Fiscal Year 2019

U.S. Army Medical Materiel Development Activity
(USAMMDA)

Summary of:
Annual Historical Report

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SECTION 1: MISSION

Mission:

Develop and deliver quality medical solutions to protect, treat, and sustain the health of our Service Members.

Ethos:

UNITED in SERVICE to our Nation’s Warfighters.

SECTION 2: COMMANDER'S COMMENTS

In June 2019, I proudly assumed command of the U.S. Army Medical Materiel Development Activity. Despite the amount of change that was taking place throughout the Army, our organization experienced continued success with regard to the military medical products and devices that we are developing for our Warfighters worldwide. Without question, our USAMMDA team is dedicated to protecting and preserving the lives of our nation's Warfighters, and we will do whatever it takes to ensure their safety remains a top priority. As always, we realize our military forces depend on our organization to provide effective medical solutions that enhance the readiness of our Servicemen and –women, and we can never fail in this task.

This past year, as part of the U.S. Army's realignments, we were pleased to welcome additional team members from the U.S. Army Medical Materiel Agency. Dr. Tyler Bennett and his group formed the Warfighter Deployed Medical Systems Project Management Office, charged with oversight of the medical materiel database to ensure the standardization and availability of critical materiel for our military. Composed of two product management offices, Medical Device Assemblage Management and Medical Modernization, the WDMS PMO manages medical sets, kits, and outfits and ensures these items are procurable, maintainable, and sustainable for the warfighter.

While the WDMS PMO provided a new office for USAMMDA, its name was part of the PMO renaming effort which occurred during the summer of 2019. With this update, our Force Health Protection Division remained unchanged, while the PMO names became:

- Warfighter Brain Health PMO (formerly Neurotrauma and Psychological Health)
- Warfighter Expeditionary Medicine and Treatment PMO (formerly Combat Trauma and Acute Rehabilitation)
- Warfighter Health, Performance and Evacuation PMO (formerly Medical Systems Support and Evacuation
- Warfighter Protection and Acute Care PMO (formerly Pharmaceutical Systems)

Our organization is pleased with the success garnered by all of our PMO teams and Force Health Protection Division over the past year. These important accomplishments include our WBH PMO's establishment of multiple Cooperative Research and Development Agreements to develop such technologically advanced products as the "Q-Collar" and the "EyeBOX" for the prevention of Traumatic Brain Injury. The novel Q-Collar is a wearable neck-collar device designed to prevent and/or mitigate mild TBI or concussion in wounded Warriors, while the EyeBOX is intended to measure and analyze eye movements as an aid in the diagnosis of concussion within one week of head injury. Our work on these two novel products highlights USAMMDA's continued effort to prevent or reduce the number of TBI incidents among our Warfighters throughout the world.

Our WDMS PMO oversaw the contract award for a new joint-deployable 64-slice computed tomography scanner to replace the current CT scanner, which is now obsolete. The new CT scanner will provide our military with a non-invasive, cross-sectional imaging system that enhances the field surgeon's ability to diagnose wounded Warfighters in a deployed setting at the field hospital. Speaking of our field hospitals, our WDMS team has been focused on the Army's critical Hospital Center conversion project, which is a full-scale effort to transform current Combat Support Hospitals, both within and outside of the United States, to the Hospital Center configuration. This new structure will allow our wounded Warfighters to receive emergency and/or hospital treatment close to the point-of-injury, which will help them return to battle, or stabilize their conditions before evacuation from theater.

During the past year, our WEMT PMO began clinical trials with a commercial partner for the ResQFoam product, which is the primary candidate for our Non-compressible Hemorrhage Control program. Other than definitive surgery, currently there is no solution to address non-compressible torso hemorrhage, commonly known as "bleeding out," which is the leading cause of potentially survivable death on the battlefield. We hope to save the lives of both military and civilian patients with this product. With regard to its Extremity Injury Repair–Vascular program, the WEMT PMO aims to create a solution to repair blood vessels, by restoring blood circulation to extremities with a product that requires minimal preparation, resists infection and is useable by any type of surgeon — providing a more effective method in mass casualty events compared to the current standard of care. The team's lead candidate for its EIR-V program is the Human Acellular Vessel. In 2019, under a compassionate-use Investigational New Drug application approved by the U.S. Food and Drug Administration, the HAV was used twice to save the limbs of retired veterans. Truly, this was an amazing story!

In an age of ever-advancing smart phone applications that make our lives easier, our WHPE PMO team successfully deployed two unique mobile apps, which can be used on both iOS and Android devices to help support our Warfighters in the field. The Altitude Readiness Management System (ARMS) mobile app provides squad leaders with the ability to plan, monitor and manage unit altitude sickness risk, and predict task performance. The app displays acclimatization status, aids in acclimatization to high altitudes, and provides suggestions to prevent altitude sickness to ensure mission success. The Soldier Water Estimation Tool mobile app is used to anticipate the amount of water needed to sustain Soldier hydration (in liters per hour), and also seeks to minimize the volume of water that needs to be carried. This novel app will assist Infantry Units in mitigating and avoiding heat injuries, and help avoid the consumption of too much water (hyponatremia).

During 2019, our WPAC PMO continued its outstanding work with the FDA-approved malaria prophylactic drug Tafenoquine. Tafenoquine prevents mission-degrading illness, prolonged convalescence, development of chronic symptoms (recurring fever) in deployed troops, and optimizes performance, ensuring the Warfighter can remain in the fight by providing protection from malaria. The WPAC team also moved forward with its development of a U.S.-based freeze-dried plasma product, with its submission of the first part of the FDP rolling Biologics License Agreement to the FDA last spring. The success of this submission was critical in helping advance an FDA-approved FDP product forward of Role of Care 2 and closer to the point-of-injury, which may enable life-saving administration of this anti-hemorrhage therapy to begin sooner on the battlefield.

In July 2019, under the Department of the Army, the USAMMDA Force Health Protection Division and the U.S. Army Medical Research Institute of Infectious Diseases signed an Exclusive Licensing Agreement granting within a field of use, a royalty-bearing, revocable biological materials license for MP-12, which is a live attenuated Rift Valley Fever virus vaccine candidate, to Sabin Vaccine Institute. As there is no currently licensed vaccine to protect against RVF, this vaccine development and licensure project will help support our deployed troops, as well as public health efforts for the civilian population, in regions where RVF is endemic. Again, we continue to work tirelessly to make sure our Warfighters are healthy and ready to fight, wherever the fight may be.

As we begin to celebrate the 35th anniversary of our organization's establishment, we are extremely proud of these, and our many other accomplishments. Our USAMMDA team remains dedicated to the mission, and to our Warfighters — and we refuse to be complacent. We acknowledge the changing landscape of the battlefield, and the ways in which wars are fought today. When it comes to materiel solutions to keep our military strong, ready and in the fight, we are always looking ahead, to satisfy their critical requirements. We need our Warfighters, and they need us.

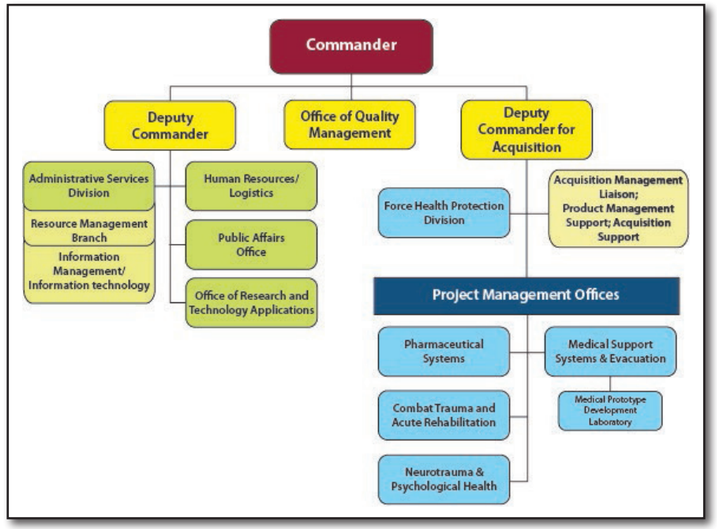
I am honored to work with this great organization. We have one of the best missions within the Department of Defense, as our solutions ultimately help to protect and save the lives of our men and women in the field. Our whole team — military, civilian and contractor personnel — is dedicated to making it all happen, and our team is among the very best throughout the Army.

