution. Height-adjustable desks will permit the staff to sit and stand throughout the day while working. Research has shown that height-adjustable desks reduce job-related injuries, illnesses, and stresses while increasing job satisfaction, which leads to improved productivity, alertness, and physical fitness.

DCoE upgraded its Xerox network printers to scan documents and automatically forward them to user e-mail accounts. This new energy efficient feature reduces costs, minimizes time spent scanning, and replaces out-dated equipment.

DCoE provided office chairs based on an ergonomic, elastic design concept, on the build-out floors. The chairs support a range of different postures shown to be typical in the modern workplace.

DCoE incorporated into the remodeled spaces a Wellness Room on the third floor designed to meet the needs of lactating mothers.

Logistics

DCoE continues to transform its property accountability system by utilizing Defense Medical Logistics Standard Support (DMLSS) database, which delivers an automated and integrated information system with a comprehensive range of medical material, equipment, war reserve materiel and facilities management functions for the MHS.

The following property adjustments were identified during the reporting period:

Property Value		Turned in to DRMO		Lateral Transfer	
QTY	COST	QTY	Cost	QTY	Cost
2229	$3,858,396.98	2107	$659,939	0	0

Item Unique Identification (IUID)

Record with IUID Assigned	Record requiring IUID	Equipment requiring labels	Equipment Physically labeled	Percentage of Equipment Labeled
30	43	13	30	90%

Construction

The Build-Out and Co-Location Project achieved 100% government approval for the Design Intent Drawings (DIDs) and construction commenced in September 2014. Once the Build-Out and Co-Location Project is complete, it will mark the fulfillment of DCoE's long standing initiative to co-locate the entire organization, inclusive of the centers, into one building, rather than six separate locations within the National Capital Region. The Build-Out and Co-Location Project at Silver Spring Metro Center One encompassed floors 1, 3, 4, and 5.

DCoE debuted a "Build-Out and Co-Location Newsletter" to communicate the progression of the Build-Out and Co-Location project and developed a "Build-Out and Co-Location" mailbox to allow team members to communicate with move stakeholders about the progression of the project.

Health and Environment – N/A

Other

Ebola Deployments

Public Health Service Officers CDRs Anne Dobmeyer and James A. Blankenship both deployed on the first Ebola deployment to establish and maintain the Monrovia Medical Unit in Liberia from Oct 19, 2014 to Dec 20, 2014. CDR Dobmeyer's residence state of Ohio had a very restrictive quarantine requirement that would have caused her husband and children to be quarantined at home with her, so she was housed by PHS in Gaithersburg, MD facility until 9 January 2015. Her sacrifice included being away from her spouse and children during the December holiday period. Both officers are to be thanked for their exceptional service and personal sacrifice for participating in that international health mission.

Awards

Real Warriors

A. Platinum Hermes Creative Award, Social Marketing category (May 2014)
B. Public Relations Society of America (PRSA) Silver Anvil Award of Excellence, Public Service/Government category (June 2014)
C. Ragan Health Care PR & Marketing Award, "Best Health Campaign" (August 2014)

T2

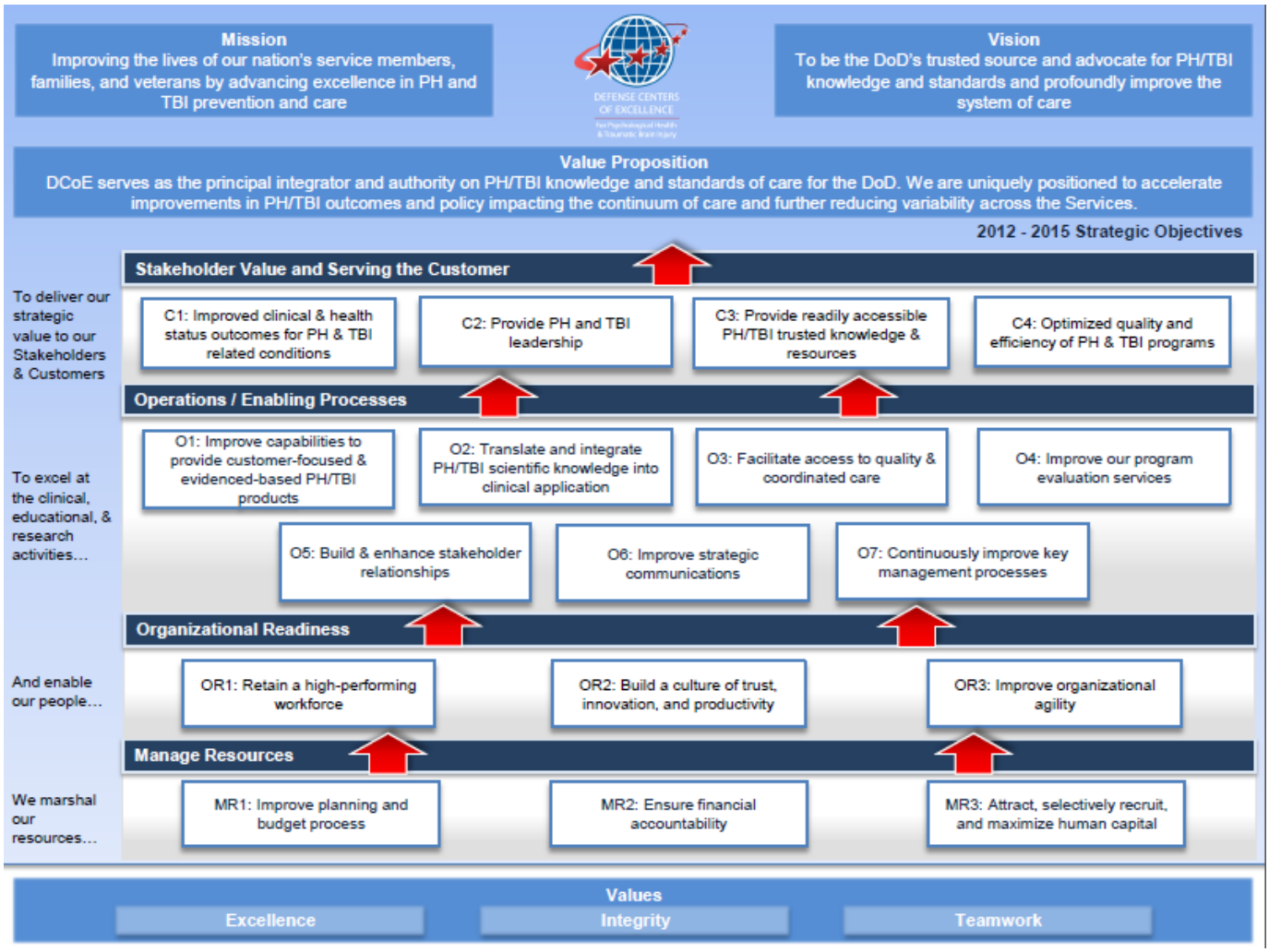
A. The Virtual Hope Box smartphone app received the 2014 Defense Department Innovation Award

B. T2's Moving Forward online course (http://startmovingforward.dcoe.mil) received five awards in 2014: a Silver Award for the Television, Internet, & Video Association of DC for Government/Web-based resource, a Silver OMNI Inter-media Award, a Silver Innovative Award from the Federal Government Distance Learning Association, a Best in Class Interactive Media Award and a Gold Brandon Hall Award

C. T2's Parenting for Service Members online course (http://militaryparenting.dcoe.mil/) also received five awards in 2014: a Silver Award from the Television, Internet, and Video association of DC for a Government/Web-based resource, a Gold Innovative OMNI Inter-media Award, a Gold Innovative Award from the Federal Government Distance Learning Association, a Best in Class Interactive Media Award and a Gold Brandon Hall Award

Appendices

APPENDIX A. 2012 – 2015 Strategic Objectives



APPENDIX B. Fiscal Year 2014 Research Data:

	DCOE Element	Study title	Purpose	Number of Personnel Assigned
1	DHCC	Stepped Enhancement of PTSD Services Using Primary Care: A Randomized Effectiveness Trial	Establish and evaluate a Caregiver Peer Visitor program at Walter Reed Army Medical Center (WRAMC) to support the servicemen and women who are admitted to WRAMC with Operation Iraqi Freedom/Operation Enduring Freedom (OIF)/(OEF) polytrauma injuries.	4.5
2	DHCC	Brothers at War Film: Determining the effect of the film on opinions of Stigma and Help-Seeking Behavior for Behavioral Health	Gain valuable insight on the unique challenges and stressors that impact service members, veterans, National Guardsmen and reservists and military Families.	1
3	DHCC	Refining a Single Item PTSD Screener (SIPS) for Use in DoD Primary Care	To investigate brain activation during a spatial conflict task and on an attention network task in relation to cognitive and behavioral evidence of dysregulation; to investigate behavioral dysregulation in relation to multimodality brain imaging and functional status.	1.5
4	DHCC	Evaluate Stigma Reduction Efforts in the DoD	Evaluate the safety of an in-home, web based Behavioral Activation (BA) treatment as an intervention for PTSD, determine the effectiveness of in-home BA as treatment for PTSD delivered via web cam, monitor PTSD symptoms to determine if there is an association between BA treatment and reductions in PTSD symptomalogy, examine patient compliance, treatment satisfaction, and over all feasibility of the web based intervention, identify best practices to guide the implementation of other web based tele-mental health interventions.	1
5	DHCC	Sleep in the Military: An evaluation of Military Programs and Policies Sleep Resources and Tips for Line Leaders	To investigate the extent and severity of chronic sequelae and poor outcomes after TBI in active duty and retired military populations to assist health care researchers and military policy makers in developing future studies and treatment programs that will improve the care provided to this population.	1

