U.S. Army Medical Research and Development Command

MEDICAL PRODUCTS

Third Edition

2019

THE U.S. WARFIGHTER RUNS ON OPERATIONAL READINESS

INTRODUCTION

This biennial publication details the United States (U.S.) Army Medical Research and Development Command's (USAMRDC) medical materiel product development efforts. This 2019 (Third) Edition focuses on the medical materiel development and life cycle management efforts of the USAMRDC's medical Project Management Offices (PMO) and also includes a section on the knowledge products under development by our Science and Technology partners. Through the U.S. Congress, the U.S. Army and the Defense Health Agency provide support to these programs.

This book is organized into two major sections. The first describes materiel products designed to maintain operational readiness, treat wounded Service Members, and return them to the fight. The second describes knowledge products that inform medical and operational practices, such as Clinical Practice Guidelines.

Our government, academic, and industry acquisition partners, crucial in assisting us in delivering timely solutions, are highlighted in the product descriptions and in the appendices.

As we send our Soldiers, Sailors, Airmen, and Marines into harm's way, we need innovative medical materiel solutions enabling the very best in health and medical care before, during, and after any contingency. We owe our Warfighters nothing less.

We hope that you find this product book to be a valuable and informative resource.

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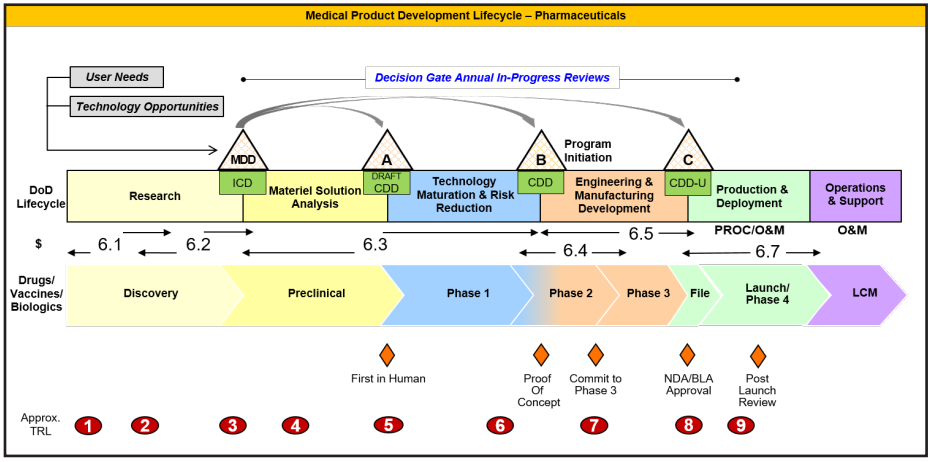
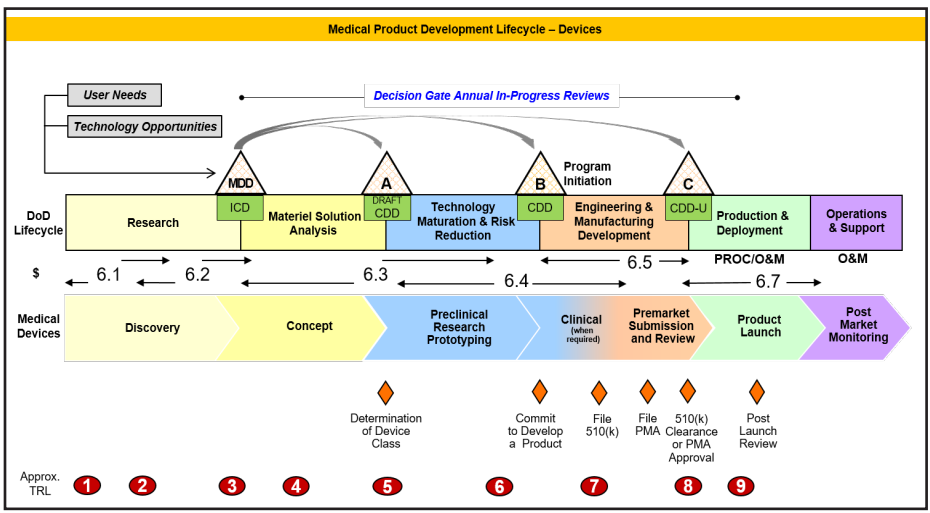
MATERIEL PRODUCTS

MEDICAL ACQUISITION IN THE DEPARTMENT OF DEFENSE

The acquisition process utilized by the USAMRDC integrates the Department of Defense (DoD) acquisition system based on the DoD Instruction 5000.02 (August 10, 2017) with the U.S. Food and Drug Administration's (FDA) medical product development process and medical industry best practices. The maps below illustrate the model developmental process for pharmaceuticals and medical devices and how the DoD processes are aligned to those of the FDA. Both of these models are tailored to the individual program. All medical pharmaceuticals and devices must be approved for use by the FDA before they can be fielded.





Medical product acquisition is managed by PMOs. These offices apply a disciplined approach to plan, organize, secure, and manage resources to efficiently deliver medical products. Products enter the acquisition process when a Materiel Development Decision (MDD) is approved by the Milestone Decision Authority. From that point on, the product moves through a pathway individually tailored for its specific situation, which includes all, or some, of the acquisition phases (Material Solution Analysis, Technology Maturation & Risk Reduction, etc.) and Milestone (MS) decisions (A, B, and C), ultimately leading to fielding of health- and life-sustaining solutions for the Warfighter to accomplish the Army mission.

POSITIONING MEDICAL PRODUCT ACQUISITION FOR MULTI-DOMAIN OPERATIONS

The USAMRDC leverages medical research and development, partnerships, technology modernizantion efforts, and knowledge solutions to deliver products that meet the medical needs of the U.S. Army and DoD, both today and in the future's multi-domain operations (MDO). The USAMRDC PMOs directly support the DoD and U.S. Army mission to provide state-of-the-art medical care to the deployed Warfighter.

Military medical capabilities in the deployed environment are currently organized into distinct levels of care, from point of injury to definitive care. Field Manual 4-02, Army Health System, describes the four roles of care and their associated capabilities:

Role 1: The first medical care deployed military patients receive is provided at Role 1 (also referred to as unit-level medical care). This role of care includes: immediate lifesaving measures, prevention and treatment of disease and non-battle injury (DNBI), combat and operational stress preventive measures, and patient location and acquisition. Treatment emphasizes those measures necessary to return the patient to duty, or stabilize them for evacuation to the next appropriate role of care. Care is provided by the combat medic, combat lifesaver, and through self- or buddy-aid at or near the point of injury; by a physician, physician assistant, or medic at the battalion aid station; and by the combat medic or flight paramedic during medical evacuation.

Role 2: In the U.S. Army, Role 2 care is provided at brigade support medical companies (BSMC) and at medical companies (area support) (MCAS). Role 2 provides advanced trauma and emergency medical treatment, including continuing treatment started in Role 1. If necessary, additional emergency measures that do not exceed those dictated by immediate necessity are instituted. Role 2 care has the capability to provide packed blood products; limited x-ray, laboratory, and dental support; combat and operational stress control; preventive medicine; and, when augmented, physical therapy and optometry services. The BSMC and MCAS may be augmented by collocation of a Forward Surgical Team or Forward Resuscitative Surgical Team (FRST) to provide surgical capabilities for non-transportable patients who would not survive further evacuation without surgical intervention.

Role 3: Medical care in an operational Medical Treatment Facility (MTF) staffed and equipped to provide care to all categories of patients. This role of care expands the support provided at Role 2 and includes resuscitation, initial wound surgery, damage control surgery, and postoperative treatment. Patients who are unable to tolerate and survive movement over long distances receive surgical care in a hospital as close to the supported unit as the tactical situation allows. This role includes provisions for: evacuating patients from supported units and providing support on an area basis to units without organic medical assets.

Role 4: Medical care found in U.S. based hospitals and robust overseas facilities. Mobilization requires expansion of military hospital capacities and the inclusion of Department of Veterans Affairs (VA) and civilian hospital beds in the National Disaster Medical System to meet the increased demands created by the evacuation of patients from the area of focus. These hospitals represent the most definitive medical care available within the medical care system.

Future medical care during large-scale combat operations (LSCO) within MDO will require new solutions to address increased numbers of casualties, different types of injuries, and the potential for limited ability to rapidly evacuate patients to higher roles of care. While casualties will be evacuated as quickly as possible, the ability to evacuate patients may be limited in some phases of MDO requiring a paradigm shift from the "Golden Hour" of Operation Iraqi Freedom (OIF) and Operation Enduring Freedom (OEF) to prolonged care, including patient holding and life support for 24+ hours on the battlefield. The LSCO will require proactive approaches to disease prevention and treatment to maintain operational readiness and prevent unnecessary loss to combat effectiveness due to DNBI; technologies for more effective medical care at or near the point of injury and during evacuation; smaller and lighter medical devices to diagnose and treat injuries, both physical and mental, and monitor care especially when evacuation is delayed; and techniques to enhance the Warfighter's ability to deal with longer and more isolated deployments. The USAMRDC Medical PMOs are working with Science and Technology partners and the U.S. Army Medical Center of Excellence's (MedCoE) Capabilities Development and Integration Directorate (CDID) to develop medical materiel solutions to future Warfighter medical needs through all phases of MDO. Our goal is to help ensure the U.S. Army and Joint Force have the medical tools necessary to help win any future fight against near-peer adversaries.

U.S. ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND PROJECT MANAGEMENT OFFICES

The **Warfighter Brain Health PMO** seeks to develop and deliver brain health medical solutions across the continuum of care. Their developmental efforts support the detection, prevention, and treatment of neurotrauma and promoting the psychological health of Service Members. They focus on the development of clinical drugs, therapies, and diagnostics for TBI, PTSD, and other psychological health conditions.

The **Warfighter Deployed Medical Systems PMO** is the focal point for medical materiel life cycle management in the U.S. Army. They consist of two Product Management Offices:

- The **Medical Modernization Product Management Office** develops, procures, and manages the modernization of fielded medical devices. They manage the requirement to modernize and replace a fielded capability when the existing medical equipment becomes unsupportable or unaffordable due to obsolescence.

- The **Medical Devices Assemblage Management Product Management Office** organizes and manages all of the U.S. Army equipment packages (Medical Unit Assemblages) that are fielded to support patient and animal care from Roles 1 through 3. They coordinate with the Defense Logistics Agency (DLA) - Troop Support, MedCoE, and the U.S. Army Medical Logistics Command on acquisition and logistic actions to integrate new and modernized medical equipment into fielded assemblages.

The **Enterprise Information Technology PMO** sustains a suite of enterprise Information Management/Information Technology (IT) solutions that meet the needs of the USAMRDC and their collaborators. This involves planning and executing the acquisition of medical IT solutions for medical research, and the configuration and sustainment of these solutions for USAMRDC's medical research activities in accordance with DoD; FDA; Assistant Secretary of the Army for Acquisition, Logistics, and Technology; Defense Health Agency; and U.S. Army Futures Command policies and regulations. They also coordinate with USAMRDC medical research and development functional sponsors in the prioritization and successful implementation of USAMRDC-wide IT solutions. All of these FDA required products are compliant with the overarching requirements found in the FDA Title 21 of the Code of Federal Regulations (CFR), Part 11, for electronic records and electronic signatures.

The **Warfighter Expeditionary Medicine and Treatment PMO** seeks to field FDA-approved medical devices, drugs, and biologics that fulfill the unmet requirements identified by the Service end user. This is accomplished either through the development of a new capability or by improving upon existing capabilities. Their developmental efforts are focused on products for hemorrhage detection and control, improving organ support, advancing tissue treatment and repair, and managing sensory organ damage; as well as, enabling technologies needed to support these advancements.

The **Warfighter Health, Performance, and Evacuation PMO** develops, rapidly prototypes, and procures medical support products. Their efforts are focused on preventive medicine, operational medicine, MEDEVAC and treatment platforms, medical shelters and infrastructure, combat casualty care support systems, and medical prototype development.

The **Warfighter Protection and Acute Care PMO** focuses on developing products to sustain Service Member health and maintain operational readiness through continually improving product acquisition strategies, and by implementing innovative solutions to accelerate the development and fielding of medical products. Their developmental efforts are focused on vaccines and biologics, drugs (antimalarial, antimicrobial, and pain management), infectious diseases diagnostics, and hemorrhage control and resuscitation products to prevent, diagnose, and treat U.S. Service Members both in the continental U.S. (CONUS) and during deployments.

PARTNERS

In order to provide the Warfighter with the products they need, the USAMRDC PMOs partner with three key Army organizations in developing all of our medical products:

The **MedCoE CDID** develops concepts and integrates capabilities to improve medical support to our Army and the Joint Force. Our partnership is critical in order to ensure that products developed by the USAMRDC meet the needs of the Warfighter as defined in the requirements that CDID generates.

The **MedCoE Fielded Force Integration Directorate** integrates and synchronizes fielded force medical capabilities development. Our partnership ensures that medical products currently in the field continue to meet Warfighter needs.

The **MedCoE U.S. Army Medical Department Board (AMEDDBD)** is the sole independent operational test and evaluation agency for medical-related materiel and medical information management/information technology products. In this role, the AMEDDBD provides vital information through operational test and evaluation of candidate medical products, helping ensure that products function properly in the hands of the intended users in an operational environment.

PRODUCTS FIELDED 2012-2019

FIELDED LICENSED BY REGULATORY AGENCY

French Freeze Dried Plasma

Life-saving blood product for use in remote & austere settings

Severe blood loss is the leading preventable cause of death in combat. The French Freeze Dried Plasma (FFDP) replaces a critical component of blood, plasma, and is the only blood product that can be carried to the point of injury at room temperature. This life-saving product, provided through a partnership with the Centre de Transfusion Sanguine des Armées (Blood Transfusion Center of the French Armed Forces), was granted an Emergency Use Authorization in 2018 for the treatment of severe blood loss when other plasma products are not available. The FFDP is currently being used by U.S. Special Operations Command (SOCOM) units.

Burn Resuscitation Decision Support System – Mobile

More accurate intravenous fluid recommendations during critical hours after burn injury

Commercialized as the BurnNavigator™ under a technology transfer license from the U.S. Army, this technology is adapted for civilian use in approximately 10% of all American Burn Center certified burn units in the U.S. It received FDA licensure in 2015 as the Burn Resuscitation Decision Support (BRDSS) – Clinical, a tool for use in a fixed medical facility as part of a more complete patient management plan for fluid replacement in burn patients. The BRDSS – Mobile is fielded to the Air Force Critical Care Air Transport Team. Service Reserve and Active Duty units received this product between 2015 and 2017.

Automated Field Steam Sterilizer (P2131)

Sterilizes medical equipment while cutting water use by 90% & 20-year lifecycle management costs by 30-40% per system

This steam sterilizer replaces one that has outlived its useful life. The FDA licensed the sterilizer in 2015 and it entered full rate production and the first unit was equipped around 2016. This is a critical item for our Field Hospitals (FH), providing a means to sterilize reusable surgical and medical items in a field environment. The P2131 meets the safety requirements of the American Society of Mechanical Engineers, which sets the code for boiler and pressure vessel devices.

CL Detect™ Rapid Test

Allows detection/immediate treatment of parasite causing disfiguring lesions

Cutaneous Leishmaniasis (CL) is a parasitic disease causing disfiguring lesions that is common in tropical and subtropical areas. This hand-held "dipstick" for the rapid diagnosis of CL allows the immediate implementation of appropriate treatments, which can reduce the severity of scarring and reduce lost duty time for affected U.S. Military personnel. It received FDA licensure in 2014 and fielding began in 2015.

Medical Vital Signs Simulator

Consolidates three medical maintenance instruments into one to keep deployed medical test equipment running

Keeping life-maintaining medical equipment up and running in a deployed setting is a critical capability. The Medical Vital Signs Simulator (MVSS) is used for testing, calibrating, and repairing deployed medical equipment such as vital signs monitors and pulse oximeters. It combines the functions of three instruments into one, and in the process cuts the shipping weight from 30 pounds to 12 pounds and the shipping size from 2.5 cubic feet to 0.25 cubic feet. The MVSS weighs 5 pounds (compared to the previous 20 pound weight) and fits into a small carry-on bag. The FDA licensed the MVSS in 2014 and fielding occurred in 2016.

SAM® Junctional Tourniquet

Controls bleeding in body areas with hard to compress wounds

A leading cause of death on the battlefield is bleeding from areas that cannot be compressed easily, such as the armpit and the groin. The FDA licensed this device in 2013 for inguinal/groin area use and later for axillary/armpit use and pelvic binding, This device allows compression in these areas to reduce bleeding. Designed for one-time use, fielding began in 2015. It weighs one pound and can be positioned in under a minute in a hemorrhaging patient.

Egret™ Bed Net

Provides infectious disease protection to sleeping Soldiers

The Bed Net is a tent structure, which has been impregnated with two insecticides. It provides a barrier between the sleeping Soldier and flying insect vectors that transmit infectious disease (e.g., malaria, dengue fever, and leishmaniasis). It received registration from the Environmental Protection Agency in 2015 and is available for purchase by Units.

FIELDED NO REGULATORY AGENCY LICENSING REQUIRED

Modular Lightweight Load-carrying Equipment Medical Bag

Medical equipment bag adaptable to the medic's mission

The Modular Lightweight Load-carrying Equipment (MOLLE) Medic Bag is designed to complement the current generation of load-bearing equipment and backpacks utilized by North Atlantic Treaty Organization (NATO) Armed Forces, especially the U.S. Army and the British Army. It is carried by the Combat Medic and consists of modular components, including a Tactical Evaluation Bag, Tactical Field Care Bag, and Care Under Fire Bag. The user configures the bag to the needs of a given mission. Initial fielding occurred during OIF/OEF with more than 500 MOLLE bags shipped to Afghanistan in 2014. The MOLLE Bag is used in air/ground ambulances and in unit assemblages provided for FRST; for use in treating trauma patients, and pre- and post-operative intensive care wards.

Individual First Aid Kit Generation II

Essential individual Soldier life-saving kit redesigned to address end user issues

Fielded in 2013, the Generation II Individual First Aid Kit (IFAK) is a product improvement developed in response to user complaints related to the Generation I IFAK (fielded in 2005). Soldiers used the IFAK I extensively on the battlefield at point of injury. The IFAK II incorporates a second tourniquet in response to an increase in bilateral injuries due to increasing dismounted operations, and a chest seal, eye patch, strap cutter, Tactical Combat Casualty Care (TCCC) Card (DoD Form 1380), and Sharpie®. The modified design of the Generation II kits prevents snagging on vehicle doors/hatches during emergency egress. The DoD has procured over 134,000 IFAK IIs.

Oxygen Generator Field Portable

Reduces logistical refill and transport requirements for oxygen generation in the field

Field supply of oxygen is critical to care and the logistics associated with the transport and refill of compressed oxygen cylinders can be significant. This 12-pound portable oxygen generator reduces that logistical burden by providing a rechargeable battery-supported oxygen generation capability for up to 30 minutes, while delivering 3 liters of oxygen per minute. It augments field oxygen cylinders by enabling a continuous supply of oxygen for non-critical patients using standard electrical power. This began fielding in 2016. It is intended for use in air/ground ambulances and in unit assemblages provided for FRSTs; for use in treating trauma patients, and pre- and post-operative intensive care wards in FHs.

Tent Extendable Modular Personnel Air Supported Shelter

Uses new composite materials to replace outdated shelters for FHs

The Tent Extendable Modular Personnel (TEMPER) Air Supported (TAS) Shelter replaces a non-fire retardant FH shelter that has outlived its useful life. The use of new composite materials cuts the weight of a FH by 17 tons and can be erected by 4 Soldiers in under 30 minutes. Initially fielded in 2017, it is in Army Pre-positioned Stock for U.S. Army FHs. Its authorized use is Role 3.

Decision Aids

Using risk assessment to impact health readiness

The mobile hand-held applications (app) or decision aids described below were fielded in 2015 on the Nett Warrior End User Device for use on an Android phone. In 2018, an app was developed for use on an iPhone. Both versions are now available on the U.S. Army training app store website. These aids allow the field Commander the option of downloading the app for either operating system, depending on the platform available for the mission.

Altitude Readiness Management System

Decision aid to manage altitude illness risk and predict task performance

This is an app that can be used by leaders to predict the onset of acute mountain sickness, to manage illness induced by operating at high altitudes, and to monitor task performance at high altitudes.

Soldier Water Estimation Tool

Decision aid for Unit water needs

This is a leader's mobile app tool to predict individual/platoon/battalion water needs during a mission (in liters per hour) in order to minimize the volume of water that needs to be carried while ensuring proper Soldier hydration.

INFECTIOUS DISEASE

PREVENTION

ADENOVIRUS TYPE 4 AND TYPE 7 VACCINE, LIVE, ORAL

Annually avoids $50M in lost training time and associated medical care expenses

PARTNER(S)

- DLA - Troop Support, Philadelphia, Pennsylvania
- Military Infectious Disease Research Program (MIDRP), USAMRDC, Fort Detrick, Maryland
- Teva North America, North Wales, Pennsylvania (Teva Pharmaceutical Industries Ltd., Petah Tikva, Israel)

Adenovirus Types 4 and 7 (Ad4 and Ad7) causes a febrile respiratory illness that primarily affects military basic trainees. Before the routine availability of the adenovirus vaccine, an estimated 80% of enlisted trainees became infected during training. Of these, approximately 40% had significant illness and 20% required hospitalization.

In 1971, the initiation of adenovirus vaccinations using an orally administered tablet containing live adenovirus serotypes 4 or 7 resulted in significant reduction in the incidence of the adenovirus infection. However, in 1996, vaccine production stopped due, in part, to manufacturing issues. From 1997-1999, as the vaccine supply was exhausted, the incidence of Ad4 and Ad7 infections rose in the trainee population, accompanied by significant lost training time and an increase in medical care expenditures. By 2001, adenovirus infection was highly epidemic in DoD recruit training centers.

In 2001, the U.S. Army contracted with Barr Laboratories (since acquired by Teva Pharmaceuticals Industries), to resume production of the adenovirus vaccine. The product received FDA licensure in 2011, vaccine administration resumed at all U.S. Military recruit training sites. Since that time, incidence of this illness declined 100-fold. In 5 years, the vaccine prevented an estimated 75,000 cases resulting in over 250,000 training days saved.

The Warfighter Protection and Acute Care (WPAC) PMO manages vaccine sustainment through the DLA and the U.S. Army Medical Materiel Agency (USAMMA). Over 1.7 million doses of the vaccine have been shipped to recruit centers.

This capability is administered at Role 4 to protect Service Members, primarily trainees.

Reference: Radin JM, Hawksworth AW, Blair, PJ et al. Dramatic decline of respiratory illness among military recruits after the renewed use of adenovirus vaccines. Clinical Infectious Disease 2014; 59(7): 962-68.

ACQUISITION PHASE

- Operations & Support

FUNDING SOURCE

- Defense Health Program

CHIKUNGUNYA VACCINE

Emerging infectious disease in tropical and subtropical regions

PARTNER(S)

- MIDRP, USAMRDC, Fort Detrick, Maryland
- PaxVax Inc., Redwood City, California (acquired by Emergent Biosolutions, Inc., Gaithersburg, Maryland)
- Themis GmbH, Vienna, Austria
- Walter Reed Army Institute of Research (WRAIR), Silver Spring, Maryland

Chikungunya is caused by the Chikungunya virus (CHIKV). It is carried by the Aedes mosquito, which is also a vector for other infectious diseases of military significance, such as dengue and yellow fever. Chikungunya is a widespread emerging infectious disease that is present in all tropical and subtropical regions, with outbreaks occurring in Africa, Asia, Europe, and the Western Hemisphere.