I am sure everyone is looking forward to another great year, as we continue to support our nation's priorities. We must remain poised and committed to the task at hand, while continuing to remain one step ahead of our adversaries. Although our national military strategy may change, saving lives will always be the key to the strength and success of our country. Our Warfighters will continue to ask for our help, and we will continue to provide whatever they may need.

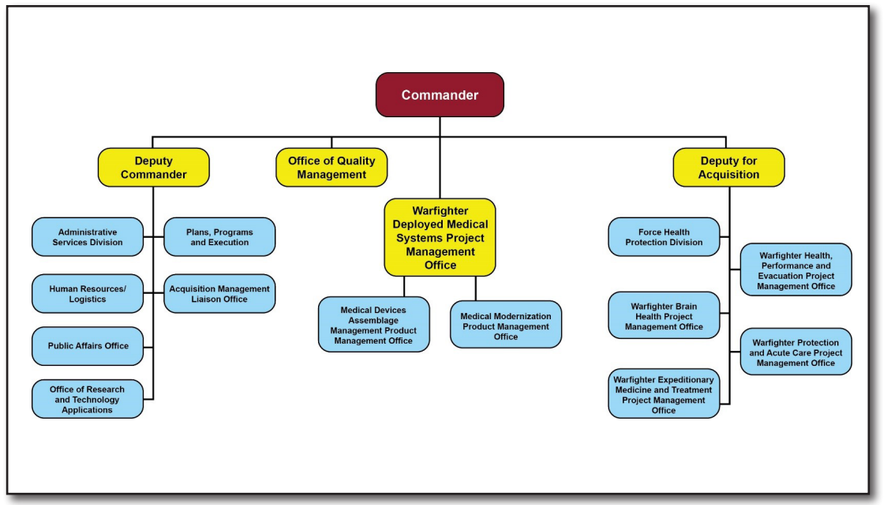
At USAMMDA, we save lives with everything we do, each and every day!

COL Gina E. Adam, Commander
USAMMDA

SECTION 3: ORGANIZATION CHARTS



FY19 Organization chart from October 1, 2018, to June 30, 2019.



FY19 Organization chart from July 1, 2019 to September 30, 2019.

SECTION 4: OFFICE OF RESEARCH AND TECHNOLOGY APPLICATIONS

Office of Research and Technology Application

USAMMDA was granted Laboratory status on January 3, 2007, in a memo from Dr. Claude M. Bolton, Jr., 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 as the advanced medical materiel activity.

FOCUS AREAS:

- The USAMMDA Office of Research and Technology Application Chief and staff are part of the Office of Commander and report directly to the Commander for technology transfer/agreement efforts. They are supported by the USAMRDC ORTA, and by the USAMRDC Office of the Staff Judge Advocate.

- The ORTA supports all USAMMDA medical product development PMOs, executive agency staff, USAMRDC Office of Regulated Activities and the USAMRDC Headquarters agreement requirements.

- USAMMDA successfully initiates, drafts and negotiates to execution many technology transfer agreements with domestic and foreign industry partners, and universities to collaborate in advanced medical product development towards U.S. Food and Drug Administration product licensure and product commercialization to benefit and support Service Members.

ACCOMPLISHMENTS:

1) A total of 173 new Technology Transfer and Interagency Agreements were executed in FY19. In-kind industry partner contribution for the FY was estimated at $10 million.

2) USAMMDA has an approximate total of 377 active agreements. These include Cooperative Research and Development Agreements, Memorandums of Understanding, Memorandums of Agreement, Material Transfer Agreements, Interagency Support Agreements, Interagency Agreements, Nondisclosure Agreements, Patent License Agreements, Over-arching Agreements, and Individual Investigator Agreements.

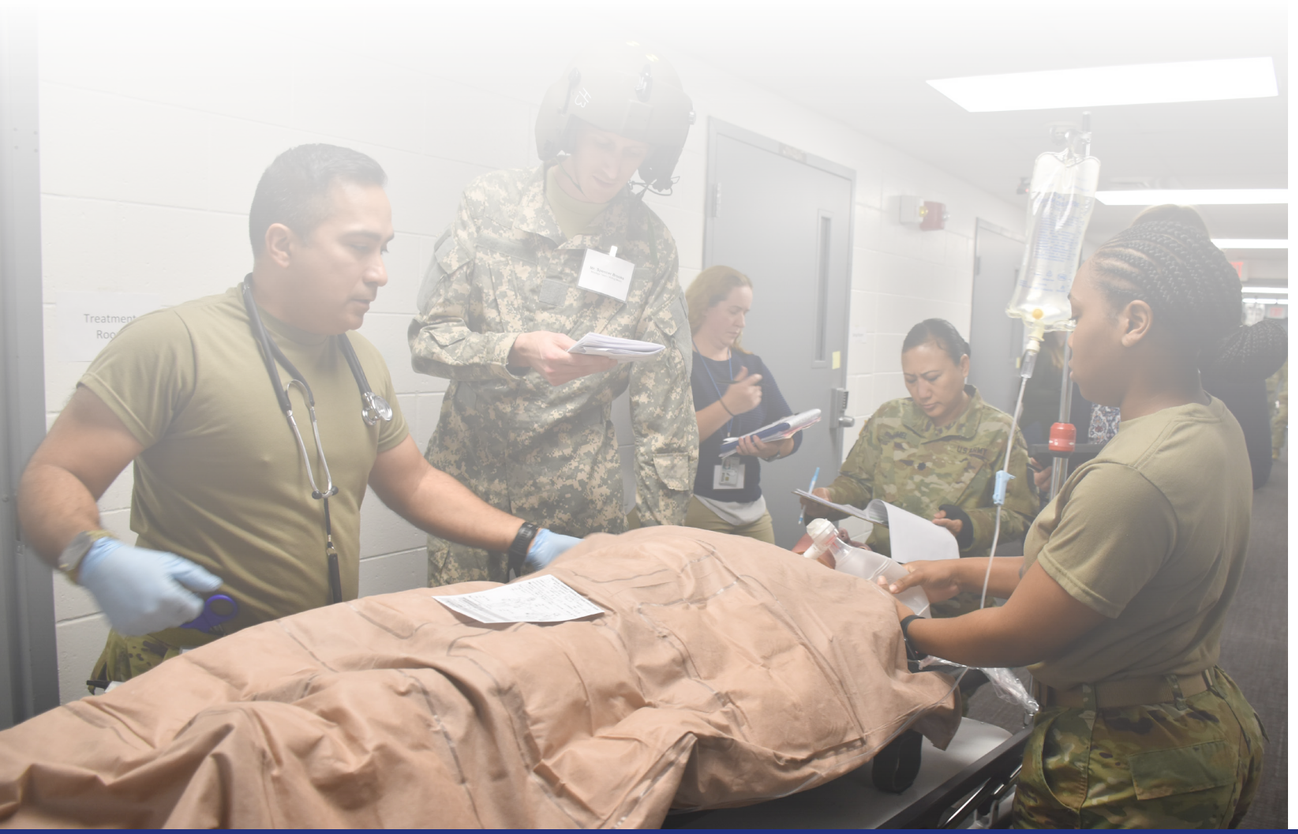
PARTNERSHIPS:

- Amivas – IV AS: In 2017, the CRADA partnership with Amivas was established for the development of Intravenous Artesunate, which is for the initial treatment of severe and complicated malaria. The U.S. Army's intellectual property has assisted in Amivas to continue development and treatment by collaborating together to file a U.S. FDA-approved product for treatment in U.S. military and civilian populations. This CRADA partnership has resulted in an Exclusive royalty-bearing license agreement between both parties.

