USAMRMC

Advanced Development Products 2015

ACKOWLEDGEMENTS

The U.S. Army Medical Research and Materiel Command wishes to acknowledge the following individuals and organizations for their support in advancing the development of medical products that save lives.

The U.S. House of Representatives and the U.S. Senate Armed Services Committees

The U.S. House of Representatives and the U.S. Senate Appropriations Committees

The Assistant Secretary of Defense for Health Affairs; the Defense Health Affairs Agency and the Defense Health Affairs - Research, Development and Testing Program

The Assistant Secretary of the Army for Acquisition, Logistics, and Technology

The Surgeon Generals of the U.S. Army, the U.S. Navy, and the U.S. Air Force

The U.S. Army Medical Department Center and School

The National Institutes of Health

The Food and Drug Administration

The Advanced Development community also wishes to acknowledge their science and technology and fielding partners within the USAMRMC to include:

Science and Tecnology Program Area Directorates

U.S. Army Aeromedical Research Laboratory (USAARL)

U.S. Army Institute of Surgical Research (USAISR)

U.S. Army Medical Research Institute of Chemical Defense (USAMRICD)

U.S. Army Center for Environmental Health Research (USACEHR)

U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID)

U.S. Army Research Institute of Environmental Medicine (USARIEM)

U.S. Army Medical Materiel Agency (USAMMA)

U.S. Army Medical Research Acquisition Activity (USAMRAA)

U.S. Army Medical Materiel Center-Europe (USAMMCE)

U.S. Army Medical Materiel Center-Korea (USAMMCK)

Walter Reed Army Institute of Research (WRAIR)

Congressionally Directed Medical Research Programs (CDMRP)

Telemedicine & Advanced Technology Research Center (TATRC)

TABLE OF CONTENTS

TABLE OF CONTENTS

TABLE OF CONTENTS

WELCOME

The U.S. Army Medical Research and Materiel Command mission is to responsively and responsibly create, develop, deliver and sustain medical capabilities for the Warfighter. As the U.S. Army's Medical Life Cycle Manager, the USAMRMC selects, modifies and procures commercial medical materiel solutions for approximately 95 percent of Army medicine's requirements. For the remaining 5 percent and as a Department of Defense leader for the advancement of military medicine, the USAMRMC sponsors the research and development of both materiel and knowledge-based medical products. Collectively, these seek to enhance Warfighter health and resilience, continuously improve downrange health delivery and promote faster recovery and rehabilitation after traumatic injury. The USAMRMC addresses problems whose solutions do not attract either a significant commercial or academic interest, or that need a timely solution, or are programs directed by Congress. Examples include products to mitigate the effects of blast injuries and vaccines, diagnostics and treatments for infectious diseases endemic to remote regions of the world where military personnel deploy.

While the military's technical base (e.g., science laboratories plus academic and industry partners) use basic and applied research to explore concept feasibility and perform early investigations of medical products and information, Advanced Development takes products showing promise in the technical base to the finish line – Food and Drug Administration approval, and subsequent fielding and sustainment in sets, kits and outfits. This process requires DOD acquisition community support for the medical need, and the integration of multiple technical, regulatory and managerial disciplines.

The Advanced Development of drugs, biologics and devices falls into six basic areas: military infectious disease, combat casualty care, military operational medicine, clinical and rehabilitative medicine, radiation health effects and medical information management/ information technology. At the USAMRMC, advanced product development is overseen by the Principal Assistant for Acquisition, the Army's Milestone Decision Authority for medical materiel product development, who guides eight program management offices located in two Advanced Development organizations, the U.S. Army Medical Materiel Development Activity and the U.S. Army Medical Materiel Agency.

THE USAMRMC ADVANCED DEVELOPMENT ORGANIZATIONS	
The USAMMDA Program Management Offices	The USAMMA Program Management Offices
• Pharmaceutical Systems • Medical Support Systems • Human Immunodeficiency Virus • Hyperbaric Oxygen • Tissue Injury and Regenerative Medicine	• Medical Devices • Integrated Clinical Systems • Helicopter Medical Evacuation/ MEDEVAC Mission Equipment Package

This publication highlights the accomplishments of the USAMRMC's Advanced Development community and provides information on the materiel and knowledge products, which are either currently in Advanced Development or which have been recently fielded.

2011-2014 ADVANCED DEVELOPMENT ACCOMPLISHMENTS

FDA-CLEARED/APPROVED

- ***Adenovirus Vaccine.*** An oral vaccine to prevent febrile respiratory illness caused by Adenovirus Types 4 & 7 in military recruits during basic training. Up to 10 percent of basic trainees are infected with Adenovirus Type 4 or 7, causing an average three - four lost duty days and occasional deaths. This vaccine was re-developed by the Walter Reed Army Institute of Research and was FDA-licensed in 2011.
- ***Burn Resuscitation Decision Support System-Mobile.*** Approved by the FDA in 2014 for clinical use, this device provides intravenous fluid recommendations for burn patients during the initial 24 to 72 hours after burn injury. Excessive fluid administration in these patients can result in intestinal rupture and death. This software program monitors the burn patient's fluid levels and provides hourly recommendations for fluid administration. This was developed by the U.S. Army Institute of Surgical Research with FDA regulatory support from the USAMMDA.
- ***CL Detect™ Rapid Test.*** A hand-held "dipstick" device for the rapid diagnosis of cutaneous leishmaniasis. CL is a parasitic disease causing disfiguring lesions that is found in tropical and subtropical areas. The availability of a diagnostic device allows immediate implementation of appropriate treatments, which can reduce the severity of scarring and reduce lost duty time for affected U.S. military personnel. The device was cleared by the FDA in 2014.
- ***An Expanded Access Treatment Program for Cutaneous Leishmaniasis.*** In 2013, the FDA approved the use of a Topical Paromomycin + Gentamicin cream (WR279,396) for use in DOD Medical Treatment Facilities only. This allows for all DOD Healthcare beneficiaries to receive WR279,396 until the product is formally approved by the FDA for more widespread use.
- ***SOLX® System Blood Collection System.*** Developed as part of the Red Blood Cell Extended Life Program as a new whole blood collection system. Red blood cells produced by this system demonstrate improved cell quality for a storage period of 42 days, theoretically reducing complications that may be associated with RBC storage lesions. The system received FDA approval in 2013.

FIELDED

- ***Modular Lightweight Load-Carrying Equipment Medic Bag.*** In 2014, more than 500 MOLLE Medic Bags were shipped to Afghanistan. This new bag is lighter, lower profile and compatible with the Soldier's body armor. This effort is part of a collaborative effort between the USAMMDA and PEO Soldier (PM Soldier Protection and Individual Equipment).
- ***Individual First Aid Kit Generation II.*** In 2014, 134,580 of the Generation II kits were procured for fielding to deploying units. Based on theatre feedback, the design was modified to prevent snagging on vehicle doors/hatches during emergency egress. This effort was a collaboration between the USAMMDA and PEO Soldier (PM Soldier Protection and Individual Equipment) as part of a Rapid Fielding Initiative.
- ***Electronic Data Capture of Clinical Trials Data.*** This information system enables electronic transmission of data from clinical trials on investigational new drugs and vaccines to the FDA in compliance with 21 CFR Part 11. It consists of an industry-standard commercial-off-the-shelf electronic publishing software system organized in a format approved by the FDA and Army regulations. It is the only known system in the DOD and supports Army, Navy and Chemical and Biological Defense Program submission of medical product documents to the FDA. Developed by the USAMRMC, the system was implemented in 2013.

2011-2014 ADVANCED DEVELOPMENT ACCOMPLISHMENTS

- ***Vector Pathogen Detection Devices for Dengue, Malaria and Leishmaniasis.*** These three devices enable field Preventive Medicine personnel to test for infectious disease pathogens in trapped insects (vectors), thus ensuring the ability to advise the commander and enable the institution of effective field preventive measures and vector control protocols.
- ***Alternative Arthropod Insect Repellent.*** This effort addresses warfighter noncompliance for the use of DEET-based insect repellents because of odor, skin irritation, etc. Two commercially available non-DEET topical skin repellents have received a National Stock Number (SkinSmart® from Coleman, Wichita, Kansas and Natrapel® from Tender Corporation, Littleton, New Hampshire). Also, an additional DEET-based compound, Ultra 30™, has been added to the contingency pesticide list. This effort is currently in the Operations and Support Phase.
- ***Remote Diagnostic Access.*** This capability enables biomedical engineers to remotely troubleshoot and maintain Computed Tomography scanners in theatre. This was fielded in response to ARCENT ONS 10-3114 in 2012.
- ***Joint Biological Agent Identification Detection System Augmentation Set.*** This was accepted into service in October 2013.
- ***Medical Equipment Set, Physical Therapy.*** This is medical equipment used for physical therapy. It was accepted into service in 2013.
- ***Veterinary Clinical Chemistry Analyzer.*** This medical equipment is used to analyze blood samples from military working animals as an aid to diagnosis and treatment. It was accepted into service in 2013.
- ***Ultrasound Unit Diagnostic, Veterinary.*** This medical equipment supports the diagnosis and treatment of military working animals. It was accepted into service in 2013.
- ***Combined Camouflage Face Paint.*** This product combines a five-color Combined Camouflage face paint with the insect repellent, DEET. A National Stock Number has been assigned to the product, which is in the Operations and Support Phase. The commercial partner is Iguana, LLC (Thomasville, Georgia).
- ***Diode Laser Light Meter.*** This device is used during periodic maintenance, testing and calibration of medical equipment. It was accepted into service in 2013.