Chikungunya is characterized by acute onset of fever and severe joint pain. Other symptoms include severe and debilitating pain in the hands and feet, headache, muscle pain, arthritis, conjunctivitis, nausea/vomiting, and rash. A majority of infected people become symptomatic. To date, no vaccine or medication exists to prevent CHIKV infection/disease.

Chikungunya reached the Americas in late 2013, with local transmission reported on islands in the Caribbean. In 2014, public health officials reported local transmission in Florida, Puerto Rico, and the U.S. Virgin Islands. In 2015, CHIKV disease became a nationally notifiable condition, reportable to the Centers for Disease Control and Prevention (CDC) by state and local health departments. There is little information on the natural history of CHIKV in DoD populations, but recently a significant increase was observed in the number of cases among DoD healthcare beneficiary populations. In 2015, the Defense Medical Surveillance System identified over 150 confirmed CHIKV cases among Service Members and DoD healthcare beneficiaries, representing a significant increase in cases. This disease causes a high risk of disruptions in military operations due to high attack rates in non-immune populations leading to an estimated 3-10 lost duty days and the potential for long-term disability and in rare cases, encephalitis and death.

Two CHIKV vaccine development programs are being tracked under USAMRDC Cooperative Research and Development Agreements (CRADA). Sponsored by PaxVax (recently acquired by Emergent Biosolutions) and Themis, both have undergone Phase 2 (safety and initial effectiveness testing) clinical trials in Puerto Rico and the companies are currently formulating their next steps.

This capability will be administered at Role 4 to protect Service Members prior to deploying or being stationed in areas where the disease is prevalent.

Reference: Medical Surveillance Monthly Report Vol. 22 (10) Oct 2015

ACQUISITION PHASE

- Materiel Solution Analysis

FUNDING SOURCE

- U.S. Army

DENGUE TETRAVALENT VACCINE

Protection against the world's fastest spreading mosquito-borne viral illness

Dengue is the most rapidly spreading mosquito-borne viral disease in the world. In the last 50 years, the incidence has increased 30-fold with geographic expansion to new countries and from urban to rural settings. The infection rate in U.S. Forces has increased in proportion to frequency of operations in endemic areas. Today, dengue fever is a leading cause of hospital admissions in military units operating in the tropics. Approximately 13% of SOCOM personnel have evidence of initial exposure, predisposing them to more severe complications such as severe bleeding, shock, or even death with a second exposure.

The dengue virus has four serotypes. Each serotype causes acute, incapacitating illness characterized by severe head, muscle, joint and eye pain; as well as, fever lasting from four to seven days. A second infection with a different dengue serotype is not uncommon and may result in a more severe, often fatal, hemorrhagic form of the disease. As U.S. Forces shift to the Pacific theater, an area that is endemic for dengue, U.S. Troops are increasingly at risk.

Currently, there are no licensed vaccines or drugs to prevent or treat dengue fever and its often fatal variant, dengue hemorrhagic fever. Various vaccine developmental efforts are underway that would provide protection against all four dengue virus serotypes. This vaccine, if successful, will protect our Troops from the four (tetravalent) types of dengue, reducing lost duty days and death.

Reference: Dengue: Guidelines for diagnosis, treatment, prevention and control: new edition. Geneva: World Health Organization; 2009. 1, Epidemiology, Burden of Disease and Transmission. Available from: https://www.ncbi.nlm.nih.gov/books/NBK143159/

DENGUE TETRAVALENT VACCINE INCREMENT 1

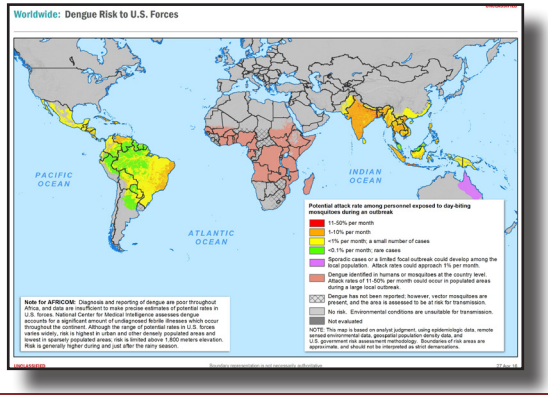
PARTNER(S)

- Armed Forces Research Institute of Medical Sciences (AFRIMS), Bangkok, Thailand
- MIDRP, USAMRDC, Fort Detrick, Maryland
- Sanofi Pasteur, Swiftwater, Pennsylvania and Lyon, France
- Takeda Pharmaceuticals International, Inc., Deerfield, Illinois
- WRAIR, Silver Spring, Maryland

The USAMRDC initially partnered with Sanofi Pasteur to develop a tetravalent dengue vaccine (Dengvaxia™). Researchers conducted Phase 3 (large safety and effectiveness study/testing) clinical trials for this vaccine in endemic areas, with over 40,000 volunteers vaccinated. The USAMRDC provided field sites for these trials in Thailand and the Philippines. Based on the results, Sanofi Pasteur licensed the vaccine in several countries and has filed a Biologics License Application (BLA) with the FDA. However, this vaccine only has utility in individuals who have already experienced infection with one of the dengue serotypes, resulting in a limited use indication. Based on this, a panel of military medical experts determined that the Dengvaxia™ vaccine is not suitable for widespread military use.

Currently, the USAMRDC is collaborating with Takeda on the development of their tetravalent dengue vaccine candidate under a CRADA. The USAMRDC is assisting in the field testing of the Takeda vaccine candidate as part of Phase 3 clinical trials in Thailand and the Philippines. Assuming that these trials are successful, Takeda will apply for a BLA with the FDA. This effort is projected to field in Fiscal Year 2021 (FY21).

This capability is intended for administration at Role 4 to protect Service Members prior to deploying or being stationed in areas where the disease is prevalent.



ACQUISITION PHASE

- Engineering & Manufacturing Development

FUNDING SOURCE

- U.S. Army

DENGUE TETRAVALENT VACCINE INCREMENT 2 (ALTERNATE DENGUE VACCINE)

PARTNER(S)

- AFRIMS, Bangkok, Thailand
- GlaxoSmithKline (GSK) Biologicals, Antwerp, Belgium
- Hawaii Biotech, Inc., Aiea, Hawaii
- MIDRP, USAMRDC, Fort Detrick, Maryland
- Naval Medical Research Center (NMRC), Silver Spring, Maryland
- Vical, Inc., San Diego, California
- WRAIR, Silver Spring, Maryland

The Dengue Tetravalent Vaccine Increment 2 is a risk migation effort exploring new ways to protect against the disease. Numerous alternate approaches are under development globally, with 13 vaccine candidates in various stages. Increment 2 is currently in Phase I (safety and dosage testing) clinical development. The various approaches to Increment 2 are listed below. Several of these candidates are being studied for their ability to boost the immune response of the primary vaccine, which may enhance tetravalent immunity.

- Investigation of a tetravalent, classically attenuated live virus dengue vaccine
  - WRAIR in conjunction with GSK Biologicals
- Early phase development of a purified inactivated virus dengue vaccine
  - WRAIR in conjunction with GSK Biologicals
- DNA-based vaccine, Phase I clinical trial
  - NMRC
- Evaluation of recombinant protein vaccine candidates
  - WRAIR and NMRC in conjunction with Hawaii Biotech, Inc.

This capability is intended for administration at Role 4 to protect Service Members prior to deploying or being stationed in areas where the disease is prevalent.

ACQUISITION PHASE

- Technology Maturation & Risk Reduction

FUNDING SOURCE

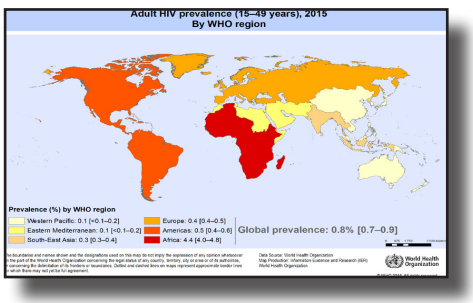
- U.S. Army

HUMAN IMMUNODEFICIENCY VIRUS VACCINE

Potential to reduce infections by 70-80% and subsequent loss in personnel

PARTNER(S)

- Bill and Melinda Gates Foundation, Seattle, Washington
- CDC, HIV/AIDS, Atlanta, Georgia
- Center for HIV-AIDS Vaccine Immunology, Duke University, Durham, North Carolina
- Division of AIDS, National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health, Bethesda, Maryland
- Global HIV Vaccine Enterprise, New York City, New York
- Global Solutions for Infectious Diseases, San Francisco, California
- GSK Biologicals, Antwerp, Belgium
- Henry M. Jackson Foundation for the Advancement of Military Medicine, Bethesda, Maryland
- HIV Vaccine Trials Network, Seattle, Washington
- Infectious Disease Clinical Research Program, Uniformed Services University of the Health Sciences Bethesda, Maryland
- International AIDS Vaccine Initiative, New York City, New York
- Janssen Vaccine and Prevention Unit, B.V., New Brunswick, New Jersey
- MIDRP, USAMRDC, Fort Detrick, Maryland
- President's Emergency Plan for AIDS Relief, Washington, District of Columbia
- Scripps Institute, La Jolla, California
- WRAIR, Silver Spring, Maryland
- Major academic partners include: Beth Israel-Deaconess Medical Center, Boston, Massachusetts; Duke University, Durham, North Carolina; Harvard University, Cambridge, Massachusetts; Massachusetts Institute of Technology, Cambridge, Massachusetts; New York University, New York City, New York; University of Washington, Seattle, Washington



With 35 million infections worldwide, HIV continues to pose a significant threat to military readiness and force protection, and to impact the stability and security of many nation-states. This pandemic requires long-term solutions to screen, prevent infection, and ensure leading-edge care and treatment.

Approximately 1,500 infected individuals are currently serving on Active Duty. Despite ongoing HIV prevention campaigns and the implementation of routine testing of all Service Members in 1985, the number of new infections has remained at 300-350 per year. A waiver is required for infected Service Members to be able to deploy.

A recent study estimated the annual cost to treat and care for one cohort of 300 HIV-infected Service Members to be $33 million, with a lifetime accrued cost of $1.3 billion (estimated 40 year lifetime). A HIV vaccine could reduce infections by an estimated 70-80% annually, maintain 210-280 highly trained personnel in ready status each year, and avoid an estimated $2.6 billion in healthcare costs (over a 30 year period) to the DoD and VA.[1] In addition, if a cost effective vaccine is developed with the ability of use internationally, it will help increase productivity of personnel who otherwise would have been infected, which in turn helps global economic growth and stability.[2]

References:
[1]Brown A: Cost of HIV testing in the U.S. Army. NEJM 1995; 332: 963
[2]Bulletin of the World Health Organization Past issues Volume 86: 2008 Volume 86, Number 2, February 2008, 81-160

HIV VACCINE INCREMENT 1 (GLOBAL VACCINE STRATEGY)

The USAMRDC is working with the Janssen Vaccines Unit under a CRADA to develop a HIV vaccine designed to prevent infection from multiple HIV subtypes. Under the CRADA, USAMRDC agreed to fund a contract to provide clinical monitoring for Janssen Phase 2b (safety and initial effectiveness testing) and Phase 3 (large safety and effectiveness study/ testing) clinical trials, pending the availability of funds, and Janssen agreed to seek FDA licensure should their vaccine candidate demonstrate sufficient efficacy. This effort is managed by Janssen, with input from multiple funding partners (listed on previous page).

A multi-site Phase 2b clinical proof-of-concept study in high risk individuals is underway in five southern African countries. It will provide the first evaluation of the effectiveness of the Increment 1 vaccine in a region with HIV (predominantly subtype C). During execution of the Phase 2b clinical study, Janssen intends to launch Phase 3 efficacy studies that will include sites across Africa, the European Union (EU), and North and South America. The first trial will begin in the EU and the U.S. in late 2019. The USAMRDC CRADA with Janssen supporting the development of their vaccine through Phase 3. This effort is projected to field in FY25.

This capability is intended for administration at Role 4 to protect Service Members prior to deploying or being stationed in areas where the disease is prevalent.

ACQUISITION PHASE

- Engineering Manufacturing & Development

FUNDING SOURCE

- U.S. Army

HIV VACCINE INCREMENT 2 (REGIONAL VACCINE STRATEGY)

PARTNER(S)

- Manager through Phase 1 (safety and safe dosage testing) Studies — MIDRP, USAMRDC, Fort Detrick, Maryland

The U.S. Army and the NIAID achieved modest success in the HIV RV144 vaccine trial. These results, published in the *New England Journal of Medicine* and *Lancet Infectious Diseases*, provided scientific data to inform and improve vaccine development. The acquisition of the vaccine supplier, Novartis, by GSK resulted in a renewed collaboration between the U.S. Army and NIAID that builds on the success of the RV144 trial. This involves a partnership with Duke University.

This capability is intended for administration at Role 4 to protect Service Members prior to deploying or being stationed in areas where the disease is prevalent.

ACQUISITION PHASE

- Technology Maturation & Risk Reduction

FUNDING SOURCE

- Defense Health Program

TICK-BORNE ENCEPHALITIS VACCINE

Protection against the third most operationally significant infection in the U.S. European Command

PARTNER(S)

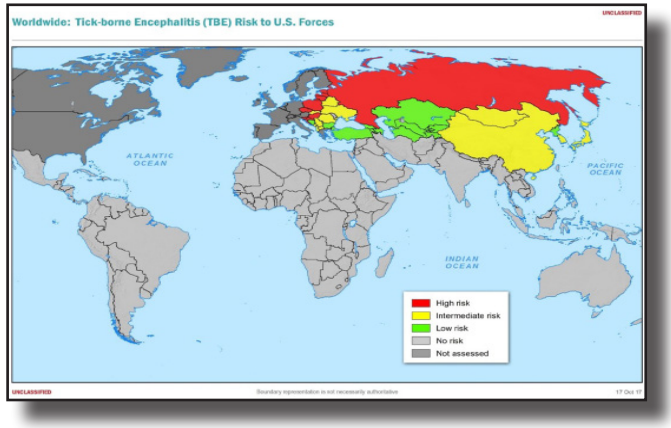
- MIDRP, USAMRDC, Fort Detrick, Maryland
- Industry partner(s) to be determined

Tick-Borne Encephalitis (TBE) is an emergent health problem in Europe, with the incidence of reported human cases in endemic regions increasing by almost 400% within the last three decades. The U.S. Defense Intelligence Agency reports that TBE virus is the third most operationally significant infectious disease in the U.S. European Command and poses a high risk to U.S. and Allied Forces supporting the NATO Alliance in Europe.

This is a viral infectious disease involving the central nervous system. The disease most often manifests as meningitis, encephalitis, or meningoencephalitis. Long-lasting or permanent neuropsychiatric consequences are observed in approximately 10 to 20% of infected patients.

The European Medicines Agency (EMA) licensed two TBE vaccines, FSME-IMMUN® in 1976, marketed by Pfizer, and Encepur® 1991, marketed by GSK. Both EMA-registered vaccines are widely available in Europe and Canada and approved for use in adults and children older than one year with a pediatric formulation. Both vaccines are administered with either a standard vaccination schedule or an accelerated schedule with protection to the patient within 14 days, which is essential in a rapid deployment scenario. Neither of these vaccines is licensed by the FDA and thus are not available for use by U.S. Forces in Europe.

The WPAC PMO is exploring the potential for a co-development effort for U.S. licensure of a TBE vaccine. Potential partners are conducting gap analyses and risk assessments prior to making a decision. Feedback is anticipated before the end of 2019.



This capability will be administered at Role 4 to protect Service Members prior to deploying or being stationed in areas where the disease is prevalent.

ACQUISITION PHASE

- Materiel Solution Analysis

FUNDING SOURCE

- U.S. Army

INFECTIOUS DISEASE

DIAGNOSTICS

Identification of Infectious Diseases Impacting Military Operations

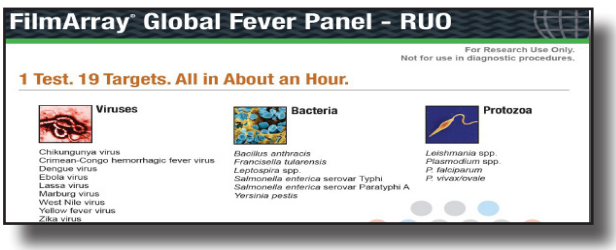
NEXT GENERATION DIAGNOSTIC SYSTEM INFECTIOUS DISEASE PANEL

PARTNER(S)

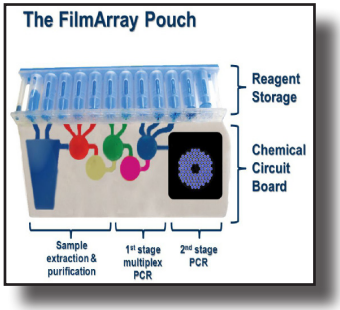
- BioFire Diagnostics, LLC, Salt Lake City, Utah (by bioMérieux, Marcy-l'Étoile, France)
- Joint Project Manager (JPM) for Chemical, Biological, Radiological, and Nuclear (CBRN) Medical, Fort Detrick, Maryland
- MIDRP, USAMRDC, Fort Detrick, Maryland

The Next Generation Diagnostic System (NGDS) Infectious Disease Panel effort is developing infectious diseases assays for use on the NGDS platform.

The NGDS platform is a FDA-cleared, ruggedized, commercial diagnostic device for the analysis of both clinical and environmental samples. This is a Joint program managed by JPM CBRN Medical under the Joint Program Executive Office for CBRN Defense. The primary function of the NGDS is to offer the Combatant Commander a medical countermeasure capability to detect biological hazards in support of Force Protection and Force Health Protection decision making. The NGDS replaced the legacy Joint Biological Agent Identification and Diagnostic System. Currently, the NGDS platform is in the Engineering & Manufacturing Development Phase and is in developmental testing to assess its ability to meet Service unique requirements.



The NGDS Infectious Disease Panel project is executed through a JPM CBRN Medical contract with BioFire. Working with the MIDRP, the WPAC PMO establishes the priority of the infectious diseases for assay development and assists BioFire in testing the panels, which occur primarily in overseas locations. They also work closely with the JPM CBRN Medical to ensure that the infectious disease program is synchronized with the chemical/biological defense program.



This capability is intended for use at Roles 2 and 3 for the Navy and Air Force and Roles 3 and 4 for the Army.

ACQUISITION PHASE

- Technology Maturation & Risk Reduction

FUNDING SOURCE

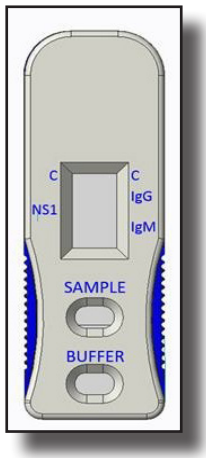
- Defense Health Program

RAPID HUMAN DIAGNOSTIC DEVICES

PARTNER(S)

- InBios International, Inc., Seattle, Washington
- MIDRP, USAMRDC, Fort Detrick, Maryland

The rapid human diagnostic device (RHDD) effort develops devices to test blood, stool, and/or other easily collected specimens for the presence of disease-causing pathogens of high military priority. The devices will be self-contained, easy to use, transportable, and capable of rapidly producing a test result (in less than two hours).



Infectious disease epidemics can incapacitate troops and significantly impact military operations. For example, during OEF 50% of deployed troops reported at at least one episode of bacterial diarrhea.[1] Because these conditions are not typical within the CONUS, it is difficult to find a commercial entity interested in developing diagnostic devices.

Currently, there are three FDA-cleared RHDD devices for Shiga toxin producing *Escherichia coli* (*E. coli*), malaria, and Cutaneous Leishmaniasis.

A contract has been awarded to InBios to develop future RHDD assays. The initial Task Order is for the development of a Dengue RHDD, with others to follow. The business case for each RHDD assay is considered before a significant investment is made. The development/implementation of commercial sustainability plans (e.g., foreign sales in endemic countries and regions) is a prerequisite for RHDD program success.

The capability is initially intended for use by laboratory technicians at Roles 2 and 3, with expansion to Role 1 if the product is granted a waiver through the Clinical Laboratory Improvement Act.

References:

[1]Putnam SD, Sanders JW, Frenck RW, et al. Self-reported description of diarrhea among military populations in operations Iraqi freedom and enduring freedom. J Travel Med 2006; 13(2): 92-9.

ACQUISITION PHASE

- Technology Maturation & Risk Reduction

FUNDING SOURCE

- U.S. Army

WHOLE BLOOD PATHOGEN REDUCTION DEVICE

PARTNER(S)

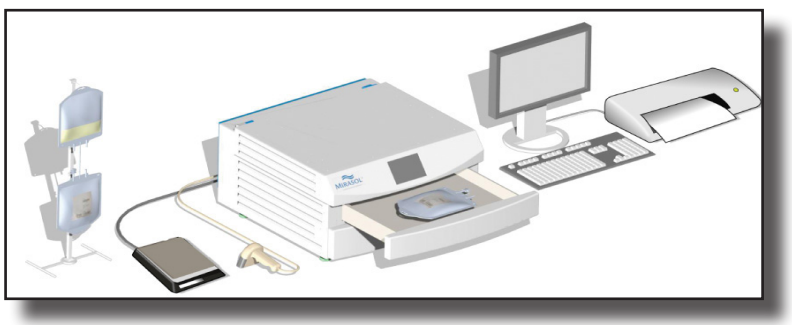
- Armed Services Blood Program Office (ASBPO), Falls Church, Virginia
- Combat Casualty Care Research Program (CCCRP), USAMRDC, Fort Detrick, Maryland
- Terumo BCT, Lakewood, Colorado

In trauma situations, whole blood is collected and transfused on the battlefield when in-house stored supplies are exhausted. This is done under a FDA-approved emergency protocol. Over the last 10 years of conflict, the ASBPO cited the number of battlefield whole blood collections and subsequent transfusions to be more than 10,000.

Deployment of a Whole Blood Pathogen Reduction Device (WBPRD) would ensure that battlefield-collected blood for transfusion continues to meet FDA safety standards. In the device under development, freshly collected units of blood are exposed to ultraviolet light in combination with riboflavin to neutralize any viruses, bacteria, or parasites that may be present in the blood. This treatment also reduces the risk of Graft-Versus-Host Disease (when a donor's cells view the recipient's body as foreign and begins to attack/damage healthy cells) that may result from blood transfusion. A European/worldwide market for the WBPRD exists because of a higher frequency of whole blood transfusions outside of the U.S.

The FDA licensing process is underway for the WBPRD. A multi-site Phase 2 (safety and initial effectiveness testing) clinical trial is in progress.

This product is intended for use at Role 3 and Blood Support Detachments.



ACQUISITION PHASE

- Engineering & Manufacturing Development

FUNDING SOURCE

- Defense Health Program

INFECTIOUS DISEASE

MALARIA TREATMENT AND PREVENTION

ANTIMALARIAL DRUGS

Countermeasures against the #1 infectious disease threat to deployed U.S. Forces

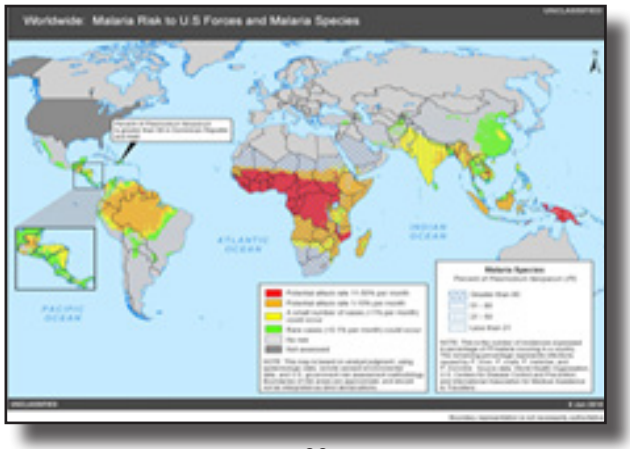
Malaria is a global health threat. An estimated 350-500 million people are infected with nearly 600,000 deaths annually. It is transmitted to humans through the bite of infected mosquitoes. Symptoms include fever, headaches, chills, nausea, and muscle aches and, in severe and complicated cases, organ failure with coma or death can occur. Malaria is categorized by the FDA as a neglected disease, with few drugs available for treatment and no industrial-base for the development of drugs to prevent the disease.