- 60 Degrees Pharmaceuticals – Tafenoquine: In 2014, the CRADA partnership with 60 Degrees Pharmaceuticals was initiated to develop, manufacture, and commercialize tafenoquine, which is a highly effective weekly malaria prophylactic drug. TQ has superior efficacy and safety profile compared to other drug treatments in the commercial marketplace, such as mefloquine, doxycycline, or malarone. This CRADA partnership has resulted in a U.S. FDA-approved (August 2018) product that is available for use in the civilian population. USAMMDA and 60 Degrees are currently working through the life cycle management and logistics in preparation for use in the U.S. military population. This partnership has also led to an exclusive royalty-based Patent License Agreement between both parties.

- Appili License Agreement - Appili Therapeutics Inc. is a pharmaceutical company focused on the acquisition and development of novel treatments targeting unmet needs in infectious disease. Appili currently has three major programs in its portfolio: ATI-1501, a taste-masked oral-suspension of metronidazole; ATI-1503, a novel antibiotic for Gram-negative bacterial infections; and ATI-1701, a vaccine for F. tularensis, the causative agent of tularemia and a bioterrorism threat. They have licensed the Army's regulatory and clinical data package for topical paromomycin. They are further developing the product with the goal of U.S. FDA licensure in the future.

- Q30 Sports Science – TBI: Q30 Sport Sciences is a device manufacturer with a uniquely developed device focused on protection against mild traumatic brain injury caused by head impacts. This is a one-of-a-kind device that is a preventative to the impacts of concussions. After an initial round of discussions between the Partner and USAMMDA, our Program manager agreed to use this device under a CRADA partnership for a round of small studies with Warfighters, for form, fit and function. If these studies are successful, the ultimate goal will be to complete the necessary research to bring this product through full FDA approval and to the marketplace for all to use.



SECTION 5: ORGANIZATIONAL NARRATIVE

The Army optimizes the medical logistics enterprise to build and sustain medical readiness in support of individual Soldiers and combat formations. Effective October 01, 2018, U.S. Army Medical Research and Materiel Command, to include its research, operational medical logistics functions and associated personnel, was reassigned from U.S. Army Medical Command and assigned to U.S. Army Materiel Command to consolidate all sustainment functions under one Army Command to support the Army's Title 10 requirements. This was the first step of the re-alignment. The next step was the complete transfer of USAMRMC medical research, development, acquisition and other relevant functions to Army Futures Command effective June 01, 2019. During this step, USAMRMC was renamed U.S. Army Medical Research and Development Command.

USAMMDA is the primary medical product development, systems management and acquisition organization within the Department of Defense and is responsible for meeting medical developmental requirements, as well as sustaining deployable medical capabilities for the Warfighter throughout the Army and other military services.

Prior to March 2019, USAMRDC's acquisition mission was shared by two of its subcommands – the USAMMDA and the U.S. Army Medical Materiel Agency. As part of the transition, the acquisition and program management teams at USAMMA were moved to USAMMDA.

By the end of February 2019, three Project Management Offices within USAMMA were combined and realigned to USAMMDA as the new PMO for Deployed Medical Systems. PMO DMS consists of two Product Management Offices: Medical Device Assemblage Management and Medical Modernization. These changes were made to improve delivery of medical equipment and more closely align to the structure of other Army PMOs.

As the Army's medical product development activity, USAMMDA's products are designed to protect and preserve the lives of Warfighters. USAMMDA develops new drugs, vaccines, devices, and medical support equipment that enhance readiness, ensure provision of the highest quality medical care to the DOD, and maximize survival of medical casualties on the battlefield. The organization is responsible for the Life Cycle Management of medical products is are accountable for the implementation, management and oversight of all activities associated with the development, production, sustainment and disposal of medical systems across the lifecycle.

USAMMDA develops and fields medical products for the U.S. Armed Forces in conjunction with the Health Readiness Center of Excellence (the combat developer), USAMMA (the logistician), and other service input.

USAMMDA project managers guide the development of medical products for the U.S. Army Medical Department, other U.S. Services, the Joint Staff, the Defense Health Agency, and U.S. Special Forces community. The process takes promising technology from DOD, industry, and academia to U.S. Forces, from the testing required for U.S. Food and Drug Administration approval or licensing, to fielding and sustainment of the finished product.

USAMMDA accomplishes its mission by exercising two core capabilities:

- Providing program management for USAMRDC medical product development, systems management and acquisition through project management, medical devices assemblage management and the modernization of medical equipment.

- Serving as the Health Affairs Lead Service for Investigational New Drug treatment, prophylaxis and diagnostic capabilities (Force Health Protection Division).

PROJECT MANAGEMENT

The USAMMDA Project Management Offices provide coaching and mentorship to companies or investigators in order to mitigate risks during development, to optimize regulatory and business strategies, and to advance the product to the clinic, and our Warfighters, as quickly as possible. This is accomplished by cultivating relationships with military, academia and industry, and by leveraging Service laboratories to ensure that wounded Warfighters have the right medical solutions at the right places in the field, and ultimately through all Roles of Care. In June 2019, USAMMDA's five PMOs were renamed to highlight the Warfighter as the main focus, and to convey more accurately the specific mission of each. The revised PMO names are:

- **Warfighter Brain Health PMO** (Formerly Neurotrauma & Psychological Health): The WBH PMO leads the development and acquisition of materiel products to Warfighters suffering from brain injuries and psychological health issues. The mission of the WBH PMO is to develop and field FDA-approved medical solutions across the continuum of care that aid in the detection, protection, sustainment, prevention and treatment of neurotrauma and psychological health conditions, such as traumatic brain injury, post-traumatic stress disorder and suicide.

- **Warfighter Deployed Medical Systems PMO**: Formed in April 2019, the mission of the WDMS PMO is to develop, deliver and sustain deployed medical capabilities for the Warfighter. The WDMS PMO is comprised of a team of experts in DOD acquisition and project management, clinicians, scientists and technical support personnel. The WDMS PMO accomplishes its mission through two product management offices:

  - Medical Devices Assemblage Management: The MDAM product management office oversees all Army medical unit assemblages by providing acquisition lifecycle management of Class VIII medical equipment, unit assemblages, devices and ancillary medical items to support human and animal patient care.

  - Medical Modernization: The Medical Modernization product management office develops, procures and manages the modernization of medical devices to enhance the readiness and lethality of the Warfighter.

- **Warfighter Expeditionary Medicine and Treatment PMO** (Formerly Combat Trauma and Acute Rehabilitation): The WEMT PMO leads the development and fielding of FDA-cleared or -approved medical devices, drugs, and biologics that fulfill the unmet requirements identified by the Service end-user. Focus areas include hemorrhage detection and control, extremity injury repair, combat burns and wounds, multi-organ support, extremity injury repair, sensory systems acute treatment and imaging devices. These solutions can be a new capability development effort or an improvement upon existing capabilities.

  Our team of experts includes DOD acquisition and project management professionals, clinicians, engineers, scientists and entrepreneurs who work together to search for innovative diagnostic and therapeutic solutions to address unique, and sometimes catastrophic injuries sustained by our Warfighters. The WEMT PMO addresses challenges to medical product innovation through two lines of effort: 1) Product Development and 2) Biomanufacturing Innovation.