FULL RATE PRODUCTION DECISION (FIELDING PENDING)

- ***Noise Immune Stethoscope.*** This stethoscope provides auscultation capability in noisy environments, including ground and air evacuation, where traditional acoustic stethoscopes are ineffective. It was developed by the U.S. Army Aeromedical Research Laboratory and the USAMMA and was approved for FRP in 2013.
- ***Oxygen Generator Field Portable.*** This provides an oxygen generation capability at Role One and Two facilities without the logistic sustainment burden of compressed oxygen cylinders. The USAMMA was a partner in the development of this device, which was approved for FRP in 2013.

2011-2014 ADVANCED DEVELOPMENT ACCOMPLISHMENTS

ACQUISITION, MATERIEL AND LOGISTICS

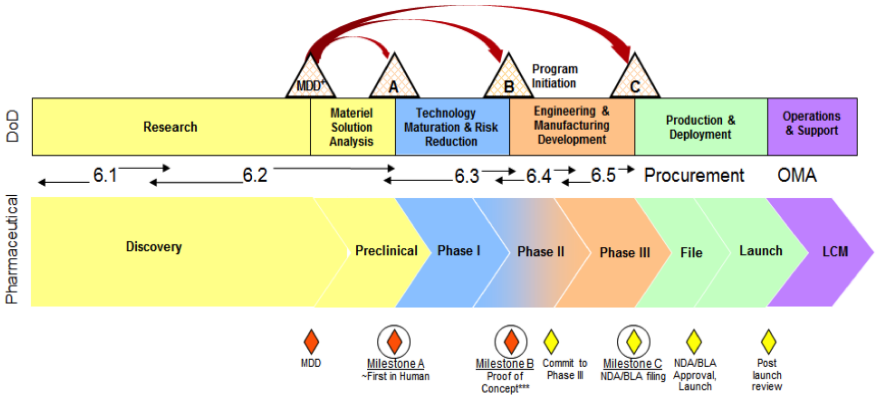
- ***Depot and Field Level Medical Maintenance Support.*** Completed more than 4,800 equipment work orders and rebuilt 1,300+ pieces of equipment, which avoided approximately $7.7M in new procurement costs.

INTERNATIONAL AFFAIRS

- Supported the U.S. Army Security Assistance Command in managing the medical commodity for Foreign Military Sales program, which managed 48 cases valued in excess of $82M, while providing medical equipment and supplies to 43 different countries around the globe.

MEDICAL ACQUISITION PROCESS MAP

The USAMRMC acquisition process integrates the DOD acquisition process with the U.S. Food and Drug Administration's medical product development process. This map illustrates how the processes are aligned, and serves as an aide for individuals to better understand the maturity level of the individual products that follow.



Discovery	*Basic and applied research to find new potential solutions and feed the acquisition process.*
LCM	*Life Cycle Management. The process of managing the development and use of a product from inception through scientific/ engineering design and manufacture to service and disposal (as needed).*
MDA	*Milestone Decision Authority. The executive-level decision maker with authority to approve acquisition program investments, plans and milestones. MDAs have full latitude to tailor programs in the most effective and efficient structure possible, unless constrained by statute.*
MDD	*Materiel Development Decision. This is the initial entry point to DOD's acquisition process, directing various studies to refine the initial requirement and potential solution sets.*
MS A	*Acquisition Milestone A. An investment decision to pursue specific product or design concepts, and commit resources to mature potential technology solutions, further refine requirements, and build formal arrangements with industry partners.*
MS B	*Acquistion Milestone B. Commits the resources needed to conduct advanced product development, leading to production and fielding of the product.*
MS C	*Acquisition Milestone C. Grants authority to begin actions related to production and/or fielding of a product to the Army.*
NDA/BLA	*New Drug Application/Biologic License Application. This is the formal request made to the FDA to "approve" a new product. Supported by voluminous scientific data gathered during the earlier clinical trials, and analyzed according to stringent FDA guidelines.*

OMA	*Operations and Maintenance, Army. A congressional appropriation used to fund a variety of short-term purchases including civilian salaries, expenses of operational military forces, training and education, depot maintenance, spare parts, and assets with a unit cost less than $250K.*
Clinical Trials	*Experiments that are conducted with human subjects or patients.*
Phase I	*Small scale human experiments, primarily to ensure safety of a new product.*
Phase II	*Mid-sized human experiments, to begin determining safety and efficacy before larger investments in development are made.*
Phase III	*Large and often expensive human experiments, to verify product safety and efficacy, and support FDA approval. FDA may require hundreds to thousands of human subjects to support their decision-making.*
Preclinical	*Experimental work conducted prior to using a product in any humans, most typically in animals. Focuses on mechanisms of action, alternate strategies or targets, and safety signals relative to human use.*
6.1-6.5	*Categories of congressionally appropriated funding related to Research, Development Test and Evaluation (RDTE) [Also called Program 6 Funds].*

ADVANCES IN BLOOD PRODUCTS

From 2001 to 2011, it is estimated that 24 percent of combat deaths occur before the patient reached a Medical Treatment Facility. Of these, the major cause of death was blood loss.[1] Many of these deaths may have been potentially survivable.

Recent efforts in blood products research have centered on ensuring the safety of blood collected and transfused on the battlefield, and in advancing the development of blood component therapy (e.g., plasma, platelets). These efforts are described on the following pages.

[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):5431-5437

ENSURING THE SAFETY OF BLOOD UNITS COLLECTED ON THE BATTLEFIELD

Under trauma situations, whole blood is collected and transfused on the battlefield when in-house supplies are exhausted. This is done under FDA-approved emergency protocol. Over the last 10 years of conflict, the Armed Forces Blood Program Office cited the number of battlefield whole blood collections, and subsequent transfusions, to be more than 10,000. Ensuring that battlefield-collected blood units are processed in accordance with FDA regulations is a top priority. These products will be used in Role of Care Level Two and/or Three facilities and blood support detachments.

WHOLE BLOOD PATHOGEN REDUCTION DEVICE

PARTNERS

- Terumo BCT, Lakewood, Colorado
- Puget Sound Blood Center, Seattle, Washington
- Hoxworth Blood Center, Cincinnati, Ohio
- Armed Forces Blood Program Office, Falls Church, Virginia
- U.S. Army Institute of Surgical Research, San Antonio, Texas

The Whole Blood Pathogen Reduction Device will ensure that battlefield collected blood for transfusion continues to meet FDA safety standards. Freshly collected units 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 has been shown to reduce the risk of Graft Versus Host Disease that may result from blood transfusion. A European/worldwide market for the Whole Blood Pathogen Reduction Device has already been established because of a higher frequency of whole blood for transfusions outside of the U.S.

The Whole Blood Pathogen Reduction Device will be an FDA-approved device. A multi-site Phase One/Two Clinical Trial was completed in 2014, and a pivotal clinical trial is planned for 2015. In addition, prototype transport cases for the device will be evaluated in 2015.

The USAMMDA's Pharmaceutical Systems Project Management Office is the Advanced Development lead for this product.

ACQUISITION STATUS

- Post Milestone B

TRANSFUSION TRANSMITTED DISEASE

RAPID DIAGNOSTIC DEVICE

PARTNER

- Medmira, Inc., Nova Scotia, Canada

Before blood is transfused, it is tested for the presence of infectious diseases such as HIV, Hepatitis B and Hepatitis C. For blood collected on the battlefield, per FDA emergency protocol, this testing is currently performed with non-FDA-approved or non-donor FDA-approved test kits. After transfusion, the donor blood is re-tested stateside or at overseas military reference laboratories with FDA-approved donor test kits.

The Transfusion Transmitted Disease Rapid Diagnostic Device will align the battlefield whole blood collection and transfusion process with FDA regulatory requirement to test blood units with FDA-approved donor test kits prior to transfusion.