Malaria represents the #1 infectious disease threat to deployed U.S. Forces. In endemic countries, the attack rate in unprotected Service Members has been reported as high as 44% (Murray, 2003). Throughout the past 13 years, medical providers diagnosed approximately 100 cases per year in deployed U.S. Troops. On average, each case results in 7 to 10 lost duty days and poses a significant operational risk.

Resistance to currently available anti-malarial drugs is now widespread in Africa and Southeast Asia, regions where U.S. Troops frequently deploy. Untreatable malaria is again emerging in Cambodia. To protect U.S. Troops deployed in endemic areas of the world, the USAMRDC is pursuing development of new antimalarial drugs with a focus on drugs effective against drug resistant strains of the malaria parasite.

The DoD has adopted a proactive approach to improve available therapies. These efforts heavily leverage external partnerships to achieve results.

Reference: Murray CK, Yun HC, Markelz AE, Ikulicz JF, Vento TJ, Burgess TH, Cardile AP, Miller RS. 2015. Special Report - Operation United Assistance: Infectious Disease Threats to Deployed Military Personnel. Military Medicine, 180, 6:626.

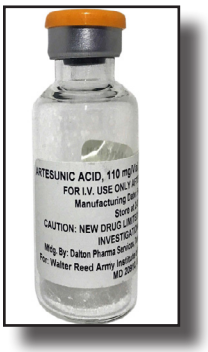


ANTIMALARIAL DRUG INTRAVENOUS ARTESUNATE

PARTNER(S)

- Amivas, LLC, Silver Spring, Maryland
- Dalton Pharma Services, Toronto, Ontario, Canada
- MIDRP, USAMRDC, Fort Detrick, Maryland
- WRAIR, Silver Spring,Maryland

Currently, quinidine gluconate is the only FDA-approved drug available in the U.S. to treat military and civilian personnel with severe or complicated malaria. The manufacturer has discontinued production because the drug has significant side effects, such as the potential to induce heart failure. To replace quinidine gluconate, the U.S. Army is developing intravenous artesunate (IVAS), a new drug to treat severe and complicated malaria.



Artesunate is a derivative of the compound Artemisinin, an antimalarial compound extracted from the Chinese herb *Artemisia annua*. It is widely used in countries outside of the U.S. and has a well-established safety profile.

This effort seeks to develop artesunate in an intravenous form as a replacement for quinidine gluconate. Intravenous artesunate is endorsed by the World Health Organization as a first-line treatment for severe malaria. Clinical trials conducted in the U.S., Canada, and in Kenya and Thailand demonstrated that IVAS is highly effective against severe and complicated malaria.

The WPAC PMO in conjunction with Amivas submitted a New Drug Application (NDA) to the FDA for IVAS in 2019. In the interim, IVAS is available to U.S. Military and civilians (through the CDC) under a Treatment Investigational New Drug (IND) application. The WPAC PMO maintains the supply contract for materials provided under the IND. This effort is projected to field in FY20.

This capability is intended for use at Roles 3 and 4.

ACQUISITION PHASE

- Engineering & Manufacturing Development

FUNDING SOURCE

- U.S. Army

ANTIMALARIAL DRUG TAFENOQUINE

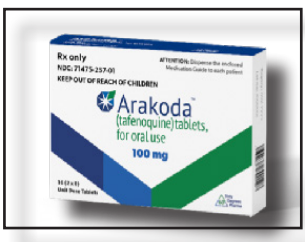
PARTNER(S)

- GSK, Philadelphia, Pennsylvania
- Medicines for Malaria Venture, Geneva, Switzerland
- MIDRP, USAMRDC, Fort Detrick, Maryland
- 60^{O} Pharmaceuticals, LLC, Washington, District of Columbia and Australia
- WRAIR, Silver Spring, Maryland

Malaria is caused by a parasite of the genus *Plasmodium* (*P.*) of which four different species affect humans: *P. falciparum, P. malariae, P. ovale*, and *P. vivax*. A new malarial drug, Tafenoquine (TQ), originally developed by the WRAIR, was licensed by the FDA in 2018 as both a therapeutic (for prevention of *P. falciparum* and *P. vivax*) and a prophylactic (malaria prevention) drug.

In 2014, 60° Pharmaceuticals, LLC, became the U.S. Army's partner and commercial sponsor for the development of TQ for prophylaxis of all species of malaria, and for the licensing of TQ both in Australia by the Therapeutic Goods Administration (TGA) and in the U.S. with the FDA. The GSK is supporting the effort by providing access to its manufacturer in India for the formulation and manufacturing of tablets. 60° Pharmaceuticals, LLC will commercialize the product and make it available to the U.S. Military. The TQ drug is approved for weekly administration to prevent malaria (all species) by both the FDA (Arakoda™) and the TGA (Kodatef™).

Additionally, and in parallel with the prophylaxis effort, GSK in partnership with Medicines for Malaria Venture developed TQ for the radical cure of *P. vivax* to replace Primaquine. Submission of GSK's NDA to the FDA was also approved by the FDA (Krintafel™) and the TGA (Kozenis™) in 2018. The GSK's indication is for a single-dose treatment to clear the *P. vivax* parasites from the blood and liver (versus 14 daily doses of Primaquine).



The TQ drug is the first new malaria drug in nearly 20 years for both of these indications. This drug represents a significant increase in the U.S. Military's ability to control malaria in Deployed Forces. It will be available for deploying Military in FY20.

This capability is intended for administration at Roles 2, 3, and 4.

ACQUISITION PHASE

- Production & Deployment

FUNDING SOURCE

- U.S. Army

CASUALTY CARE

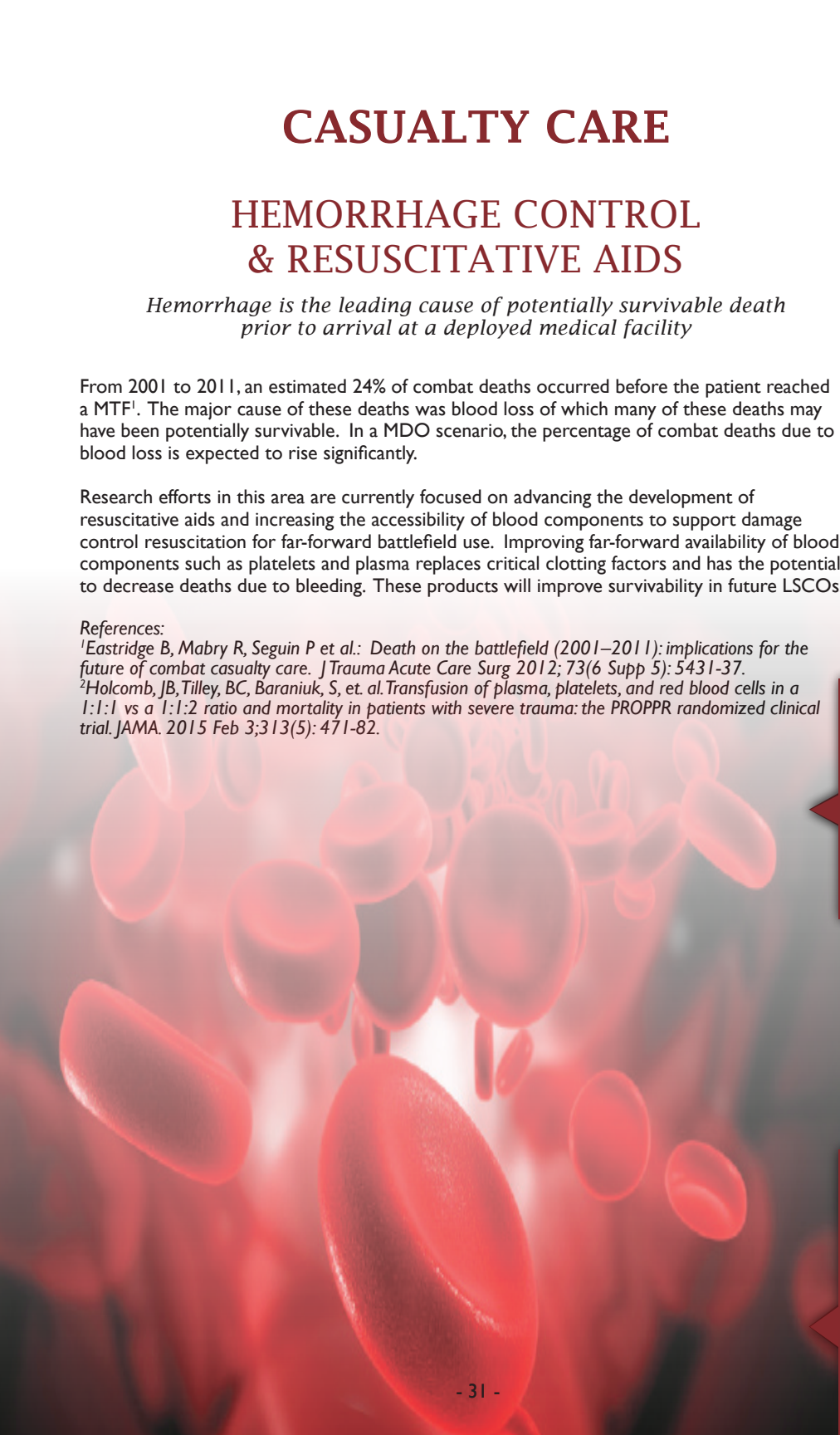
HEMORRHAGE CONTROL & RESUSCITATIVE AIDS

Hemorrhage is the leading cause of potentially survivable death prior to arrival at a deployed medical facility

From 2001 to 2011, an estimated 24% of combat deaths occurred before the patient reached a MTF[1]. The major cause of these deaths was blood loss of which many of these deaths may have been potentially survivable. In a MDO scenario, the percentage of combat deaths due to blood loss is expected to rise significantly.

Research efforts in this area are currently focused on advancing the development of resuscitative aids and increasing the accessibility of blood components to support damage control resuscitation for far-forward battlefield use. Improving far-forward availability of blood components such as platelets and plasma replaces critical clotting factors and has the potential to decrease deaths due to bleeding. These products will improve survivability in future LSCOs.

References:
[1]Eastridge B, Mabry R, Seguin P et al.: Death on the battlefield (2001–2011): implications for the future of combat casualty care. J Trauma Acute Care Surg 2012; 73(6 Supp 5): 5431-37.
[2]Holcomb, JB, Tilley, BC, Baraniuk, S, et. al. Transfusion of plasma, platelets, and red blood cells in a 1:1:1 vs a 1:1:2 ratio and mortality in patients with severe trauma: the PROPPR randomized clinical trial. JAMA. 2015 Feb 3;313(5): 471-82.



BREATH TEST FOR PULMONARY OXYGEN TOXICITY

PARTNER(S)

- Military Operational Medicine Research Program (MOMRP), USAMRDC, Fort Detrick, Maryland
- NMRC, Silver Spring, Maryland

Acute Respiratory Distress Syndrome is reported in 32% of Military casualties with burns, and may be associated with a 40-50% mortality in the general population (Belenkiy, 2014). Using a Volatile Organic Compound-based breath test, this project seeks to identify breath biomarkers for use as an individualized data to guide clinical decision making.

This capability is intended for use at Role 3.

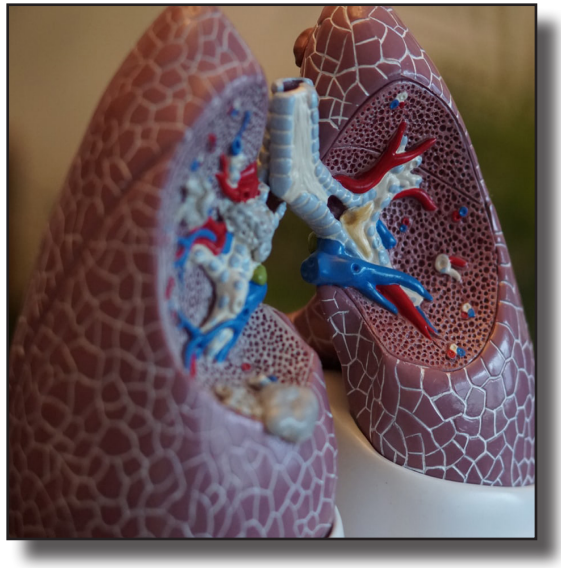
Reference: Belenkiy SM1, Buel AR, Cannon JW, Sine CR, Aden JK, Henderson JL, Liu NT, Lundy JB, Renz EM, Batchinsky AI, Cancio LC, Chung KK. J Trauma Acute Care Surg. 2014 Mar;76(3):821-7. doi: 10.1097/TA.0b013e3182aa2d21.

ACQUISITION PHASE

- Pre-Materiel Development Decision

FUNDING SOURCE

- Defense Health Program



COLD-STORED PLATELETS

PARTNER(S)

- ASBPO, Falls Church, Virginia
- CCCRP, USAMRDC, Fort Detrick, Maryland
- U.S. Army Institute of Surgical Research (USAISR), Joint Base San Antonio-Fort Sam Houston (JBSA-FSH), Texas
- Industry partner(s) to be determined

Preliminary studies demonstrate that Cold-Stored Platelets (CSP) may be superior to conventional room temperature platelets for bleeding patients. Cold storage also lowers the risk of bacterial contamination and may extend platelet function from 7 days to between 14 and 21 days. A longer shelf life and minimal logistical requirements will enable CSPs to be available for far forward damage control resuscitation.

Through a collaboration with the FDA under Public Law 115-92, CSPs with a 14-day shelf life received initial approval in 2019 for use by the DoD when room temperature platelets are not available. This product will only be produced by ASBPO for military blood banks.

In addition, the DoD will pursue FDA licensure of CSPs for all bleeding patients to extend the shelf life to 21 days and ensure our civilian blood bank partners can provide surge capacity for platelets in case of large-scale combat, helping to ensure life-saving blood products are available to support MDOs.

This capability is intended for use at Roles 2 and 3.

ACQUISITION PHASE

- Technology Maturation & Risk Reduction

FUNDING SOURCE

- Defense Health Program

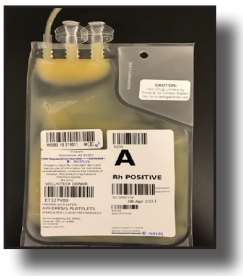
Photo Reference: Blood Services, Brooke Army Medical Center

CRYOPRESERVED PLATELETS

PARTNER(S)

- ASBPO, Falls Church, Virginia
- CCCRP, USAMRDC, Fort Detrick, Maryland
- USAISR, JBSA-FSH, Texas
- Industry partner(s) to be determined

The use of platelets on the battlefield to control bleeding is limited by a short window from collection to expiration (five days); a room temperature storage requirement, which increases the risk of bacterial contamination in the platelet unit; the need for constant agitation of the unit; and a gradual decline in platelet function over time.



The Cryopreserved Platelet Product (CPP) consists of human platelets that are frozen and preserved in a solution that protects the platelets during freezing. Units of the CPP are stored frozen for up to two years, allowing pre-positioning in anticipation of need during a future conflict.

The Dutch Military Health Service used CPP in the Balkans and in Afghanistan. The CPP is not currently licensed for clinical use by the FDA. Once FDA licensed, the CPP will be produced by U.S. Military blood banks and managed as a blood product for the battlefield by the ASBPO. Phase 1 (safety and safe dosage testing) and Phase 2 (safety and initial effectiveness testing) clinical trials are currently in progress at multiple blood research centers. This effort is projected to field in FY27.

This capability is intended for use at Roles 2 and 3.

ACQUISITION PHASE

- Engineering & Manufacturing Development

FUNDING SOURCE

- U.S. Army

EXTRACORPOREAL LIFE SUPPORT LUNG/RENAL

PARTNER(S)

- CCCRP, USAMRDC, Fort Detrick, Maryland
- Medica S.p.A., Medolla, Italy
- Wearable Artificial Organs Inc, Beverly Hills, California

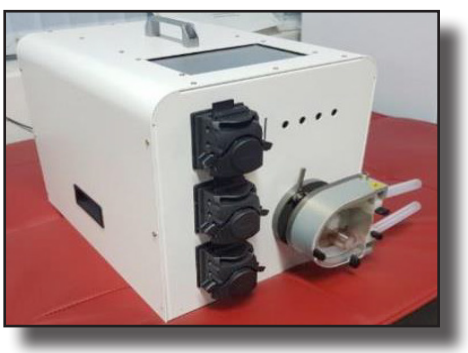
Extracorporeal life support (ECLS) is a technique that provides prolonged cardiac and respiratory support to persons whose heart and lungs have been weakened to the point that they are unable to provide an adequate amount of gas exchange or blood circulation to sustain life. The ECLS can be paired with continuous renal replacement therapy to replace kidney function.

Acute lung injury and acute respiratory distress syndrome affects 26-33% of all critically injured combat casualties (Cannon, 2011). Acute kidney injury is a significant and common consequence of military trauma. The treatment of casualties with severe lung and renal injury as soon as possible after injury is critical to their survival.

This effort supports the development of a portable device capable of sustaining organ function (e.g., lungs and kidney). It is planned for use at Role 3 and in patient evacuation. Early application of ECLS technologies, such as extracorporeal membrane oxygenation, may benefit critically ill combat casualties. Market Research for industry partners is on-going.

This capability is initially intended for use at Role 3 and during evacuation.

Reference: Cannon J, Zonies D, Benfield R, Elster E, Wanek S: Advanced en-route critical care during combat operations. Bulletin of the American College of Surgeons 2011; 96(5): 21-29.



ACQUISITION PHASE

- Technology Maturation & Risk Reduction

FUNDING SOURCE

- U.S. Army

FREEZE-DRIED PLASMA

PARTNER(S)

- ASBPO, Falls Church, Virginia
- CCCRP, USAMRDC, Fort Detrick, Maryland
- SOCOM, MacDill Air Force Base, Florida
- Vascular Solutions, Minneapolis, Minnesota (a wholly-owned subsidiary of Teleflex, Wayne, Pennsylvania)
- Westat, Rockville, Maryland

Clot-promoting proteins in the plasma of freshly collected whole blood are unstable; however, when the plasma is separated from the red cells in whole blood and frozen separately at -18°C within 8 hours of collection, the clotting proteins remain stable for up to one year. This component product, Fresh Frozen Plasma (FFP), is shipped frozen to theater on dry ice and stored in large, specialized freezers until needed. Unfortunately, up to an estimated 30% of FFP units are unusable in the deployed environment because of breakage during shipment or the need to discard after five days from thawing because they were not used. The large logistical component, the need for a product closer to the point of injury, plus the high incidence of waste, is driving the need for an improved product.

Freeze-Dried Plasma (FDP) also retains clotting proteins. It consists of freeze-dried (lyophilized) human plasma packaged for rapid reconstitution and administration. It can be shipped in ruggedized containers, stored at refrigerator temperature (potentially room temperature), and reconstituted in less than six minutes. The FDP product reduces the need for large freezers and their accompanying power and space needs and decreases waste related to product expiration; as a result, can be used farther forward on the battlefield where the need only increases during MDO in prolonged care situations.

The French FDP product that is in use by SOCOM cannot meet the needs of conventional Forces due to production capacity for the product. In order to meet the demand for FDP across the DoD, Vascular Solutions/ Teleflex is developing the FDP product under a CRADA. Clinical trials are being conducted by Westat under contract with the WPAC PMO. Ultimately, Vascular Solutions/Teleflex will be the regulatory sponsor for the FDA submission of a BLA and will commercialize the product. This effort is projected to field in FY21.

This capability is intended for use at Roles 2 and 3, with the potential for deployment farther forward.

ACQUISITION PHASE

- Engineering & Manufacturing Development

FUNDING SOURCE

- U.S. Army

HEMORRHAGE DETECTION

PARTNER(S)

- CCCRP, USAMRDC, Fort Detrick, Maryland
- Masimo Corporation, Irvine, California
- Nonin Medical, Plymouth, Minnesota
- Telemedicine and Advanced Technology Research Center (TATRC), USAMRDC, Fort Detrick, Maryland
- USAISR, JBSA-FSH, Texas
- University of Maryland at Baltimore, Baltimore, Maryland

This program seeks to develop a technology that will identify patients at risk for life-threatening bleeding and shock in those cases where bleeding may not be obvious (e.g., internal bleeding).

This work will contribute to the development of triage and evacuation priorities; as well as, guidelines for the blood products needed for intervention in these patients. Market research for new technologies is ongoing.

This capability is intended for use at Roles 1, 2, and 3 and during evacuation.

Reference: Eastridge B, Mabry R, Seguin P, et al. Death on the battlefield (2001–2011): implications for the future of combat casualty care. J Trauma Acute Care Surg 2012; 73(6 Supp 5): 5431-37.

ACQUISITION PHASE

- Technology Maturation & Risk Reduction

FUNDING SOURCE

- Defense Health Program

NON-COMPRESSIBLE HEMORRHAGE CONTROL

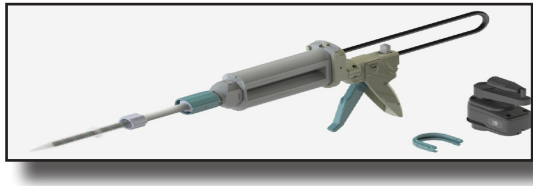
PARTNER(S)

- Arsenal Medical, Inc., Watertown, Massachusetts
- CCCRP, USAMRDC, Fort Detrick, Maryland
- Critical Innovations, LLC., Inglewood, California

From October 2001 to June 2011, 598 lives could have been potentially saved if a non-compressible hemorrhage control agent had been available on the battlefield. Uncontrolled bleeding from injured vessels within the torso, at the junction of an extremity and the torso, and at other locations that prevent the use of a tourniquet to control the bleeding is cited as the cause of over 90% of the potentially survivable deaths on the battlefield (Eastridge, 2012). The current standard of care for non-compressible hemorrhage is definitive surgery, which is not available at point of injury. Currently, there are no materiel solutions available to providers in the far-forward environment that can significantly control non-compressible hemorrhage.

Considering its complexity, it is unlikely that this gap will be closed by a single solution. The final, fielded solution(s) will be a family of systems, based on the end user and the intended environment. This program seeks material products capable of rapidly controlling massive bleeding that current compressible solutions cannot address. The proposed device(s) will temporarily stabilize the patient until the bleeding is permanently stopped by a surgeon.

Two solutions are currently under contract as potential components of a family of systems to address noncompressible hemorrhage.



ResQFoam™ (Arsenal Medical) consists of two components that, when mixed together, react to form a hemostatic foam that expands rapidly when mixed with actively flowing blood to stop bleeding. In 2017, the FDA approved an Investigational Device Exemption application for this product. This product will be tested in a multi-center clinical trial that is anticipated to start in 2020.

The Fast Onset Abdominal Management or F.O.A.M.™ device (Critical Innovations) is a small tube that contains a material with polymers that resemble foam. After inserting the device into an open wound, the foam applies pressure to the vessels, which stops internal bleeding.

This capability is intended for use at Roles 1, 2, and 3.

Reference: Eastridge B, Mabry R, Seguin P et al.: Death on the battlefield (2001–2011): implications for the future of combat casualty care. J Trauma Acute Care Surg 2012; 73(6 Supp 5): 5431-37.