- **Warfighter Health, Performance and Evacuation PMO** (Formerly Medical Support Systems & Evacuation): The WHPE PMO develops, tests and fields medical evacuation, field hospital infrastructure, combat casualty care support, Soldier optimization, and operational and preventive medicine solutions for the Service Member. The office collaborates with the Army Medical Department, Army Program Executive Offices, the Defense Health Agency, Joint PEO Chemical & Biological Defense, Training and Doctrine Command, and the Armed Forces Pest Management Board for integration of medical support products on ground, air, and Soldier platforms.

  As an enabler of solutions for transition, the Medical Prototype Development Laboratory within the WHPE PMO rapidly designs and builds prototype medical systems, and hardens commercial off-the-shelf products for use in the field environment. 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 USAMRDC resource is instrumental in providing prototype design, fabrication, and evaluation/testing, as well as fixes for products, components and systems.

- **Warfighter Protection and Acute Care PMO** (Formerly Pharmaceutical Systems): The WPAC PMO leads the development and fielding of pharmaceutical and biological products – drugs, vaccines, diagnostics, protective and therapeutic modalities – for use against infectious diseases and similar products for combat casualty care. The office works 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 FDA and the U.S. Environmental Protection Agency. The WPAC PMO accomplishes its mission through the establishment of partnerships with industry (foreign and domestic), other governmental agencies (within and outside of the United States) and academia.

Force Health Protection Division

The Force Health Protection Division is a Lead Service under Health Affairs. FHP develops and manages protocols for biological threats that are naturally occurring, accidental or intentionally released. The office provides an urgent treatment capability using novel investigational countermeasures to protect U.S. Forces against manmade or natural threats in accordance with federal regulations and DOD instructions. Another capability of FHP is interim fielding of DOD's promising IND products as treatment protocols for our Warfighters until the products have been licensed by the FDA. The mission of the FHP is to provide a safe and compliant program to protect U.S. Forces using IND countermeasures; provide logistical support for the unique requirements for acquisition, storage, shipping and testing of investigational countermeasures; and deploy investigational countermeasures in support of military commanders or civilian authorities.

PART I: PROJECT MANAGEMENT OFFICES
CHAPTER ONE

Warfighter Brain Health

The Warfighter Brain Health PMO (formerly known as Neurotrauma and Psychological Health PMO) was formed in May 2011 to support the advanced development of materiel products to protect, sustain and care for Service Members with neurotrauma, including TBI and psychological health concerns. The mission of the WBH PMO is to develop and deliver brain health medical solutions, across the continuum of care, that aid in the detection, prevention, and treatment of neurotrauma and psychological health of our Service Members and Veterans.

The WBH PMO leverages program and project management, medical subject matter, and DOD acquisition expertise to drive research and development activities relevant to the development of medical materiel products to protect, sustain, restore and care for Service Members and Veterans suffering from injuries caused by TBI and traumatic events. The Military Operational Medicine, Combat Casualty Care, and Clinical and Rehabilitative Medicine Program Area Directorates look to the WBH PMO for advanced development expertise and strategic guidance during the early phases of the research, development and acquisition process.

According to the Congressional Research Service, TBI and PTSD present significant health and quality-of-life problems that affect over 400,000 Service Members, Veterans and their families. According to the 2008 RAND Corporation report, the prevalence of PTSD among Service Members previously deployed to Afghanistan in support of Operation Enduring Freedom, and to Iraq in support of Operation Iraqi Freedom is 13.8 percent; the national civilian incidence rate is 6.8 percent.

ACCOMPLISHMENTS:

1) **Traumatic Brain Injury Prevention – Q-Collar**

The Q-Collar is being developed through a Cooperative Research and Development Agreement with Q30 Innovations, Inc, in Westport, Connecticut. This collaboration enables the WBH PMO to independently assess a novel, wearable neck-collar device designed to prevent and/or mitigate mild TBI or concussion in U.S. Service Members. The test results will inform future acquisition strategy development by identifying feasibility of use within the U.S. Military. Furthermore, the tests will identify any necessary modifications prior to the use by U.S. Service Members. If the Q-Collar proves to be suitable, safe, and effective, it could substantially reduce the incidence of concussion in garrison as well as in theater.

Figure 1.1. Q-Collar.

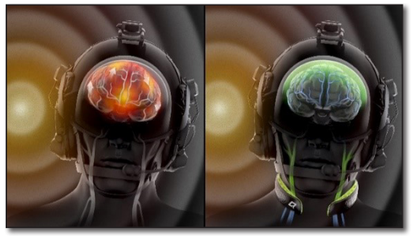


Figure 1.2. Blast wave without Q-Collar (left); blast wave with Q-Collar (right).

2) **Traumatic Brain Injury Prevention – EyeBOX**

Oculogica, Inc., a CRADA partner, received FDA De Novo approval for classification of the EyeBOX system as a Class II Traumatic Brain Injury eye movement assessment aid in December 2018. The EyeBOX is intended to measure and analyze eye movements as an aid in the diagnosis of concussion within one week of head injury in patients five through 67 years of age in conjunction with a standard neurological assessment of concussion. This technology candidate is being tracked as a candidate under the Non-Invasive Neuro Assessment Device program.

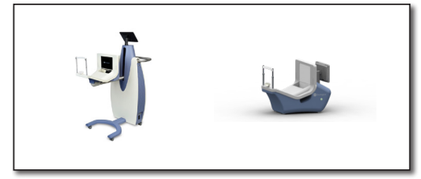


Figure 1.3. FDA-approved EyeBOX device.

3) **Post-traumatic Stress Disorder Drug Treatment – Psychometric Evaluation of the Clinician Administered PTSD Scale for Diagnostic and Statistical Manual of Mental Disorders [DSM]-5 (CAPS-5) and the PTSD Symptom Scale Interview for DSM-5 (PSSI-5) in an Active Duty and Military Veteran Sample**

This study began participant enrollment in April 2019 and the outcomes will inform test and evaluation of drug treatments for PTSD in Service Members. Study partners include Cincinnati Veterans Affairs Medical Center, Tripler Army Medical Center, Walter Reed National Military Medical Center, and Boston Veterans Affairs Healthcare System. The study will eliminate the lack of understanding of clinical assessment tools (e.g., CAPS-5) that are currently widely used as symptom severity measures for clinical trial entry criteria and outcome measures in a military population by evaluating the psychometric properties of the CAPS-5 and PSSI-5 assessment tools in active-duty military personnel and Veterans, and will compare the CAPS-5 to the previous gold-standard tool, the CAPS-IV. Biomarkers believed to be related to PTSD (e.g., biofluid biomarkers, cognitive and physiological markers, and neural activity as measured by electroencephalogram) will be collected to inform future targeted interventions in specific groups of patients and support other large-scale biomarker discovery efforts in the field.

4) **Traumatic Brain Injury Identification – User forum to identify unmet needs in the clinical management of TBI in the deployed setting**

The goal of the forum was to gather information from end-users to better inform the Non-Invasive Neuro Assessment Device and TBI-Point of Injury programs acquisition strategies and ensure the alignment of product development efforts with the most critical user needs. WBH PMO staff identified two significant areas of development that would aid medical providers in the triage and treatment of TBI in Service Members: Diagnosis/identification/triage of moderate to severe of TBI at Role 1/Role 2, and Return-to-Duty decisions for suspected mild TBI, primarily in training, garrison/Role 4, and possibly Role 3.