The TTDRDD is a rapid clinical test consisting of two devices FDA-approved for donor blood testing. The devices will test the donated blood for HIV 1/2, Hepatitis B surface antigen, Hepatitis B core antigen and Hepatitis C.

The USAMMDA's Pharmaceutical Systems Project Management Office is the Advanced Development lead for this product.

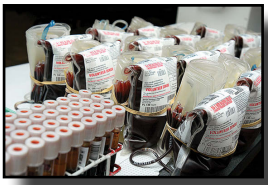
ACQUISITION STATUS

- Post Milestone A

RED BLOOD CELL EXTENDED LIFE

PARTNERS

- Haemonetics Corporation, Braintree, Massachusetts
- Hemerus Medical, LLC, Saint Paul, Minnesota
- University of Cincinnati, Cincinnati, Ohio
- Armed Services Blood Program Office, Falls Church, Virginia



This product extends the shelf life of blood by two weeks, while maintaining blood quality. It marks the first new development in blood storage in 25 years.

The shelf life of a unit of red blood cells, only 42 days from collection to expiration, drives a significant logistical chain to maintain a consistent supply of fresh blood to forward deployed units. Most blood is collected stateside and, despite streamlined transportation from CONUS, a unit's shelf life is decreased to 35 days or less by the time it arrives in theatre. Extending the shelf life is considered key to reducing red blood cell waste due to outdating, and in mitigating blood shortages in combat, emergency or natural disaster situations.

In 2012, the Hemerus Medical, LLC's SOLX® red blood cell filter and additive solution (AS-7) received the world's first CE Marking for 56 day red blood cell storage. At the same time, it was shown to maintain the quality of the blood as it aged, which has been reported to potentially impact patient outcomes. The CE Marking is the manufacturer's declaration that the product meets the requirements of the applicable European Conformity directives. In 2013, the FDA approved this product for use in the U.S. for a 42-day red blood cell storage period. Hemerus Medical LLC (now owned by Haemonetics) is currently pursuing a 56-day red blood cell storage indication with the FDA. The USAMMDA's Pharmaceutical Systems Project Management Office provided technical and financial support for the development of the SOLX® System.

Shortly after FDA approval, Haemonetics moved to replace the SOLX® red blood cell filter with an alternate filter. This required a New Drug Application supplement to the FDA and the performance/completion of equivalency studies. As a result, SOLX® market release has been delayed by 18 months to early 2015.

ACQUISITION STATUS

- Post Milestone C
- Future procurement of this product will be funded by the Armed Service Blood Program Office

MAKING LIFE-SAVING BLOOD COMPONENTS AVAILABLE FAR FORWARD TO TREAT MASSIVE BLOOD LOSS

The blood components used to treat massive blood loss caused by combat wounds include plasma and platelets. Given on the battlefield, they are critical in stopping bleeding by replacing clotting factors lost as a result of excessive bleeding or massive transfusion. In the past, the availability of these products far forward has been compromised by logistical and storage requirements. The products described below will be deployed at Role of Care Level Two and Three facilities, with the potential for deployment farther forward.

FREEZE-DRIED PLASMA

PARTNER

- Vascular Solutions, Inc., Minneapolis, Minnesota
- U.S. Army Institute of Surgical Research, San Antonio, Texas

Clot-promoting proteins in the plasma of a unit of freshly collected blood are unstable. However, when the plasma is separated and frozen at -18^{oC} within eight hours of collection, the clotting proteins remain stable for up to one year. This component, Fresh Frozen Plasma, is shipped frozen to the atre on dry ice and stored in large, specialized freezers until needed. It has been reported that up to 30 percent of FFP units are unusable because of breakage during shipment, or are discarded after five days because of pre-thawing to ensure availability when needed. The large logistical component, plus the high incidence of waste, has driven the need for an improved product.

Freeze-Dried Plasma is an equivalent product to FFP. It consists of lyophilized human plasma packaged for rapid reconstitution and administration. It can be shipped in ruggedized containers and stored at refrigerated, or potentially, room temperature. It can be reconstituted in less than six minutes. The Freeze-Dried Plasma product reduces the need for large freezers and the accompanying power and space needs, and decreases waste due to product expiration.

The USAMMDA's Pharmaceutical Systems Project Management Office is the Advanced Development lead for this effort. Vascular Solutions, Inc., will support the manufacturing requirements and will be the FDA regulatory sponsor.

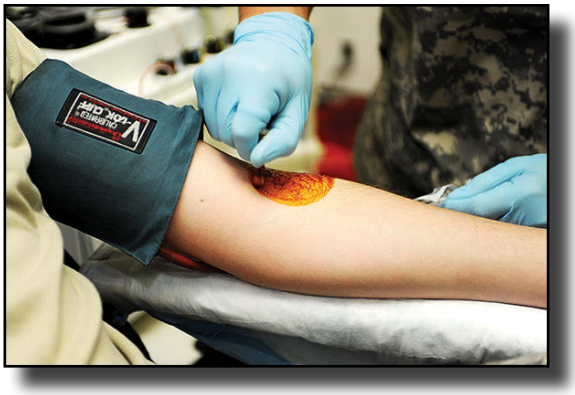
ACQUISITION STATUS

- Post Milestone B

CRYOPRESERVED PLATELETS

PARTNERS

- Clinical Research Management, Inc., Hinckley, Ohio
- Fast-Track Drugs and Biologics, Inc., North Potomac, Maryland
- Dartmouth-Hitchcock Medical Center, Hanover, New Hampshire
- Hoxworth Blood Center, Cincinnati, Ohio
- Puget Sound Blood Center, Seattle, Washington
- U.S. Army Blood Program, San Antonio, Texas
- U.S. Army Institute of Surgical Research, San Antonio, Texas
- Armed Services Blood Program Office, Falls Church, Virginia



Currently, the supply of platelets on the battlefield is limited because of specialized collection procedures, a very short shelf life (five days) and the need for specific storage conditions (room temperature under constant agitation).

The Cryopreserved Platelet Product consists of frozen human platelets preserved in a solution that protects the platelets during freezing. Because units of CPPs can be stored frozen for up to two years, they can be pre-positioned in anticipation of need during a future conflict.

CPPs were used by the Dutch Military Services in the Balkans and in Afghanistan with promising results. Recent studies have shown CPPs to be safe and effective for treatment of abnormal bleeding in cardiopulmonary bypass patients. The use of CPPs is not currently approved for clinical use by the FDA.

Once FDA-approved, CPPs will be produced by U.S. military blood banks and managed as a blood product for the battlefield by the Armed Services Blood Program Office. A Phase One/Two clinical study in thrombocytopenic patients sponsored by the World Health Organization is currently underway. Recovery and survival studies have been completed. The target date for fielding this product is 2020.

The USAMMDA's Pharmaceutical Systems Project Management Office is the Advanced Development lead for this effort.

ACQUISITION STATUS

- Post Milestone B

PLATELET-DERIVED HEMOSTATIC AGENT

PARTNERS

- Cellphire, Inc., Rockville, Maryland
- Entegrion, Inc., Triangle Park, North Carolina
- Biomedical Advanced Research Defense Authority, U.S. Department of Health & Human Services, Washington, District of Columbia

This effort will develop a platelet-derived product that can be rapidly reconstituted and administered to help stop severe bleeding resulting from trauma. Two separate Platelet Derived Hemostatic Agent product development efforts are underway. Each is a freeze-dried product for intravenous administration. Each is being developed for different indications. Both are intended for stockpiling.

Stasix® (Entegrion, Inc.) is being developed by the DOD for the treatment of acute non-compressible hemorrhage. Thrombosomes® (Cellphire, Inc.) is being developed by BARDA as a primary treatment for acute radiation syndrome under the FDA-Animal Rule. Once additional studies are complete, one product will be down-selected for Advanced Development. The PDHA is not considered to be a replacement for platelet transfusion and will be regulated as a biologic by the FDA.

The USAMMDA's Pharmaceutical Systems Project Management Office is the DOD's Advanced Development lead for this effort.

ACQUISITION STATUS

- Post Material Development Decision

XSTAT-30™

PARTNERS

- RevMedx, Inc., Portland, Oregon
- U.S. Air Force Medical Support Agency, Falls Church, Virginia
- U.S. Special Operations Command, MacDill Air Force Base, Florida
- Defense Health Agency, Medical Logistics Division, Fort Detrick, Maryland

A significant number of combat wounds occur in regions of the torso where compression cannot be applied, such as the pelvis or shoulder. Bleeding from these types of wounds is called non-compressible hemorrhage. Currently, there are no products specifically designed for treating this type of bleeding, which is a leading cause of death on the battlefield.