6	DHCC	Deployment Life Study: Longitudinal Assessment of Family Readiness	To measure test-retest reliability of four computerized neuropsychological test batteries in a sample of healthy soldiers over a 3-6 week interval.	1
7	DHCC	Family Resilience in the Military: An evaluation of Military Programs and Policies	To assess validity of four computerized neuropsychological test batteries (ImPACT, CogState, ANAM, CNS Vital Signs) using traditional neuropsychological testing. To measure the sensitivity and specificity of the computerized batteries to cognitive impairment as measured by traditional neuropsychological testing.	1
8	DHCC	Population Health Research Translation Support Services	Pilot study to determine the feasibility of a novel computer-based program to meet post-discharge needs for subjects complaining of deployment-related cognitive deficits. To determine feasibility in terms of improvement in subjective complaints, performance on neuropsychological tests, and compliance and satisfaction with the computer program.	6.4
9	DHCC	Availability and Efficacy of Military-Culture Appropriate PH Treatment and Services for Geographically Distant US Service Members and Their Families	Evaluate the safety of an in-home, web based BA treatment as an intervention for depression, determine the effectiveness of in-home BA as treatment for depression delivered via web cam, monitor PTSD symptoms to determine if there is an association between BA treatment and reductions in PTSD symptomology, examine patient compliance, treatment satisfaction, and over all feasibility of the web based intervention compared to in person BA treatment, identify best practices to guide the implementation of other web based telemental health interventions.	1
10	DHCC	Innovative Practices for Supporting Psychological Health and TBI	To determine if standardized auricular acupuncture or semi-standardized traditional Chinese acupuncture (TCA) alleviates headaches more effectively than usual care alone in a cohort of active duty military service members with mild to moderate TBI. To obtain preliminary estimates for future trial design.	1
11	DHCC	PH Treatment Needs and Outcomes of Minority Service Member Groups in DoD	To determine whether the addition of Interactive Medicine (IM) training leads to improvements in attention and memory, better secondary outcomes such as post-concussion symptom status, vocational functioning, and quality of life, and	1

			normalization of electrocortical functioning, at 6 months in comparison to rehabilitation treatment as usual.	
12	DHCC	Assessment of the Impact of Fidelity to Clinical Practice Guidelines on Treatment Outcomes for PTSD and MDD in the MHS	The primary aim of this study is to evaluate the safety and efficacy of NNZ-2566 for the acute treatment of mild TBI in adults.	1
13	DHCC	Extent, Efficacy and Effectiveness of Integrative Medicine Approaches to the Prevention and Treatment of Psychological Health Conditions and TBI in the DoD	The goal of this exempt protocol is to allow for the analysis of RESPECT Mil program data for the purpose of reporting to military and scientific audiences.	1
14	DHCC	Framework for Quality Assessments of Defense Department TBI and PH Systems of Care	The primary goal of this project is to optimize our Single-item PTSD Screen such that it performs the same or better than the Primary Care PTSD Screen, and demonstrate that it can identify patients with varying degrees of symptom distress.	1
15	DHCC	Framework for Quality Assessments of Defense Department TBI and PH Systems of Care (aka, 'System Capacity')	To investigate the relative influence mild traumatic brain injury, post-traumatic stress disorder, and combat experience has on aggressive behavior in our military personnel.	1
16	DHCC	Multiple somatic symptoms in U.S. military personnel: Competing risk analysis of three-year incidence, mortality, and resolution	This study will explore the technology uses and needs of both military mental health providers and service members.	0.2
17	DHCC	A Retrospective Analysis of 30-months of RESPECT-Mil Based on Program Surveillance Data and Care Facilitator Case Files	To investigate the linkage of brain activation to performance of cognitive control and working memory tasks during scanning in service personnel at 3 to 42 months following TBI associated with blast injury compared to non-blast extracranial injury. To investigate other linkages such as cognitive reserve, executive function, neuropsychiatric co-morbidities, and overall outcome in service personnel imaged at 3 to 42 months post-TBI compared to non-blast extracranial injury.	0.025

18	DHCC	Veterans Status and Health and Mortality in Older Americans	To use DTI and magnetization transfer imaging in veterans and service members who sustained blast-induced TBI in Iraq or Afghanistan to investigate the integrity of white matter microstructure in relation to brain activation associated with performing cognitive control and working memory tasks during fMRI.	0.1
19	DHCC	Evaluating Alternate Response Formats of the Posttraumatic Stress Disorder Checklist, Civilian Version (PCL-C)	To determine the: extent to which the findings regarding the strong association between anger and combat PTSD previously found for Vietnam Veterans (who were assessed after the war) apply to Veterans from Iraq and Afghanistan (assessed for current war Veterans), effect that different exposure levels to anger/aggression in the home during upbringing have on current anger levels, Norms of and validity for the Dimensions of Anger Reactivity scale using current war Veterans and, The differences between Active Duty soldiers and Army Reservists in post-deployment psychological adjustment including anger.	0.025
20	DHCC	Randomized Trial of Telephonic Psychotherapy and Case Management for Combat-Related Posttraumatic Stress Disorder	The overall aims of this study are a) to identify factors associated with suicide ideation and documented suicide attempts among US military personnel hospitalized during the period 2001-2006 and b) to determine the subsequent rate and type of post-discharge health service utilization.	1
21	DHCC	RWC Research: Extended Outcomes Research	To evaluate the efficacy of telephone-based neuropsychological testing for patients experiencing chronic sequelae, 5 to 15 years after TBI.	1
22	DHCC	RWC Research: Best Practices	To test the relation between mTBI and vestibulo-spatial cognition (spatial navigation and verticality perception). Test the relation between vestibulo-spatial cognition, balance, and dizziness symptoms following an mTBI.	1
23	DHCC	Understanding Current Practice in Treatment of Mild Traumatic Brain Injury in the Military Health System (Component 2 Secondary Data Analysis)	Assess the current state of existing anti-stigma and health promotion campaigns as well as certain programs with an anti-stigma focus developed prior to and after the launch of the campaign in May 2009.	1

24	DHCC	Pathways, Experiences, and Outcomes of Primary Care Versus Specialty Care Treatment for PTSD and Depression in Active Duty Service Members	Measure the independent effects of mTBI, time since injury, PTSD, and post concussive symptom burden on brain morphometry.	1
25	DHCC	Cost-effectiveness of Integrative Medicine Approaches to the Prevention and Treatment of Psychological Health	PTEC2 is a comprehensive online survey of personal technologies used by service members and their Families. The purpose of this research is to identify which personal electronic device might best serve for remote behavioral health care and information.	1
26	DHCC	Longitudinal Assessment of Family Readiness: The Deployment Life Study	Structured Assessment for Evaluation of TBI (SAFE-TBI) is a semi-structured interview plus common data elements to assess evidence for TBI. The purpose of this study is to determine the test/retest reliability and initial validity of the SAFE-TBI in Soldiers who screen positive for possible TBI in the PDHA.	1
27	DHCC	Evaluation of the Behavioral Health in the Patient Centered Medical Home Initiative	The goal of this 2-site RCT is to develop and evaluate Delivery of Self Training and Education for Stressful Situations – Telephone compared to usual primary care treatment for PTSD.	1
28	DHCC	Review of Suicide Prevention Programs, Phase II and III (RAND "Postvention in the Defense Department: The Evidence, DoD Policies and Procedures, and Perspectives of Survivors" Study)	This guide is intended to assist military leaders in their response to military suicides in their ranks. The report will summarize current DoD and service-specific policies and procedures for responding to military death generally and suicide specifically. The guide documents the extent to which DoD programs and policies reflect state-of-the-art suicide postvention practices; provides a snapshot of how installations across the services currently respond to suicide; and develops recommendations that the DoD may consider to improve its response to suicides.	1

29	DHCC	Review of Suicide Prevention Programs, Phase II and III (RAND "Gatekeepers in the Army and Marine Corps Suicide Prevention Program: Perspectives of Chaplains and NCOs" Study)	This study is intended to identify factors that may help chaplains and NCOs perform suicide prevention duties. The data collected will be used to answer questions such as: "How comfortable are NCOs, chaplains, and chaplain assistants in asking others if they are thinking about suicide? What helps or hinders NCOs, chaplains, and chaplain assistants in referring someone with suicidal thoughts for help?"	1
30	DHCC	Understanding Current Practice in Treatment of Mild Traumatic Brain Injury in the Military Health System (Component 1 Technical Expert Advisory Group)	To ensure that all military and VA patients with TBI receive TBI specific evaluations and care, including standardized patient outcome data. To describe clinical characteristics of TBIs sustained in theatre and correlate etiology of TBI with demographics, injury severity, associated injuries, symptomatology, and outcomes.	1
31	DHCC	Programs Addressing Psychological Health and Traumatic Brain Injury among U.S. Military Service Members and their Families	To evaluate neuropsychological test results of blast related vs. non-blast related injuries. To evaluate test results of patients who have received neuroimaging vs. those who have not. Based on this evaluation, we aim to determine if there is a significant difference in test results for the two populations. To assess the use of the Test of Memory and Malingering (TOMM) in neuropsychological testing and to determine its significance in planning treatment and determining duty status. To investigate the TOMM pass/fail rate in a mild traumatic brain injury population vs. PTSD population, vs. dual diagnosis.	1
32	DHCC	Psychosocial and Clinical Factors Associated with Outcomes Among a Sample of Psychiatric Inpatients: A Prospective Study	Identify and evaluate existing programs, practices, tools, and policies related to promoting healthy sleep practices within the military and DoD.	1
33	DHCC	Pilot Trial of Inpatient Cognitive Therapy for the Prevention of Suicide in Military Personnel with Acute Stress Disorder or Post-Traumatic Stress Disorder	Measure the impact of the Real Warriors Campaign, the extended outcomes research will gather psychosocial and behavioral intention data.	1