5) **TBI Treatment – Limited User Testing of the Banyan Biomarkers Brain Trauma Indicator™ (BTI) benchtop assay system**

The WBH PMO, with its partners, Banyan Biomarkers, Womack Army Medical Center, and the Defense and Veterans Brain Injury Center, employed LUT to assess the feasibility of incorporating this test into clinical care, to assess provider and technician proficiency as well as address provider and technician education needs. This assessment is the first-ever installation of a TBI blood test into DOD's Military Health System, and serves as a critical step in the delivery of blood-based biomarkers for TBI evaluation. The outcomes of this assessment will inform the development and acquisition of future TBI biomarker products for forward ROC.

Figure 1.4. Banyan BTI™.

6) **TBI Treatment – Phase 3 clinical trials to develop a field-deployable whole blood assay TBI**

The WBH PMO awarded Abbott Point of Care Inc. a $35 million contract to develop, though the conduct of phase 3 clinical trials, a field-deployable whole blood assay TBI. This development effort is focused on development of the assay, but will leverage the modernization of the currently fielded i-STAT device as it transitions to the modernized i-STAT Alinity. Initially, the i-STAT TBI assay will be validated in plasma by utilizing remaining clinical trial samples from the Banyan effort; enabling FDA clearance in 2020. In parallel, the i-STAT TBI whole blood assay will be validated in a prospective study with FDA clearance anticipated in 2021. The whole blood assay will provide advantages to medical personnel through eliminating the need to spin-down blood samples, including: reduced logistical burden, use in forward roles of care and provision of results within 15 minutes of blood sample acquisition. The development of a whole blood TBI assay will provide a vital readiness capability to Warfighters, enabling lethality through preservation of combat power.

Figure 1.5. Abbott i-STAT Alinity Point of Care devices and assay cartridge.

7) **TBI Treatment – TBI DT agreement awarded for TRACK-TBI NET**

The TBI DT agreement was awarded through the Medical Technology Enterprise Consortium in September 2018 to the University of California-San Francisco for TRACK-TBI NET. Executing multiple Phase 2 clinical trials to fully characterize TBI drug candidates and to identify those with the best chance for success in a Phase 3 trial. Selected TBI drug candidates' industry sponsors will be invited to participate in an Industry Day prior to further consideration or final selection for partnership. This effort will result in an FDA-approved commercial drug product to treat TBI acutely in MTFs as well as far forward Roles of Care.

CHAPTER TWO

Warfighter Deployed Medical Systems

The Warfighter Deployed Medical Systems PMO provides leadership oversight and integration of the separate PMOs involved with advanced technology and introduction of a myriad of products for the medical treatment facilities and operational forces. With oversight of two distinct product management offices, Medical Devices Assemblage Management and Medical Modernization, the WDMS PMO is the focal point for materiel life cycle management in the Army.

The WDMS PMO exists to advance medical acquisition project management as part of the USAMMDA missions, and to provide technical expertise up, down, and across the USAMRMC acquisition domain. The WDMS PMO oversight and management responsibilities span the transition of products from the science and technology community, through advanced development and into sustainment arenas.

The MDAM team provides acquisition lifecycle management of medical equipment, unit assemblages, devices and ancillary medical items to support human and animal patient care, ensuring that the Warfighter has the necessary equipment and materiel to meet their assigned missions. Its mission is critical to the success of current and future field medical treatment from the Army's Roles of Care 1 to 3.

The mission of the Medical Modernization office is to provide and manage required medical capabilities through continuous analysis, test and evaluation, and acquisition of medical materiel. In FY19, Medical Modernization Assistant Product Managers researched, procured, and implemented numerous technological upgrades to the existing portfolio of medical devices utilized throughout ROC 1-3 in support of Service Members worldwide.

ACCOMPLISHMENTS:

1) **Hospital Center Conversion**

Thirteen of 24 Hospital Centers were equipped in FY19. Hospital Centers provide increased trauma care capability and offer a wider range of modular clinical capabilities than the legacy Combat Support Hospital. Wounded Warfighters receive emergency/hospital treatment close to the point-of-injury, allowing the Warfighter to return to the fight, or to stabilize the condition before transport to a Medical Treatment Facility, therefore playing a role in Soldier Lethality.

Figure 2.1. 10th Field Hospital, Fort Carson, Colorado, conducts Field Training Exercise to demonstrate Hospital Center capabilities in conjunction with the Medical Oxygen Concentrator assessment conducted by Medical Modernization PMO, USAMMDA.

2) Computed Tomography Scanner

A contract was awarded for a new 64-slice CT scanner in May 2019. The test plan and lifecycle sustainment plan are in progress, and procurement is estimated to occur in the first quarter of FY21. The joint deployable CT scanner replaces the current CT, which is now obsolete, and provides a non-invasive, cross-sectional imaging system that enhances the field surgeon's ability to diagnose wounded Warfighters in a deployed setting at the field hospital. Failure to provide a replacement device causes the loss of a critical imaging modality used to diagnose possible internal trauma experienced by a wounded Warfighter, resulting in unwarranted morbidity or death.

3) Forward Resuscitative Surgical Team Conversion

In FY19, 31 of 46 FRSTs were equipped. FRSTs are strategically placed in areas between the point-of-injury and higher Roles of Care to provide surgical and resuscitative capabilities. The addition of the resuscitative function allows for the FRST to provide prolonged field care, increasing stabilization of the Warfighter in accordance with the concept of Multi-Domain Operations.

4) Hamilton T1 Ventilator Fielding to CENTCOM

The Hamilton T1 Ventilator contract was re-awarded on July 19, 2019. Thirty devices were procured on July 31, 2019, for the 8th Army. In June 2019, CENTCOM raised an urgent patient safety risk with obsolete ventilators in the field. The Medical Devices Assemblage Management office secured funding through an unfinanced requirement, and purchased 54 Hamilton T1 ventilators to replace unsafe equipment with estimated delivery date of November 2019. Fielding the ventilators to CENTCOM will improve patient care and alleviate patient safety risk. An operational ventilator is vital for critical care patients, and remains the difference between life and death.

5) Vital Signs Monitor

In June 2019, market research for the vital signs monitor was completed. The vital signs monitor is capable of relaying critical information regarding patient vitals to healthcare providers via non-invasive means. The item is for patient monitoring and is used for emergency land and air transport. The vital signs monitor is critical to the assessment of the patient in order to return them to the fight.

CHAPTER THREE

Warfighter Expeditionary Medicine and Treatment

Our mission in the Warfighter Expeditionary Medicine and Treatment PMO is to develop and deliver U.S. FDA-cleared or approved medical devices, drugs, and biologics that fulfill the unmet requirements of Service end-users, either through development of a new capability or by improving upon existing capabilities. The WEMT PMO's team of experts includes DOD acquisition program management professionals, clinicians, engineers, scientists, and entrepreneurs who work together to search for innovative diagnostic and therapeutic solutions to address unique, and sometimes catastrophic injuries sustained by our Warfighters.

To prepare for the next fight, we must improve the resiliency and survivability of our Warfighters, as they are the military's most valuable capability. During large-scale combat operations in a multi-domain environment, preservation of life is essential to maintaining this critical capability. Translating this into the acquisition paradigm, the Warfighter becomes our "system." Our programs cover this gamut, touching every system of the human body. However, in the process of developing products that address specific conditions, the solutions that are pushed forward must align with the needs of the whole "system."