XSTAT-30™ (RevMedX, Inc., Portland, Oregon), is designed to control bleeding associated with non-tourniquet and non-compressible injuries, such as those found in the groin or armpit regions of the body.

The XSTAT-30™ consists of mini sponges contained in a compact delivery device that fits in the medic's aid bag. This technology involves injecting small, rapidly-expanding cellulose sponges coated with chitosan into a wound cavity using a syringe-like applicator. Within 30 seconds of contact with blood, the sponges expand to fill the wound cavity. This creates a temporary barrier to blood flow, and provides pressure to stop bleeding. In swine animal models, the sponges have stopped the flow of blood within four minutes of delivery and maintained it for up to four hours. An X-ray detectable marker on each sponge ensures the ability to locate and remove the sponges in a surgical setting.

The XSTAT-30™ was approved in April 2014 by the FDA as a medical device. It is intended for battlefield use for the control of bleeding from junctional wounds in the groin or axilla not amenable to tourniquet application in adults and adolescents. It is not indicated for use in the thorax, pleural cavity, mediastinum, abdomen, retroperitoneal space, sacral space above the inguinal ligament; or tissues above the clavicle. It is cleared for use as a temporary device and should be removed by surgical intervention within four hours of application.

The USAMMA is serving as the Advanced Development lead for the product. The XSTAT-30™ is currently in a pre-production phase and is expected to be fielded by the U.S. Special Operations Command in early 2015.

ACQUISITION STATUS

- Post Milestone A

[1]Eastridge BJ, Mabry RL, 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: S431.

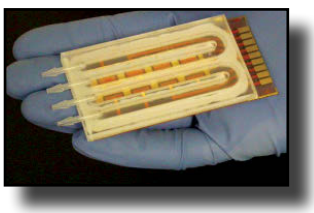
ENVIRONMENTAL SENTINEL BIOMONITOR

ENSURING A SAFE WATER SUPPLY

PARTNERS

- Agave Biosystems, Ithaca, New York
- ANP Technologies, Inc., Newark, Delaware
- Biosentinal, Inc., Austin, Texas
- Nanohmics, Austin, Texas
- U.S. Army Edgewood Chemical Biological Center, Aberdeen Proving Ground, Maryland
- U.S. Army Center for Health Promotion and Preventive Medicine, Aberdeen Proving Ground, Maryland
- U.S. Army Center for Environmental Health Research, Fort Detrick, Maryland

Providing a safe, high quality supply of water to deployed troops is a key element in preventing disease which, along with non-battle injuries, debilitates more Soldiers than combat.



The Environmental Sentinel Biomonitor system provides a substantial increase in current capabilities. It provides an ability to rapidly screen water for a wide range of potentially toxic chemical contaminants (from industrial or agricultural sources) and for chemicals/contaminants whose presence cannot currently be detected. The ESB system complements fielded preventive medicine testing methods, such as the Water Quality Analysis Set.

The ESB system consists of two hand-held toxicity sensors. It is intended for use by preventive medicine personnel at the Brigade Combat Team Level and higher. The ESB system will be a Class VIII item intended for inclusion in the WQAS-PM kit, which is on the Table of Organization and Equipment for Preventative Medicine Detachments (Level Three) and for BCT Preventative Medicine sections (Level Two).

The USAMMDA's Medical Support Systems Program Management Office is the Advanced Development lead for this product.

ACQUISITION STATUS

- Post Milestone B
- Engineering and manufacturing development contracts were awarded in 2013

TRANSPORT TELEMEDICINE

PROVIDING CONTINUITY OF MEDICAL CARE FROM POINT OF INJURY THROUGH MEDEVAC

PARTNERS

- Sierra Nevada Corporation, Las Vegas, Nevada
- Nevada National Guard, Reno, Nevada
- U.S. Army Aeromedical Research Laboratory, Fort Rucker, Alabama

One of the U.S. Army's most significant medical gaps is the inability to capture a complete history of medical treatment from point of injury through medical evacuation/MEDEVAC and transfer to the next Level of Care.

The goal of this effort is to provide an integrated system that (1) provides a treatment history for the patient's medical record and (2) during transport record data on the patient's physiological status from attached medical devices. The data will be transmitted real-time to the next Level of Care to:

- Augment medical situational analysis to better prepare the medical treatment facility for incoming casualties
- Provide clinical information on patient condition through data recorded by attached medical devices
- Give more accurate clinical and treatment information for the patient's medical record
- Allow for telementoring

During an evacuation mission, the medics primary responsibility is to stabilize the patient, with the secondary responsibility to document the care provided. However, the receipt of paper-based documentation at the next Level of Care is sporatic and leadership intervention has been needed to ensure that complete records are entered into the Electronic Health Record. Generally, documentation of care provided during evacuation is accomplished after the episode of care is given, resulting in little ability to impact patient outcome with actionable information.

The goal of this effort is to field an integrated system capable of capturing injury and care data while the patient is en-route or at a remote location, and transmitting it through existing military radio systems to the next Level of Care. The system consists of a user device, an access point and a ground station. The project has a phased rollout.

- Increment 1 for helicopters
- Increment 2 for ground vehicles

The USAMMA is the Advanced Development lead for this effort.

ACQUISITION STATUS

- Post Milestone A

INTRA-COMPARTMENTAL PRESSURE RELIEF

AID IN THE DIAGNOSIS AND/OR TREATMENT OF COMPARTMENT SYNDROME

PARTNERS

- Nonin Medical, Plymouth, Minnesota
- Twin Star Medical, Minneapolis, Minnesota

A majority of battlefield injures involve the arms and legs. These injuries can be isolated or can occur in combination with other injuries (e.g., vascular, penetrating and/or blunt trauma, crush injury, burns, fractures). These injuries can raise the pressure within enclosed spaces in the body, also referred to as intra-compartmental pressure, which puts the patient at risk for developing Acute Compartment Syndrome. Failure to reduce elevated intra-compartmental pressure can result in a restriction of the blood supply to the muscles, the breakdown of muscle tissue, kidney damage and even death.

The clinical diagnosis of ACS is difficult in unconscious or anesthetized trauma patients who are unable to communicate. Here, intra-compartmental pressure measurements guide treatment decisions. When intra-compartmental pressure is high, existing Current Practice Guidelines call for cutting connective tissue surrounding the involved muscles, blood vessels or nerves to relieve the pressure. These actions have been associated with wound infection, chronic limb swelling, increased incidence of deep vein thrombosis, limited limb movement upon recovery and nerve dysfunction. Studies examining the complications of ACS and its impact on clinical outcomes are underway.

Currently, the lack of diagnostic aids to assist the clinician in the diagnosis of ACS is a capability gap. Various technologies are being investigated. The compartment syndrome device can be invasive or non-invasive. Ideally, the goal is a minimally-invasive or non-invasive device.

The USAMMA's Medical Devices Program Management Office, the Advanced Development lead for this project, is working with industry partners to further investigate and mature these technologies.

ACQUISITION STATUS

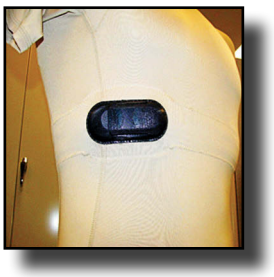
- Post Material Development Decision

ADVANCED PHYSIOLOGICAL MONITOR

CONTINUOUS RECORDING OF PATIENT VITAL SIGNS DURING TRANSPORT WITH E-TRANSFER TO NEXT LEVEL OF CARE

PARTNERS

- Sotera Wireless, Inc., San Diego, California
- Flashback Technologies, Boulder, Colorado
- U.S. Army Aeromedical Research Laboratory, Fort Rucker, Alabama
- U.S. Army Institute of Surgical Research, San Antonio, Texas



Knowing an incoming patient's physiological status prior to arrival would give a medical treatment facility time to assemble the medical assets best suited to immediately address that patient's needs. Currently, there is no uninterrupted monitoring or e-transfer of a patient's physiological condition from point of injury.

Current practice calls for the use of the Tactical Combat Casualty Care cards to record patient data at the point of injury. Useful for capturing patient vital signs at one point in time, these cards are easily misplaced or discarded as the patient is transferred from one means of transport/Level of Care to another. Various stand-alone vital sign monitors are currently stocked in the Army's Sets, Kits and Outfits for use at Role of Care Levels One to Four. A new requirement calls for the development of a smaller/lighter monitor for use in aeromedical transport.

This project is an opportunity to involve the joint community in considering inputs for an advanced physiological monitor to continuously monitor patient vital signs with e-transfer of the data to the next Level of Care, and e-recording to the patient health care record. Major considerations involve interoperability (facility to facility, monitor to monitor, transport to ground), platforms (hardware, software), technology and infrastructure.