ACQUISITION PHASE

- Technology Maturation & Risk Reduction

FUNDING SOURCE

- Defense Health Program

CASUALTY CARE

PAIN MANAGEMENT

Relief from pain at point of injury

BATTLEFIELD PAIN MANAGEMENT KETAMINE

PARTNER(S)

- Clinical and Rehabilitative Medicine Research Program (CRMRP), USAMRDC, Fort Detrick, Maryland
- Emergent BioSolutions, Gaithersburg, Maryland
- iX Biopharma Ltd, Singapore, Singapore

Low-dose ketamine has emerged as a potentially effective opioid alternative. Ketamine's pain-relieving properties have long been recognized both alone and more commonly in combination with other analgesics. It was licensed in 1970 as an anesthetic (used to reduce or eliminate pain during surgery) for intravenous or intra-muscular administration. However, since that time it has been widely used off-label as an analgesic (used for pain relief after trauma) in both the pre-hospital and hospital settings in civilian and military communities. Off-label use is the legal use of a drug as directed by a physician in a manner different from that described on the FDA-approved drug label, which describes the approved use of the drug. The established effects of ketamine, beyond the primary analgesic effect, make it particularly valuable for battlefield pain management.

The primary objective of this program is to seek FDA licensure for the addition of intramuscular analgesic use to the product label (currently ketamine is indicated for anesthesia only).

This capability is intended for use at Roles 1, 2, 3, and 4.

ACQUISITION PHASE

- Technology Maturation & Risk Reduction

FUNDING SOURCE

- Defense Health Program

BATTLEFIELD PAIN MANAGEMENT SUFENTANIL

PARTNER(S)

- AcelRx Pharmaceuticals, Inc., Redwood City, California
- CRMRP, USAMRDC, Fort Detrick, Maryland

Guidelines from the Tactical Combat Casualty Care Committee outline the recommended treatment of severe pain caused by trauma. These include the use of non-steroidal anti-inflammatory drugs (e.g., ibuprofen), ketamine (off-label use), and opioids (e.g., fentanyl and morphine). In the past, the use of opioids has demonstrated the potential for significant side effects (e.g., hypotension, respiratory depression, and a potential for dependence).

Sufentanil is an opioid drug used to relieve pain and is administered by medical providers. In a civilian setting, it is used for short periods of time, primarily in operating suites and critical care settings for immediate pain relief. With support from the DoD, AcelRx developed a fast-acting, tamper proof, easily dispensed sufentanil-based product for use on the battlefield either shortly after injury or during patient transport to relieve acute pain. This product is taken orally (under the tongue) and has demonstrated minimal side effects. Label indications recommend use for no more than 72 hours.

The developmental effort for sufentanil began as a grant awarded to AcelRx in 2011. The FDA approved the NDA in 2018 and the new drug was given the trade name, DSUVIA™. This effort is projected to field in FY20.

This capability is intended for use at Roles 1, 2, 3, and 4.

ACQUISITION PHASE

- Engineering & Manufacturing Development

FUNDING SOURCE

- Defense Health Program

CASUALTY CARE

EXTREMITY INJURY REPAIR (EIR)

Improving limb salvage and function

EIR — BONE

PARTNER(S)

- CRMRP, USAMRDC, Fort Detrick, Maryland
- Industry partner(s) to be determined

This effort focuses on the development of medical products to treat severe bone injuries resulting from trauma. The products being considered for development include biologics, devices, and regenerative medicine options.

The products will stabilize complex/open fractures from the point of injury to theater MEDEVAC, treat non-healing fractures in order to treat/prevent osteomyelitis (bone infection), repair damage to the unique craniomaxillofacial-related bone and soft tissue structures, and/or prevent/treat rapidly progressive degenerative joint disease following trauma.

This capability is intended for use at Roles 2, 3, and 4.

ACQUISITION PHASE

- Materiel Solution Analysis

FUNDING SOURCE

- Defense Health Program

EIR — MUSCLE

PARTNER(S)

- Cedars-Sinai Medical Center, Los Angeles, California
- CRMRP, USAMRDC, Fort Detrick, Maryland
- Fibralign Corporation, Sunnyvale, California
- University of Pittsburgh, Pittsburgh, Pennsylvania

Frequently, extremity injuries involve volumetric muscle loss (VML), which is defined as the loss of critical muscle mass beyond which the body cannot naturally rebuild to the original mass. This condition is also related to a decline in remaining muscle function.[1-2]

A VML is associated with the loss of particular cell types essential for muscle regeneration. It affects the tendons that connect the muscles to the bone, which enable movement of the limb or other body part. Currently, there are no medical treatments for VML. Long-term outcomes are poor because of incomplete muscle regeneration and continuing loss may result in permanent disability.[3-4]

This effort seeks to identify treatment solutions for trauma-induced muscle and muscle/tendon junction injuries that require permanent repair. The goal is a medical capability that can restore the normal or near-function of the injured muscle group.

This capability is intended for use at Role 4.

References:
[1]Owens BD, Kragh JF, Macaitis J, Svoboda SJ, Wenke JC: Characterization of extremity wounds in Operation Iraqi Freedom and operation enduring freedom. J Orthop Trauma 2007; 21: 254–57.
[2]Grogan BF, Hsu JR, Consortium STR, et al: Volumetric muscle loss. J Amer Acad Orthop Surg 2011: 19: 35–S37.
[3]Rivera JC, Corona BT: Muscle-related disability following combat injury increases with time. US Army Med Dep J 2016: 30–35.
[4]Owens JG et al: Return to running and sports participation after limb salvage. J Trauma Acute Care Surg 2011; 71: S120–S124.

ACQUISITION PHASE

- Materiel Solution Analysis

FUNDING SOURCE

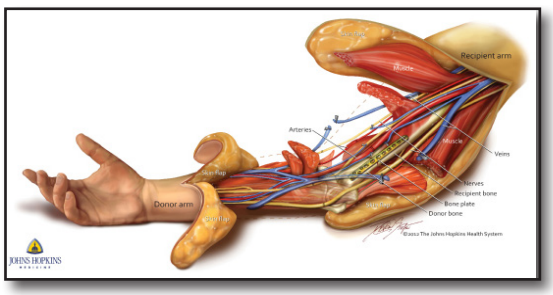
- Defense Health Program

EIR — NERVE

PARTNER(S)

- Baylor College of Medicine, Houston, Texas
- Brigham and Women's Hospital, Boston, Massachusetts
- CRMRP, USAMRDC, Fort Detrick, Maryland
- Hackensack University Medical Center, Hackensack, New Jersey
- Johns Hopkins University, Baltimore, Maryland
- Massachusetts Institute of Technology (MIT), Cambridge, Massachusetts
- Mayo Clinic and Foundation, Rochester, Minnesota
- TDA Research Inc., Wheat Ridge, Colorado
- University of California Los Angeles, Los Angeles, California
- University of Missouri, Columbia, Missouri
- University of Pennsylvania, Philadelphia, Pennsylvania
- University of Pittsburgh, Pittsburgh, Pennsylvania
- University of Rochester, Rochester, New York
- Vanderbilt University, Nashville, Tennessee
- Virginia Commonwealth University, Richmond, Virginia
- Wake Forest University, Winston-Salem, North Carolina
- WRAIR, Silver Spring, Maryland
- Walter Reed National Military Medical Center (WRNMMC), Bethesda, Maryland

Injuries due to trauma impact all tissue types, but the most problematic of these is nerve injury. The decision to repair injuries to nerves is made by the clinician on a case-by-case basis. In some circumstances it is possible to surgically repair nerve pathways, but in other circumstances natural regrowth is the best treatment. These treatment/repairs have a low to moderate success rate.



This effort aims to identify treatment solutions for war-related/trauma-induced nerve injuries that require permanent repair to re-establish peripheral nerve function. The resulting medical capability will restore function of the injured peripheral nerves back to a normal or near-normal state.

This capability is intended for use at Role 4.

ACQUISITION PHASE

- Materiel Solution Analysis

FUNDING SOURCE

- Defense Health Program

EIR — VASCULAR

PARTNER(S)

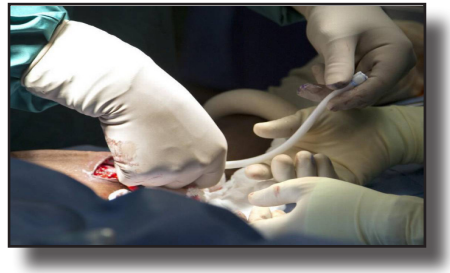
- CRMRP, USAMRDC, Fort Detrick, Maryland
- Humacyte, Inc., Morrisville, North Carolina
- Johns Hopkins University, Baltimore, Maryland
- University of Maryland at Baltimore, Baltimore, Maryland
- University of Washington, Seattle, Washington
- WRAIR, Silver Spring, Maryland
- Yale University, New Haven, Connecticut

Between 2002 and 2009, extremity injury accounted for up to 79% of the reported trauma cases from theater (White, 2011). Extremity injuries are primarily caused by improvised explosive devices and high-energy explosions, which result in severe fractures, significant soft tissue loss, and vascular injuries. The ability to re-establish blood flow through a severely damaged artery in order to keep the injured limb functional remains a significant challenge.

Current methods to reconstruct blood vessels often rely on transferring veins or arteries from other parts of the body to the injured area. Unfortunately, due to the nature of combat injuries, those tissues are often not available in severely wounded Service Members. Other materials used as substitutes must be sufficiently durable to withstand decades of high-demand use, considering the young age of affected Warfighters.

HUMACYL® (Humacyte) is intended for use in surgeries to replace severely damaged blood vessels. This unique product is a bio-engineered frame made of human proteins. After it is surgically placed in the patient, the patient's own cells colonize the protein frame, more closely mimicking the patient's own blood vessel. The FDA gave HUMACYL® the designation of Regenerative Medicine Advanced Therapy. This means that the FDA will help facilitate the efficient development and expedited review of the HUMACYL® human acellular vessel for vascular access. For this application, the intended use is in dialysis patients.

The DoD is supporting the application of this product for trauma indications, specifically in cases of extremity vascular injury repair.



This capability is initially intended for use at Role 3, with the potential for future use at Role 2.

Reference: White JM, Stannard A, Burkhardt GE, et al.: The epidemiology of vascular injury in the wars in Iraq and Afghanistan. Ann Surg 2011; 253(6): 1184-9.

ACQUISITION PHASE

- Technology Maturation & Risk Reduction

FUNDING SOURCE

- U.S. Army

CASUALTY CARE

WOUND REPAIR

Increasing wound closure while reducing infection and scarring

BURN TREATMENT SKIN REPAIR

PARTNER(S)

- CRMRP, USAMRDC, Fort Detrick, Maryland
- CCCRP, USAMRDC, Fort Detrick, Maryland
- Keratin Biosciences, Winston-Salem, North Carolina
- Rutgers University, New Brunswick, New Jersey
- Spectral MD, Dallas, Texas
- Stratatech, Madison, Wisconsin (a Mallinckrodt Pharmaceuticals company, Staines-upon-Thames, United Kingdom)

Historically, this effort has looked at burn wound progression, functional skin regeneration, and burn scarring treatments. Investments have included drugs and devices to limit burn conversion (Rutgers University); StrataGraft®, a biologically-active, universal donor skin tissue that provides immediate wound coverage while promoting tissue regeneration; and KeraStat®, a gel for decreasing time to wound closure and decreasing scarring. In 2017, the KeraStat® Gel received FDA clearance (510(k) pathway).

The need for more effective solutions in prolonged care situations highlighted the need for a strategic approach to addressing wounds, to include burns. For example, one large analysis of combat casualties in 2008 showed that explosions account for 79% of injuries, which often result in burn injuries (Lashof-Sullivan, 2014). In the future, this effort will focus on developing products with the most promise for effectively treating wounds in an acute care setting.

This capability is intended for use at Roles 2 and 3.

Reference: Lashof-Sullivan, MM, Shoffstall E, Atkins KT, Keane N, Bir C, VandeVord P, Lavik EB, Proc Natl Acad Sci USA, 2014 Jul 15; 111(28): 10293–10298; Published online 2014 Jun 30. doi: 10.1073/pnas.1406979111

ACQUISITION PHASE

- Technology Maturation & Risk Reduction

FUNDING SOURCE

- Defense Health Program

CASUALTY CARE

SENSORY INJURY REPAIR

Innovative approaches to preserve vision and hearing

PHARMACEUTICAL INTERVENTIONS FOR NOISE INDUCED HEARING LOSS ACUTE EXPOSURE TREATMENT

PARTNER(S)

- CRMRP, USAMRDC, Fort Detrick, Maryland
- DoD Hearing Center of Excellence, Lackland Air Force Base, Texas
- Keratin Biosciences, Winston-Salem, North Carolina
- Rutgers University, New Brunswick, New Jersey
- Spectral MD, Dallas, Texas
- Stratatech, Madison, Wisconsin (a Mallinckrodt Pharmaceuticals company, Staines-upon-Thames, United Kingdom)
- Washington University School of Medicine, St. Louis, Missouri

Inherently noise-hazardous environments make Service Members particularly vulnerable to sensorineural hearing loss, which is also called noise induced hearing loss. Current hearing protection strategies include noise barrier devices (e.g., hearing protection devices), noise reduction strategies in conjunction with engineering (e.g., reduce noise at the source), and administrative controls (e.g., limiting the amount of time spent in noisy environments). Currently, there is no FDA-licensed pharmacologic prevention or treatment to reverse hearing loss due to noise injury.

The DoD recognizes a need to identify alternative protective strategies. Hearing is critical to Warfighters during combat operations, comprising 50-60% of one's situational awareness.[1] Hearing loss also remains second highest service-related disability claim by Veterans, and those receiving compensation due to hearing loss increased from 15.9% in 2005 to 24.4% in 2015.[2] One alternative protective strategy involves the use of pharmaceutical agents to interrupt biological pathways that cause permanent hearing injury and any subsequent irreversible hearing loss.

The goal of this effort is development of a FDA-licensed rescue drug for noise induced hearing loss to complement current hearing protection strategies. These may include pharmaceuticals aimed at addressing both acute and chronic exposure preventative drugs and treatment.

This capability is intended for use at Roles 1, 2, 3, and 4.

References:
[1]Garinther and Peters, Army RD&A Bulletin 1990;JAN-FEB:1-5.
[2]Veterans Benefits Administration Annual Reports

ACQUISITION PHASE

- Technology Maturation & Risk Reduction

FUNDING SOURCE

- Defense Health Program

TEMPORARY CORNEAL REPAIR

PARTNER(S)

- Ashvattha Therapeutics, LLC, Redwood City, California
- Chromologic, LLC, Monrovia, California
- CRMRP, USAMRDC, Fort Detrick, Maryland
- Luna Innovations Inc., Roanoke, Virginia
- Triton Systems, Inc., Lowell, Massachusetts
- USAISR, JBSA-FSH, Texas
- University of Southern California, Los Angeles, California

Combat eye injuries remain a significant cause of disability among wounded Warfighters, despite the use of combat eye protection. These injuries are life-changing for the patient, and incur long-term costs in terms of lifetime treatment, rehabilitation, loss of potential income, and associated psychological strains. From 2001 to 2017, there were over 6,000 military eye injuries with a high risk of blindness, with 43% of these patients ultimately going blind in at least one eye (Frick, 2019). These percentages are expected to increase in prolonged care environments.

Delayed treatment of open-eye injuries resulting from combat significantly increases the likelihood of poor visual outcomes for patients. Treatment of severe eye injuries must occur within 24-36 hours of injury or vision will be permanently lost. This effort is developing a non-surgical solution designed to temporarily close severe, penetrating injuries to the eye. This device will stabilize the eye until the injury is permanently repaired by an ophthalmologist.

This capability is initially intended for use by an ophthalmologist at Role 3, and later by other physicians at Role 2 with the appropriate tools and training.

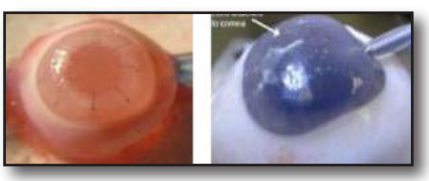
Reference: Frick KD, Singman EL: Cost of military eye injury and vision impairment related to traumatic brain injury: 2001–2017. Military Medicine 2019; 184 (5-6): E 493.

ACQUISITION PHASE

- Technology Maturation & Risk Reduction

FUNDING SOURCE

- U.S. Army



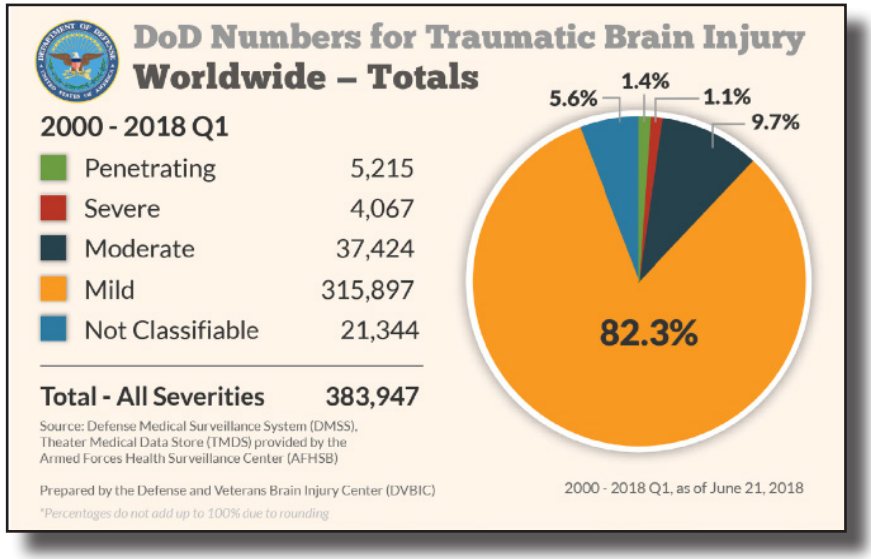
TRAUMATIC BRAIN INJURY

A TBI is a critical issue for Military Service Members and Veterans in both the training and deployed environments. Over the past 18 years, the DoD documented more than 383,000 case of TBI, of which 10% were moderate or severe (DVBIC, 2018). The high rate of TBI and blast-related concussions from training and combat operations affects the health of individual Service Members; as well as, Troop readiness.

A TBI results in physical, cognitive, social, emotional, and behavioral effects with outcomes ranging from complete recovery to permanent disability or death. Diagnosis of TBI relies on clinical examination and CT scans. The standard of care for treatment of mild TBI (mTBI) or concussion is rest and management of symptoms with long-term care by neurologist, psychiatrist, physiatrist, and neuropsychologists. The standard of care for moderate to severe TBI often requires neurological intensive care and neurosurgery followed by intensive rehabilitation. Currently there are no FDA-licensed drugs or devices to reduce the damage to the brain from TBI.

The DoD is seeking far forward solutions to diagnose, treat, and safely return Service Members to duty after TBI.

Reference: http://dvbic.dcoe.mil/dod-worldwide-numbers-tbi



TRAUMATIC BRAIN INJURY

DIAGNOSTICS

Detecting the signature battlefield injury

BRAIN IMAGING

PARTNER(S)

- CCCRP, USAMRDC, Fort Detrick, Maryland
- Industry partner(s) to be determined

This ultrasound technology development effort will allow clinicians to visualize brain structures and related abnormalities in real time. The technology will aid in the early identification of brain injuries (e.g., subdural hemorrhages, midline shift, and foreign bodies), enable early diagnosis, and expedite treatments.

This capability is intended for use at Roles 2, 3, and 4.

ACQUISITION PHASE

- Pre-Materiel Development Decision

FUNDING SOURCE

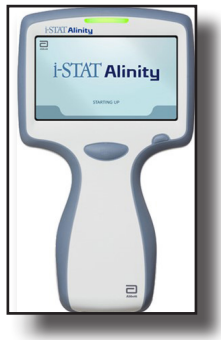
- Defense Health Program

LABORATORY ASSAY FOR TBI

PARTNER(S)

- Abbott Laboratories, Abbott Park, Illinois
- Abbott Point of Care, Princeton, New Jersey and Ottawa, Ontario, Canada
- Banyan Biomarkers, Inc., San Diego, California and Alchua, Florida
- CCCRP, USAMRDC, Fort Detrick, Maryland
- Defense and Veterans Brain Injury Center, Falls Church, Virginia
- WRAIR, Silver Spring, Maryland
- Womack Army Medical Center, Fort Bragg, North Carolina

The Laboratory Assay for TBI (LATBI) program focuses on transferring the FDA-licensed TBI blood biomarker test, called the Banyan Brain Trauma Indicator™, onto a field-deployable point of care device used in forward settings as a triage tool to inform evacuation decisions. The Banyan Brain Trauma Indicator™ received a FDA license in 2018. It helps rule-out the need for a CT scan of the head by testing for two blood biomarkers.



The LATBI acquisition strategy leverages a commercial device that is currently authorized for fielding in the Army's SKOs. The Abbott Laboratories' i-STAT® is a FDA-licensed medical device used for the evaluation of basic blood tests. Abbott Laboratories is in the process of modernizing/redesigning their current version of the i-STAT®.

Initial validation of the i-STAT® TBI assay will use plasma to accelerate the FDA licensing process, then a clinical trial to validate the presence of TBI biomarkers in whole blood will follow. Once FDA licensed, providers at Role 2 will use the modernized i-STAT® with the TBI assay to determine the need for a head CT, as long as the patient is tested within 24 hours of the TBI. This capability may eliminate up to a third of unnecessary patient evacuations to Role 3 for a head CT. This effort is projected to field in FY21.

Future increments will focus on the ability of the TBI biomarker blood test to directly diagnose mTBI and predict those who are prone to improvement versus those who will need further follow-on care.

This capability is intended for use at Roles 2 and 3.

ACQUISITION PHASE

- Engineering & Manufacturing Development

FUNDING SOURCE

- U.S. Army

NEXT GENERATION LABORATORY ASSAY FOR TBI

PARTNER(S)

- Abbott Laboratories, Abbott Park, Illinois
- CCCRP, USAMRDC, Fort Detrick, Maryland
- WRAIR, Silver Spring, Maryland
- Industry partner(s) to be determined

The Next Generation (NG) LATBI effort is for far-forward Role 1 settings. It is envisioned as a hand-held disposable platform with the ability to test different sample types (e.g., saliva, urine, body fluids, or finger prick blood) for novel biomarkers signifying the presence of a TBI. This point-of-injury device will enable a fast, objective assessment of TBI with a sensitivity and specificity of over 90% and without the logistical burden associated with the cold storage test reagents, special power requirements, and platform weight.

As the result of DoD science and technology investments, new biomarkers for TBI are identified on an ongoing basis. Early proof of concept studies using different sample types, characterization studies using pre-clinical models, and early pilot clinical studies are underway. These new biomarkers will complement those biomarkers detected in the Banyan Brain Trauma Indicator™. Assessment of disposable test platforms, such as dipstick or glucometer type devices using these different sample types is also underway.

The ultimate goal of the NG LATBI is to clinically validate a new biomarker(s) with sufficiently high specificity and sensitivity to rule out TBI, but which also show that a Service Member is able to return to duty without the risk of compounded injury if exposed to additional TBI.

This capability is intended for use at Roles 1 and 2.