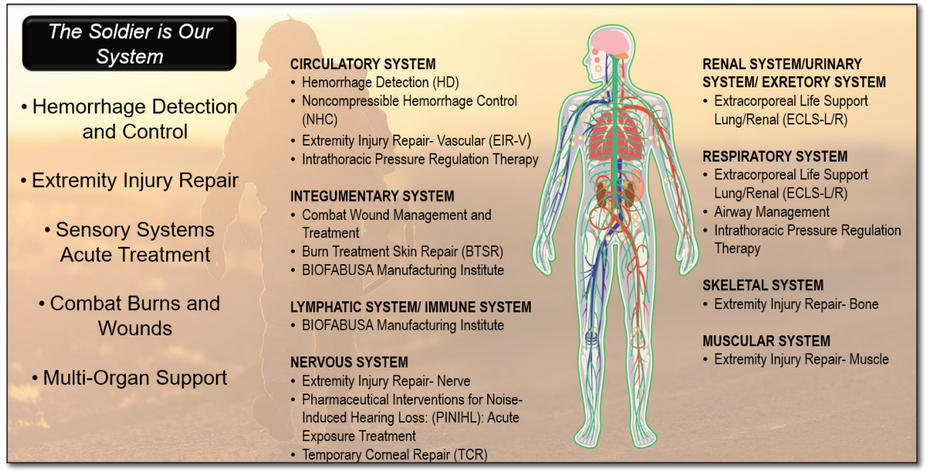


Figure 3.1. The Soldier is Our System

ACCOMPLISHMENTS:

1) ResQFoam

The Secretary of the Army signed the Exception From Informed Consent waiver in order to begin clinical trials for Arsenal Medical Inc. ResQFoam, the lead candidate for the Noncompressible Hemorrhage Control program. Other than definitive surgery, there is no solution to address non-compressible torso hemorrhage, which is the leading cause of potentially survivable death on the battlefield. This clinical trial, and subsequent potential approval of this device, could save the lives of military and civilian patients who would otherwise bleed to death.

Figure 3.2. Arsenal Medical ResQFoam™

2) Humacyte Human Acellular Vessel

The Extremity Injury Repair-Vascular's program lead candidate, Humacyte Human Acellular Vessel, was added to the Medical Product Acceleration Committee list to accelerate the program by potentially leveraging other Real World Evidence. In 2019, the HAV was used twice under a compassionate-use Investigational New Drug application approved by the FDA to save the limbs of retired veterans. The EIR-V program aims to create a solution to repair blood vessels, restoring blood circulation to extremities that requires minimal preparation, resists infection and is useable by any type of surgeon; allowing it to be a more effective solution in mass casualty events compared to the current standard of care.

Figure 3.3. Humacyte Human Acellular Vessel.

3) Major Contract Action: Temporary Corneal Repair Program

The Temporary Corneal Repair Program was able to leverage investments from the Congressionally Directed Medical Research Programs and transfer contract management of the University of Southern California's device to preserve vision after traumatic injury (contract value $3.2 million). In multi-domain operations when evacuation will be delayed or resources limited, it will be critical to non-surgically stabilize these injuries in order to restore vision to wounded Warfighters.

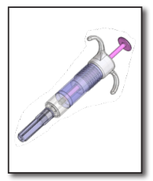


Figure 3.4. Device to preserve vision after traumatic eye injury.

4) Major Contract Action: Pharmaceutical for Induced Noise Hearing Loss

The Pharmaceutical for Induced Noise Hearing Loss program awarded a $7.2 million contract to University of Washington, for a drug to minimize hearing loss in Service Members after a noise-induced injury. Currently, no FDA-approved drug exists to prevent or treat hearing loss. Hearing is critical to Service Members during combat operations, comprising 50 to 60 percent of one's situational awareness.

CHAPTER FOUR

Warfighter Health, Performance and Evacuation

The Warfighter Health, Performance and Evacuation PMO is a multidisciplinary team with broad mission capabilities for the advanced development of medical products for the U.S. Army and the Defense Health Agency. The WHPE PMO's mission is to develop, procure and sustain the best medical evacuation, combat support hospital infrastructure, combat casualty care support, and operational and preventive medicine solutions for the Warfighter.

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 WHPE PMO resides the Medical Prototype Development Laboratory, which designs, creates drawings and technical data packages for, and rapidly prototypes far-forward medical equipment in support of the USAMRDC. 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.

The WHPE PMO supports 12 Unit Assemblages and 25 individual products, in two separate areas, for the USAMRDC 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

Product managers direct program resources and defend program content and structure during science and acquisition forums.

The WHPE 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-based research efforts.

ACCOMPLISHMENTS:

1) Altitude Readiness Management System Mobile Application

The WHPE PMO successfully deployed the iOS version of the ARMS app to the U.S. Army Training and Doctrine Command App Gateway. ARMS is an integrated Mobile App on handheld devices providing squad leaders the ability to plan, monitor and manage unit altitude illness risk, and predict task performance. The app will provide acclimatization status, aid in acclimatization to high altitudes and provide suggestions to prevent altitude sickness to ensure mission success. The ARMS app can now be downloaded to android and iOS smartphones or tablets in addition to the Nett Warrior Market Place. This will allow for a larger user base and

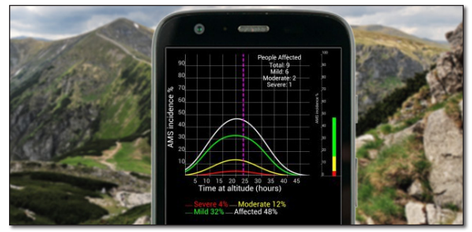


Figure 4.1. Altitude Readiness Management System Mobile App.

accessibility to the ARMS Mobile Apps in order to aid Mountain Warfare tactical units in avoiding troop health issues pertaining to altitude sickness. Partners for this effort include TRADOC Capability Manager – Mobile, U.S. Army Research Institute of Environmental Medicine, and the Massachusetts Institute of Technology – Lincoln Labs.

2) Soldier Water Estimation Tool Mobile App

The WHPE PMO successfully deployed the iOS version of the SWET app to the TRADOC App Gateway. The SWET app is used to anticipate the amount of water needed to sustain Soldier hydration (in liters per hour), while at the same time seeking to minimize the volume of water that needs to be carried. The SWET app can now be downloaded to android and iOS smartphones or tablets in addition to the Nett Warrior Market Place. This will allow for a larger user base and accessibility to the SWET Mobile Application in order to aid and assist Infantry Units in mitigating and avoiding heat injuries as well as the consumption of too much water (Hyponatremia). Partners for this effort include TRADOC Capability Manager – Mobile, USARIEM, and Massachusetts Institute of Technology – Lincoln Labs.

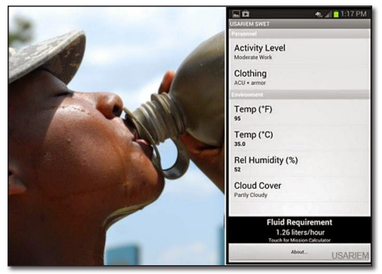


Figure 4.2. Soldier Water Estimation Tool Mobile App

3) Health Readiness and Performance System

The Health Readiness and Performance System is an integrated system of wearable sensors that provides Commanders with actionable information to improve performance and mitigate non-battle injuries during training and operations. It is using an incremental approach with operational capabilities dropped every two years starting in FY22. The first increment focuses on reducing heat injuries with future increments addressing hydration status, alertness, cognition & physical readiness. HRAPS pioneered the first incarnation of a heat strain monitor in training capability to the 75th Ranger Regiment at Ft. Benning, Georgia. It consists of Odic, Inc.'s first generation Heat Injury Prevention Systems, also referred to as the OBAN, which is a chest-strap-based system. The second generation HIPS will be delivered to the 75th Ranger Regiment in 2QFY20 with improved capability that incorporates direct user feedback. Future incarnations will encompass multiple training locations including other service sites.

Concurrently, development of a wearable sensor for use in an operational, tactical environment has begun under an award with the Medical Technology Enterprise Consortium. This patch-based physiological monitoring system (PSM) being developed by LifeLens Technologies, LLC, will meet all operational requirements including monitoring for a 72 hour mission duration. It will be sent to the 75th Ranger Regiment as well as other training and field sites for user feedback and testing.