Various technologies are being investigated. For example, Sotera Wireless, Inc., is developing a vital signs monitor to continuously record patient data from the point of injury. Flashback Technologies uses an algorithm, the Compensatory Reserve Index, as a predictor of shock resulting from fluid loss due to bleeding or dehydration.

The USAMMA's Medical Devices Program Management Office, the Advanced Development lead for this project, is working with industry partners such as the ones mentioned above to further investigate and mature these technologies.

ACQUISITION STATUS

- Post Material Development Decision

BURN RESUSCITATION DECISION SUPPORT SYSTEM - MOBILE

PROPER FLUID RESUSCITATION TO BURN PATIENTS DURING THE CRITICAL 24-72 HOURS AFTER INJURY

PARTNERS

- Arcos Medical, San Antonio, Texas
- U.S. Army Institute of Surgical Research, San Antonio, Texas

Proper fluid resuscitation is vital to reducing complications and death during treatment of burn victims. Excessive fluid administration in these patients can result in intestinal rupture and death. The Burn Resuscitation Decision Support System uses an algorithim-based decision assist system for managing fluid resuscitation of the severely burned patient.

In 2007, the U.S. Army Institute of Surgical Research began using a Burn Resuscitation Decision Support System in their burn wards. By 2008, using the BRDSS algorithm and computerized decision aid became a standard practice. While the system improved outcomes inside the burn ward, the USAISR still found many burn patients arriving who had clearly been given too much fluid. In an effort to extend the success of the BRDSS, the USAISR proposed a mobile version of the Burn Resuscitation Decision Support System.

In 2011, with the support of the U.S. Army Medical Department Directorate of Combat and Doctrine Development, the Burn Resuscitation Decision Support System – Mobile entered into the Engineering and Manufacturing Development phase of the acquisition lifecycle with a Materiel Development Decision. The USAMMA's Medical Devices Program Management Office was assigned as the Advanced Development lead. A Cooperative Research and Development Agreement was signed with Arcos, Inc. The BRDSS-M was cleared by the FDA in 2013.

The BRDSS-M software was designed to meet military specifications. The system uses a standard Panasonic CF-H2 Toughbook tablet as the hardware platform, but the locked-down operating system only runs the BRDSS-M software. It is designed to be used in a deployed setting by nurses and doctors not experienced in treating burn patients. The device has received an airworthiness certification.

In 2013, the BRDSS-M project met a full-rate production decision review, and the USAMMA was granted permission to begin a procurement contract to field this device. It will be tracked by the Patient Movement Item system.

ACQUISITION STATUS

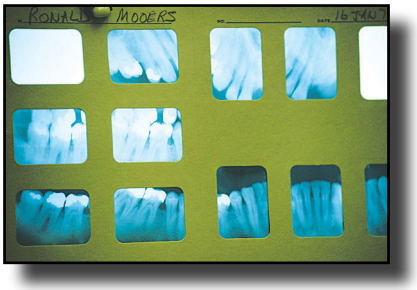
- Full-Rate Production

ANTI-PLAQUE CHEWING GUM

PREVENTION AGAINST CARIES AND PERIODONTAL DISEASE

PARTNERS

- Indiana University Oral Health Research Institute, Indianapolis, Indiana
- Walter Reed Army Institute of Research, Silver Spring, Maryland



Studies of dental emergencies among deployed troops participating in Operations Desert Shield/Storm, Operations Enduring and Iraqi Freedom and the peace-keeping operation in Bosnia, showed a dental emergency rate ranging from 13 – 23 percent of Service Members per year. Most of these were related to plaque-induced caries and periodontal problems.

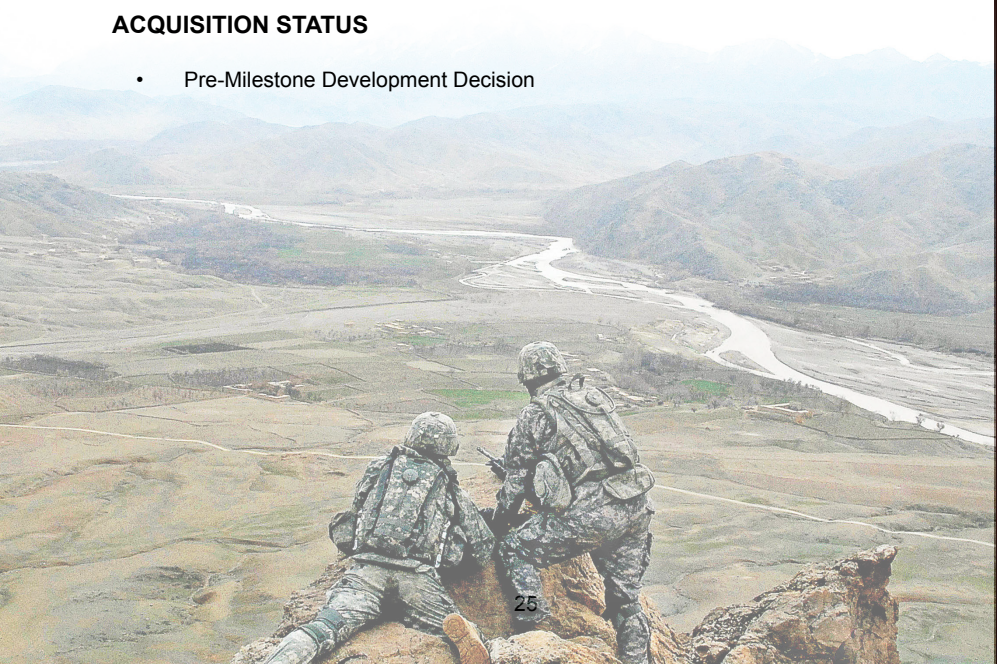
This product will be a FDA-approved anti-plaque, sugar-free chewing gum containing an antimicrobial peptide to help reduce and control dental plaque-associated gingivitis and infection. It is estimated that chewing one piece, three times a day or following meals for 20 minutes, will provide at least six hours of protection.

The first in-human Phase One/Two trial is underway in Indiana. The goal is to transition the technology to industry, pending successful Phase One/Two and plaque regrowth studies.

The USAMMDA's Pharmaceutical Systems Project Management Office is the Advanced Development representative for this effort, which is still in development in the technical base.

ACQUISITION STATUS

- Pre-Milestone Development Decision

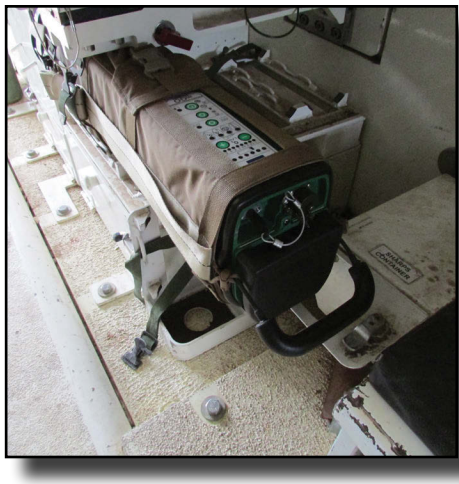


OXYGEN GENERATOR, FIELD PORTABLE

UPGRADING OXYGEN DELIVERY ON THE BATTLEFIELD

PARTNERS

- Chart Industries, Ball Ground, Georgia
- Ultra Electronics, Lanham, Maryland
- JBC Corp., Virginia Beach, Virginia
- U.S. Army Aeromedical Research Laboratory, Fort Rucker, Alabama



In a hospital setting, supplemental oxygen is available at the bedside either from a small oxygen concentrator or piped-in from a large oxygen generator through an oxygen distribution system. In a patient transport setting, the Army has traditionally relied on high-pressure oxygen cylinders. Supplying compressed oxygen to a battlefield environment not only presents a safety hazard, but also carries with it a substantial logistics trail.

To address the safety and logistics issues related to providing oxygen on the battlefield, the Army Combat Developers developed a requirement for a field portable oxygen generator. It calls for a three-liter-per-minute oxygen generator similar to a 'D' cylinder that can be plugged into vehicle power or used in a standard wall plug.

Chart Industries has developed the Saros (originally developed by SeQual, acquired by Chart Industries) to address this requirement. This product has been adopted by the Army Special Forces into their Tactical Combat Casualty Care Casualty Evacuation sets. Other OGFP devices have been developed by JBC Corp. and Ultra Electronics.

The USAMMA's Medical Device Program Management Office is the Advanced Development lead for this product.