34	DHCC	Preliminary Analysis of Soldier 360˚Leader Comprehensive Fitness Course	The primary objectives of this study are to 1) Assess service members' preferences for mode of communication from health care providers, 2) Assess service members' general privacy concerns regarding communication from health care providers 3) Evaluate potential communication formats, and 4) examine the association between attitudes about social stigma and preferences for communication from health care providers.	1
35	DHCC	Post Admission Cognitive Therapy for the Inpatient Treatment of Military Personnel with Suicidal Behaviors: A Multi-Site Randomized Controlled Trial	To ensure that all military and VA patients with TBI receive TBI specific screening, treatment, and follow up while collecting standardized patient outcome data.	1
36	DVBIC	A Psychometric Comparison of Brief Computerized Neuropsychological Assessment Batteries: *Test-Retest Reliability*	To develop a measure of military mental health stigma, evaluate its psychometric properties within a military sample, and disseminate the results.	0.62
37	DVBIC	A Psychometric Comparison of Brief Computerized Neuropsychological Assessment Batteries: *Validity Study*	To assess the utility and reliability of four pain assessment instruments during the rehabilitation of persons with polytrauma and to examine the influence of cognitive impairment.	0.4
38	DVBIC	The Effect of Telephone Follow-up on outcome for Service Members with Mild TBI: Concussion Treatment after combat Trauma (CONTACT)	(1) Assess existing practice patterns through evaluation of current utilization rates of CPGs for PTS and MDD; (2) Assess variation from best practices through evaluation of the extent to which providers adhere to CPGs for PTS and MDD; and (3) Assess the impact of use of PTS and MDD CPGs on clinical outcomes.	0.033
39	DVBIC	Structured Telephonic Testing 5 to 15 Years after TBI	To decrease complexity of Return to Duty assessments by identifying visual function biomarkers that are affected by concussion.	0.06

40	DVBIC	Identifying US Military Service Members with Multiple Medically Diagnosed TBIs Using Administrative Databases	To explore the mental health needs of rural and remote service members and their Families, to include evaluation of telehealth services to address identified mental health needs.	0.23
41	DVBIC	Exploring the Natural History of Traumatic Brain Injury within a Military Cohort-A Longitudinal Database and Blood Banking Study: Comprehensive pathway	The overall objective of this study is to compare the brain-computer interface-heart rate variability (BCI-HRV) training with the WRNMMC and FBCH standard of care. Specific aims are (1) to determine whether BCI-HRV training, performed in an optimized training environment, improves the effectiveness of mTBI treatment over current WRNMMC and FBCH standards of care and (2) to determine whether BCI-HRV training, performed in an optimized training environment, improves the effectiveness of mTBI treatment over BCI-HRV conducted in a standard clinical setting.	7.5
42	DVBIC	Exploring the Natural History of Traumatic Brain Injury within a Military Cohort – A Longitudinal Database and Blood Banking Study: Brief Pathway	To improve the ability to predict PTSD in service members with mild TBI. To evaluate the associations between baseline indices of brain structure and function (measured within days of injury) and the development of PTSD symptoms measured at baseline and 3 and 6 months later. To compare brain changes following impact vs. blast mild TBI.	0.75
43	DVBIC	Data Analysis for Defense and Veterans Head Injury Program Protocol IV Combat Training Traumatic Brain Injury: A Surveillance Study in Paratroopers	To evaluate the effects of plasticity-based, adaptive cognitive remediation on the cognitive abilities, functional status and quality of life in soldiers and veterans diagnosed with persistent post-concussive symptoms following mTBI as compared to a computer-based control group. The secondary objective of this study is to demonstrate equivalency in safety effects reported between the treatment and control groups.	0.24
44	DVBIC	Deployment Related Mild Traumatic Brain Injury: Incidence, Natural History, and Predictors of Recovery in Soldiers Returning from OIF/OEF (Warrior STRONG)	1. To determine the acceptability to service members of the Brothers at War film. 2. To determine the effect of viewing the Brothers at War film on opinions of stigma and help seeking behaviors. 3. To determine the effect of viewing the Brothers at War film and participating in the post film discussion and journaling activities on opinions of stigma and help seeking behaviors.	1

45	DVBIC	Post-Deployment Traumatic Brain Injury and/or Post-Traumatic Stress Disorder: A Qualitative Study (Sub-study under protocol titled: "Deployment Related Mild Traumatic Brain Injury: Incidence, Natural History, and Predictors of Recovery in Soldiers Returning from OIF/OEF")	To conduct a multi-site randomized controlled trial of the Caring Letters intervention, to evaluate the utility of the Caring Letters intervention in reducing suicide mortality and self-inflicted injuries among service members and veterans, to evaluate whether the time period preceding the suicidal act is greater among service members and veterans randomly assigned to the Caring Letters intervention.	0.2
46	DVBIC	Feasibility Study of A Novel Neuro-feedback Technology for Persistent Post-Concussive Symptoms in Soldiers	This is an ongoing collaboration with the CDC's National Violent Death Reporting System (CDC-NVDRS) that involves linkage of 2 large governmental data systems (DoDSER) and CDC-NVDRS to explore distal and proximal factors that may relate suicide completions among current and former military personnel.	0.49
47	DVBIC	Epidemiology of Headache Disorders in a Military Cohort with and without TBI	To describe the short-term durability of functional outcomes for veterans with TBI. To identify factors that may inhibit functional independence and associated with poor outcomes. To identify clinical characteristics of TBI veterans with and without PTSD. To compare gains in functional outcomes achieved after (PRC) discharge among veterans with mild, moderate, and severe TBI and without PTSD. To assess utilization of follow-up services among TBI veterans after discharge from the PRC.	0.51
48	DVBIC	Post-traumatic Headache in Soldiers: A retrospective record review of patients presenting to the TBI Center for evaluation and treatment of headache	To examine the critical issues related to the identification and characterization of the anatomic, molecular, and physiological mechanisms of chronic brain injury and potential neurodegeneration.	0.07
49	DVBIC	Pain Drawings,Headache Diagnosis and Mild TBI in Soldiers: A retrospective case series	To evaluate the effectiveness and relative cost of two alternative Traumatic Brain Injury rehabilitation strategies in patients with moderate to severe TBI. To evaluate the effectiveness of Sertraline as an adjuvant to two alternative TBI rehabilitation strategies. To further develop and validate outcome measures that define the short and long term neurologic, behavioral, cognitive and psychosocial consequences of moderate to	1

			severe TBI.	
50	DVBIC	Onabotulinum Toxin A in the treatment of Post-traumatic Headache in Soldiers: A retrospective record review of patients presenting to the TBI Center for evaluation and treatment of headache	As a first step toward this goal, we propose to use data from T2 to conduct the first stage of a feasibility study. Specifically, we will attempt to match Social Security numbers (SSNs) of Soldiers who have had suicidal thoughts and/or behaviors in the Army DoDSER against SSNs of veterans seeking mental health services at any VA in the United States. Once this first step has been accomplished, we also aim to describe the group of veterans with DoDSERs who are accessing VA services (i.e., demographic information, military service variables, and health care utilization variables) in an attempt to better understand this group. It is anticipated that if this study is successful, a next step would be to explore the possibility of Army DoDSER data sharing with VA partners toward attainment of the following long-term goals: 1. Sharing information on history of active duty suicidal thoughts and/or behaviors among discharged individuals seeking mental health services in VA systems; 2. Facilitating identification of these veterans; 3. Reducing VA clinician burden through effective access to existing data that may help in assessment and treatment planning; 4. Lowering health care costs through effective early management; 5. Improving quality of care for veterans seeking services through VA outpatient mental health clinics.	0.04
51	DVBIC	A Prevalence Study of Chronic Problems and Sequelae after TBI in the Military and Veteran Populations	To empirically determine risk factors for, and protective measures against, suicide behaviors in the Army.	0.04

52	DVBIC	Use of the Personality Assessment Inventory in the Neuropsychological evaluation of U.S. Service Members following Traumatic Brain Injury	Evaluation of the Clinical Efficacy of Virtual Reality Exposure Therapy (VRET) for PTSD Relative to Prolonged Exposure (PE) and Wait List Control, Objective 2: Examination of the Relationship between Physiological Arousal and Emotional Engagement, Objective 3: Evaluation of the Relationship between Perceptions of Stigma, Patient Satisfaction, and Treatment Adherence.	0.1
53	DVBIC	San Antonio DVBIC Prospective Traumatic Brain Injury Clinical Tracking Repository	To conduct a descriptive study designed to integrate clinical outcomes research into the treatment of TBI patients. To ensure that military and veteran TBI patients receive TBI-specific evaluation and follow-up, while collecting standardized outcome data that will allow us to evaluate the relative efficacy and cost of various TBI treatment and rehabilitation strategies. To define impact of injury and optimal care for victims of TBI.	0.04
54	DVBIC	A Longitudinal Study of Chronic TBI in OEF/OIF/OND Veterans and Service Members	Evaluate the extent, efficacy, cost-effectiveness, and added value of IM approaches for the prevention and treatment of PH conditions.	0.26
55	DVBIC	NMC San Diego Defense and Veterans Brain Injury Center Tracking Protocol	To create a TBI health registry. To identify the number of cases of TBI in OEF/OIF. To demonstrate and evaluate the cost-benefit and service delivery outcomes of a comprehensive service delivery for TBI. To participate in national studies of TBIMS. To examine the long-term implications of injury in regards to employment and community re-integration. To evaluate rehabilitation treatment outcomes to define clinical practice guidelines, develop research studies, and guide policy decisions.	1
56	DVBIC	Retrospective Chart Review of Neuropsychological Testing in the Defense and Veterans Brain Injury Center at the Naval Medical Center San Diego	To determine the incidence and performance impact of traumatic brain injuries among Army paratroopers and identify possible prevention measures and therapeutic interventions.	0.2