Partners for this effort include the 75th Ranger Regiment, USARIEM, Massachusetts Institute of Technology – Lincoln Labs, LifeLens Technologies, LLC, Odic, Inc., U.S. Army Combat Capabilities Development Command Soldier Center, and the Georgia Tech Research Institute.

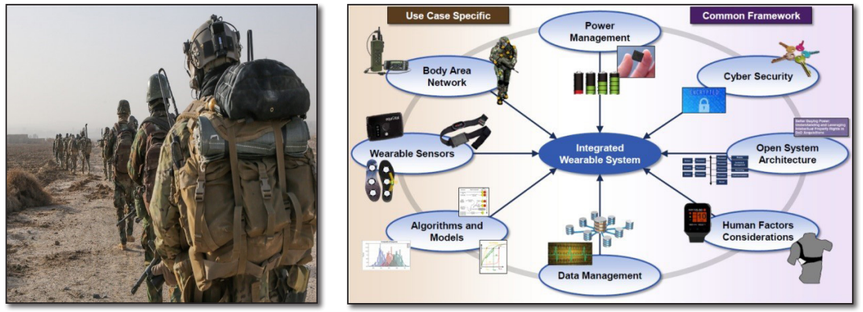


Figure 4.3. HRAPS Integrated Wearable System

Medical Prototype Development Laboratory

The Medical Prototype Development Laboratory is comprised of a small team of engineers and engineering technicians with an 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 USAMRDC. The MPDL is capable of rapidly prototyping medical systems 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.

MISSION

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 USAMRDC 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:

- Functional
- Simple to operate
- Compact
- Lightweight
- Easy to assemble (no tools)
- Interchangeable
- Packaged in a low-volume cube

The MPDL strives to provide innovative designs and quality workmanship. Its 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 Service Member faster.

CHAPTER FIVE

Warfighter Protection and Acute Care

The mission of the Warfighter Protection and Acute Care PMO is to develop and deliver U.S. FDA-approved infectious disease drugs, vaccines, and diagnostics; blood products and components; and drugs for battlefield pain management to protect and sustain the Warfighter. The challenge of the WPAC PMO 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 FDA and the EPA. The WPAC PMO accomplishes its mission through the establishment of partnerships with industry (foreign and domestic), other governmental agencies (United States and Outside the Continental U.S.), and academia. These partnerships range from total U.S. government contracting and funding for the effort, to USAMRDC participation as a "Contract Research Organization" in efforts of mutual interest that will lead to a licensed product available for military use. The WPAC PMO serves as an investor, broker, manager and facilitator for such efforts on behalf of the USAMRDC and the DOD.

Current WPAC PMO efforts focus on the development of drugs for the prevention and treatment of the parasitic disease malaria, the development of vaccines to prevent viral infections (Dengue, HIV and Adenovirus), diagnostics for infectious diseases (e.g., Dengue, Chikungunya virus, diarrheal diseases), and hemorrhage control and resuscitation products such as freeze-dried human plasma and cryopreserved platelets.

ACCOMPLISHMENTS:

1) Malaria Prophylactic Drug – Tafenoquine

Tafenoquine is an FDA-approved weekly prophylactic drug for the prevention of malaria in nonimmune adults with normal enzymatic activity (G6PD). Tafenoquine prevents mission-degrading illness, prolonged convalescence, development of chronic symptoms (recurring fever) in deployed troops, and optimizes performance, ensuring the Warfighter can remain in the fight by providing protection from malaria. 'Fire and Forget' weekly dosing reduces logistical requirements and improved compliance. No other anti-malarial drug offers the same comprehensive protective coverage. The partner in this effort is 60 Degrees Pharmaceuticals, LLC.

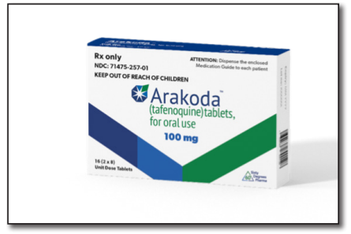


Figure 5.1. Tafenoquine trade name Arakoda.

2) Battlefield Pain Management – Sufentanil NanoTabs

The FDA approved DSUVIA®, a sublingual sufentanil tablet, on November 2, 2018 for acute pain management with support from the USAMRDC and USAMMDA. The sufentanil tablet is only delivered by a healthcare professionals using a disposable, pre-filled, single-dose applicator and administered for the treatment of moderate-to-severe acute pain in a medically supervised setting. DSUVIA®'s approval will ensure additional effective pain relief products are available at, or very close to the point of injury. The partner in this effort is AcelRx Pharmaceuticals, Inc.

Figure 5.2. Sufentanil NanoTabs.

3) Freeze-Dried Plasma

Intrinsik Health Sciences, on behalf of Cooperative Research and Development Agreement partner Vascular Solutions (a wholly owned subsidiary of Teleflex), submitted the first part of the FDP rolling Biologics License Agreement (No. 125702) to the FDA on March 29, 2019 for the limited distribution license under the accelerated approval pathway. Submission of the first part of the FDP rolling BLA is a step closer to being able to position an FDA approved FDP product forward of Role of Care 2 and closer to the point-of-injury, enabling life-saving administration of this anti-hemorrhage therapy to begin sooner on the battlefield. The partner in this effort is Vascular Solutions (a Wholly-Owned Subsidiary of Teleflex).

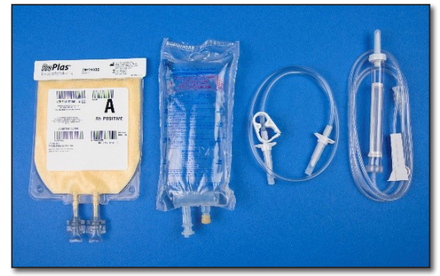


Figure 5.3. Freeze-dried plasma.

PART II: FORCE HEALTH PROTECTION DIVISION

Force Health Protection

The Force Health Protection Division under the responsibility of the Assistant Secretary of Defense (Health Affairs) is the DOD Lead Agent on behalf of the Secretary of the Army as Lead Component, and the Surgeon General of the Army under DOD Instruction 6200.02 for use of an unapproved medical product under an Emergency Use Authorization or Investigational New Drug application in response to man-made or natural threats. The mission of the FHP Division is to provide rapid operationalization to the Warfighter of investigational treatment, diagnostic, or prophylactic options through strategic early equipping against high-consequence threats in accordance with federal regulations and DOD instructions. The team manages critical tasks to provide a safe, compliant program to protect U.S. Forces using IND countermeasures, provide logistical support for the unique requirements of acquisition, storage, shipping, and testing of investigational countermeasures, deploy investigational countermeasures in support of civilian authorities or military commanders, and provide training, program management, FDA-compliant protocols, and regulatory reporting.

COLLABORATION:

On May 23, 2019, FHP and USAMMDA signed the CRADA with The Republic of France, Ministry of Defense, for the processing of therapeutic plasma by the French Military Health Service – French Freeze-Dried Plasma. The DOD has entrusted the Centre de transfusion sanguine des Armées with the production of freeze-dried human plasma for U.S. Forces. The CRADA will support the U.S. Army application for a biologics license application to the U.S. FDA for FFDP.

On September 23, 2019, the Special Immunizations Program Senior Advisory Board was stood up. This strategic level group brings all decision makers from the varied SIP stakeholders to one collaborative body to chart the path forward for this unique capability. Chemical-Biological Defense Program members include Joint Product Lead Chemical, Biological, Radiological and Nuclear Defense Enabling Biotechnologies and CBRND-Medical under the Joint Program Executive Office as well as the Defense Threat Reduction Agency Joint Science and Technology Office. Other members include the SIP PMO lead, the Director of FHP and USAMRDC legal. In addition, regulatory Subject Matter Experts are represented by the Office of the Surgeon General, Army's Sponsor's Representative and JPEO's One Network of Excellence for Regulatory Affairs and Quality Assurance.