ACQUISITION STATUS

- Post Milestone C
- Full-Rate Production is in negotiation

DEPLOYABLE OXYGEN GENERATOR, SMALL 15 LITERS PER MINUTE

UPGRADING OXYGEN DELIVERY ON THE BATTLEFIELD

PARTNERS

- Chart Industries, Ball Ground, Georgia
- U.S. Air Force Life Cycle Management Command, Wright-Patterson Air Force Base, Ohio

The Army has supported the development of a three-liter per minute oxygen concentrator designed for military applications (Oxygen Generator, Field Portable).

However, both the Army Combat Developers and their Air Force counterparts recognized a need for a 15-liter-per-minute oxygen concentrator capable of providing sufficient oxygen for the most critically ill and injured patients. The larger oxygen concentrator will have the same safety and logistics advantages of the Army's OGFP. This product represents a coordinated development effort between the Army and the Air Force.

A 15-liter-per-minute oxygen concentrator is currently in developmental testing under an Air Force Milestone Development Decision. This is the last step prior to submission for FDA clearance. The Army intends to deploy the DOGS-S with the Forward Surgical Teams and on Medical Evacuation helicopters.

The USAMMA's Medical Device Program Management Office is the Advanced Development lead for this project.

ACQUISITION STATUS

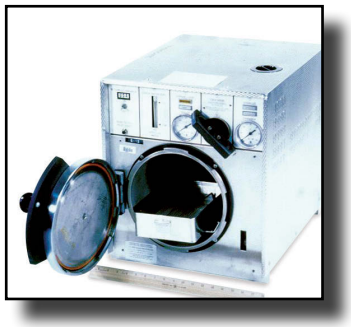
- Air Force Milestone Development Decision; currently in Engineering and Manufacturing Development Phase

STEAM STERILIZER, FIELD PORTABLE

BATTLEFIELD STERILIZATION OF MEDICAL INSTRUMENTS AND MEDICAL WASTE

PARTNERS

- Fort Defiance Industries, Loudon, Tennessee



Steam sterilization is the accepted standard of care for sterilization of non-heat-sensitive products. Medical treatment facilities use steam sterilization to kill infectious microorganisms on material and on surgical instruments before disposal or reuse. A variety of sterilization methods exist (e.g., steam, gas, radiation, chemical), all of which have advantages and limitations.

The Role of Care, Level Three Army Combat Support Hospital uses large-chamber steam sterilizers that were developed in the late 1960s. These sterilizers are outdated in design and have significant logistical challenges in terms of power and water requirements. The CSH sterilizer modernization effort is supported by an Army-developed Capability Development Document, but the project has applications across the joint medical environment.

Operational and environmental testing was performed on four commercial sterilizer models or advanced prototypes to assess their suitability for field use. Based on this testing, the model P2131 steam sterilizer from Fort Defiance Industries was selected as the only model meeting the Army's requirements. This system consists of a large-chamber sterilizer with an integral steam generator built into its transportation case. It also has a separate water softener and water recovery system. A competitive contract was awarded to Fort Defiance Industries to deliver a final production model of their modernized sterilizer system.

The new sterilizer will meet all modern sterilizer standards, including FDA 510(k) clearance, and will have improved throughput and sterilization effectiveness, automated control and data logging (reduces operator error, workload), improved safety features, reduced water consumption (>90 percent), reduced power consumption and reduced scale build-up. Delivery is anticipated by early 2015, pending completion of the FDA regulatory review process.

The USAMMA's Medical Device Program Management Office is the Advanced Development lead for this project.

ACQUISITION STATUS

- Pre-production contract awarded

ARMORED MULTI-PURPOSE VEHICLE MEDICAL TREATMENT/EVACUATION VARIANTS

REPLACES THE OUTDATED M113 AMBULANCE

PARTNERS

- Project Manager, Armored Brigade Combat Team, Fort Benning, Georgia
- Product Manager, Armored Multi-Purpose Vehicle, Warren, Michigan
- U.S. Army Maneuver Center of Excellence, Fort Benning, Georgia

Picture displayed is of the Armored Medical Evacuation Vehicle from the 90s as a representation

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 will retire the M113 family of vehicles by 2018. Replacement will be through the Armored Multi-Purpose Vehicle program.

The Army Medical Department working with Product Manager AMPV, Project Manager Armored Brigade Combat Team, the U.S. Army Maneuver Center of Excellence and the U.S. Army Medical Department Directorate of Combat and Doctrine Development, is developing requirements for the next generation of fighting vehicles that includes requirements for medical ground evacuation and treatment.

For this effort, the USAMMDA's Medical Support Systems Program Management Office worked with Project Manager ABCT to identify potential AMPV evacuation and treatment vehicles to replace the M113 family of vehicles. The USAMMDA MSS PMO revised the Performance Specifications for the medical variants for Project Manager 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.

ACQUISITION STATUS

- System Development and Demonstration phase contract award is anticipated for 2015
- Fielding of the first equipped unit is expected in 2020

MAXXPRO PLUS LONG WHEEL BASE AMBULANCE

SAFE TRANSPORT OF WOUNDED WARRIORS FROM THE FRONT LINES

PARTNERS

- Project Manager, Mine-Resistant Ambush Protected, Warren, Michigan
- Navistar Defense, Madison Heights, Michigan

The MaxxPro Plus is a Mine-Resistant Ambush Protected vehicle built to withstand ballistic arms fire, mine blasts, improvised explosive devices and other emerging threats. In 2013, the Vice Chief of Staff of the Army released the MRAP III study, which called for the conversion of 301 MaxxPro Plus vehicles to ambulances for Army Pre-Position stock. This retrofit will use the litter loading system developed for the MRAP Dash ambulance, a smaller, lighter variant of the MaxxPro Plus, which has an independent suspension system, a litter loading system that allows for faster patient load times compared to conventional military ambulances and an ergonomic configuration to reduce musculoskeletal injuries. The MRAP Dash ambulance also allows for side-by-side patient configuration, giving the medic better access to casualties.

The USAMMDA's Medical Support Systems Program Management Office supported the MRAP III study. It also sponsored the development of the MaxxPro Plus MRAP Litter Load/Lift System through Navistar Defense. The ambulance is currently undergoing programmatic testing before final production.

ACQUISITION STATUS

- After testing is complete in 2015, the 301 vehicles will be converted and sent to Army Pre-Position Stock for use in future conflicts

FUTURE MEDICAL SHELTER/FORCE PROVIDER
REPLACES AGING SHELTERS WITH EXPEDITIONARY, LIGHTWEIGHT, ENERGY EFFICIENT STRUCTURES

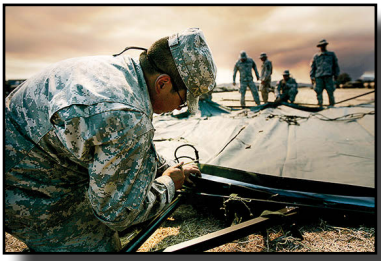
TACTICAL SHELTER MODERNIZATION

PARTNER

- U.S. Army Natick Research, Development & Engineering Command/Shelter Technology, Engineering & Fabrication, Directorate, Natick, Massachusetts

A critical element for the Army Combat Support Hospital/Field Hospital is the ability to provide forward deployed care in the form of a mobile treatment facility. Tactical Shelters are mobile, transportable structures designed for a functional requirement. They provide an environmentally controllable space for human habitation/use, and/or permanent equipment storage or operation.

SOFT-WALL SHELTER MODERNIZATION



The Soft Wall Shelter is a tactical shelter consisting of an air-supported and frame-supported fabric structure that can be transported and assembled on site. The existing CSH/FH infrastructure consists of SWSs that provide patient wards and support functions that are critical to current operations. The life expectancy for existing SWSs has exceeded the 10 year life expectancy, and current stocks of shelters require replacement because of safety issues. It is estimated that, within five years, the CSHs will not be able to support SWS deployments using current stocks. In addition, these shelters are heavy, require significant set-up time and do not meet the most recent requirements. The SWS modernization effort will provide a lightweight, energy efficient and expeditionary SWS for the Level of Care, Role Three CSH and the new Army Field Hospital.

The USAMMDA's Medical Support System Program Management Office is conducting an analysis to review and assess potential materiel solutions, consider the economic analyses of this materiel acquisition from the DOD and field command perspective and address the identified mission capability gap(s).

ACQUISITION STATUS

- Post Material Development Decision

RIGID-WALL SHELTER MODERNIZATION

PARTNER

- U.S. Army Natick Research, Development & Engineering Command, Natick, Massachusetts
- Core Composites in Bristol, Rhode Island

The Rigid Wall Shelter is a tactical shelter consisting of pre-sized expandable and non-expandable shelters that can be transported by land, sea or air. The RWS requires minimal site preparation and no specialized setup. It is used in combat support hospitals to house the laboratory, pharmacy, blood bank and radiology and can be also be used for surgery.