57	DVBIC	Aggression in Military Personnel: Investigation of the Influence of Mild Traumatic Brain Injury, Post-Traumatic Stress Disorder, and combat Experience	To ensure that all military and VA patients with TBI receive TBI specific evaluations and care, including standardized patient outcome data. To describe clinical characteristics of TBIs sustained in theatre and correlate etiology of TBI with demographics, injury severity, associated injuries, symptomatology, and outcomes.	0.39
58	DVBIC	Exploring the natural history of traumatic brain injury within a Military Cohort: A Longitudinal Database and Blood Banking Study Brief Pathway	To ensure that all military and Department of Veterans Affair patients with traumatic brain injury receive TBI-specific screening, treatment and follow-up, while at the same time collecting standardized patient outcome data. To determine the effectiveness and relative cost of TBI evaluation and treatment strategies for military and VA medical systems. To provide the military medical communities with evidence based guidelines to optimize care for survivors of TBI.	0.21
59	DVBIC	The Defense and Veterans Brain Injury Center TBI Clinical Patient Registry	To determine the incidence and performance impact of traumatic brain injuries among Army paratroopers and identify possible prevention measures and therapeutic interventions.	0.57
60	DVBIC	Investigating the Neurologic Effects of Training Associated Blast	The objectives for this study are three-fold: 1) to examine what risk and protective factors (demographic characteristics, event location, event methods, deployment history, information about past military experience, medical history, psychological and social history variables) are associated with DoD suicide events (including suicidal ideation, attempted suicides, and completed suicides), 2) to evaluate trends in DoD suicide events across time, and 3) to compare service members with reported suicide events to the broader DoD service member population.	0.21
61	DVBIC	Core Evaluation Protocol	To compare the effects of individualized scheduled telephone support (ISTS) and UC on post-concussion symptom severity at 6 month follow up, as measured by the Rivermead Post Concussion Symptoms Questionnaire, to compare the effects of ISTS and UC on symptoms of emotional distress at 6 month follow up, as measured by the Brief Symptom Inventory Global Severity Index.	1

62	DVBIC	Prospective Traumatic Brain Injury Tracking Protocol (CTF)	Understand the effects of deployment on military Families, and identify the antecedents and consequences of Family readiness by collecting longitudinal data from Families across the deployment cycle.	0.85
63	DVBIC	VA Polytrauma Rehabilitation Center Traumatic Brain Injury Model Systems	Determine how deployment-related mTBI affects the health, productivity, and quality of life among soldiers returning from Iraq and Afghanistan. Assist health care providers by identifying soldiers with persistent symptoms and problems resulting from mTBI and providing continued assessments and follow-ups that can facilitate efficient and effective treatment interventions. Determine how PTSD and other associated injuries affect recovery from mTBI. Contribute to the development of mTBI identification and treatment algorithms that will benefit future military and civilian populations.	0.31
64	DVBIC	Minneapolis VA Prospective Traumatic Brain injury Tracking Protocol	To better understand the nature of physical changes to the brain of concussive brain injury patients.	0.3
65	DVBIC	Longitudinal, Multi-domain Assessment of Neurodegeneration in Veterans	The purpose of this two-year randomized controlled trial is to evaluate the clinical impact of a virtual hope-box smartphone app on suicide ideation or self- harm behavior in a broad veteran patient population.	1
66	DVBIC	Long-term Outcomes from TBI	Investigate use of tDCS applied to DLPFC as a technique to enhance cognitive control. Measure changes in risk-taking behaviors pre- and post-tDCS. Identify predictors of change in cognitive control across measures and time of tDCS sessions. Investigate the relationship between performance measures of impulsivity and performance measures of risk-taking .	1
67	DVBIC	Prospective TBI Clinical Tracking Study	To determine prevalence of post-concussive symptoms after blast related mTBI. To determine early predictive factors for the development of PCS after blast injury. To characterize late objective impairments after blast induced mTBI to aid in the development of targeted interventions and measures. To determine trajectory of symptoms to better characterize outcomes.	1

68	DVBIC	Epidemiological Study of Mild Traumatic Brain Injury Sequelae Caused by Blast Exposure During Operations Iraq and Enduring Freedom	To describe the incidence & natural history of headache disorders in a representative sample of recently deployed soldiers with & without TBI. To redefine/define the phenotype of chronic headaches occurring during or after deployment with the aim of differentiating symptoms between trauma and non-trauma related headache and also between neurological symptoms or deficits that may be specifically related to PTH rather than mTBI *per se.* To describe baseline factors that appear to predict a better or worse prognosis for headache disorders in order to identify soldiers who may particularly benefit from early and aggressive treatment. To describe the effect of chronic headache on performance and functioning over one year. To determine whether specific biomarkers previously identified in the pain / trauma literature are predictive of headache onset or persistence.	0.27
69	DVBIC	Defense and Veterans Brain Injury: Prospective Traumatic Brain Injury Protocol	1. Analyze evidence-based stigma reduction actions and campaigns and establish evidence-based guidelines for DoD. 2. Conduct inventory of all current DoD/Services programs that impact barriers to care and/or stigma 3. Perform gap analysis to determine if current programs are achieving designated purpose of reducing stigma.	0.05
70	DVBIC	Characterization and Care Coordination of Polytrauma Patients	The purpose of this protocol is to evaluate the alternate form reliability of a modified version of the Posttraumatic Stress Disorder Checklist, Civilian Version, which includes a revised likert scale designed to simplify scoring and reduce response error.	1
71	DVBIC	Olfactory and Taste Dysfunction Among US Military Personnel Deployed to Iraq and Afghanistan: A Feasibility Study	The PE mobile app is designed to increase engagement/compliance with gold standard PE treatment. The app provides 1) instant access to educational materials, 2) a tool for the training/practice of breathing exercises, 3) a device for recording therapy sessions/patients' traumas and immediate recording of distress during in vivo exercises and imaginal exposure. This pilot study compared traditional PE and PE Mobile App enhanced PE with regard to homework assignment completion, knowledge of PTSD, satisfaction, and symptom reduction.	0.29

72	DVBIC	Extending Smart Home Technology for Cognitively Impaired Veterans to Delay Institutionalization (Part II)	The proposed project will evaluate the performance of such a collaborative care approach in an MHS context. Key questions of interest will include relative improvement in clinical outcomes, fidelity to programming models, cost effectiveness, process assessment and impact on PCP workflow and patient satisfaction with received care.	0.42
73	DVBIC	James A. Haley V.A. Hospital Prospective and Retrospective Traumatic Brain Injury Tracking Protocol	To characterize the inpatient rehabilitation experience of patient groups differing in etiology, initial severity and length of stay by providing a summary of the percentages of time spent with various providers e.g., PT, OT, Psychology, RT, Speech) during inpatient stays in the Minneapolis PRC. To assess basic functional outcomes via Functional Independence Measure (FIM) scores upon admission and discharge.	1
74	DVBIC	Defense and Veterans Brain Injury Center James A. Haley V.A. Hospital Prospective and Retrospective Traumatic Brain Injury Tracking Protocol	To evaluate the effectiveness and adherence to the DVBIC tools supporting the Progressive Return to Activity clinical recommendation (CR), and identify the need or opportunity to revise the CR and ultimately enhance the patient's outcome.	0.04
75	DVBIC	ProTECT Phase III – Progesterone for the Treatment of Traumatic Brain Injury	Retrospective review and analysis of suicide event reporting.	3
76	DVBIC	Diffusion Tensor Imaging in the Evaluation of Blast Traumatic Brain Injury	To test and evaluate human factors dimensions associated with use of the VirtuSphere©, a novel technology designed to enhance the experience of immersion in virtual reality therapies. The goal of the proposed study is to evaluate a cutting-edge virtual reality (VR) navigation technology that has the potential to increase the immersion experience during virtual reality-based therapies such as exposure therapy, which integrates prolonged exposure into a virtual environment.	0.42

77	DVBIC	Outcome After Mild Traumatic Brain Injury Treated at BAMC	Database request is to improve our understanding of the utilization and efficacy of computer-based cognitive rehabilitation tools in the Brain Fitness Center (BFC) by developing a data repository that contains pertinent patient demographic information, survey data, the results of an objective cognitive assessment, and patient participation data.	0.23
78	DVBIC	An fMRI Study of TBI Associated with Blast Injury Cycle II	To improve our understanding of TBI in a military cohort by developing a data repository that contains pertinent TBI-related information, including neurobehavioral, neurocognitive, neuroimaging, blood specimen, and sensory/motor data. To document long term patient outcomes up to fifteen years.	0.3
79	DVBIC	A Randomized Exploratory Study to Evaluate Two Acupuncture Methods for the Treatment of Headaches Associated with TBI	To evaluate the effectiveness of cognitive rehabilitation in OIF/OEF service members with a history of mild traumatic brain injury and persistent (3-24 months post-injury) cognitive complaints.	1
80	DVBIC	Military Blast-related TBI: A Study of Neuroanatomical and Neurobehavioral Sequelae and Low Cost Clinical Intervention	Pilot study to provide the basis for designing a larger scale study of substance use following TBI. Provide preliminary statistical estimates of the magnitude of key relationships. To evaluate extent and timing of relationship between recent TBI and substance misuse among injured soldiers. To identify risk factors for development or exacerbation of substance misuse.	1
81	DVBIC	Brain Indices of Risk for PTSD after Mild Traumatic Brain Injury	To create a database (i.e. data registry) to use as a foundation for future research queries on topics such as neuropsychological functioning, symptom validity testing, and other research interests.	1
82	DVBIC	An fMRI Study of TBI Associated with Blast Injury	The proposed research project will develop a database in collaboration with other federal agencies to provide population-based estimates of the rates of suicide among service members with and without a history of deployment to OIF/OEF, and non-deployed veterans from the beginning of OIF/OEF forward.	1