ACQUISITION PHASE

- Pre-Materiel Development Decision

FUNDING SOURCE

- Defense Health Program

NON-INVASIVE NEUROASSESSMENT DEVICE

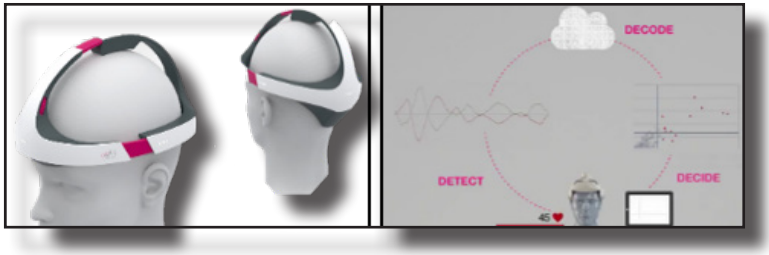
PARTNER(S)

- CCCRP, USAMRDC, Fort Detrick, Maryland
- Jan Medical, Mountain View, California
- Oculogica, New York City, New York
- U.S. Central Command, MacDill Air Force Base, Tampa, Florida
- 82nd Airborne Division, Fort Bragg, North Carolina

At present, a combination of self-reporting of symptoms and assessment by a medical provider determine the severity of brain injury. The Non-invasive Neuroassessment Device (NINAD) effort is seeking a FDA-licensed device to aid clinicians in determining the need for a head CT scan in pre-hospital settings. This device should reliably and accurately provide objective assessments that will inform evacuation decisions in far-forward roles of care. The device will be an adjunct to standard clinical practice. Candidate devices will undergo operational and environmental assessments to determine suitability and inform the acquisition strategy.

In addition, the Warfighter Brain Health PMO is working to build on the NINAD to incorporate the ability to assess the presence of mTBI related deficits or impairments using different neurological perspectives such as eye-tracking, vestibular/balance, and cognitive function. The intent for this additional capability is to have a reliable and accurate objective assessment that aids clinicians in making decisions on returning a Warfighter to duty. Currently, the market research is ongoing to identify materiel candidates with potential to fill this additional capability gap.

This capability is intended for use at Roles 1, 2, 3, and potentially 4 with the additional capability.



ACQUISITION PHASE

- Materiel Solution Analysis

FUNDING SOURCE

- U.S. Army

TBI POINT OF INJURY TRIAGE DEVICE

PARTNER(S)

- CCCRP, USAMRDC, Fort Detrick, Maryland
- Infrascan, Inc., Philadelphia, Pennsylvania
- Neural Analytics, Los Angeles, California

The TBI Point of Injury Triage device is intended as an aid to diagnose moderate to severe TBI. Combat medics and providers far-forward on the battlefield lack the capability to diagnose this condition. The device will enable this capability by informing evacuation, triage and treatment, improving survivability, and decreasing the progression of brain damage in injured Warfighters.

This effort will deliver a FDA-licensed medical device for use by military first responders. It will measure physiological parameter(s) associated with progression of brain injury and provide actionable information in the forward battlefield environment. It will be a first-of-a-kind capability to inform triage and evacuation decisions.

This capability is intended for use at Roles 1, 2, and 3.

ACQUISITION PHASE

- Materiel Solution Analysis

FUNDING SOURCE

- Defense Health Program

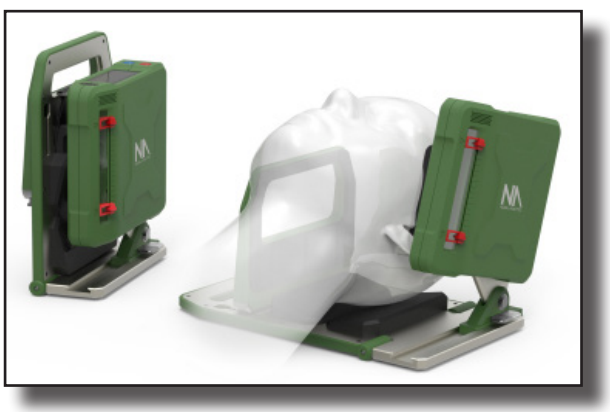


Photo Reference: Business Wire

TRAUMATIC BRAIN INJURY

RESUSCITATIVE AGENTS & TREATMENTS

Correcting or reducing injuries to the brain

ALTERNATIVE THERAPIES FOR TBI

PARTNER(S)

- CCCRP, USAMRDC, Fort Detrick, Maryland
- Fortuna Fix, Laval, Quebec, Canada
- Neuralstem, Inc., Germantown, Maryland
- SanBio, Mountain View, California
- University of Florida, Gainesville, Florida
- University of Miami, Coral Gables, Florida
- University of Texas at Houston, Houston, Texas
- WRAIR, Silver Spring, Maryland

Preventing or slowing progression of brain injury is critical to reduce the effects of moderate to severe TBI on health, survival, and the ability to resume normal life activity.

This effort will explore and develop alternative non-drug therapies to treat moderate to severe TBI.

Several areas of research are being pursued. These involve the use of bone marrow derived stem cells. The University of Texas at Houston is conducting an early Phase 2 (safety and initial effectiveness testing) human clinical trial. Neuralstem is piloting a Phase 1 (safety and safe dosage testing) clinical trial to support a FDA IND application. In addition, work is ongoing on pre-clinical work using animal models to develop mitochondrial targeted neuroprotection therapeutics.

This capability is intended for use at Roles 1, 2, 3, and 4.

ACQUISITION PHASE

- Pre-Materiel Development Decision

FUNDING SOURCE

- Defense Health Program

RESUSCITATIVE AGENTS FOR TBI TREATMENT FOR MODERATE/SEVERE CASUALTIES

PARTNER(S)

- CCCRP, USAMRDC, Fort Detrick, Maryland
- Industry partner(s) to be determined

Stabilization of brain function is critical during the first few hours post injury, when triage and evacuation decisions are top priority for severely injured Service Members. Resuscitative treatments that limit brain damage at the point of injury could significantly decrease life-long disability.

Patients with moderate to severe TBI typically also experience significant blood loss, hemorrhagic shock, and the subsequent lack of oxygen to the brain, which can worsen the TBI, ultimately leading to worsening illness and/or death. Treatment includes resuscitation fluids, but the data indicates that some of the commonly used fluids might be harmful when administered in large quantities. Improved strategies and therapies for resuscitation and stabilization that counter blood loss and minimize brain damage may improve TBI outcomes and enhance long term recovery.

This program includes basic science and clinical studies to develop strategies and therapies that replenish blood loss, minimize progression of brain injury, maximize brain recovery, and improve outcomes for Service Members suffering moderate to severe TBI.

This capability is intended for use at Roles 1, 2, 3, and 4.

ACQUISITION PHASE

- Pre-Materiel Development Decision

FUNDING SOURCE

- U.S. Army

TBI DRUG TREATMENT INCREMENT 1 MODERATE/SEVERE TBI

PARTNER(S)

- CCCRP, USAMRDC, Fort Detrick, Maryland
- Transforming Research and Clinical Knowledge for Traumatic Brain Injury Network (TRACK-TBI NET), University of California at San Francisco, San Francisco, California (coordinator)
- Industry partner(s) to be determined based on TBI drug candidate selection

The TBI-drug treatment (TBI-DT) Increment 1 seeks to deliver a FDA-licensed treatment option for moderate to severe TBI patients, which will limit or reverse neurologic damage and/or slow progression of injury visible on CT or magnetic resonance imaging. The goal of this effort is to decrease morbidity and mortality, improve cognitive outcomes, and restore brain function.

There are no FDA-licensed drugs for the treatment of TBI. Current standard of care, in both military and civilian medicine, is life-supportive interventions.

Over 30 clinical trials for TBI drugs have failed despite decades of research by government and private industry drug sponsors. This prompted a paradigm shift in the TBI-DT acquisition strategy, which involves focusing on risk reduction in Phase 2 (safety and initial effectiveness testing) clinical trials. Focused investment in Phase 2 trials will improve the quality and quantity of TBI drugs in the developmental pipeline and enable better characterization of drug candidates, reducing risk and cost prior to entering Phase 3 (large safety and effectiveness study/testing) clinical trials.

The TBI-DT effort will focus on new drugs or repurposed drugs that are FDA licensed for other indications. For this project, the DoD entered into a public-private partnership with the TRACK-TBI NET. This organization is experienced in recruiting individuals with TBI and can rapidly execute multiple FDA-regulated Phase 2 clinical trials.

This capability is intended for use at Roles 1, 2, 3, and 4.

ACQUISITION PHASE

- Technology Maturation & Risk Reduction

FUNDING SOURCE

- Defense Health Program

TBI DRUG TREATMENT INCREMENT 2 MILD TBI

PARTNER(S)

- CCCRP, USAMRDC, Fort Detrick, Maryland
- TRACK-TBI NET, University of California at San Francisco, San Francisco, California (coordinator)
- WRAIR, Silver Spring, Maryland
- Industry partner(s) to be determined based on TBI drug candidate selection

Currently, there are no FDA-licensed drugs for the treatment of mTBI or concussion. The majority of affected individuals return to normal function following a period of rest; however, data indicates that up to 25% of those diagnosed with concussion do not return to normal after rest and may suffer persistent post-concussive symptoms such as headache, sleep disturbances, fatigue, and neuropsychological deficits that do not resolve naturally.

The TBI-DT Increment 2 aims to develop a drug treatment that is safe and effective in reducing symptoms of mTBI and improving cognitive and mental health outcomes. To accomplish this, Increment 2 will leverage the partnerships and infrastructure of Increment 1 to develop and field a drug treatment for the significant proportion of concussion patients that do not improve.

This capability is intended for use at Roles 1, 2, 3, and 4.

ACQUISITION PHASE

- Technology Maturation & Risk Reduction

FUNDING SOURCE

- Defense Health Program

POST-TRAUMATIC STRESS DISORDER

PTSD DRUG TREATMENT

PARTNER(S)

- Cincinnati Veterans Affairs Medical Center (VAMC), Cincinnati, Ohio
- Cohen Veterans Bioscience, New York City, New York
- MOMRP, USAMRDC, Fort Detrick, Maryland

A PTSD is one of the most common mental health disorders resulting from a combat experience. There were 118,829 cases of PTSD among OEF, OIF, and Operation New Dawn deployed Service Members between 2001 and 2013.[1] It is estimated that 10-15% of U.S. combat-deployed Service Members develop some PTSD symptoms.[2]

Although over 130 PTSD related clinical drug trials have been conducted since 1987, only 2 FDA-licensed drugs are available to treat PTSD. These drugs, however, have limited effectiveness in treating combat-related PTSD.

This program seeks to identify alternative treatments for military-related PTSD by developing new FDA-licensed drugs and testing existing FDA-licensed medications for use in PTSD. A four-year study managed by the Cohen Veterans Bioscience will test a minimum of two potential drugs simultaneously by using an innovative Phase 2 (safety and initial effectiveness testing) clinical trial design that utilizes a personalized medicine approach to treatment. After drug selection, the Phase 2 clinical trial is scheduled to start by 2020. The results of this trial identify drugs for Phase 3 (large safety and effectiveness study/testing) testing, planned to start in 2022.

Simultaneously, the Cincinnati VAMC is evaluating the psychological measurement properties of the two clinical assessment tools used to evaluate Active Duty Military personnel and veterans. This study will also assess potential cognitive, physiological, neural markers of PTSD and will collect biological samples (e.g., blood) for future testing to inform targeted interventions. The study began enrolling participants in 2019.

This capability is intended for use at Roles 1, 2, 3, and 4.

References:

[1]Fisher H: A Guide to US Military Casualty Statistics: Operation New Dawn, Operation Iraqi Freedom, and Operating Enduring Freedom. Congressional Research Service 2014. Available at https://www.hsdl.org/?view&did=750720

[2]Vasterling JJ, Taft CT, Proctor SP, et al.: Establishing a methodology to examine the effects of war-zone PTSD on the family: the family foundations study. Internal J Methods Psychiatry Res 2015; 24(2): 143–55.

ACQUISITION PHASE

- Technology Maturation & Risk Reduction

FUNDING SOURCE

- Defense Health Program

EVACUATION

LITTER MODERNIZATION

Modernizing dated equipment for safer & more efficient casualty evacuation

LITTER STRAP MODERNIZATION

PARTNER(S)

- Alphapointe, Kansas City, Missouri
- New York City Industries for the Blind, New York City, New York (under the AbilityOne Program, Arlington, Virginia)
- U.S. Army Aeromedical Research Laboratory (USAARL), Fort Rucker, Alabama
- USAMMA, Fort Detrick, Maryland

During MEDEVAC, casualties are strapped to litters in the transport vehicles. Two major environmental stressors that routinely occur during evacuation, vibration and displacement due to sudden movement, can impact a patient's medical condition. The current litter strap has safety issues related to inadequately supporting the casualty during patient movement.

The Warfighter Health, Performance, and Evacuation (WHPE) PMO is working with the New York City Industries for the Blind under the AbilityOne program to address the issues related to the current litter strap in the ground and air ambulance sets. This modernization effort will provide a strap that minimizes patient movement on litters for all ground, rotary-wing aircraft, and fixed-wing aircraft used during MEDEVAC, while at the same time providing stabilization and immobilization for head, neck, or spinal cord of injured patients.

This capability is intended for use at Roles 1, 2, and 3 and during evacuation.

ACQUISITION PHASE

- Production & Deployment

FUNDING SOURCE

- U.S. Army

RESCUE LITTER MODERNIZATION

PARTNER(S)

- C Company, 3rd General Support Aviation Battalion, 82nd Aviation Regiment, Fort Bragg, North Carolina
- DLA, Philadelphia, Pennsylvania
- Jungle Warfare Training Center (JWTC), Schofield Barracks, Hawaii
- Skedco, Tualatin, Oregon
- USAARL, Fort Rucker, Alabama
- U.S. Army Medical Evacuation Proponency Directorate (MEPD), Fort Rucker, Alabama
- USAMMA, Fort Detrick, Maryland

The current Skedco rescue litter was fielded to the U.S. Army Medical Department's (AMEDD) medical equipment sets more than 30 years ago. Users have expressed the need: (1) for a smaller and lighter litter, (2) for easier casualty access, (3) to replace the multiple straps with a 5-point harness design, and (4) for stronger attachment points to the litter for hoisting. The goal of this effort is to modernize this litter, which is designed for all terrain rescue and to achieve a 40% reduction in stowage space for the litter.

The current rescue litter is hoisted onto MEDEVAC platforms (helicopters) and used for water rescue, and to remove injured Warfighters from remote areas (e.g., mountain areas, deep jungles), and from collapsed buildings.

This effort is supported by users from the Air Force Special Operations Para Rescue, U.S. Marine Corps, and the U.S. Army MEPD. The new litter was tested at Fort Bragg and the JWTC.

This capability is intended for use at Roles 1 and 2 and during evacuation.

ACQUISITION PHASE

- Production & Deployment

FUNDING SOURCE

- U.S. Army

7309 STANDARD AND QUAD-FOLD LITTER MODERNIZATION

PARTNER(S)

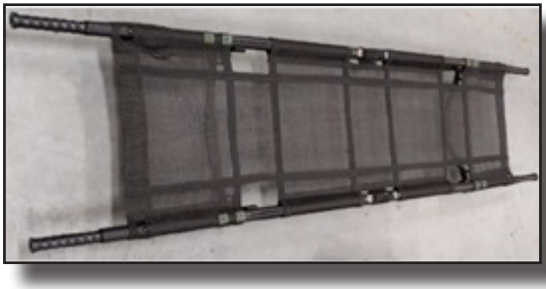
- AbilityOne, Arlington, Virginia
- Seattle Industries for the Blind, Seattle, Washington
- USAARL, Fort Rucker, Alabama
- USAMMA, Fort Detrick, Maryland

United States Army requirements call for the ability to use all ground, rotary-wing aircraft, and fixed wing aircraft (operating from point of injury to CONUS facilities) to evacuate casualties. The current standard 7309 NATO litter is not compliant with all of the available types of evacuation platforms, including the Mine-Resistant Ambush Protected vehicles currently in theater. Experience during OIF demonstrated that none of the five different litters in the inventory fit all of the NATO MEDEVAC platforms. This effort modernizes the current standard 7309 litter to enable use on all air and ground evacuation platforms and provides a quad-fold version for improved stowage.

The WHPE PMO is working with the Seattle Industries for the Blind to make changes to the current standard 7309 litter by:

- Upgrading the existing litter to meet current standards
- Providing a quad-fold version of the litter that will meet safe to fly standards

This capability is intended for use at Roles 1, 2, and 3 and during evacuation.



ACQUISITION PHASE

- Production & Deployment

FUNDING SOURCE

- U.S. Army

EVACUATION

EVACUATION PLATFORMS

Medical and casualty evacuations are essential to support the Army's top priority — the Warfighter

ARMORED MULTI-PURPOSE VEHICLE MEDICAL TREATMENT/EVACUATION VARIANTS

PARTNER(S)

- Project Manager (PM), Armored Brigade Combat Team (ABCT), Fort Benning, Georgia
- PM, Armored Multi-Purpose Vehicle (AMPV), Warren, Michigan
- U.S. Army Combat Capabilities Development Command (CCDC) Ground Vehicle Systems Center (GVSC), Warren, Michigan
- U.S. Army Maneuver Center of Excellence, Fort Benning, Georgia

The M113 ambulance dates back to 1962. The current fleet of M113 ambulance and treatment variants do not meet current mission requirements and the U.S. Army plans to retire the M113 family of vehicles through the AMPV Program.

For this effort, the WHPE PMO worked with PM, ABCT to identify potential AMPV evacuation and treatment vehicles to replace the M113 family of vehicles. The PMO revised the performance specifications for the medical variants for PM, ABCT and is coordinating medical equipment set test assets for the program. They continue to advise the program as members of the AMPV Integrated Product Team.

This capability is intended for use in Roles 1, 2, and 3.

ACQUISITION PHASE

- Engineering & Manufacturing Development

FUNDING SOURCE

- U.S. Army

JOINT LIGHT TACTICAL VEHICLE CASUALTY EVACUATION

PARTNER(S)

- Oshkosh Corporation, Oshkosh, Wisconsin
- U.S. Army Aberdeen Test Center, Aberdeen Proving Ground (APG), Maryland
- U.S. Army MEPD, Fort Rucker, Alabama
- U.S. Army Program Executive Office (PEO) Combat Support and Combat Service Support (CS&CSS) - Joint Light Tactical Vehicle (JLTV) PMO, Warren, Michigan

Casualty Evacuation (CASEVAC) using non-medical transportation platforms requires CASEVAC kits to adapt the platform and enable movement of the wounded from the battlefield to the next levels of medical care. During OEF and OIF, many of the 52,049 wounded Service Members were evacuated in this way. In future conflicts, units will use the JLTV for CASEVAC of patients. Because of this, linking the CASEVAC kit to the JLTV is critical to ensure and maintain battlefield medical readiness.

A CASEVAC kit comprises the hardware to load and safely hold a patient facing upwards into a vehicle of opportunity, a "scoop & run" capability. Since there is no program for a separate JLTV ambulance in the near future, the current focus is to develop requirements to get CASEVAC kits into the JLTV program.

The WHPE PMO supported the development of a kit that will potentially meet this requirement. The PMO's Medical Prototype Development Laboratory rapidly developed the prototype of this kit. The PEO CS&CSS - JTLV PMO issued a work directive to Oshkosh Corporation to validate the connection points for the prototype kit inside the current JLTV troop-carrying vehicle.

This capability is intended for use with Roles 1, 2, and 3.

ACQUISITION PHASE

- Operations & Support

FUNDING SOURCE

- U.S. Army

MEDEVAC MISSION EQUIPMENT FOR FUTURE VERTICAL LIFT

PARTNER(S)

- Bell Helicopter Textron Inc., Fort Worth, Texas
- The Boeing Company, Chicago, Illinois
- Sikorsky Aircraft Corporation, Stratford, Connecticut (A Lockheed Martin Company, Bethesda, Maryland)
- USAARL, Fort Rucker, Alabama
- U.S. Army MEPD, Fort Rucker, Alabama
- U.S. Army PEO Aviation, Product Directorate Medical Evacuation, Huntsville, Alabama
- U.S. Army PEO Aviation, PM Future Vertical Lift, Huntsville, Alabama

Future Vertical Lift (FVL) is a Joint Service helicopter program led by the U.S. Army that will replace the entire U.S. Military helicopter fleet beginning in the 2030s. The program is developing a family of manned and unmanned rotary-wing aircraft to dominate the skies over future battlefields. Advances in technology provide improved performance, speed, range, and lift capabilities. Capitalization on these advances will increase efficiencies for the Aeromedical Evacuation (AE) role to save life, limb, and eyesight while providing the best AE system possible for the Warfighter. Adding a MEDEVAC potential is a planned mission capability under the FVL program.

The WHPE PMO is working with PEO Aviation, Product Directorate Medical Evacuation to manage the design, development, and validation of air evacuation mission equipment for the FVL family of systems.

This capability is intended for Role 1, 2, and 3.

ACQUISITION PHASE

- Technology Maturation & Risk Reduction

FUNDING SOURCE

- U.S. Army

MEDEVAC MISSION EQUIPMENT PACKAGE FOR UH-60 BLACK HAWK

PARTNER(S)

- Air Methods, Greenwood Village, Colorado
- Forward Looking Infra-Red (FLIR) Systems Inc., Wilsonville, Oregon
- The Lighthouse for the Blind, Inc., Seattle, Washington
- U.S. Army CCDC Aviation & Missile (A&M) Center, Aviation Engineering Directorate, Redstone Arsenal, Alabama
- U.S. Army MEPD, Fort Rucker, Alabama
- U.S. Army PEO Aviation, Product Directorate Medical Evacuation, Huntsville, Alabama

The UH-60 Black Hawk MEDEVAC MEP converts a standard "slick" (basic configuration with only self-protective weapons) UH-60 Black Hawk helicopter into a dedicated MEDEVAC specific helicopter.

The MEDEVAC MEP components are: (1) Patient Handling System - Interim MEDEVAC Mission Support System, capable of securely transporting a mix of four ambulatory or litter patients; (2) moveable, crash worthy Medical Attendant Crew Seats; (3) Relocated Crew Communications System for the Flight Paramedic; (4) Black Hawk Advanced MEDEVAC Window and the FLIR Sensor to locate patients and provide obstacle clearance during confined-area landing and rescue-hoist operations; (5) Electrical Power Converter and Distribution for medical devices and provisions to store the Medical Equipment Set tools.

There are 279 UH-60 MEDEVAC conversions planned by 2020.

This capability is intended for Roles 1, 2, and 3.

ACQUISITION PHASE

- Production & Deployment

FUNDING SOURCE

- U.S. Army

EVACUATION

CAPTURING MEDICAL DATA FROM POINT OF INJURY

Ensuring a complete medical record of casualty care

MEDICAL HANDS-FREE UNIFIED BROADCAST SYSTEM INCREMENT 1

PARTNER(S)

- Sierra Nevada Corporation, Sparks, Nevada
- U.S. Army CCDC A&M Center, Systems Simulation, Software, and Integration (S3I) Directorate, Redstone Arsenal, Alabama
- U.S. Army PEO Command, Control, and Communications - Tactical (C3T), PM Joint Battle Command - Platform, APG, Maryland
- U.S. Army PEO Soldier, PM Nett Warrior, Fort Belvoir, Virginia

One of the U.S. Army's medical gaps is the inability to capture a complete history of patient medical treatment from point of injury through MEDEVAC and follow-on transfer to the next level of care.

This program exists to alert, rally, and prepare a receiving deployed MTF for incoming patients and reduce burden of medics on MEDEVAC platforms. The Medical Hands-free Unified Broadcast (MEDHUB) System automatically captures and stores medical data from patient care devices via wireless connection and transmits this data to the receiving MTF via existing DoD Satellite Networks. In addition, it allows for the hands-free electronic creation of the TCCC Card and records essential medical data elements in the Soldier's Electronic Health Records.