The current RWS system, consisting of one and two-sided International Standards Organization approved shelters, is more than 25 years old, has demonstrated weaknesses in flooring, is energy inefficient and has an insufficient storage capability for shipping containers (6-stack high). It does not meet the new requirements which include improved energy efficiency, stronger floors without deformation, “nine-stack high” capability for shipping containers, construction with composite materials, an auto-leveling system, advanced insulation, collective protection liner kits for force protection and high efficiency particulate air/humidity control. The RWS is still in production, but modifications have been requested by the Army Medical Department in order to meet the new requirements.

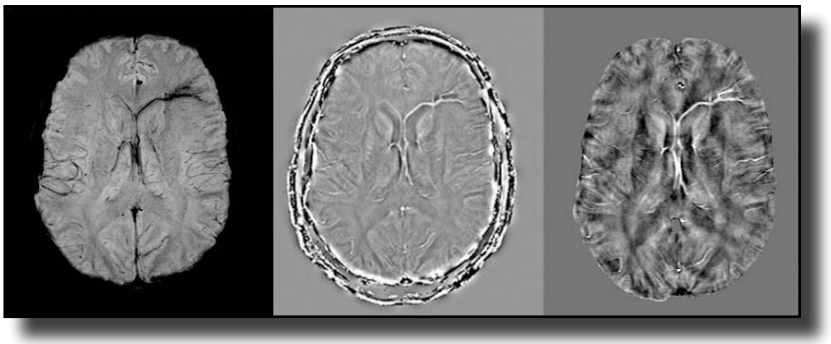
The AMEDD Investment Strategy Working Group has tasked the USAMMDA’s Medical Support System Program Management Office to prepare a funding strategy for the RWS with two courses of action for the RWS’s in production (partial retrofit and full retrofit) in order to meet the new requirements.

ACQUISITION STATUS

- Post Milestone B

TRAUMATIC BRAIN INJURY-RELATED PRODUCTS
ADDRESSING ONE OF THE SIGNATURE INJURIES OF OIF/OEF

AIDS ASSISTING IN TBI DIAGNOSIS AND RETURN-TO-DUTY AND CARE REFERRAL DECISIONS



Traumatic brain injury is defined as damage to the brain resulting from external mechanical force, such as rapid acceleration or deceleration, impact, blast waves or penetration by a projectile. TBI can be categorized as mild, moderate or severe. It results in a host of physical, cognitive, social, emotional and behavioral effects, with outcomes ranging from complete recovery to permanent disability or death.

Over the past 10 years, the military has documented 307,283 cases of TBI (82 percent mild TBI; 9 percent moderate/severe TBI).[1]

Although TBI is associated with a deployed environment, more than 80 percent of cases occur in non-deployed settings. TBI is a growing problem in the civilian sector because of sports-related concussions. It is estimated that the U.S. spends more than $50 billion per year on medical problems related to TBI.

The current standard of care for TBI is rest, with long-term management by neurologists, psychiatrists, physiatrists and neuropsychologists. Currently, there is no FDA-approved drug to reduce the brain damage or sequelae that result from TBI.

The Glasgow Coma Scale is the most commonly used system for classifying TBI severity. It grades a person's level of consciousness based on verbal, motor and eye-opening reactions to stimuli. Because the GCS grading system has a limited ability to predict outcomes, complimentary models have been proposed.

The USAMMA's Medical Device Program Management Office is the Advanced Development lead for this project and is working with industry partners to further investigate and mature technologies to improve the diagnosis and treatment of TBI.

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

PHYSIOLOGICAL NEURODIAGNOSTICS

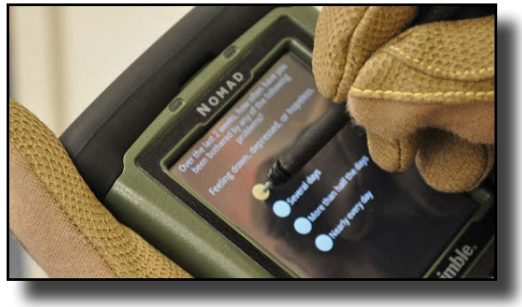
NON-INVASIVE NEURODIAGNOSTICS

PARTNERS

- Sync-Think, Boston, Massachusetts
- Neurokinetics, Pittsburgh, Pennsylvania
- Contect, University of Notre Dame, South Bend, Indiana
- NeuroWave, Cleveland Heights, Ohio
- BrainScope, Bethesda, Maryland
- AnthroTronix, Silver Spring, Maryland

Various non-invasive technologies exist that can detect the symptoms of TBI, even if they are not easily recognizable. Examples include the tracking of eye movements, measuring balance, quantitative electroencephalogram analysis, voice analysis and reaction-time testing.

This effort explores those non-invasive technologies which, when used in conjunction with clinical data and diagnostic aids such as the Glasgow Coma Scale and neuroimaging, could help to refine TBI diagnosis, return-to-duty determinations or the decision to refer the injured Warfighter to a higher Level of Care.



ACQUISITION STATUS

- Post Material Development Decision

PORTABLE NEUROMODULATION STIMULATOR™

PARTNERS

- Nuero-Habilitation Corporation, Philadelphia, Pennsylvania
- University of Wisconsin, Madison, Wisconsin

The Portable Neuromodulation Stimulator ™ is a tool to assist in better outcomes for those suffering from neurological disorders resulting from TBI.

The PoNS™ is designed to augment traditional therapeutic treatments. It uses a sequenced pattern of electrical pulses to stimulate the facial nerves that innervate the back of the human tongue. This excites the natural flow of neural impulses to the brain-stem and cerebellum. Studies have demonstrated that when PoNS™ stimulation lasts 20 minutes or more, a reorganization of neuronal circuits may occur in the brain. This may result in neurological improvement in some functional areas, such as balance.

A PoNS™ clinical trial is in the planning stages. The results will support a de-novo submission to the FDA with an anticipated clearance date of 2016. Once FDA cleared, the Army will pursue broader applications for the device.

ACQUISITION STATUS

- Post Material Development Decision

DRUG THERAPY FOR TRAUMATIC BRAIN INJURY

PARTNERS

- Neuren Pharmaceuticals, Ltd., Bethesda, Maryland
- Walter Reed Army Institute of Research, Silver Spring, Maryland

This effort focuses on a FDA-approved drug specifically for the treatment of mild to moderate-severe TBI. The drug, NNZ-2566, is a synthetic analogue of a naturally occurring molecule produced by the brain in response to injury. NNZ-2566 has been shown to reduce the magnitude of the three components of the TBI cascade: excitoxicity, inflammatory processes and neuronal death. Two formulations will be developed – one intravenous and one oral.

In collaboration with scientists at the Walter Reed Army Institute of Research, Neuren Pharmaceuticals, Ltd., filed an Investigational New Drug application with the FDA for the IV formulation of the drug. It was granted Fast Track Designation by the FDA in 2009, and Phase Two trials are currently underway (Sponsor: Neuren Pharmaceuticals LTD).

An IND application for an oral formulation has been submitted to the FDA. The 82nd Airborne Division at Fort Bragg in Fayetteville, North Carolina, has agreed to participate in the Phase Two clinical study.

This product is intended for use at Level of Care, Roles One to Three (Role Three for IV formulation; Role One to Three for oral formulation).

ACQUISITION STATUS

- Post Milestone A

LABORATORY ASSAY FOR TRAUMATIC BRAIN INJURY

PARTNERS

- Banyan Biomarkers, Alchua, Florida
- Abbot Point of Care, Princeton, New Jersey
- Phillips Group Innovation, Eindhoven, Netherlands
- Future Diagnostics, Wijchen, Netherlands
- Walter Reed Army Institute of Research, Silver Spring, Maryland

A biomarker is defined as a measurable entity that can indicate a physiological state. In conjunction with the Walter Reed Army Institute of Research, a blood assay has been developed to detect biomarkers of TBI. The assay tests for the presence/levels of two blood proteins which have been linked to the presence of a head injury.

A clinical study was completed in March 2014. Submission to the FDA for assay approval is expected in September 2015. Since the primary means to detect TBI is through imaging, the first indications of the LATBI will be as follows:

> *The assay is to be used in conjunction with other clinical information as an aid in the evaluation of patients over the age of 18 presenting with suspected traumatic brain injury (Glasgow Coma Scale score 9-15) within 12 hours of injury to assist in determining the need for a CT scan of the head.*

As research gathers more data, this indication will be refined. The ultimate goal of this effort is the use of the biomarkers as indicators of the diagnosis and recovery of TBI.