83	DVBIC	BRAVE Trial: Broad-spectrum Cognitive Remediation Available to Veterans--Effects of a Brain Plasticity-based Program in Mild Traumatic Brain Injury	To improve our understanding of TBI in a military cohort by developing a data repository that contains neurobehavioral, neurocognitive, and clinical interview data on service members who were injured since October 2001; or have at least one deployment to OIF/OEF for non-injured healthy controls.	0.023
84	DVBIC	Biofeedback Treatment of mTBI Pathology Utilizing an Optimized Training Environment	To improve our understanding of TBI in a military cohort by developing a data repository that contains pertinent TBI-related information, including neurobehavioral, neurocognitive, neuroimaging, blood specimen, and sensory/motor data. To document long term patient outcomes up to fifteen years.	0.05
85	DVBIC	The Nature and Frequency of Clinical Interventions for Comprehensive Inpatient Rehabilitation at the Minneapolis VA PRC: A Model	To decrease the risk for institutionalization among veterans with cognitive impairments who are enrolled in the tampa polytrauma network system of care using an innovative set of technologies in the home.	0.21
86	DVBIC	Enhancing Cognitive Control Using Transcranial Direct Current Stimulation	Evaluate the extent, efficacy, cost-effectiveness, and added value of IM approaches for the prevention and treatment of PH conditions.	0.63
87	DVBIC	Assessing Pain in Persons with Polytrauma and Differing Cognitive Levels: Intensity Scale Utility & Reliability	This project will assess the association between Facebook usage during deployment and behavioral and general health outcomes.	0.39
88	DVBIC	Retrospective Analysis of Brain Morphometry in Mild Traumatic Brain Injury: A Pilot Study	Identify and evaluate existing programs, models and policies related to Family resilience in the military, psychological health of Families, and TBI-related Family functioning.	0.29
89	DVBIC	Treatment for Social Competence in Military Veterans, Service Members and Civilians with Traumatic Brain Injury	The primary objective is to examine the feasibility of successfully delivering Prolonged Exposure therapy utilizing virtual worlds technology, resulting in decreased symptoms of PTSD in Soldiers.	0.2

90	DVBIC	Traumatic Brain Injury Rehabilitation: A controlled, randomized multicenter study of interdisciplinary programs with adjuvant pharmacotherapy	To explore the personality characteristics of a sample of Army soldiers who received a Traumatic Brain Injury and were evaluated in the Neuropsychology Service, TBI Clinic at Darnall Army Medical Center between 3 December 2008 and 30 April 2010.	1
91	DVBIC	Study of Cognitive Rehabilitation Effectiveness in Mild Traumatic Brain Injury (SCORE!)	To demonstrate feasibility of delivery, and effects on electrocortical, cognitive, emotional, symptom status, and vocational functioning, of a time-limited, intensive treatment program of Global Z-Score Neuro-feedback Technology.	3.74
92	DVBIC	Imaging Support of Study of Cognitive Rehabilitation Effectiveness in Mild Traumatic Brain Injury (iSCORE)	Develop objective qualitative and quantitative assessment measures for PH and TBI system of care within the MHS.	1.41
93	DVBIC	A Randomized, Controlled, Trial of Interactive Metronome Technology for Remediation of Cognitive Difficulties Following Blast-Related Traumatic Brain Injury	Develop objective qualitative and quantitative assessment measures for PH and TBI system of care within the MHS.	0.36
94	DVBIC	A Randomized Controlled Pilot Study of the Effectiveness and Feasibility of Novel Rehabilitation approaches for OIF and OEF Patients with Persistent Complaints of Cognitive Dysfunction Following TBI	Conduct a longitudinal study of the health/supportive care needs of s caring for a service member or veteran who incurred a moderate/severe TBI during deployment to OIF/OEF. To develop a measure of Health-Related Quality of Life for use among caregivers of Military Traumatic Brain Injury: TBI-CareQOL.	0.00625
95	DVBIC	Expanding Our Understanding of Computer Based Cognitive Rehabilitation in the Military Population—a Longitudinal Brain Fitness Center Database	To determine the number of service members who had multiple medical encounters resulting in a TBI diagnosis from 2000 through 2011; to determine which of these medical encounters was indicative of an incident TBI event; to estimate the number of service members who had more than one TBI.	0.082
96	DVBIC	Health Related Quality of Life in Caregivers of Service Members with Military Related Traumatic Brain Injury:TBI-CareQOL Development	To investigate longitudinal structural and functional imaging changes over time that correlate with outcome following a trial of cognitive rehabilitation. To investigate the neural correlates of fatigue and	3.61

			misperception of effort as they relate to treatment outcome following mild TBI.	
97	DVBIC	A Demonstration Program to Test the Efficacy of Peer Visitation for Caregivers of Veterans of OIF/OEF with Polytrauma/Blast-related Injury	The purpose of this study is to evaluate archival data on the problematic behaviors, stage of change, and pros and cons of changing that behavior identified by 186 service members.	0.050
98	DVBIC	Spatical Navigation after Combat Exposure: A Pilot Study	This project will compare an in-home telehealth with CBTi app treatment to usual care among Soldiers with insomnia.	0.29
99	DVBIC	Neruocognitive Assessment of Blast Exposure Sequela in Training	To identify and evaluate the effectiveness of DoD programs designed to support PH and TBI by (1) canvassing current programs/initiatives to develop a comprehensive catalog of existing efforts and a taxonomy to characterize them, (2) conducting independent evaluations of the most promising programs/interventions that have not been evaluated to date, and (3) developing toolkit materials to support program evaluation.	0.31
100	DVBIC	Women and Traumatic Brain Injury: Retrospective Cohort Analysis	Investigate the relationship between timing and intensity of blast exposures, and the development and recovery of physiological and behavioral changes.	1
101	DVBIC	Chronic Effects of Neurotrauma Consortium	To ensure that all military and Department of Veterans Affair patients with traumatic brain injury receive TBI-specific screening, treatment and follow-up, while at the same time collecting standardized patient outcome data. To determine the effectiveness and relative cost of TBI evaluation and treatment strategies for military and VA medical systems. To provide the military medical communities with evidence based guidelines to optimize care for survivors of TBI.	1

102	DVBIC	Assessments of the pupillary light reflex and eye movements for early identification of Warfighters with acute mTBI/concussion	The objective of this investigation is to empirically determine risk factors for, and protective measures against, suicide behaviors in the Army. We predict that rates of PTSD diagnoses, legal problems (e.g. Article 15), failed intimate relationships (e.g. divorces), and financial problems (e.g. bankruptcy) will be higher among suicide cases than control cases.	0.2
103	DVBIC	A Randomized, Double-Blind, Placebo-Controlled Study of the Safety and Efficacy of NNZ-2566 in the Acute Treatment of Adults with Mild Traumatic Brain Injury	Understand the effects of deployment on military Families, and identify the antecedents and consequences of family readiness by collecting longitudinal data from families across the deployment cycle.	1
104	DVBIC	Evaluation of the DVBIC Progressive Return to Activity Clinical Recommendation Tool	To investigate potential neurodegeneration and cognitive decline in a Veteran TBI. To investigate measurements of retinal nerve layers and domains of cognition, behavior, and clinical symptomatology.	1
105	DVBIC	Richmond VA Prospective Traumatic Brain Injury Protocol	Provide timely information to the DoD that can be used to help assess and improve the quality of care for service members with a TBI.	1
106	DVBIC	Traumatic Brain Injury and Substance Use Disorders Among Injured Soldiers	Provide timely information to the DoD that can be used to help assess and improve the quality of care for service members with a TBI.	1
107	DVBIC	WRAMC Prospective Traumatic Brain Injury Tracking Protocol	To create a TBI health registry. To identify the number of cases of TBI in OEF/OIF. To demonstrate and evaluate the cost-benefit and service delivery outcomes of a comprehensive service delivery for TBI. To participate in national studies of TBIMS. To examine the long-term implications of injury in regards to employment and community re-integration. To evaluate rehabilitation treatment outcomes to define clinical practice	1

			guidelines, develop research studies, and guide policy decisions.	
108	DVBIC	Palo Alto VA Prospective TBI Clinical Tracking Study	To measure effectiveness of the Group Interactive Structured Treatment (GIST) intervention with multisite implementation. To identify the potent ingredients associated with the GIST intervention.	1
109	T2	A Pilot Study of In-Home Tele-Behavioral Health Care Utilizing Behavioral Activation for PTSD	Evaluate the safety and technical feasibility of an in-home, web based Behavioral Activation treatment as an intervention for PTSD, examine patient compliance, treatment satisfaction with home-based behavioral health care, and identify best practices to guide the implementation of other web based tele-mental health interventions.	0.70
110	T2	Characteristics of Suicides among Current and Former Military Personnel: Findings from the National Violent Death Reporting System and Defense Department Suicide Event Reports	This is an ongoing collaboration with the CDC's National Violent Death Reporting System NVDRS that involves linkage of 2 large governmental data systems DoDSER and CDC-NVDRS to explore distal and proximal factors that may relate suicide completions among current and former military personnel.	0.2
111	T2	Evaluation of the VirtuSphere as a Virtual Reality Navigation Enhancement	This study evaluated the VirtuSphere©, a cutting-edge virtual reality navigation technology to assess its utility in increasing the immersion experience during virtual reality-based therapies such as exposure therapy, which integrates Prolonged Exposure into a virtual environment. Soldier satisfaction with the VirtuSphere© was also evaluated.	0.10
112	T2	Clinician Access to Soldier Suicide Information	This study was designed to examine the feasibility of linking non-fatal DoDSERs with enterprise level VA records. The short-term goal is to describe the group of Veterans with DoDSERs who are accessing the VA to better understand this group. Long-term goals include to sharing information to help clinicians flag high risk veterans in order to facilitate treatment planning and improve quality of care.	0.10

113	T2	Service Member Outreach and Follow-Up from Health care Providers Survey Study	The objectives of this study is to determine soldiers' preference and privacy concerns for follow-up care and communications from their providers after they completed primary treatment, their preferred choices of contact medium (e.g. mail, phone, email), and how stigma for behavioral health care might influence their preferences for follow-up.	0.10
114	T2	The Effect of Telephone Follow-Up on Outcome for Service Members with Mild TBI/PTSD	Individualized scheduled telephone support provides injury-related education, training in problem solving, and focused behavioral strategies for problems (e.g., anxiety, depression) that commonly occur with mild traumatic brain injury. The purpose of this study is to determine whether ISTS can reduce post-concussion symptom severity and improve the wellbeing of service members with mTBI at 6 and 12 month follow ups compared to treatment as usual.	4.6
115	T2	Defense Department Suicide Event Report DoDSER Data Analysis	The objectives for this study are three-fold: 1) to examine what risk and protective factors (demographic characteristics, event location, event methods, deployment history, information about past military experience, medical history, psychological and social history variables) are associated with DoD suicide events (including suicidal ideation, attempted suicides, and completed suicides), 2) to evaluate trends in DoD suicide events across time, and 3) to compare service members with reported suicide events to the broader DoD service member population.	0.2
116	T2	Assessing Mental Health Treatment Stigma in the Military	To develop a measure of military mental health stigma, evaluate its psychometric properties within a military sample, and disseminate the results.	0.05
117	T2	The Association between Suicide and OIF/OEF Deployment History	The proposed research project will develop a database in collaboration with other federal agencies to provide population-based estimates of the rates of suicide among service members with and without a history of deployment to OIF/OEF, and non-deployed veterans from the beginning of OIF/OEF forward.	0.75
118	T2	Comparing Virtual Reality Exposure Therapy to Prolonged Exposure in the	Evaluation of the Clinical Efficacy of Virtual Reality Exposure Therapy for PTSD Relative to Prolonged Exposure and Wait List Control,	3.45