By providing increased situational awareness of number of patients, estimated time of arrival, injuries, interventions, patient status, and patient vitals, MEDHUB will increase Soldier survivability. This system will improve patient care, safety, and survivability by making hospitals better prepared for incoming patients and providing a more complete medical history.

This capability is intended for use at Roles 1, 2, and 3.

ACQUISITION PHASE

- Technology Maturation & Risk Reduction

FUNDING SOURCE

- U.S. Army

MEDICAL HANDS-FREE UNIFIED BROADCAST SYSTEM INCREMENT 2

PARTNER(S)

- Sierra Nevada Corporation, Sparks, Nevada
- U.S. Army CCDC A&M Center, S3I Directorate, Redstone Arsenal, Alabama
- U.S. Army PEO C3T, PM Joint Battle Command - Platform, APG, Maryland
- U.S. Army PEO Soldier, PM Nett Warrior, Fort Belvoir, Virginia

In 2018, the Critical Care Flight Paramedic Medical Task Saturation Study revealed that improving drug accuracy and limiting dosing errors during MEDEVAC could reduce disability and death, improving Soldier life and return to duty. The MEDHUB Increment 2 supports transport medication management.

The MEDHUB Drug Organizational Safety Equipment (DOSE) is a medical device for use during MEDEVAC. It will provide FDA-licensed advanced medical decision support algorithms to increase the accuracy of drug dosages administered during evacuation. The MEDHUB DOSE system will automate the calculation of proper dosing of medications based on the Army Medic's Standard Medical Operating Guidelines.

Use of DOSE will increase drug safety, management, and accountability by tracking drug inventory levels and providing confirmation controls. This system will improve patient care, safety, and outcome without adding additional burden to the medic.

This capability is intended for use at Roles 1, 2, and 3 and evacuation.

ACQUISITION PHASE

- Technology Maturation & Risk Reduction

FUNDING SOURCE

- U.S. Army

SHELTERS

SHELTER MODERNIZATION

Delivering expeditionary, lightweight, energy efficient hospital structures to the Tactical Commander

Tactical shelters are mobile, transportable structures that provide environmentally controllable space for medical treatment, which is critical to the Army's Combat Support Hospital (CSH)/FH mission for deployed care.

RIGID WALL SHELTER MODERNIZATION

PARTNER(S)

- Core Composites, Bristol, Rhode Island
- DLA Distribution Hill, Hill Air Force Base, Utah
- U.S. Army CCDC GVSC, Warren, Michigan
- U.S. Army CCDC Soldier Center, Natick, Massachusetts
- USAMMA, Fort Detrick, Maryland

The legacy Rigid Wall Shelter (RWS) system is more than 25 years old and does not meet mission requirements.

The RWS is a tactical shelter consisting of pre-sized expandable and non-expandable modules that can be transported by land, sea, or air. The RWS houses laboratory, pharmacy, blood bank, radiology, and surgical functions. It requires minimal site preparation and no specialized setup. It is used in CSHs and FHs.

Figure 1-1. Composite Expandable Shelter (CES).

Modernized RWS composite kits are in production. Current shelters are retrofitted with a stronger floor constructed with composite materials, and have an auto-leveling system as an option. The floors are constructed to resist deformation and vibration, increasing stability for operating room procedures.

This capability is intended for use at Roles 2 and 3.

ACQUISITION PHASE

- Production & Deployment

FUNDING SOURCE

- U.S. Army

SOFT WALL SHELTER MODERNIZATION

PARTNER(S)

- DLA, Philadelphia, Pennsylvania
- HDT Global, Tanner, Alabama
- U.S. Army CCDC Soldier Center, Natick, Massachusetts
- USAMMA, Fort Detrick, Maryland

The TEMPER Shelters or Soft Wall Shelters (SWS) have exceeded their 10-year life expectancy and the current stock of shelters require replacement because of safety issues.

The new SWS, known as TEMPER TAS, is a tactical shelter consisting of a frame using air-supported beams and a fabric structure that can be transported and assembled in a deployed setting. Currently, SWSes house patient wards and support functions within the existing Army CSH/FH infrastructure.

These TAS shelters are being fielded to core FH commands, Army pre-positioned stock, and to the Medical Materiel Readiness Program (who centrally manage FHs for the United States Army Reserve). These shelters reduce the weight of each FH by 17 tons and deploy approximately 50% faster than current aluminum framed TEMPER shelters.

This capability is intended for use at Roles 2 and 3.

ACQUISITION PHASE

- Production & Deployment

FUNDING SOURCE

- U.S. Army

OCCUPATIONAL HEALTH

CHEMICAL PATIENT PROTECTIVE WRAP

Protecting non-ambulatory patients in potentially contaminated environments

PARTNER(S)

- JPM Protection PMO, Stafford, Virginia
- Pine Bluff Arsenal, Pine Bluff, Arkansas
- Polo Custom Products, Topeka, Kansas
- U.S. Army CCDC Chemical Biological Center (CBC), APG, Maryland
- U.S. Army CCDC Soldier Center, Natick, Massachusetts

The Chemical Patient Protective Wrap (CPPW) is a disposable device that will protect patients during transport from/through areas contaminated by chemical and biological agents. The CPPW allows treatment while protecting patients and providers from contamination from pathogens of operational and clinical concern.

The WHPE PMO manages the CPPW stock. With support from CCDC CBC, this PMO contracted with Polo Custom Products for delivery of commercial CPPWs.

Additionally, the WHPE PMO, in collaboration with the JPM Protection PMO and CCDC Soldier Center, is establishing Pine Bluff Arsenal as an organic supplier of CPPWs.

This capability is intended for use during evacuation.

ACQUISITION PHASE

- Production & Deployment

FUNDING SOURCE

- U.S. Army

ENVIRONMENTAL SENTINEL BIOMONITOR

Ensuring a safe water supply from toxic chemicals in deployed locations

PARTNER(S)

- ANP Technologies, Inc., Newark, Delaware
- Nanohmics, Austin, Texas
- U.S. Army Center for Environmental Health Research (USACEHR), Fort Detrick, Maryland
- U.S. Army CCDC CBC, APG, Maryland
- U.S. Army Public Health Center, APG, Maryland

Providing a safe, high-quality supply of water to deployed troops is a key element in keeping Soldiers healthy and mission ready.

The Environmental Sentinel Biomonitor (ESB) system substantially expands existing capabilities to rapidly screen water for a wide range of potentially toxic chemical contaminants (including those from industrial or agricultural sources). The ESB system complements other water quality testing methods currently used in the field such as the Water Quality Analysis Set-Preventive Medicine (WQAS-PM).

The ESB system consists of two hand-held toxicity sensors. The ESB system will become a component of the WQAS-PM, which is used by Preventive Medicine Detachments and Brigade Combat Team Preventive Medicine sections. The manufacturing contract for the ESB was awarded in 2018 and the first units are scheduled to be fielded in 2020. Planned product improvements to further reduce size, weight, and cost are underway.

This capability is intended for use at the Brigade level and higher by Preventive Medicine personnel.

ACQUISITION PHASE

- Production & Deployment

FUNDING SOURCE

- U.S. Army

HEALTH READINESS AND PERFORMANCE SYSTEM

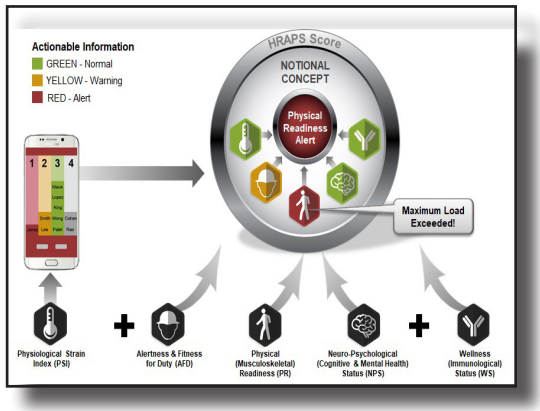
Leaders' operational health risk management

PARTNER(S)

- Georgia Tech Applied Research Corporation, Atlanta, Georgia
- MIT, Lincoln Laboratory, Lexington, Massachusetts
- MilTech Corporation, Bozeman, Montana
- The MITRE Corporation, Bedford, Massachusetts and McLean, Virginia
- MOMRP, USAMRDC, Fort Detrick, Maryland
- U.S. Army PEO Soldier - PM Soldier Warrior (SWAR), Fort Belvoir, Virginia
- U.S. Army Research Institute of Environmental Medicine (USARIEM), Natick, Massachusetts

Unit leaders lack real-time data on the physiology and mental state of their teams to effectively inform operational health risk management. The Health Readiness and Performance System (HRAPS) is a wearable, physiological data collection system that communicates accurate, real-time, actionable information about health, readiness, and performance to both Service Members and unit leaders. The HRAPS will include the following incremental capabilities:

- New organic capability for leaders to reduce heat injuries in training and collect data to improve algorithms (Increment T)
- New operational capability to provide alerts for impending heat strain (Increment 1)
- Expanded capability to provide alerts for indicators such as hydration status, impending musculoskeletal injury, alertness status, and environmental exposures (Increment 2+)



The HRAPS capabilities will help derive an integrated score for readiness, health, and performance. Ultimately, data-driven decisions based on HRAPS scores will enhance readiness, reduce injuries, increase force health protection, and optimize performance and combat effectiveness of the Joint Force.

The Marine Corps Systems Command – Ground Combat Element Systems has agreed to utilizing the HRAPS during a training exercise in a simulated combat environment.

This capability is intended for use at the Squad level and above.

ACQUISITION PHASE

- Platform: Engineering & Manufacturing Development (PEO Soldier managed)
- Components: Technology Maturation & Risk Reduction; Engineering & Manufacturing Development (USAMRDC managed)

FUNDING SOURCE

- Defense Health Program

DECISION AIDS

Using risk assessment to impact readiness

CANINE THERMAL MONITOR COLLAR & SIMULATED HEAT ENDURANCE PLANNER MOBILE APPLICATION

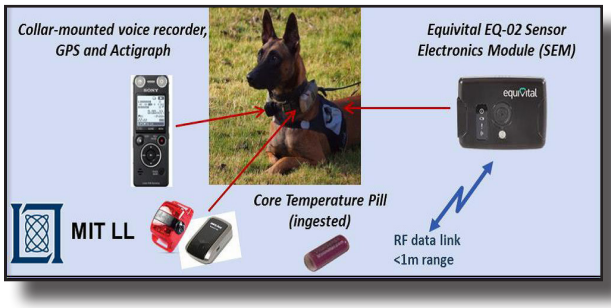
PARTNER(S)

- MIT, Lincoln Laboratory, Lexington, Massachusetts
- U.S. Army PEO Soldier - PM SWAR, Fort Belvoir, Virginia
- USARIEM, Natick, Massachusetts
- U.S. Army Training and Doctrine Command (TRADOC), Fort Eustis, Virginia

The U.S. Military employs over 2,800 Military Working Dogs (MWD), each costing over $40,000 annually to train, feed, and maintain. The Army Operational Need Statement determined a need for real-time physiological monitoring of MWDs to ensure readiness during critical high-risk missions.

The MWD is a critical member of tactical missions and is susceptible to similar injuries as its human counterparts. Heat injury is the most common MWD illness because of their highly active state and often extremely hot work environments.

The Canine Thermal Monitoring Collar and the accompanying Simulated Heat Endurance Plan mobile app are designed to provide physiological data analysis on a MWD's well-being. Used together, they will predict safe work durations and recovery times based on predicted body temperature. This prediction will incorporate specific training or operational scenarios and environmental conditions, the biophysical properties of the MWD (breed, size, weight and color), their physical activity levels, and the type of activity (e.g., detection vs. patrol). This MWD technology will enable Dog Handlers and Veterinarians to determine the ability of the MWD to accomplish the mission from the perspective of thermal burden.



The MIT, Lincoln Laboratory is developing the collar and software app. This mobile app will be compatible with an iPhone operating system (iOS) and an Android operating system (Android). It will be available on the Nett Warrior Marketplace and the TRADOC App Gateway.

The software is being operationally tested with the plan to deploy it in FY20.

This capability is intended for use at Squad Level and higher by Tri-Service Military Dog Handlers, specifically for use in planning combat and training missions.

ACQUISITION PHASE

- Engineering & Manufacturing Development

FUNDING SOURCE

- Defense Health Program

COLD WEATHER ENSEMBLE DECISION AID

PARTNER(S)

- MIT, Lincoln Laboratory, Lexington, Massachusetts
- MOMRP, USAMRDC, Fort Detrick, Maryland
- U.S. Army PEO Soldier - PM SWAR, Fort Belvoir, Virginia
- USARIEM, Natick, Massachusetts
- U.S. Army TRADOC, Fort Eustis, Virginia

Exposure to cold is detrimental to health, activity level tolerance, and performance. Despite advancements in personal protective equipment, cold injuries continue to afflict Active Duty Service Members. From 2012 through 2017, an estimated 2,500 Soldiers had at least one medical encounter related to cold exposure, with frostbite being the most common cold injury.

The Cold Weather Ensemble Decision Aid mobile app supplements information found in Army Technical Bulletin – Medical 508, Prevention and Management of Cold-Weather Injuries. It uses USARIEM's Six Cylinder Thermal Model to predict cold weather endurance times (i.e., the point in time when hypothermia or cold injury of extremities may occur) under specific mission scenarios, while taking into account environmental conditions, activity levels, and clothing properties. This state-of-the-art decision aid serves as a cold weather injury countermeasure and was developed to optimize readiness for cold weather operations, prevent cold injury, assist in proper clothing selection, and provide guidance for mission planning.

This mobile app will be compatible with iOS and Android and available on the Nett Warrior Marketplace and the TRADOC App Gateway.

This capability is intended for use at the Squad level and above, specifically for mountain warfare operations and training missions.

Reference: O'Donnell FL, Stahlman S, Oetting AA: Update: cold weather injuries, Active and Reserve components, U.S. Armed Forces, July 2012–June 2017. DHA MSMR, Medical Surveillance Monthly Report. 2017; 24(10): 12-14.

ACQUISITION PHASE

- Pre-Materiel Development Decision

FUNDING SOURCE

- U.S. Army

ENVIRONMENTAL EXPOSURE ELECTRONIC (E3) FORM

PARTNER(S)

- Johns Hopkins University Applied Physics Laboratory, Columbia, Maryland
- MOMRP, USAMRDC, Fort Detrick, Maryland
- USACEHR, Fort Detrick, Maryland
- U.S. Army PEO Soldier - PM SWAR, Fort Belvoir, Virginia
- U.S. Army TRADOC, Fort Eustis, Virginia

Warfighters face occupational and environmental exposures to toxic industrial chemicals (TIC) and toxic industrial materials (TIM) in operational environments. The E3 Form is a mobile app for documenting potential/actual exposure to TICs and TIMs. The E3 Form supports the requirement for reporting, tracking, and assessing occupational and environmental exposures among Military personnel.

This mobile app will be compatible with iOS and Android and available on the Nett Warrior Marketplace and the TRADOC App Gateway.

This capability is intended for use at the Squad level and above, specifically for use by the Preventive Medicine Physician and Environmental Science/Engineering Officer, and other Preventive Medicine personnel within the Occupational and Environmental Health Mission Space.

ACQUISITION PHASE

- Pre-Materiel Development Decision

FUNDING SOURCE

- U.S. Army

HEALTHY EATING, ACTIVITY, AND LIFESTYLE TRAINING HEADQUARTERS MOBILE APPLICATION

PARTNER(S)

- MOMRP, USAMRDC, Fort Detrick, Maryland
- Pennington Biomedical Research Center, Baton Rouge, Louisiana
- USARIEM, Natick, Massachusetts

The Army Healthy Eating, Activity, and Lifestyle Training Headquarters (H.E.A.L.T.H.) is a mobile app that is the handheld counterpart to the web-based Army H.E.A.L.T.H. program. It is designed to empower Soldiers, Family Members, and retirees to adopt a healthy/safe lifestyle change on a year-round basis. It targets weight management needs and compliance to Army Regulation (AR) 600-9 and the Army Physical Fitness Test (APFT).

This H.E.A.L.T.H. mobile app utilizes evidence-based material/databases and specialized tools based on Soldier standards (e.g., APFT, AR 600-9). The online/mobile formatted program includes personalized eating, fitness tools, tools to help Soldiers stay fit and meet AR 600-9 and APFT standards, and a family program to aid all Military members to achieve improved nutrition, fitness, sleep and mind/body health.

This mobile app will be compatible with iOS and Android. It will be available on the Nett Warrior Marketplace and the TRADOC App Gateway.

This capability is intended for the personal use of every Soldier whether in deployed combat or peacetime operations, and for their Families at home station.

ACQUISITION PHASE

- Pre-Materiel Development Decision

FUNDING SOURCE

- Defense Health Program

HEAT STRAIN DECISION AID MOBILE APPLICATION

PARTNER(S)

- MIT, Lincoln Laboratory, Lexington, Massachusetts
- MOMRP, USAMRDC, Fort Detrick, Maryland
- U.S. Army PEO Soldier - PM SWAR, Fort Belvoir, Virginia
- USARIEM, Natick, Massachusetts
- U.S. Army TRADOC, Fort Eustis, Virginia

Heat illness threatens the individual health and performance of Soldiers. Over the past decade, the U.S. Army reported a yearly average of two to three fatalities from heat stroke, and many more nonfatal cases of exertional heat illness. Even a minor heat illness can significantly degrade performance.

Army researchers developed a mobile app that enables accurate prediction of the likelihood of heat illness, after considering the training and/or operational environment.

The Heat Strain Decision Aid (HSDA) Mobile Application will assist leaders or training cadre in performing risk assessments for heat injury based on information about the Soldier, their environment, clothing, and activity. Geared for Infantry and mission planners, the HSDA combines state-of-the-art laboratory-based models and the USARIEM's Six Cylinder Thermal Model to predict the risk of heat illness/injury in Soldier populations. The HSDA estimates core temperature and calculates recommended safe work times, water requirements, and risk of heat casualties if guidance is not followed.

The HSDA is adaptable to computers and tablets and compatible with iOS and Android. It will be available on the Nett Warrior Marketplace and the TRADOC App Gateway.

This capability is intended for use at the Squad level and above, specifically for use in planning combat and training missions.

ACQUISITION PHASE

- Pre-Materiel Development Decision

FUNDING SOURCE

- Defense Health Program

MENTAL ACUITY

PARTNER(S)

- MOMRP, USAMRDC, Fort Detrick, Maryland
- TATRC, USAMRDC, Fort Detrick, Maryland
- U.S. Army PEO Soldier - PM SWAR, Fort Belvoir, Virginia
- U.S. Army TRADOC, Fort Eustis, Virginia
- WRAIR, Silver Spring, Maryland

Sleep loss is ubiquitous in the military operational environment. The resulting fatigue constitutes a threat to the ability of the Soldier to effectively perform under operational conditions (i.e., mental acuity). The Mental Acuity mobile app is a leader tool that enables leaders to predict Soldier readiness. It compiles individual information on an on-going basis in order to predict a real-time response to sleep deprivation.

The mobile app is a wearable technology that: (1) quantifies current, and predicts future, Warfighter mental acuity; (2) objectively measures the maximum duration of a Soldier's ready state under conditions of high operations; and (3) provides individualized countermeasure guidance. The algorithm uses an individual's recent sleep history, their circadian rhythm of alertness, and their level of sensitivity to sleep loss to generate more accurate individualized predictions of alertness.

This mobile app will be compatible with iOS and Android. It will be available on the Nett Warrior Marketplace and the TRADOC App Gateway.

This capability is intended for use at Squad Level and higher and for personnel in deployed combat or peacetime operations.

ACQUISITION PHASE

- Pre-Materiel Development Decision

FUNDING SOURCE

- U.S. Army

DEPLOYED MEDICAL SYSTEMS

Modernization efforts for comercial equipment and medical assemblages

DEPLOYABLE COMPUTED TOMOGRAPHY SCANNER

PARTNER(S)

- Air Force Medical Readiness Agency, Fort Detrick, Maryland
- DLA, Philadelphia, Pennsylvania
- Naval Medical Logistics Command, Fort Detrick, Maryland
- Siemens Healthcare Diagnostics, Inc., Tarrytown, New York
- Western Shelters, Eugene, Oregon

A CT scanner makes use of computer-processed combinations of multiple X-ray images taken non-invasively from different angles to produce cross-sectional (tomographic) images of specific areas of a scanned patient. This project aims to replace the CT scanner currently in the Army inventory since it is no longer maintainable due to unavailability of repair parts.

The Siemens Healthcare 64/128 slice SOMOTOM go.Top CT scanner was selected to replace the current device. It uses a large detector to deliver an acquisition speed of up to 175mm per second, which makes it ideal for trauma scanning. The Warfighter Deployed Medical Systems PMO is using government refurbished International Organization for Standardization (ISO) shelters to house the CT scanner to reduce cost. Siemens Healthcare and Western shelters will work together to integrate the ISO shelter with the CT scanner. The first unit will be delivered in 2019 for First Article Testing.

This capability is intended for use at Role 3.

ACQUISITION PHASE

- Operations & Support

FUNDING SOURCE

- U.S. Army

FIELD HOSPITAL CONVERSION

PARTNER(S)

- USAMMA, Fort Detrick, Maryland
- U.S. Army Reserve, Fort Bragg, North Carolina

The FH Force Design Update (FDU) conversions commenced in FY17 and are currently scheduled to be completed by FY22.

In 2005, the Commanding General, MedCoE, directed the redesign of the present CSH in response to a series of observations and lessons learned from global operations and in support of AMEDD transformation goals. A comprehensive operational analysis conducted by the CDID revealed that a 248-Bed CSH design failed to achieve optimal hospitalization services in support of full spectrum operations.

Following guidance to resource the CSH in a modular design led to the final organizational concept featuring a set of five components that can be combined in a number of ways to provide a flexible, modular, and tailorable hospitalization capability.

The FH FDU increases selective surgical and emergency medicine specialties and improves essential clinical capabilities without growing personnel requirements. It also expands early trauma capabilities, increases intensive care capacity, and adds CT scanners and microbiology lab capabilities as essential components.

This capability is the Army's Role 3.

ACQUISITION PHASE

- Operations & Support

FUNDING SOURCE

- U.S. Army

VITAL SIGNS MONITOR

PARTNER(S)

- Industry partner(s) to be determined

The Army is working to replace three outdated vital signs monitors while exploring the ability for increased functionality of capnography and electrocardiography to complement vital signs monitoring. Current devices have exceeded their life expectancy and require replacement.

Replacing three existing devices with a single product will reduce logistics and maintenance burden on the Army. Advances in technology now allow all required patient parameters to be monitored by one device.

Initial market research indicated several commercially available devices that may meet the Army's needs. These include the Philips Intellivue MP2/XP monitor, the Zoll Propaq M, and the Remote Diagnostics Technologies Limited Tempus Pro.

Market research is ongoing and candidate devices are undergoing a range of operational tests to determine their suitability for use in deployed environments.

This capability is intended for use with Roles 2 and 3.

ACQUISITION PHASE

- Operations & Support

FUNDING SOURCE

- U.S. Army

Photo Reference: Phillips, Zoll, and Remote Diagnostics Technologies

ENABLING TECHNOLOGIES

Medical IT solutions to enable product research, development and FDA licensure

ELECTRONIC COMMON TECHNICAL DOCUMENT

PARTNER(S)

- Liquent, Inc., a Parexel® Company, Horsham, Pennsylvania
- Office of Regulated Activities (ORA), USAMRDC, Fort Detrick, Maryland

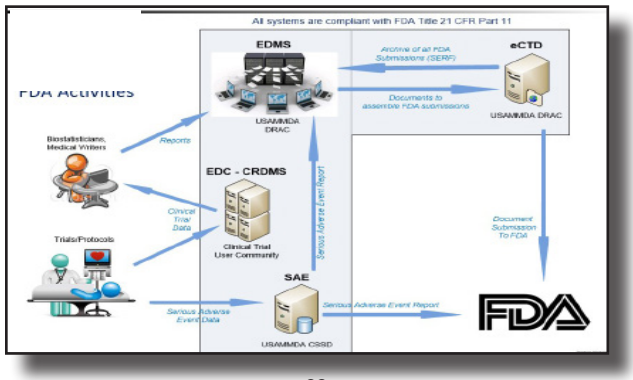
The Electronic Common Technical Document (eCTD) software is used to generate submission packages into an electronic format that conforms to strict FDA guidelines. The system is utilized by the USAMRDC ORA and allows the Command to produce eCTD formatted submissions while retaining complete control of regulatory documentation.