On December 4, 2019, FHP conducted refresher training for U.S. Army Medical Research Institute of Infectious Diseases Department of Medicine and On Call Staff. An FHP overview, current IND portfolio, and treatment protocols were among the topics trained. In addition to FHP staff, Dr. Janice Rusniak, an infectious disease SME, provided an overview of the diseases covered by the protocols.

FHP's Medical Countermeasure Surveillance advisor continued active participation with the Armed Forces Health Surveillance Center Epidemiology Chiefs' team that oversees global epidemiological surveillance across all services and several Federal agencies. The MCS advisor participated in daily telephone conferences with members of the Department of Homeland Security's National Bio-surveillance Integration Center and NBIC partners. NBIC evaluates emerging and ongoing biological events occurring globally that impact human, animal, plant, and environmental health. Surveillance of emerging infectious diseases and outbreaks allows FHP to anticipate events that could affect U.S. Forces globally.

ACCOMPLISHMENTS:

1) Exclusive Licensing Agreement for MP-12 for Rift Valley Fever

On July 22, 2019, the Department of the Army (USAMMDA and USAMRIID) signed an Exclusive Licensing Agreement granting within a field of use, royalty-bearing, revocable biological materials license to MP-12, a live attenuated Rift Valley Fever virus vaccine candidate, to Sabin Vaccine Institute. MP-12 was originally developed under a U.S. Army contract by The Salk Institute-Government Services Division in the 1980s. Inventory of MP-12 has been managed by the Special Immunization Program, but has not been the subject of active development or clinical evaluations in recent years. Upon conclusion of the license agreement, SVI intends to further develop the MP-12 vaccine and to achieve licensure by the FDA. To date, no licensed vaccine exists to protect against RVF. The development and licensure of this vaccine will provide a needed capability to support deployments to regions where RVF is endemic, and will support public health efforts for the civilian populations in these areas.

2) FHP Maintains Stamaril as an Alternative to Yellow Fever Vaccine

On April 26, 2019, Sanofi-Pasteur, the only FDA-approved manufacturer of Yellow Fever Vaccine (YF-VAX®), notified the DOD of a shipping hold due to packaging issues. The YF-VAX® is a required vaccine within U.S. Southern Command, U.S. Africa Command, and certain areas in U.S. European Command Area of Responsibility. FHP has an FDA-approved protocol for Stamaril for military personnel that could be activated, upon request, to offset manufacturing and/or packaging issues with the U.S. manufactured product, thus continuing to provide this required vaccine to the combatant commanders. Stamaril is a safe and efficacious alternative to YF-VAX®, licensed in Europe, which could be used under FHP expanded access protocol to address the need for military personnel.

3) FHP Established Satellite Site for IV Artesunate Use

In April 2019, a satellite site was established for the Expeditionary Resuscitative Surgical Team in East Africa to use IND IV Artesunate for "Treatment IND Protocol: Intravenous Artesunate for Treatment of Severe Malaria in the United States Hospitals and Health Facilities Outside of the United States" S-15-17, IND 64,769. Special Forces physicians, familiar with FHP treatment protocol, wanted to bring the treatment protocol to East Africa as severe malaria is prevalent in the area. The site is under the Principal Investigator at Landstuhl Regional Medical Center/Germany, a permanent site for the protocol. As the medical teams rotate every four months, it was decided to make the East Africa site personnel Sub Investigators under LRMC's PI. As each team rotates in, a virtual site initiation visit is done by the ORA CRA with FHP PM Support.

4) FHP Assists with Special Immunizations Program during the U.S. Army Medical Research Institute of Infectious Diseases BSL Suspension

On July 18, 2019, the Centers for Disease Control issued a cease and desist order halting all biological select agents and toxin research at USAMRIID. The SIP provides investigational vaccines, not available elsewhere, to at-risk DOD, academic, and other federal agency personnel, for Tularemia, Q-Fever, RVF, and Venezuelan, Eastern, and Western Encephalitis. The FDA requires recurring stability testing of the vaccines. Because of the use of select agents in these stability tests, they must be performed in BSL suites. No new animal testing or new human subject enrollment has been allowed until the USAMRIID BSL suspension is lifted.

5) FHP Closes Several Existing Protocols

During 2019, several existing protocols were closed due to closure of the product development pathway or clinical sites. These included: "A Phase 2 Treatment Protocol of IV Ribavirin in Adult Subjects with Hemorrhagic Fever with Renal Syndrome in the 121st Combat Support Hospital Seoul, Korea," "Arbekacin Treatment of Adult Patients with Infections Caused by Multi-Resistant Bacteria," and "Paromomycin + Gentamycin Topical Cream Treatment Program for Individuals with Uncomplicated CL."

6) IND 136258 for Topical Paromomycin Transferred to Private Company to Pursue Licensure

IND 136258 for Topical Paromomycin was transferred to a private company to pursue licensure. The associated protocol, "Paromomycin Topical Cream Treatment Protocol for Individuals with Uncomplicated Cutaneous Leishmaniosis" was closed. The FHP product management support team worked closely with Office of Regulatory Affairs to close all sites and produce the Final Clinical Study Reports.

Current Protocols and Emergency Use Authorizations:

IND #	Title
65480	DOD Protocol for the Use of Cidofovir as a Treatment for Adverse Reactions Associated with Vaccinia Virus Vaccination, USAMRDC IRB A-11801
65480	DOD Contingency Protocol for Emergency Use of Cidofovir as a Treatment for Smallpox, USAMRDC IRB A-11161
65480	Intravenous Cidofovir Clinical Protocol to Treat Orthopox Infection and Adverse Reactions Associated with Vaccinia Virus Vaccination USAMRDC IRB # To Be Determined 10480
3723	Protocol for Vaccination of Selected Volunteers with Pentavalent Botulinum Toxoid to Protect against Botulinum A Toxin Toxicity, USAMRDC IRB A-12006
117,933	Clinical Protocol to Treat Individuals with Tecovirimat (ST-246) after Exposure to Orthopox Viruses, USAMRDC IRB M-10331
16,666	A Phase 2 Treatment Protocol of IV Ribavirin in Adult Subjects with Hemorrhagic Fever with Renal Syndrome in LRMC Landstuhl, Germany; Brooke Army Medical Center IRB C.2008.197; USAMRMC IRB A-15314 IV Ribavirin Protocol to Treat Individuals with Viral Hemorrhagic Fever (Crimean Congo Hemorrhagic Fever or Lassa Fever) S-13-08; HQUSAMRMC IRB M-10439.
64769	Treatment IND Protocol: IV Artesunate for Treatment of Severe Malaria in the U.S. Hospitals and Health Facilities Outside of the United States S-15-17; HQ USAMRMC IRB M-10419
17193	Contingency Expanded Access Protocol for Vaccination Against Yellow Fever Using Stamaril HQ USAMRMC IRB M-10566

Figure FHP.1. Current Protocols.

Date	Title	Intended Use
9 July 2018	Pathogen Reduced Leukocyte-Depleted FDP manufactured by the Centre de Transfusion Sanguine des Armées	For U.S. military forces for the treatment of hemorrhage or coagulopathy during an emergency involving agents of military combat (e.g., firearms, projectiles, and explosive devices) when plasma is not available for use or when the use of plasma is not practical.

Figure FHP.2. Active Emergency Use Authorizations

U.S. Army Medical Materiel Development Activity

USAMMDA

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