		Treatment of Soldiers with Post Traumatic Stress Disorder	Objective 2: Examination of the Relationship between Physiological Arousal and Emotional Engagement, Objective 3: Evaluation of the Relationship between Perceptions of Stigma, Patient Satisfaction, and Treatment Adherence.	
119	T2	Anger and Psychological Adjustment of Soldiers who have Sought Mental Health care	To determine the: extent to which the findings regarding the strong association between anger and combat PTSD previously found for Vietnam Veterans (who were assessed after the war) apply to Veterans from Iraq and Afghanistan (assessed for current war Veterans), effect that different exposure levels to anger/aggression in the home during upbringing have on current anger levels, Norms of and validity for the Dimensions of Anger Reactivity scale using current war Veterans and, The differences between Active Duty soldiers and Army Reservists in post-deployment psychological adjustment including anger.	0.15
120	T2	Moodtracker Functionality Testing	T2 Mood Tracker is an “app” for smartphones and other mobile devices that enables users to rate their moods, to self-monitor across time, and to report their emotional experiences to health providers. The purpose of this study was to field-test the utility, usage, ease of use and functionality of the T2 MoodTracker with a sample of redeployed soldiers under treatment for behavioral health issues at a Warrior Transition Unit.	0.05
121	T2	Comparing Suicide Risk Factors Between Army -wide Suicide Cases and a Control Sample of Ft. Lewis Soldiers	To empirically determine risk factors for, and protective measures against, suicide behaviors in the Army.	0.5
122	T2	Usability and Utility of a Virtual Hope Box for Reducing Suicidal Ideation	The objective of this study was to conduct a proof of concept development and evaluation of a virtual hope-box smartphone app to supplement in-person clinical therapy for service members with suicide ideation or behavior.	0.6
123	T2	Effectiveness of a Virtual Hope Box Smartphone App in Enhancing Veterans' Coping with Suicidal Ideation: A Randomized Clinical Trial	The purpose of this two-year randomized controlled trial is to evaluate the clinical impact of a virtual hope-box smartphone app on suicide ideation or self- harm behavior in a broad veteran patient population.	4.05

124	T2	MilitaryKidsConnect.org: Peer-to-Peer Support via an online Message Board	Retrospective review of MilitaryKidsConnect.org message board. To assess the peer support being provided by the online program.	0.1
125	T2	PTEC2: A Comprehensive Online Survey of Personal Technologies among Service Members, Veterans and s	PTEC2 is a comprehensive online survey of personal technologies used by service members and their Families. The purpose of this research is to identify which personal electronic device might best serve for remote behavioral health care and information.	0.10
126	T2	Positive and Negative Aspects of Facebook Usage by Service Members During Deployment and Associations with Social Support	Cross sectional survey study conducted in Afghanistan to describe patterns of Facebook use during deployment, evaluate the relationship between Facebook use and social support, and to examine positive and negative experiences of Facebook use.	0.05
127	T2	Reliability and Initial Validation of the INTRuST Structured Assessment for Evaluation of TBI	SAFE-TBI is a semi-structured interview plus common data elements to assess evidence for TBI. The purpose of this study is to determine the test/retest reliability and initial validity of the SAFE-TBI in soldiers who screen positive for possible TBI in the PDHA.	4.01
128	T2	An Analysis of Technology Use by Service Members and Military Members	This study will explore the technology uses and needs of both military mental health providers and service members.	0.10
129	T2	Increasing the Clinical Fidelity of Stages of Change and Decisional Balance: Self-Generated Problematic Behaviors and Pros verses Cons	The purpose of this study is to evaluate archival data on the problematic behaviors, stage of change, and pros and cons of changing that behavior identified by 186 service members.	0.10
130	T2	Evaluation of a Mobile Application to Supplement Prolonged Exposure Therapy	The PE mobile app is designed to increase engagement/compliance with gold standard PE treatment. The app provides 1) instant access to educational materials, 2) a tool for the training/practice of breathing exercises,	0.05

			3) a device for recording therapy sessions/patients' traumas and immediate recording of distress during in vivo exercises and imaginal exposure. This pilot study compared traditional PE and PE Mobile App enhanced PE with regard to homework assignment completion, knowledge of PTSD, satisfaction, and symptom reduction.	
131	T2	Feasibility of Virtual Worlds Technology to Deliver Prolonged Exposure Therapy to Soldiers with Post-Traumatic Stress Disorder	The primary objective is to examine the feasibility of successfully delivering Prolonged Exposure therapy utilizing virtual worlds technology, resulting in decreased symptoms of PTSD in Soldiers.	0.10
132	T2	A Randomized Controlled Trial of In-Home Tele-behavioral Health Care Utilizing Behavioral Activation for Depression	Evaluate the safety of an in-home, web based BA treatment as an intervention for depression, determine the effectiveness of in -home BA as treatment for depression delivered via web cam, monitor PTSD symptoms to determine if there is an association between BA treatment and reductions in PTSD symptomalogy, examine patient compliance, treatment satisfaction, and over all feasibility of the web based intervention compared to in person BA treatment, identify best practices to guide the implementation of other web based telemental health interventions.	6.7
133	T2	Caring Letters for Military Suicide Prevention: A Randomized Controlled Trial	To conduct a multi-site randomized controlled trial of the Caring Letters intervention, to evaluate the utility of the Caring Letters intervention in reducing suicide mortality and self-inflicted injuries among service members and veterans, to evaluate whether the time period preceding the suicidal act is greater among service members and veterans randomly assigned to the Caring Letters intervention.	6.95
134	T2	JBLM DoDSER Control Study	The objective of this investigation is to empirically determine risk factors for, and protective measures against, suicide behaviors in the Army. We predict that rates of PTSD diagnoses, legal problems (e.g. Article 15), failed intimate relationships (e.g. divorces), and financial problems (e.g. bankruptcy) will be higher among suicide cases than control cases.	0.50

135	T2	Evaluation of the Self-Directed Violence Classification System (SDVCS) for Classification of Suicide Events Reported in the Defense Department Suicide Event Report	Retrospective review and analysis of suicide event reporting.	0.20
136	T2	Virtual Worlds as Model for Stepped Care: An Evaluation of the National Center for Telehealth and Technology's Virtual PTSD Experience	This project will evaluate the T2 Virtual PTSD Experience to examine the utility of virtual worlds.	0.10

APPENDIX C. Fiscal Year 2014 Sample of Research Milestones Achieved

DCOE Element	Study title	Milestones Achieved/Progress/Reports
DHCC	Sleep in the Military: An evaluation of Military Programs and Policies Sleep Resources and Tips for Line Leaders	Final report being reviewed after comments were adjudicated by RAND PIs. Will be scheduling final briefing for DHCC and DCoE leadership in November or December of 2014 with concurrent WHS release.
DHCC	Innovative Practices for Supporting Psychological Health and TBI	All but one study is in process of being written. Five out of six of the remaining studies are in varying stages of internal review.
DVBIC	A Psychometric Comparison of Brief Computerized Neuropsychological Assessment Batteries: *Test-Retest Reliability*	Manuscript published in Archives of Clinical Neuropsycyhology.
DVBIC	The Effect of Telephone Follow-up on outcome for Service Members with Mild TBI: Concussion Treatment after combat Trauma	Development of publications continue in collaboration with UW researchers.
DVBIC	Post-Deployment Traumatic Brain Injury and/or Post-Traumatic Stress Disorder: A Qualitative Study (Sub-study under protocol titled: "Deployment Related Mild Traumatic Brain Injury: Incidence,	Manuscript has been prepared by collaborating staff of the Denver VA Medical Center and cleared by PAO and is now in the publication submission process.

	Natural History, and Predictors of Recovery in Soldiers Returning from OIF/OEF")	
DVBIC	Onabotulinum Toxin A in the treatment of Post-traumatic Headache in Soldiers: A retrospective record review of patients presenting to the TBI Center for evaluation and treatment of headache	Paper submitted to Headache June, 2014.
DVBIC	A Prevalence Study of Chronic Problems and Sequelae after TBI in the Military and Veteran Populations	Descriptive paper prepared, submitted to DCoE's PAO.
DVBIC	San Antonio DVBIC Prospective Traumatic Brain Injury Clinical Tracking Repository	Presentations: IBIA 2014 1 poster, 1 presentation.
DVBIC	Long-term Outcomes from TBI	Primary manuscript describing functional outcomes under development. Initiate literature search and data analysis for a second manuscript on service needs, utilization, and barriers, and predictors thereof. Initiate literature search for third manuscript on predictors of life satisfaction.
DVBIC	Prospective TBI Clinical Tracking Study	Manuscript describing historical and descriptive analysis of CTF under draft.