ELECTRONIC DATA CAPTURE CLINICAL RESEARCH DATA MANAGEMENT SYSTEM

PARTNER(S)

- NMRC, Silver Spring, Maryland
- ORA, USAMRDC, Fort Detrick, Maryland
- Oracle® InForm™ Global Trial Management, Redwood City, California
- U.S. Army Medical Research Institute of Infectious Diseases, Fort Detrick, Maryland
- WRAIR, Silver Spring, Maryland
- WRNMMC, Bethesda, Maryland

The Electronic Data Capture – Clinical Research Data Management System is a centralized data capture system supporting the life cycle of clinical trial studies. Use of this technology provides for command-wide efficiencies in the conduct of clinical trials, improving communication with the clinical trial sites and the standardization of processes. While the product provides for complete support for clinical trials, the system is also used for non-FDA regulated studies.



ELECTRONIC DOCUMENT MANAGEMENT SYSTEM

PARTNER(S)

- OpenText, Waterloo, Ontario, Canada

The Electronic Document Management System satisfies the requirements imposed by the FDA for electronic storage, electronic signature and auditing. In Production since 2006, the system meets the requirements codified in the FDA's 21 CFR Part 11 guidelines for regulated activities and aids in collaboration efforts across the USAMRDC medical research, development, and acquisition community.

PRODUCT ACCOUNTABILITY SYSTEM

PARTNER(S)

- LabVantage, Somerset, New Jersey
- ORA, USAMRDC, Fort Detrick, Maryland

LabVantage software was procured in 2018 and implemented to create the current Product Accountability System. The LabVantage product serves as the basis for an enterprise Laboratory Information Management System for the USAMRDC. Anticipate the system becoming fully operational capable in late 2019.

SERIOUS ADVERSE EVENT

PARTNER(S)

- ORA, USAMRDC, Fort Detrick, Maryland
- Oracle®, Redwood City, California

The purpose of the Serious Adverse Event product is to provide an IT system to improve the effectiveness, efficiency, and regulatory compliance of Serious Adverse Event reporting. The Serious Adverse Event system has been implemented and verified to meet USAMRDC business and system requirements, certified and accredited to meet DoD, Army, and USAMRDC Information Assurance operations requirements, and validated to satisfy the FDA requirements for electronic records (Title 21 CFR Part 11).

PRODUCT ACQUISITION STATUS SUMMARY TABLE				
CAPABILITY DEVELOPMENT EFFORT	**FUNDING SUPPORT**	**TECHNOLOGY READINESS LEVEL***	**NEXT MILESTONE (WHEN)**	**PAGE**
Pre-Materiel Development Decision				
Alternate Therapies for TBI	Defense Health Program	6	MDD (FY22)	54
Brain Imaging	Defense Health Program	6	MDD (TBD)	49
Breath Test for Pulmonary Oxygen Toxicity	Defense Health Program	4-5	MDD (TBD)	32
Next Generation Laboratory Assay for TBI	Defense Health Program	5	MDD (TBD)	51
Resuscitative Agents for TBI Treatments for Moderate/Severe Casualties	U.S. Army	1-2	MDD (FY22)	55
Materiel Solution Analysis				
Chikungunya Vaccine	U.S. Army	4	MS A (FY20)	18
Extremity Injury Repair – Bone	Defense Health Program	4-6	MS A (FY23)	41
Extremity Injury Repair – Muscle	Defense Health Program	4-6	MS A (FY23)	42
Extremity Injury Repair – Nerve	Defense Health Program	5-6	MS A (FY23)	43
Non-Invasive Neuroassessment Device	U.S. Army	6	MS A (FY21)	52
TBI Point of Injury Triage Device	Defense Health Program	6	MS A (FY21)	53
Tick-Borne Encephalitis Vaccine	U.S. Army	6	MS A (FY23)	24
Technology Maturation & Risk Reduction				
Battlefield Pain Management – Ketamine	Defense Health Program	5-6	MS B (FY22)	39
Burn Treatment Skin Repair	Defense Health Program	5	MS B (FY22)	45
Cold-Stored Platelets	Defense Health Program	6	MS B (FY20)	33
Dengue Tetravalent Vaccine Increment 2 (Alternate Dengue Vaccine)	U.S. Army	5	MS B (FY25)	21
Extracorporeal Life Support – Lung/Renal	U.S. Army	5-6	MS B (FY22)	35
Extremity Injury Repair – Vascular	U.S. Army	7	MS B (FY21)	44
Health Readiness and Performance System – Components	Defense Health Program	6	N/A	72
Hemorrhage Detection	Defense Health Program	5-7	MS B (FY21)	37

PRODUCT ACQUISITION STATUS SUMMARY TABLE				
CAPABILITY DEVELOPMENT EFFORT	**FUNDING SUPPORT**	**TECHNOLOGY READINESS LEVEL***	**NEXT MILESTONE (WHEN)**	**PAGE**
Human Immunodeficiency Virus Vaccine – Increment 2 (Regional)	Defense Health Program	6	MS B (FY22)	23
MEDEVAC Mission Equipment for Future Vertical Lift	U.S. Army	5-6	MS A (FY21)	64
Medical Hands-free Unified Broadcast System – Increment 1	U.S. Army	8	MS C (FY20)	66
Medical Hands-free Unified Broadcast System – Increment 2	U.S. Army	4	MS C (FY23)	67
Next Generation Diagnostic System Infectious Disease Panel	Defense Health Program	7	N/A	25
Non-Compressible Hemorrhage Control	Defense Health Program	4-6	MS B (FY21)	38
Pharmaceutical Interventions for Noise Induced Hearing Loss — Acute Exposure Treatment	Defense Health Program	7	MS B (FY22)	46
PTSD Drug Treatment	Defense Health Program	5-6	MS B (FY22)	58
Rapid Human Diagnostic Devices	U.S. Army	7	MS B (FY20)	26
TBI Drug Treatment – Increment 1 – Moderate/Severe TBI	Defense Health Program	6	MS B (FY22)	56
TBI Drug Treatment – Increment 2 – Mild TBI	Defense Health Program	6	MS B (FY22)	57
Temporary Corneal Repair	U.S. Army	4	MS B (FY22)	47
Engineering & Manufacturing Development				
Antimalarial Drug – Intravenous Artesunate	U.S. Army	7	MS C (FY20)	29
Armored Multi-Purpose Vehicle Medical Treatment/Evacuation Variants	U.S. Army	4	N/A	62
Battlefield Pain Management – Sufentanil	Defense Health Program	7	MS C (FY20)	40
Canine Thermal Monitor Collar & Simulated Heat Endurance Planner Mobile Application	Defense Health Program	6	N/A	73
Cryopreserved Platelets	U.S. Army	7	MS C (FY27)	34
Dengue Tetravalent Vaccine Increment 1	U.S. Army	7	MS C (FY21)	20
Freeze-Dried Plasma	U.S. Army	7	MS C (FY20)	36
Human Immunodeficiency Virus Vaccine – Increment 1 (Global)	U.S. Army	7	MS C (FY26)	23
Laboratory Assay for TBI	U.S. Army	7	MS C (FY21)	50
Whole Blood Pathogen Reduction Device	Defense Health Program	6-7	MS C (FY25)	27

PRODUCT ACQUISITION STATUS SUMMARY TABLE				
CAPABILITY DEVELOPMENT EFFORT	FUNDING SUPPORT	TECHNOLOGY READINESS LEVEL*	NEXT MILESTONE (WHEN)	PAGE
Production & Deployment				
Antimalarial Drug – Tafenoquine	U.S. Army	9	N/A	30
Chemical Patient Protective Wrap	U.S. Army	9	N/A	70
Environmental Sentinel Biomonitor	U.S. Army	8	N/A	71
Litter Strap Modernization	U.S. Army	9	N/A	59
MEDEVAC Mission Equipment Package for UH-60 Black Hawk	U.S. Army	9	N/A	65
Rescue Litter Modernization	U.S. Army	9	N/A	60
Rigid Wall Shelter Modernization	U.S. Army	9	N/A	68
Soft Wall Shelter Modernization	U.S. Army	9	N/A	69
7309 Standard and Quad-Fold Litter Modernization	U.S. Army	9	N/A	61
Operations & Support				
Adenovirus Type 4 and Type 7 — Vaccine, Live, Oral	Defense Health Program	9	N/A	17
Deployable Computed Tomography Scanner	U.S. Army	9	N/A	79
Field Hospital Conversion	U.S. Army	9	N/A	80
Joint Light Tactical Vehicle Casualty Evacuation	U.S. Army	4	N/A	63
Vital Signs Monitor	U.S. Army	9	N/A	81

*TECHNOLOGY READINESS LEVEL (TRL)		
TRL	DEVICES & PHARMACEUTICALS	
1	Maintain scientific awareness; technology watch. Scientific literature reviews and market surveys initiated and assessed.	
2	Hypothesis generated. Research ideas and protocols developed.	
3	Hypothesis testing and initial proof of concept demonstrated in limited number of laboratory, *in vitro*, and *in vivo* models.	
4	PoC and safety of candidate devices/systems, drug formulations, or biologic/vaccine constructs are demonstrated in defined laboratory/animal models.	
5	The FDA determines that trials may begin.	Preclinical studies sufficient to support IND applications.
6	Device safety demonstrated, support proceeding to clinical safety and effectiveness trials.	Phase 1 clinical trials completed, data supports proceeding to Phase 2 clinical trials. The IND application is prepared and submitted.
7	Clinical end points and test plans are agreed upon by the FDA.	Phase 2 clinical trials completed. Phase 3 clinical study plan approved.
8	The FDA grants premarket approval.	Phase 3 clinical trials completed.
9	Post marketing studies/surveillance. Post-marketing studies may be required.	

KNOWLEDGE PRODUCTS

Knowledge Products (KP) are defined sets of information that inform medical and operational practices, requirements documents, acquisition processes, military decision-making, and support training and educational requirements. A KP is developed for a defined end user requirement/need. Examples of KPs include Clinical Practice Guidelines (CPG), standards for equipment or personnel, injury response curves, algorithms, nutritional formulations, decision guides, exposure guidelines, and training tools. It is the information contained in the KP that is the actual product, not the medium in which the knowledge is transmitted (e.g., manuals, protocol, software, and training). The results of research (e.g., data, analyses, and publications) are not directly KPs, but serve to fill gaps in the knowledge and understanding of a military-relevant threat or other issues. These research results are combined with other findings and information, evaluated against requirements/needs, and used to create validated and defined information sets that are provided to inform the development of the final KP.

The U.S. Army Medical Research and Development Command (USAMRDC) is both a contributor of information to and a final developer/issuer of the KP. An example of USAMRDC's contributor role is a CPG. The USAMRDC laboratories conduct research that is transitioned to a clinical Center of Excellence responsible for shepherding the information through additional evaluation and development into approved military medical doctrine and procedures. An example of USAMRDC's final developer role is an impact injury response curve. In this case, the USAMRDC conducts laboratory studies to identify and validate injury responses to impacts; summarizes the information in tables, response curves, data sets, and/or algorithms; and issues the information via a technical report or other KP. The product is then transitioned in final form, with no further evaluation or development, to the end user, who might be a materiel developer who uses the information to design and test systems they are developing.

Knowledge Transition Agreements (KTA) between the USAMRDC and a transition partner organization are the formal mechanism for transitioning product efforts for further development or releasing final products. Some of the USAMRDC's key transition partners include the U.S. Army Office of the Surgeon General (OTSG); the Joint Trauma System (JTS); U.S. Army Training and Doctrine Command (TRADOC); and Soldier equipment, ground vehicle, and aviation platform development program managers. Knowledge Products may be developed and transitioned by the USAMRDC across the full spectrum of U.S. Army medicine mission areas. Examples of recent and upcoming transitions of KPs are provided in this section.

BEHAVIORAL HEALTH LEADERSHIP TRAINING

Behavioral Health Leadership knowledge products provide information to leaders regarding specific behaviors that are associated with healthier unit adjustment over and above generally good leadership. These products leverage research findings regarding domain-specific leader behaviors that target particular health-related outcomes. The primary training product derived from these findings is leadership training, a brief training module intended for behavioral health officers or their equivalents, which is intended to be provided to unit leadership teams. In addition, guidance regarding other targeted outcomes, such as combat operational stress control leadership and health-promoting leadership, will be provided as basic KPs that behavioral health officers can use as needed with leaders. These products can be used to generate a discussion regarding unit leader behaviors.

PARTNERS

- Walter Reed Army Institute of Research (WRAIR), Silver Spring, Maryland
- U.S. Army OTSG, Falls Church, Virginia

TRANSITION STATUS

- KTA signed between WRAIR and OTSG (transition date FY20)

TRAINING FAR-FORWARD BEHAVIORAL HEALTH CARE

This KP will provide the OTSG Behavioral Health Service Line with easily administered trainings, tools, and recommendations aimed at enhancing the behavioral health service delivery system in far-forward settings.

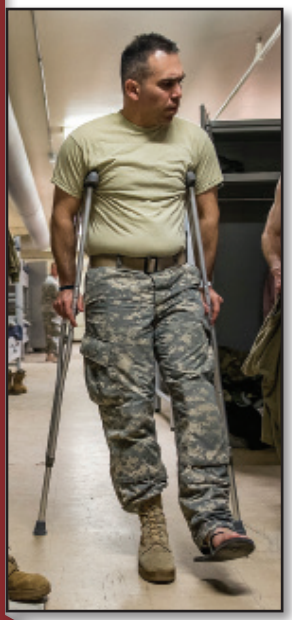
PARTNERS

- WRAIR, Silver Spring, Maryland
- U.S. Army OTSG, Falls Church, Virginia

TRANSITION STATUS

- KTA signed between WRAIR and OTSG (transition date FY21)

COMMANDER'S TOOLBOX FOR REDUCING MUSCULOSKELETAL INJURY RISKS



Musculoskeletal Injury (MSKI) continues to be the top reason (55%) Soldiers, including recruits, are placed on limited or restricted duty and are non-deployable. A MSKI, even when obtained through exercise and training, directly limits Soldiers' availability for training, deployment, and continued close combat operations. The KP being transitioned consists of research results and health and performance recommendations to reduce a MSKI from a five-year research project, the U.S. Army Research Institute of Enviornmental Medicine (USARIEM) Reduction in Musculoskeletal Injury Study. The project is designed to enable the delivery of evidence-based actionable recommendations to Army leadership to reduce MSKI in recruits during basic combat training without reducing training standards.

PARTNERS

- USARIEM, Natick, Massachusetts
- U.S. Army TRADOC, Fort Eustis, Virginia
- Consortia for Improving Medicine with Innovation and Technology (CIMIT), Boston, Massachusetts

TRANSITION STATUS

- KTA signed between USARIEM and U.S. Army TRADOC/CIMIT (transition date FY22)

FATIGUE MANAGEMENT TOOL FOR OPERATIONAL PLANNING PARTNERS

Optimization of sleep and alertness enhances both military-relevant performance (reducing errors and accidents in the operational environment) and the psychological and physiological resilience of Soldiers. The KPs include "proof of concept" for advanced techniques as well as development/validation of new techniques and strategies for enhancing Soldier alertness and performance during continuous and sustained military operations when there is little or no opportunity for restorative sleep. The KPs include strategies for enhancing resilience to sleep loss (e.g., "sleep banking") and methods to boost rapid adaptation to new time zones and/or shift work schedules (e.g., optimal timing of light exposure, use of blue light filters, nutritional interventions, etc.).

PARTNERS

- WRAIR, Silver Spring, Maryland
- U.S. Army OTSG, Falls Church, Virginia

TRANSITION STATUS

- KTA signed between WRAIR and OTSG (transition date FY24)

VALIDATION OF U.S. ARMY RANGER COLD WATER IMMERSION TABLES

Ranger School students are known to have altered thermoregulatory responses during training. Therefore, body temperature measurements under actual conditions that may be experienced in the field provide an important tool for evaluating current guidelines. The transitioned KP will be a matrix of water temperatures, depths, and measured body temperatures (including the mean, standard deviation, and range) of Ranger students under the conditions experienced during classes. These data will either support the current immersion guidelines for how long a student can be safely immersed in water of a particular depth according to water temperatures and local meteorological conditions or indicate a need for revision to the guidelines, based on whether the actual measured temperatures are above or below the range anticipated from the environmental exposures. A general guideline for immersion in cold temperatures would provide commanders with the ability to make more informed decisions about assessing and mitigating injury risk based on environmental conditions. Infantry units would benefit from a working guideline to assist commanders with mitigating risk to the Force with respect to cold water immersion limits for training and combat operations.

PARTNERS

- USARIEM, Natick, Massachusetts
- 6TH Ranger Training Battalion, Eglin Air Force Base, Florida
- U.S. Special Operations Command (SOCOM), MacDill Air Force Base, Florida

TRANSITION STATUS

- KTA signed between USARIEM and 6TH Ranger Training Battalion (transition date FY20)

SAFETY GUIDELINES FOR PROPHYLACTIC ADMINISTRATION OF HEPARINOID-BASED THERAPY FOR TBI WITH INTRACEREBRAL HEMORRHAGE

Patients with severe penetrating TBI are at the highest risk for complications due to obstruction of a blood vessel by a blood clot (thromboembolism) and increased localized swelling (hematoma). A recent retrospective clinical study showed that early administration of enoxaparin, a low molecular weight heparinoid, as a prophylactic treatment for reducing deep vein thrombosis did not increase intracerebral hematoma from TBI. However, there is no consensus among neurosurgeons regarding prophylactic use of heparinoid-based therapies in the presence of TBI, nor is sufficient data available to guide the appropriate timing or dosing regimen. The result of this study will provide the scientific basis for informing CPGs regarding the prophylactic use of heparinoids for reducing deep vein thrombosis in the presence of severe TBI.

PARTNERS

- WRAIR, Silver Spring, Maryland
- JTS, Joint Base San Antonio-Fort Sam Houston (JBSA-FSH), Texas

TRANSITION STATUS

- KTA signed between WRAIR and JTS (transition date FY24)

TRANEXAMIC ACID AS A PRE-HOSPITAL RESUSCITATION INTERVENTION FOR TBI ASSOCIATED WITH POLYTRAUMA

Acute coagulopathy was found to be higher in combat casualties with TBI compared to those without TBI. Coagulopathy is a bleeding disorder in which the blood's ability to form clots is impaired. Pre-hospital fluid resuscitation often results in loss of body heat (hypothermia), an increase in the acidity of the blood (acidosis), and a decrease in the cells and solids in the blood due to increased fluids (hemodilution). These conditions contribute to the development of coagulopathy and are associated with increased morbidity and mortality. With combat casualties, both head injury and low blood pressure due to a loss of blood are leading causes of potentially survivable deaths. A tranexamic acid (TXA) has been found to significantly reduce the risk of death caused by bleeding without increasing cardiovascular issues. This KP describes a pre-hospital TXA treatment that decreases coagulopathy and reduces intracerebral hemorrhage without causing additional complications.

PARTNERS

- WRAIR, Silver Spring, Maryland
- JTS, JBSA-FSH, Texas

TRANSITION STATUS

- KTA signed between WRAIR and JTS (transition date FY22)

RESUSCITATIVE ENDOVASCULAR BALLOON OCCLUSION OF THE AORTA

Non-compressible torso hemorrhage (NCTH) remains a major cause of deaths that are potentially preventable. The Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) is a FDA-approved device for the control of NCTH that offers temporary support of vital organs (e.g., the heart, lung, and brain). The REBOA has been useful for treating patients with abdominal, pelvic, and junctional lower extremity bleeding and, most recently, pulmonary injury. This KP will provide evidence-based information to optimize the use of the REBOA device, including when it should be applied, placement of the balloon, the appropriate period of balloon occlusion, improved balloon deflation procedures, types of resuscitation fluid used in conjunction with the device, and development of partial balloon occlusion techniques.

PARTNERS

- U.S. Army Institute of Surgical Research (USAISR), JBSA-FSH, Texas
- JTS, JBSA-FSH, Texas

TRANSITION STATUS

- KTA signed between USAISR and JTS (transition date FY23)

ACUTE TRAUMATIC COAGULOPATHY DIAGNOSTIC/TREATMENT

Acute traumatic coagulopathy results from severe trauma and hemorrhage (which are common in military casualties) and is associated with higher mortality rates compared to similarly injured patients that do not present with coagulopathy. A dynamic coagulation model will reveal the important factor(s) or deficiencies that are responsible for impairing the blood system, thus generating knowledge informing the best choice of blood or pharmaceutical product to restore coagulation. This knowledge will result in changes to clinical practice, including triage and treatment guidelines for severely injured casualties that will reduce acute traumatic coagulopathy-related morbidity and mortality.

PARTNERS

- USAISR, JBSA-FSH, Texas
- JTS, JBSA-FSH, Texas

TRANSITION STATUS

- KTA signed between USAISR and JTS (transition date FY24)

HYPOTENSIVE RESUSCITATION

Fluid resuscitation from hemorrhagic shock in the battlefield is challenging due to the limited ability to provide sufficient amounts of fluid or blood products far forward to help severely injured Service members. The current Damage Control Resuscitation CPG calls for limited crystalloid volume resuscitation together with the use of blood products in balanced ratios. This concept of hypotensive resuscitation (fluid therapy to increase blood pressure) is based on providing just enough fluid to vital organs without causing additional bleeding or diluting the remaining clotting factors that can induce hypothermia or acidosis. This KP will provide evidenced-based knowledge on resuscitative guidelines in prolonged care/prolonged care scenarios, thus reducing morbidity and mortality in this group of casualties.

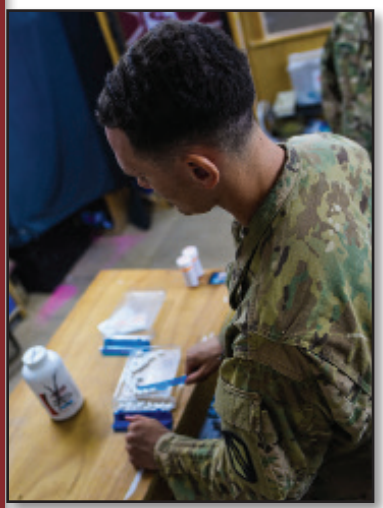
PARTNERS

- USAISR, JBSA-FSH, Texas
- JTS, JBSA-FSH, Texas

TRANSITION STATUS

- KTA signed between USAISR and JTS (transition date FY23)

PAIN MANAGEMENT CPG



The body's ability to make up for reduced circulating blood volume is called the "compensatory reserve." Reduced circulating blood volume due to hemorrhage and compensatory reserve can affect the way an injured patient responds to medication. The CPG for optimal commercially available pain medications (analgesics) that are safe for use during hemorrhage will provide combat medical personnel with clinical knowledge to improve the safety of using currently available analgesics on casualties with hemorrhage. This KP will result in revisions to the existing guidelines.