DVBIC	Epidemiological Study of Mild Traumatic Brain Injury Sequelae Caused by Blast Exposure During Operations Iraq and Enduring Freedom	Publication: Stratton KJ, Clark SL, Hawn SE, Amstadter AB, Cifu DX, Walker WC. (2014). Longitudinal interactions of pain symptoms and posttraumatic stress disorder in U.S. military service members following combat. J Pain. [Epub ahead of print]. doi: 10.1016/j.jpain.2014.07.002.
DVBIC	Extending Smart Home Technology for Cognitively Impaired Veterans to Delay Institutionalization (Part II)	Two manuscripts presented at iCOST in June with publication in Springer. Three abstracts accepted for 2 oral presentations and 1 poster presentation at Southwestern Disabilities Conference, Assistive Technology International Association, and Brain Injury Summit: A Meeting of the Minds.
DVBIC	Diffusion Tensor Imaging in the Evaluation of Blast Traumatic Brain Injury	Presentations: INS 2013 poster; INS 2014 x2 posters.
DVBIC	Outcome After Mild Traumatic Brain Injury Treated at BAMC	PTSD subgroup deactivation paper submitted to *Psychiatry Research: Neuroimaging*.
DVBIC	A Randomized, Controlled, Trial of Interactive Metronome Technology for Remediation of Cognitive Difficulties Following Blast-Related Traumatic Brain Injury	Second manuscript on ERP results has received reviewer comments from journal “Brain and Behavior" and re-analysis of data was completed and manuscript was resubmitted.
DVBIC	Expanding Our Understanding of Computer Based Cognitive Rehabilitation in the Military Population—a Longitudinal Brain	APA Conference poster presentation in August 2014.

	Fitness Center Database	
DVBIC	Health Related Quality of Life in Caregivers of Service Members with Military Related Traumatic Brain Injury:TBI-CareQOL Development	Completed military focus groups and frequency data analysis for item development. Completed narrative analysis on civilian focus group data and manuscript in development.
DVBIC	Women and Traumatic Brain Injury: Retrospective Cohort Analysis	Ongoing manuscript development: Gender and the Effects of Polytrauma: Comparative Analysis of Female Polytrauma Cohort Characteristics and Outcomes.
T2	A Pilot Study of In-Home Tele-Behavioral Health Care Utilizing Behavioral Activation for PTSD	Study completed and closed. Manuscript submitted for review.
T2	Characteristics of Suicides among Current and Former Military Personnel: Findings from the National Violent Death Reporting System and Defense Department Suicide Event Reports	Initial analyses completed and published. Additional analyses underway. This project provides an important approach to extend the benefits of DoD's suicide surveillance data. Leaders, preventionists, and others want to know how military suicides compare to US suicides that occur in the civilian sector. This project developed a strategic relationship with CDC partners who work with the National Violent Death Reporting System to link DoD and CDC data to address these kinds of questions, and to study the potential benefits. Early publications include: • Logan, J., Skopp, N.A., Reger, M.A., Gladden, M., Smolenski, D.J., Floyd, C.F., & Gahm, G.A. (in press). Suicide Circumstances among active duty US Army personnel versus US civilians: A matched case analysis. Journal of Life-Threatening Behavior.
T2	Evaluation of the VirtuSphere as a Virtual Reality Navigation Enhancement	Study completed and closed. Manuscript published.

T2	Service Member Outreach and Follow-Up from Health care Providers Survey Study	Study completed and closed. Manuscript published: Stanfill, K.E., Kinn, J., Bush, N. Soldiers' preferences for follow-up communications with behavioral health providers. Telemedicine and e-Health, 20, 8, 2014. DOI: 10.1089/tmj.2013.0306.
T2	The Effect of Telephone Follow-Up on Outcome for Service Members with Mild TBI/PTSD	Enrollment and participation are complete. Analyses are underway. Too soon for main outcomes results but a number of manuscripts are in preparation. One methods publications thus far has resulted: • Bell, K. R., Brockway, J., Fann, J. R., Cole, W. R., De Lore, J., Bush, N., Lang, A. J., Hart, T., Warren, M., Dikmen, S., Temkin, N., Jain, S., Raman, R., Stein, M. B. (2014). Concussion Treatment after Combat Trauma: Development of a Telephone Based, Problem Solving Intervention for Service Members. Contemporary Clinical Trials. 40, 54-62. DOI: 10.1016/j.cct.2014.11.001.
T2	Defense Department Suicide Event Report Data Analysis	Recent findings from DoDSER include: • Bush, N.E., Reger, M. A., Luxton, D. D., Skopp, N. A., Kinn, J. T., Smolenski, D., & Gahm, G. A. Suicides and suicide attempts in the US Military, 2008-2010. Suicide and Life-Threatening Behavior. (43) 262–273. doi: 10.1111/sltb.12012. • The Defense Department Suicide Event Report Program collects extensive information on suicides and suicide attempts from the U.S. Air Force, Army, Marine Corps, and Navy. Data are compiled on demographics, suicide event details, behavioral health treatment history, military history, and information about other potential risk factors such as psychosocial stressors that were present at the time of the event. The ultimate goal of this standardized suicide surveillance program is to assist suicide prevention in the U.S. military. Descriptive data are presented on 816 suicides and 1,514 suicide attempts reported through the program between 2008 and 2010. Other Publications from other projects that relate to this topic: • Skopp, N. A., Luxton, D. D., Bush, N., & Sirotin, A. (2011). Childhood Adversity and Suicidal Ideation in a Clinical Military Sample: Military Unit Cohesion and Intimate Relationships as Protective Factors. Journal of Social and Clinical Psychology, 30 (4), 361-377. doi: 10.1521/jscp.2011.30.4.361. • Skopp, N. A., Trofimovich, L., Grimes, J., Oetjen-Gerdes, L., & Gahm, G. A. (2012). Relations between suicide and traumatic brain injury, psychiatric diagnoses, and relationship problems among U.S. service members. Medical Surveillance Monthly Report, 19 (2), 7-11. • Luxton D. D., Trofimovich, L., & Clark, L. L., Suicide Risk among U.S. service members Following Psychiatric Hospitalization, 2001-2011. Psychiatric Services, 64. (7) doi: 10.1176/appi.ps.201200413. • Trofimovich, L., Reger, M. A., Luxton, D. D., Oetjen-Gerdes, L.

		(2013). Suicide risk by military occupation in the DoD active component population. Suicide and Life Threatening Behavior, 43. 93) 274-278, doi: 10.1111/sltb.12013.
T2	Assessing Mental Health Treatment Stigma in the Military	This study is still ongoing and collecting data. The first publication from this study thus far is: • Skopp, N.A., Bush, N.E., Vogel, D.L., Wade, N.G., Sirotin, A.P., McCann, R.A., & Metzger-Abamukong, M.J. (2012). Development and initial testing of measure of public and self-stigma in the military. Journal of Clinical Psychology, 68 (9), 1036-1047. doi:10.1002/jclp.21889. • This research developed and tested the Military Stigma Scale (MSS), a 26-item scale, designed to measure public and self-stigma, two theorized core components of mental health stigma. The sample comprised 1,038 active duty soldiers recruited from a large Army installation. Soldiers' mean age was 26.7 (standard deviation = 5.9) years, and 93.6% were male. The sample was randomly split into a scale development group (n = 520) and a confirmatory group (n = 518). Factor analysis conducted with the scale development group resulted in the adoption of two factors, named public and self-stigma, accounting for 52.1% of the variance. Confirmatory factor analysis conducted with the confirmatory group indicated good fit for the two-factor model. Both factors were components of a higher order stigma factor. The public and self-stigma scales for the exploratory and confirmatory groups demonstrated good internal consistency (a = .94 and .89; a = .95 and .87, respectively). Demographic differences in stigma were consistent with theory and previous empirical research: Soldiers who had seen a mental health provider scored lower in self-stigma than those who had not. The MSS comprises two internally consistent dimensions that appear to capture the constructs of public and self-stigma. The overall results indicate that public and self-stigma are dimensions of stigma that are relevant to active duty soldiers and suggest the need to assess these dimensions in future military stigma research.
T2	The Association between Suicide and OIF/OEF Deployment History	This recently completed study may provide the most definitive conclusions to date on the relationship between suicide and deployment, separation, and other risk factors. The cohort analyzed comprised about 4 million service members including more than 5000 suicides. The results described below were novel and important as evidenced by their publication in top tier journals (including JAMA Psychiatry), interest by the media (Los Angeles Times), and the request to present some of the results to the House Veterans Affairs Committee. In addition, the methods of the project were used to develop a new enterprise solution for the DoD/VA. Specifically, the PI had the opportunity early on in the project to present the methodology from our project to a Health Executive Committee/Joint Executive Committee (JEC) sub-workgroup. (The JEC provides senior leadership a forum for collaboration and resource sharing between VA and DoD. The Deputy Secretary of Veterans Affairs and

		the Under Secretary of Defense for Personnel and Readiness co-chair JEC meetings). The sub-workgroup had been charged with filling some of the suicide data gaps that created barriers for understanding military and veteran suicide. This research project had been specifically designed to provide a comprehensive dataset that provided suicide data from the time personnel enter the military until the end of the observation period, regardless of whether they leave military service or access VA services. The sub-workgroup was excited by the solutions our methods offered. The PI had the opportunity to lead the development of a plan to establish a new DoD/VA Suicide Data Repository that was built on the foundation of our methods. The plan was presented to senior leadership and ultimately implemented. • Reger MA, Smolenski DJ, Skopp N, Metzger-Abamukang. Kang HK, Bullman TA, Perdue S, Gahm GG. Risk of Suicide Following OEF/OIF Deployment and Separation from the U.S. Military (In Press). This retrospective cohort design used administrative data to identify dates of deployment for all service members (2001 – 2007) and suicide data (2001 – 2009) to estimate rates of suicide-specific mortality. Suicide mortality data from derived from the Defense Department Medical Mortality Registry and the National Death Index. Deployment was not associated with the rate of suicide for either those still serving in the military (HR = 0.99; 99% CI = .89, 1.11), or those who had separated from service (HR = .86; 99% CI = .72, 1.03). The rate of suicide among service members after separation from service was 72% greater than for those who remained in service through the end of 2007 (HR = 1.72; 99% CI = 1.59, 1.86). The highest suicide rates were observed during the first two years after leaving military service. Rates of suicide were also elevated for service members who separated with less than 4 years of military service or who did not separate with an honorable discharge. • Kang HK, Bullman TA, Smolenski DJ, Skopp NA, Gahm GA, Reger MA. (2015). Suicide risk among 1.3 million veterans who were on active duty during the Iraq and Afghanistan wars. Ann Epidemiol. 2015 Feb;25(2):96-100. doi: 10.1016. Based on 9,353 deaths (deployed, 1,650; non-deployed, 7,703), of which 1,868 were suicide deaths (351; 1,517), both veteran cohorts had 24-25% lower mortality risk from all causes combined, but had 41-61% higher risk of suicide relative to the US general population. However, the suicide risk was not associated with a history of deployment to the war zone. After controlling for age, sex, race, marital status, branch of service, and rank, deployed veterans showed a lower risk of suicide compared to non-deployed veterans (hazard ratio, 0.84; 95% confidence interval, 0.75- 0.95).

T2	Anger and Psychological Adjustment of Soldiers who have Sought Mental Health care	Study closed and manuscript published.
T2	Moodtracker Functionality Testing	Study completed and closed. Manuscript published: Bush NE, Ouillette G, Kinn JT. Utility of the T2 Mood Tracker Mobile Application among Army Warrior Transition Unit Service Members. Military Medicine. 179 (12), 1453-1457, 2014. DOI: 10.7205/MILMED-D-14-00271.
T2	Comparing Suicide Risk Factors Between Army -wide Suicide Cases and a Control Sample of Ft. Lewis Soldiers	Study completed and closed. Manuscript published.
T2	Usability and Utility of a Virtual Hope Box for Reducing Suicidal Ideation	The Virtual Hope Box smartphone app received the 2014 Defense Department Innovation Award. VHB has received almost unanimous and unusually enthusiastic praise from clinical providers, their patients, and from users of public download sites. Detailed findings have been published as: • Bush NE, Dobscha SK, Crumpton R, et al. A Virtual Hope Box Smartphone App as an Accessory to Therapy: Proof-of-Concept in a Clinical Sample of Veterans. Suicide & Life-Threatening Behavior, 45, 1, 2015. DOI: 10.1111/sltb.12103. • Compared with a conventional hope box integrated into VA behavioral health treatment, high-risk patients and their clinicians used the VHB more regularly and found the VHB beneficial, useful, easy to set up, and said they were likely to use the VHB in the future and recommend the VHB to peers.
T2	Effectiveness of a Virtual Hope Box Smartphone App in Enhancing Veterans' Coping with Suicidal Ideation: A Randomized Clinical Trial	A larger scale RCT is ongoing with behavioral health patients and providers at the Portland VA. 113 participants of a final target sample of 120 have already been enrolled with 75 having completed all phases of the study. We expect all participants to have completed by summer of 2015 at which point analyses will commence.

T2	PTEC2: A Comprehensive Online Survey of Personal Technologies among Service Members, Veterans and s	Study completed and closed. Manuscript published. Bush NE, Wheeler WM. Personal Technology Use by U.S. Military Service Members and Veterans: An Update. Telemed J E Health. April 2015. DOI: 10.1089/tmj.2014.0100.
T2	Reliability and Initial Validation of the INTRuST Structured Assessment for Evaluation of TBI	Manuscripts under development.
T2	An Analysis of Technology Use by Service Members and Military Members	Manuscript under development.
T2	Increasing the Clinical Fidelity of Stages of Change and Decisional Balance: Self-Generated Problematic Behaviors and Pros verses Cons	Manuscript under development.
T2	Evaluation of a Mobile Application to Supplement Prolonged Exposure Therapy	Results from this study are currently being written up. Different Projects with related outcomes: • Kuhn, E. R., Eftekhari, A., Hoffman, J. E., Crowley, J. J., Ramsey, K. M., Reger, G. M., & Ruzek, J. (in press). Clinician perceptions of using a smartphone app with Prolonged Exposure therapy. Administration and Policy in Mental Health and Mental Health Services. This study investigated mental health clinicians' (n = 163) perceptions of a patient-facing smartphone application (app) for Prolonged Exposure therapy for posttraumatic stress disorder, before its public release. After reading a description of the app, participants rated perceptions of it based on diffusion of innovations theory constructs. Perceptions were generally favorable regarding the app's relative advantage over existing PE practices, compatibility with their values and needs, and complexity. Age (\40 years), smartphone ownership, and having used apps in care related to more favorable perceptions. Smartphone ownership, relative advantage, and complexity significantly predicted intention to use the app if it were available. These findings suggest that clinicians are receptive to using a PE app and that dissemination efforts should target sub-groups of PE

		clinicians to maximize adoption. • Reger, G. M., Hoffman, J., Riggs, D., Rothbaum, B. O., Ruzek, J., Holloway, K. M., & Kuhn, E. R. (2014). The “PE Coach” smartphone application: An innovative approach to improving implementation, fidelity, and homework adherence during Prolonged Exposure. Psychological Services. 3, 342-9. doi: 10.1037/90032774. • Prolonged Exposure is an empirically supported treatment that is being disseminated broadly to providers in the Department of Veterans Affairs and Defense Department. Innovative methods are needed to support the implementation, dissemination, and patient and provider adherence to PE. The PE Coach is a smartphone application designed to mitigate barriers to PE implementation. PE Coach is installed on the patient’s phone and includes a range of capabilities for use during the PE session and after each session to support the treatment. Functions include the ability to audio record treatment sessions onto the patient’s device, to construct the in vivo hierarchy on the device, to record completed homework exercises, to review homework adherence, and to track symptom severity over time. The app also allows sessions and homework to be scheduled directly in the app, populating the device calendar with patient reminder notifications. In the final session, a visual display of symptom improvement and habituation to items on the in vivo hierarchy is presented. These capabilities may significantly improve convenience, provider implementation and adherence, and patient compliance with treatment.
T2	A Randomized Controlled Trial of In-Home Tele-behavioral Health Care Utilizing Behavioral Activation for Depression	Enrollment and participation are complete. Analyses are underway. Too soon for main outcomes results but a number of manuscripts for preliminary data are in preparation. Recent published paper: • Luxton, D.D., Pruitt, L.D., O’Brien, K., & Kramer, G. (In Press). An evaluation of the feasibility and safety of a home-based telemental health treatment for PTSD in the US military. Telemedicine and eHealth. • Presents results from the grant's pilot study project conducted with PTSD patients that demonstrated the delivery of in-home behavioral health treatment was feasible. • Pruitt, L.D., Luxton, D.D., Shore, P. (2014). Clinical Benefits of Home-Based Telemental Health. Professional Psychology: Research and Practice. doi: 10.1037/a0035461. • Luxton, D. D., Pruitt, L. D, O’Brien, K., Stanfill, K., Jenkins-Guarnieri, M., Johnson, K. et al. (2014). Design and Implementation of a Randomized Clinical Trial of Home-based Telemental Health Treatment for Military Service Members and Veterans with Depression. Contemporary Clinical Trials. 38. (1) 134-144. doi: 10.1016/j.cct.2014.04.002. Other Publications from other projects that relate to this topic: • Jenkins-Guarnieri, M., Pruitt, L.D., Luxton, D.D., Johnson, K. (In Press). Patient perceptions of telemental health: Systematic review of direct comparisons to in-person psychotherapeutic treatments.

		Telemedicine and eHealth. • Kramer, G. M. & Luxton, D. D. (in press). Telemental health for children and adolescents: An overview of legal, regulatory, and risk management issues. Journal of child and adolescent psychopharmacology. • Luxton, D. D., O'Brien, K., Pruitt, L. D., Johnson, K. & Kramer, G. (2014). Managing Suicide Risk in Home-Based Telepractice. International Journal of Psychiatry in Medicine. 48(1), 19-31. • Luxton, D. D., Pruitt, L. D. & Osenbach, J. E. Best Practices for Remote Psychological Assessment via Telehealth Technologies. Professional Psychology: Research & Practice. 45, 27-35. doi: 10.1037/900334547. • Luxton, D. D., Pruitt, L. D., O'Brien, K., Johnson, K., Kramer, G. (2014). Suicide risk management during clinical telepractice. International Journal of Psychiatry in Medicine. 48, 19-31. doi: 10.2190/PM.48.1.c. • Osenbach, J., O'Brien, K., Mishkind, M., & Smolenski, D. (2014). Synchronous Telehealth Technologies in Psychotherapy for Depression: A Meta-Analysis. Depression and Anxiety. 11, 1058-67. doi: 10.1002/da.22165. • Shore, J. H., Mishkind, M. C., Bernard, J., Doarn, C. R., Bell Jr, I., Bhatla, R., Brooks, E., Caudill, R., Cohn, E., Barthold, J., Eppolito, A., Fortney, J., Friedl, K., Hirsch, P., Jordan, P., Kim, T., Luxton, D., Lynch, M., Maheu, M., McVeigh, F., Nels . A Lexicon of Assessment and Outcome Measures for Telemental Health. Telemedicine and e-Health, 20. (3) 282 - 292. doi 10.1089/tmj.2013.0357.
T2	Caring Letters for Military Suicide Prevention: A Randomized Controlled Trial	Enrollment and participation is still ongoing. Too soon for main outcome findings. Some preliminary manuscripts: • Luxton, D. D., Thomas, E. K., Chipps, J., Relova, R. M., Brown, D., McLay, R. & Smolenski, D. J., (2014). Caring Letters for Suicide Prevention: Implementation of a Multi-Site Randomized Clinical Trial in the U.S. Military and Veteran Affairs Health care Systems. Contemporary Clinical Trials, 37. (2) 252-260. doi: 10.1016/j.cct.2014.01.007. New York: Oxford University Press. Other Publications from other projects that relate to this topic: • Luxton, D. D. (in press). Caring letters for military suicide prevention. In Sullivan, James, & Bongar (Eds.) The Oxford Handbook of Suicide in Military and Veteran Populations. • Luxton, D. D., June, J. D. & Comtois, K. A. (2013). Can post-discharge follow-up contacts prevent suicide and suicidal behavior? A review of the evidence. Crisis, 34 (1), 32-41. doi:10.1027/0227-5910/a000158.
T2	JBLM DoDSER Control Study	Enrollment and participation is complete. Results are in press.

T2	Evaluation of the Self-Directed Violence Classification System for Classification of Suicide Events Reported in the Defense Department Suicide Event Report	Study closed and two manuscripts published.