PARTNERS

- USAISR, JBSA-FSH, Texas
- JTS, JBSA-FSH, Texas

TRANSITION STATUS

- KTA signed between USAISR and JTS (transition date FY21)

EXTRACORPOREAL LIFE SUPPORT

Although advancements in the treatment of battlefield injuries may result in increased survivability of the initial phases of injury, susceptibility to sepsis (the body's overwhelming and life-threatening response to infection) and multiple-organ failure also increase. This may result in more critically ill patients with severe lung and renal injury on the battlefield and/or a larger number of patients requiring critical care, including organ support, at FHs and MTFs compared to recent conflicts. This KP will be used to inform the development of a deployable, lightweight, user-friendly Extracorporeal Life Support (ECLS) device for use in controlling oxygen and carbon dioxide exchange in critically ill patients with acute lung injury and/or filtering and purifying their blood.

PARTNERS

- USAISR, JBSA-FSH, Texas
- JTS, JBSA-FSH, Texas
- Warfighter Expeditionary Medicine and Treatment (WEMT) Project Management Office (PMO), U.S. Army Medical Materiel Development Activity (USAMMDA), Fort Detrick, Maryland

TRANSITION STATUS

- KTA signed between USAISR and JTS (transition date FY19)

TREATMENT GUIDELINES FOR ECLS USE IN FAR-FORWARD ENVIRONMENT

This set of KPs will be used to develop clinical use protocols and practice guidelines for the use of ECLS early after injury in forward environments. The ECLS can be used as an alternative to, or instead of, mechanical ventilation and as an intervention in combat casualty care. This KP will comprise of evidence-based CPGs, allowing trained personnel to provide safe, effective ECLS treatment to the severely injured in forward areas of the battlefield.

PARTNERS

- USAISR, JBSA-FSH, Texas
- JTS, JBSA-FSH, Texas

TRANSITION STATUS

- KTA signed between USAISR and JTS (transition date FY23-26)

NEW ECLS-BASED STRATEGIES TO AVOID MULTI-ORGAN FAILURE IN FAR-FORWARD ENVIRONMENT

This KP will provide evidence-based guidance for the use of new ECLS capabilities to prevent multi-organ failure in far-forward environments. This KP will inform use of new ECLS strategies following various injury patterns that increase risk of organ failure. This information will include risk factors; as well as, good/better/best criteria for monitoring injuries and strategies to prevent failure for multiple organ systems.

PARTNERS

- USAISR, JBSA-FSH, Texas
- JTS, JBSA-FSH, Texas

TRANSITION STATUS

- KTA signed between USAISR and JTS (transition date FY23)

CPG FOR EXTREMITY COMPARTMENT SYNDROME

Compartment syndrome occurs when excessive pressure builds up inside an enclosed muscle space in the body, usually as a result of bleeding or swelling after an injury. The dangerously high pressure inside the muscle space blocks the flow of blood to and from the affected tissues, potentially requiring emergency surgery to prevent permanent injury. This KP will promote modifications to the current CPG, including management of casualties at risk for compartment syndrome and those who have developed compartment syndrome in prolonged care scenarios. The knowledge generated by this research will augment evidence-based guidelines regarding the monitoring, assessment, and diagnosis of casualties at risk for developing compartment syndrome and will improve triage, treatments, and evacuation decision-making by first responders.

PARTNERS

- USAISR, JBSA-FSH, Texas
- JTS, JBSA-FSH, Texas

TRANSITION STATUS

- KTA signed between USAISR and JTS (transition date FY24)

ANTIBIOFILM THERAPY (ASSOCIATED CPG TO IMPROVE TREATMENT OF CONTAMINATED OPEN FRACTURES)

The majority of battlefield wounds are open and contaminated. Bacteria quickly divide and form a biofilm that protects them from the host's immune defenses and conventional antibiotics. Chronic infections are often the result of such biofilms. This KP will provide guidelines to improve treatment of open fractures, decrease the cost of treatment, and improve outcomes, allowing more casualties to return to duty (RTD) with fewer complications, such as wound dehiscence (rupture along surgical incisions), fracture nonunion (failure of the normal fracture healing process), or outcomes, such as late amputations.

PARTNERS

- USAISR, JBSA-FSH, Texas
- WEMT PMO, USAMMDA, Fort Detrick, Maryland
- JTS, JBSA-FSH, Texas

TRANSITION STATUS

- KTA signed between USAISR and WEMT PMO (transition date FY25)

BIOMARKER ASSAY TO PREDICT BURN WOUND SEVERITY

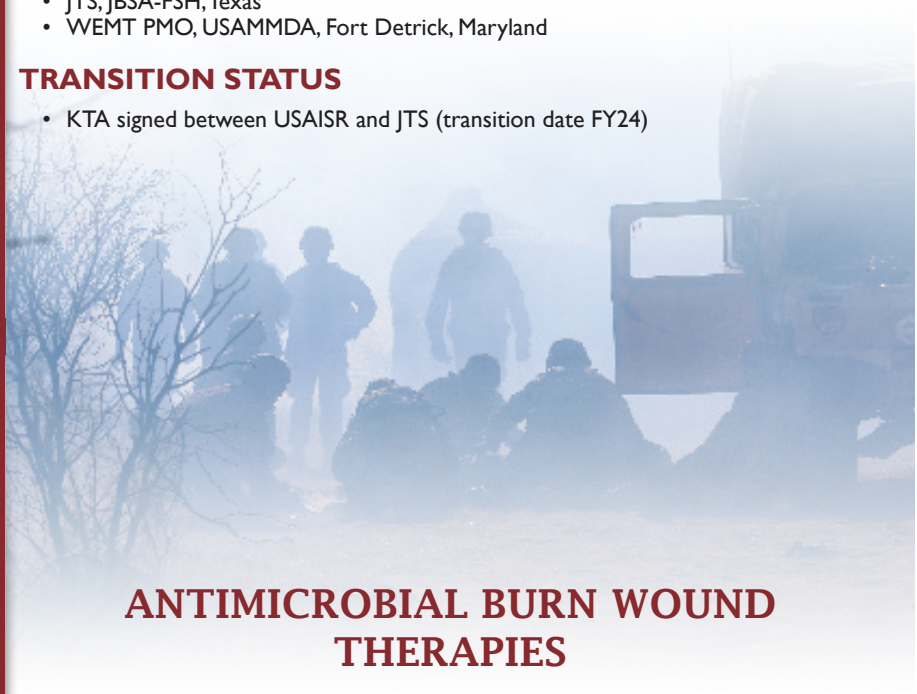
In burn patients, early determination of severity helps inform appropriate treatment and monitoring. This KP will provide the information to assist in the interpretation of biomarker results on the battlefield during prolonged care scenarios and/or evacuation. This knowledge will help determine burn wound severity (including diagnosing full-thickness burn wounds in Roles 2 and 3 to enable faster determination of healing and wound closure), inform triage and treatment, and monitor treatment efficacy. This KP will also aid in evacuation decisions by determining whether skin grafting will be necessary and providing information about skin graft viability and the potential for scar formation. This will inform potential RTD status.

PARTNERS

- USAISR, JBSA-FSH, Texas
- JTS, JBSA-FSH, Texas
- WEMT PMO, USAMMDA, Fort Detrick, Maryland

TRANSITION STATUS

- KTA signed between USAISR and JTS (transition date FY24)



ANTIMICROBIAL BURN WOUND THERAPIES

This KP will inform the development of CPGs for solutions to prevent bacterial infection after burn, decrease inflammation, and encourage the formation of new blood vessels. Information in this KP will include the best antimicrobial dosing for severely burned casualties, taking into account resources that may or may not be available. Knowledge will contribute to decreases in life-threatening complications associated with burn wound infection and increase survival.

PARTNERS

- USAISR, JBSA-FSH, Texas
- JTS, JBSA-FSH, Texas

TRANSITION STATUS

- KTA signed between USAISR and JTS (transition date FY21)

NUTRITIONALLY OPTIMIZED FOOD PRODUCTS FOR AN EXPEDITIONARY FORCE

Proper nutrition promotes optimal human performance and metabolic recovery. This KP will identify solutions to sustain performance during high op-tempo missions and reduce recovery time between missions. This knowledge will be utilized to determine methods of incorporating nutrients into highly acceptable, palatable, shelf-stable military ration components and field feeding systems. The KP will include information related to food nutrient formulations; as well as, nutritional delivery options to optimize and promote optimal human performance and metabolic recovery. The Combat Feeding Directorate will use the knowledge from this KP to develop nutritionally optimized products (materiel) for use by the Warfighter community.

PARTNERS

- USARIEM, Natick, Massachusetts
- U.S. Army Combat Capabilities Development Command (CCDC) Soldier Center,
- Natick, Massachusetts

TRANSITION STATUS

- KTA signed between USARIEM and CCDC Soldier Center (transition date FY21)

CO_2/O_2 BREATH & RESPIRATION ANALYZER SYSTEM

The CO_2/O_2 Breath & Respiration Analyzer (COBRA) being developed is a lightweight, low-cost, wearable, indirect calorimetry system capable of noninvasive, highly accurate measurements of the metabolic fuel use and metabolic energy expenditure of resting and exercising humans. The technology to be transitioned consists of the COBRA system and software. This will increase Soldier lethality by improving performance through personalized macronutrient needs assessment both during and after activity. The COBRA system will provide scientifically valid assessments of aerobic fitness, work intensity, body heat production and storage, and water and metabolic fuel requirements across a wide range of activities. This knowledge can be integrated into mission planning to improve training and physical performance.

PARTNERS

- USARIEM, Natick, Massachusetts
- WEMT PMO, Fort Detrick, Maryland
- SOCOM, MacDill Air Force Base, Florida

TRANSITION STATUS

- KTA signed between USARIEM and WEMT PMO (transition date FY20)

PHARMACOLOGIC TREATMENT OF COMBAT STRESS

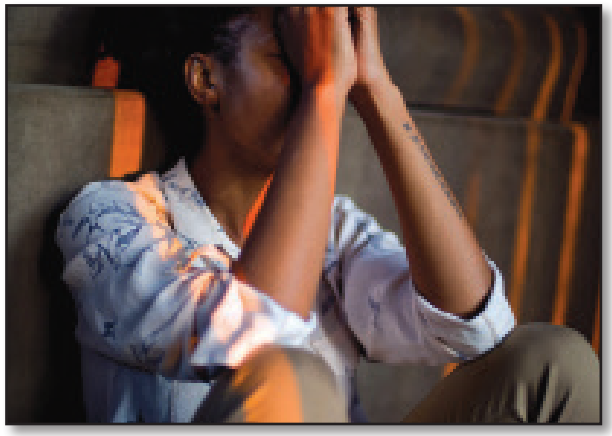
Nabilone is a drug that was developed to treat the nausea and vomiting typically caused by chemotherapy. It has been used off-label to facilitate recovery from traumatic stress exposure through improved sleep. This KP provides empirical data to support the efficacy of Nabilone. Constituent datasets within the KP include objective measures of improved sleep and improved daytime post-traumatic stress symptoms. The data collection effort will provide the OTSG Behavioral Health Service Line with an evidence base to support changes in CPGs for off-label use of Nabilone.

PARTNERS

- WRAIR, Silver Spring, Maryland
- U.S. Army OTSG, Falls Church, Virginia

TRANSITION STATUS

- KTA signed between WRAIR and OTSG (transition date FY24)



BEHAVIORAL HEALTH RETURN TO DUTY DECISION AIDS

Development of KPs from this effort is intended to provide tools and training for Army behavioral health providers aimed at enhancing behavioral health care effectiveness and provider decision-making about RTD from psychological injury. These efforts will provide easily administered trainings, assessment tools, and recommendations that providers and leaders can use to increase the accuracy of judgment for psychological RTD decisions for Service Members experiencing mental health issues.

PARTNERS

- WRAIR, Silver Spring, Maryland
- U.S. Army OTSG, Falls Church, Virginia

TRANSITION STATUS

- KTA signed between WRAIR and OTSG (transition date FY19)

RETURN TO DUTY STANDARDS FOLLOWING MUSCULOSKELETAL INJURY

A MSKI limits Soldiers' availability for training and combat operations. This KP produces recommendations (such as strategies and assessment metrics) to improve RTD decision-making following MSKI in Operational Forces and provides improved methods to evaluate Soldiers' perceived and actual readiness following injury and RTD physical testing. This will enable delivery of evidence-based, actionable recommendations to Army leadership to optimize Warfighter health, readiness, and performance by improving the RTD process and preventing re-injury.

PARTNERS

- U.S. Army TRADOC, Fort Eustis, Virginia
- U.S. Army Forces Command (FORSCOM) (3rd Infantry Division Surgeon), Fort Bragg, North Carolina
- USARIEM, Natick, Massachusetts

TRANSITION STATUS

- KTA signed between USARIEM and FORSCOM 3rd Infantry Division (transition date FY22)

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GLOSSARY

A	
A&M	Aviation & MIssle
ABCT	Armored Brigade Combat Team
Ad4	Adenovirus Type 4
Ad7	Adenovirus Type 7
AE	Aeromedical Evacuation
AFRIMS	Armed Forces Research Institute of Medical Sciences
AMEDD	U.S. Army Medical Department
AMEDDBD	U.S. Army Medical Department Board
AMPV	Armored Multi-Purpose Vehicle
Android	Android Operating System
APFT	Army Physical Fitness Test
APG	Aberdeen Proving Ground
APP	Application
AR	Army Regulation
ASBPO	Armed Services Blood Program Office
B	
BLA	Biologics License Application
BRDSS	Burn Resuscitation Decision Support System
BSMC	Brigade Support Medical Company
C	
CASEVAC	Casualty Evacuation
CBC	Chemical Biological Center
CBRN	Chemical, Biological, Radiological, and Nuclear
CCCRP	Combat Casualty Care Research Program
CCDC	U.S. Army Combat Capabilities Development Command
CDC	Centers for Disease Control and Prevention
CDD	Capability Development Document
CDD-U	Capability Development Document Update
CDID	Capabilities Development and Integration Directorate
CFR	Code of Federal Regulations
CHIKV	Chikungunya Virus

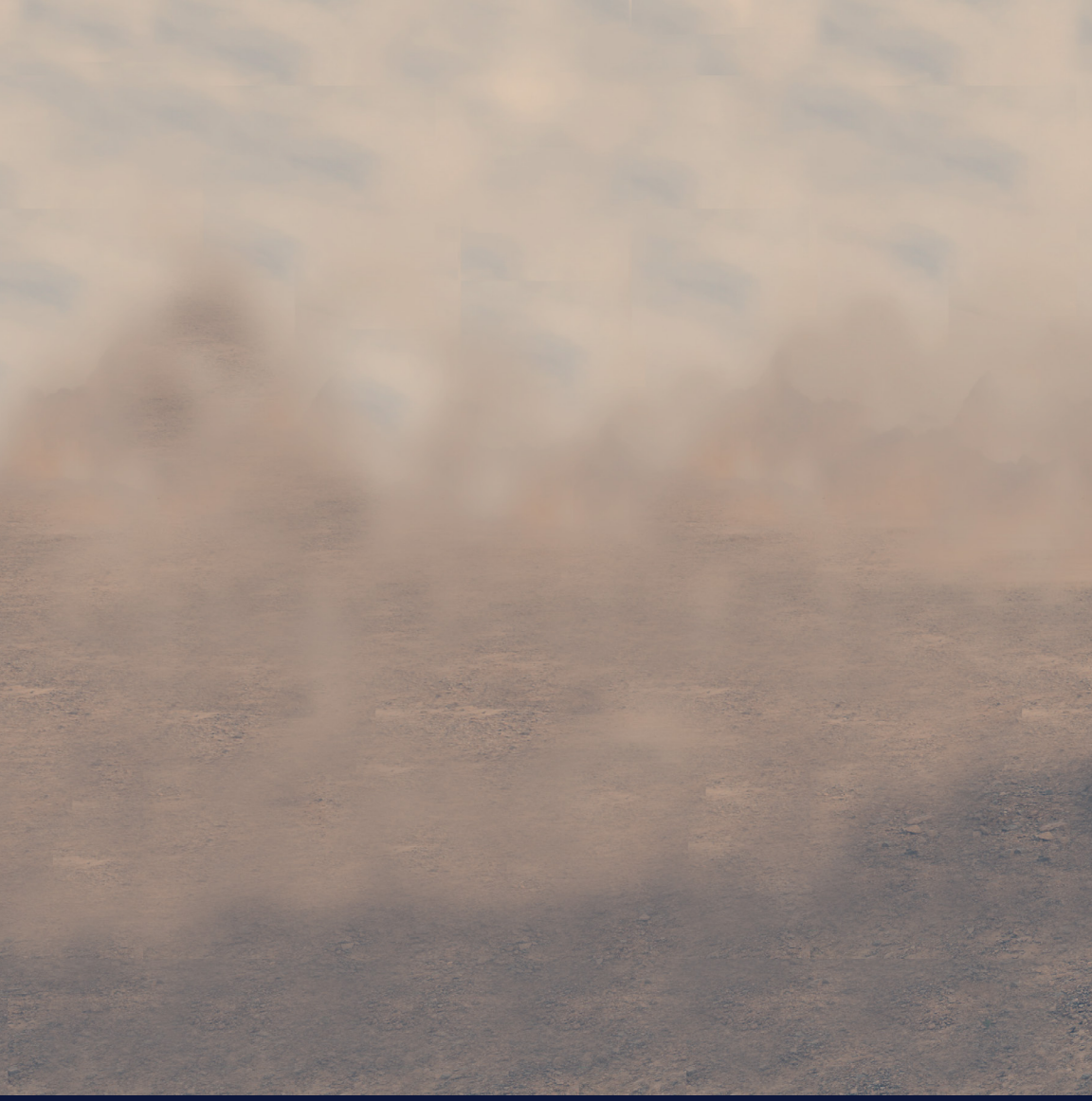
CIMIT	Consortia for Improving Medicine with Innovation and Technology
CL	Cutaneous Leishmaniasis
COBRA	CO_2/O_2 Breath & Respiration Analyzer
CONUS	Continental United States
CPG	Clinical Practice Guidelines
CPP	Cryopreserved Platelet Product
CPPW	Chemical Patient Protective Wrap
CRADA	Cooperative Research and Development Agreement
CRMRP	Clinical and Rehabilitative Medicine Research Program
CS&CSS	Combat Support and Combat Service Support
CSH	Combat Support Hospital
CSP	Cold-Stored Platelets
CT	Computed Tomography
C3T	Command, Control, Communications - Tactical
D	
DLA	Defense Logistics Agency
DNBI	Disease and Non-Battle Injury
DoD	Department of Defense
DOSE	Drug Organizational Safety Equipment
E	
E. coli	*Escherichia coli*
ECLS	Extracorporeal Life Support
eCTD	Electronic Common Technical Document
EIR	Extremity Injury Repair
EMA	European Medicines Agency
ESB	Environmental Sentinel Biomonitor
EU	European Union
E3	Environmental Exposure Electronic
F	
FDA	U.S. Food and Drug Administration
FDP	Freeze-Dried Plasma
FDU	Force Design Update

FFDP	French Freeze-Dried Plasma
FFP	Fresh Frozen Plasma
FH	Field Hospital
FLIR	Forward Looking Infra-Red
F.O.A.M.	Fast Onset Abdominal Management
FORSCOM	U.S. Army Forces Command
FRST	Forward Resuscitative Surgical Team
FVL	Future Vertical Lift
FY	Fiscal Year
G	
GSK	GlaxoSmithKline
GVSC	Ground Vehicle Systems Center
H	
H.E.A.L.T.H.	Healthy Eating, Activity, and Lifestyle Training Headquarters
HIV	Human Immunodeficiency Virus
HRAPS	Health Readiness and Performance System
HSDA	Heat Strain Decision Aid
I	
ICD	Initial Capabilities Document
IFAK	Individual First Aid Kit
IT	Information Technology
IND	Investigational New Drug
iOS	iPhone Operating System
ISO	International Organization for Standardization
IVAS	Intravenous Artesunate
J	
JBSA-FSH	Joint Base San Antonio-Fort Sam Houston
JLTV	Joint Light Tactical Vehicle
JPM	Joint Project Manager
JTS	Joint Trauma System
JWTC	Jungle Warfare Training Center
K	

KP	Knowledge Product
KTA	Knowledge Transition Agreement
L	
LATBI	Laboratory Assay for Traumatic Brain Injury
LSCO	Large-Scale Combat Operations
M	
MCAS	Medical Companies (Area Support)
MDD	Materiel Development Decision
MDO	Multi-Domain Operation
MedCoE	Medical Center of Excellence
MEDEVAC	Medical Evacuation
MEDHUB	Medical Hands-free Unified Broadcast
MEP	Mission Equipment Package
MEPD	U.S. Army Medical Evacuation Proponency Directorate
MIDRP	Military Infectious Disease Research Program
MIT	Massachusetts Institute of Technology
MOLLE	Modular Lightweight Load-carrying Equipment
MOMRP	Military Operational Medicine Research Program
MS	Milestone
MSKI	Musculoskeletal Injury
mTBI	Mild Traumatic Brain Injury
MTF	Medical Treatment Facility
MVSS	Medical Vital Signs Simulator
MWD	Military Working Dogs
N	
NATO	North Atlantic Treaty Organization
NCTH	Non-Compressible Torso Hemorrhage
NDA	New Drug Application
NG	Next Generation
NGDS	Next Generation Diagnostic System
NIAID	National Institute of Allergy and Infectious Diseases
NINAD	Non-invasive Neuroassessment Device

NMRC	Naval Medical Research Center
O	
O&M	Operations and Maintenance
OEF	Operation Enduring Freedom
OIF	Operation Iraqi Freedom
ORA	Office of Regulated Activities
OTSG	Office of The Surgeon General
P	
P.	*Plasmodium*
PEO	Program Executive Office
PM	Project Manager
PMA	Premarket Approval
PMO	Project Management Office
PROC	Procurement
PTSD	Post-Traumatic Stress Disorder
R	
REBOA	Resuscitative Endovascular Balloon Occlusion of the Aorta
RHDD	Rapid Human Diagnostic Device
RTD	Return to Duty
RWS	Rigid Wall Shelter
S	
S3I	Systems Simulation, Software, and Integration
SKO	Sets, Kits, and Outfits
SOCOM	U.S. Special Operations Command
SWAR	Soldier Warrior
SWS	Soft Wall Shelter
T	
TAS	TEMPER Air-Supported
TATRC	Telemedicine and Advanced Technology Research Center
TCCC	Tactical Combat Casualty Care
TEMPER	Tent Extendable Modular Personnel
TBD	To Be Determined
TBE	Tick-Borne Encephalitis

TBI	Traumatic Brain Injury
TBI-DT	Traumatic Brain Injury - Drug Treatment
TGA	Therapeutic Goods Administration
TIC	Toxic Industrial Chemical
TIM	Toxic Industrial Materiel
TQ	Tafenoquine
TRACK-TBI NET	Transforming Research and Clinical Knowledge for Traumatic Brain Injury
TRADOC	Training and Doctrine Command
TRL	Technology Readiness Level
TXA	Tranexamic Acid
U	
UH	Utility Helicopter
U.S.	United States
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
USAMRDC	U.S. Army Medical Research and Materiel Command formerly U.S. Army Medical Research and Materiel Command
USARIEM	U.S. Army Research Institute of Environmental Medicine
V	
VA	Department of Veterans Affairs
VAMC	Veterans Affairs Medical Center
VML	Volumetric Muscle Loss
W	
WBPRD	Whole Blood Pathogen Reduction Device
WEMT	Warfighter Expeditionary Medicine and Treatment
WHPE	Warfighter Health, Performance, and Evacuation
WPAC	Warfighter Protection and Acute Care
WQAS-PM	Water Quality Analysis Set - Preventative Medicine
WRAIR	Walter Reed Army Institute of Research
WRNMMC	Walter Reed National Military Medical Center



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