ACQUISITION STATUS

- Post Milestone B

DRUG TREATMENT FOR POST-TRAUMATIC STRESS DISORDER

Post-traumatic stress disorder is one of the most common mental health disorders resulting from the combat experience. The National Center for PTSD estimates that 11-20 percent of OEF/OIF Veterans (253,000-450,000) have PTSD, with an average per case cost for the first year of treatment of $8,300.[1,2]

This effort seeks to foster the recovery of U.S. service members and veterans with combat-related PTSD through incremental clinical trials of new pharmacotherapeutics and previously licensed FDA medications that may find alternative use as a PTSD treatment. This product is intended for use at Level of Care, Role Two and above.

The USAMMDA's Neurotrauma and Psychological Health Project Management Office is the Advanced Development lead for this effort.

ACQUISITION STATUS

- Post Milestone A

[1] Congressional Research Service, Sept. 2010.
[2] Treatment of PTSD and TBI by Veterans Health Administration, Congressional Budget Office, February 10, 2012 http://

NOISE-IMMUNE STETHOSCOPE

MONITORING OF HEART AND LUNG SOUNDS IN HIGH-NOISE ENVIROMENTS

PARTNERS

- Active Signal Technologies, Inc., Linthicum Heights, Maryland
- U.S. Army Aeromedical Research Laboratory, Fort Rucker, Alabama

In combat, common standard acoustic stethoscopes are impractical when ambient noise levels exceed 80-85 decibels. Noise-canceling electronic stethoscopes can extend the useful range up to 90 decibels. However, the noise level in some combat situations, such as a medical evacuation helicopter, can reach 120 decibels.

The U.S. Army Aeromedical Research Laboratory, a subordinate command of the USAMRMC, recognized the need for a stethoscope that could detect heart and lung sounds in operational environments where the ambient noise levels prohibit the use of a common acoustic stethoscope.

In 2009, the Directorate of Combat and Doctrine Development issued a capability production document requesting the development of a Noise-Immune Stethoscope or NIS. The USAMMA's Medical Devices Program Management Office was assigned to lead the effort. A Materiel Development Decision in April 2009 enabled the NIS to enter the Engineering and Manufacturing Development phase of the acquisition process. To help fill the documented gap, the U.S. Army utilized the Small Business Innovation Research program to work with a Maryland company, Active Signal Technologies, to develop the NIS.

The final product is a dual-mode, noise-immune stethoscope capable of operating in a standard acoustic-mode, as well as a unique Doppler-mode enabling providers to hear and observe heart and lung sounds in high-noise environments. The NIS received clearance from the FDA as a medical device in March 2011.

The U.S. Army Medical Department Board conducted a customer assessment in May and June 2013 and concluded that the NIS supports the medical mission for aeromedical evacuation. Use requires minimal training. Providers were comfortable with using the device. In December 2013, the NIS project obtained a Full-Rate Production decision and the USAMMA was given permission to begin a procurement contract to field this device.

ACQUISITION STATUS

- Full Rate Production

(BATTLEFIELD) PAIN MANAGEMENT SUFENTANIL NANOTABS®

RELIEF FROM SEVERE PAIN AT THE POINT OF INJURY WITHOUT HARMFUL SIDE EFFECTS

PARTNERS

- AcelRX Pharmaceuticals, Inc., Redwood City, California

The Tactical Combat Casualty Care guidelines outlining the treatment of severe pain caused by trauma include the use of non-steroidal anti-inflammatory drugs (e.g., ibuprofen), ketamine (off-label use) and opioids such as 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).

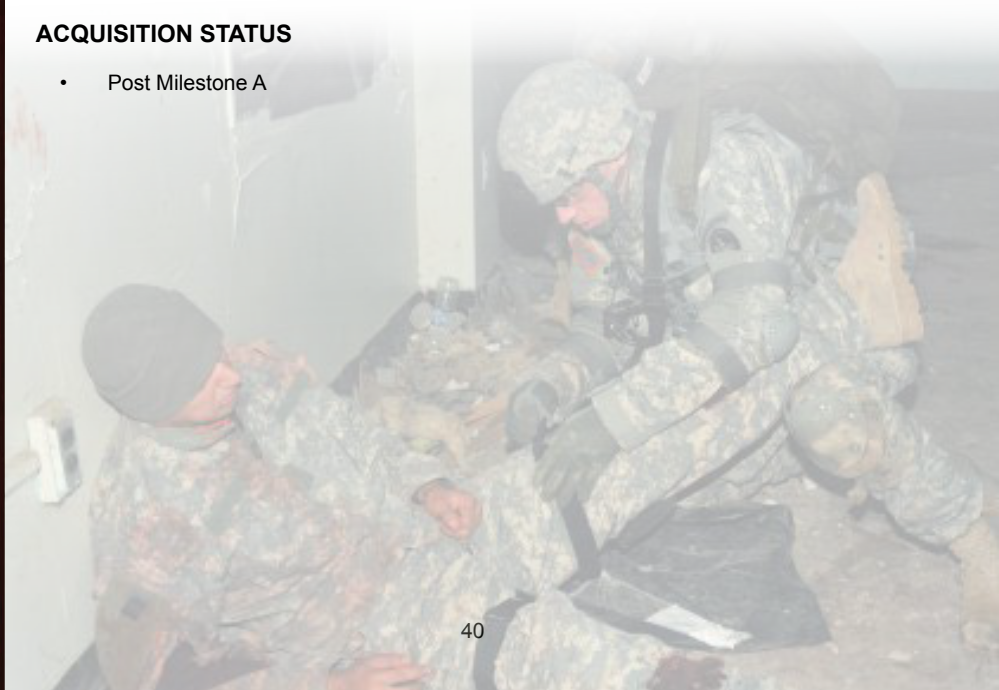
Sufentanil is an opioid drug used to relieve pain. In a civilian setting, it is primarily used in operating suites and critical care settings where pain relief is required for a short period of time. The DOD is seeking to develop a fast-acting, easily dispensed sufentanil-based product for use on the battlefield to relieve acute pain. This product should be able to be taken orally (under the tongue) and have minimal side effects. The developmental effort for the Sufentanil NanoTabs® began as a grant awarded to AcelRx Pharmaceuticals Inc. in 2011.

The USAMMDA's Pharmaceutical Systems Project Management Office is the Advanced Development lead for this product. It is meant for use in the Tactical Field Care and Tactical Evacuation Care phases of Tactical Combat Casualty Care and at Level of Care, Role One.

A manufacturing capability for a Sufentanil-based, sublingual tablet has been established. A Phase Two clinical trial involving the product is complete, and a Phase Three clinical trial is pending. A design for a single-dose delivery device for Sufentanil NanoTabs® is also complete. AcelRx is the Investigational New Device sponsor and will hold the New Drug Application upon FDA licensure.

ACQUISITION STATUS

- Post Milestone A



ADENOVIRUS TYPE 4 AND TYPE 7 VACCINE, LIVE, ORAL

AVOIDS $50M IN MEDICAL CARE EXPENSE & LOST TRAINING TIME YEARLY [1]

PARTNERS

- Assistant Secretary of Defense, Health Affairs
- Barr Laboratories, Inc., subsidiary of Teva Pharmaceuticals USA, Forest, Virginia
- Walter Reed Army Institute of Research, Silver Spring, Maryland
- Naval Health Research Center, San Diego, California
- Defense Logistics Agency, Fort Belvoir, Virginia
- Military Vaccine Agency, Falls Church, Virginia

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, it is estimated that 80 percent of enlisted trainees became infected during training. Of these, 40 percent had significant illness and 20 percent 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 to manufacturing issues. From 1997-1999, as the vaccine supply was exhausted, Ad4 and Ad7 infections in the trainee population rose, accompanied by significant losses in training time and increases in medical care expenditures. By 2001, adenovirus infections had again become highly epidemic in U.S. recruit training centers.

In 2001, the U.S. Army contracted with Barr Laboratories, Inc., to resume production of the adenovirus vaccine. FDA approval was granted for this product in 2011, and vaccine administration resumed at all U.S. recruit training sites in October 2011. In the two years since re-introducing the Ad4 and Ad7 vaccine, there has been a 100-fold decline in incidence of the illness in the basic trainee population.

ACQUISITION STATUS:

- The USAMMDA manages vaccine sustainment. In 2014, this cost totaled $31 million

[1]*Radin JM, Hawksworth AW, Blair, PJ et al: Dramatic decline of respiratory illness among military recruits after the renewed use of adenovirus vaccines. Clin Infect Dis 2014; 59(7): 962-968.*

HIV VACCINE INCREMENT 1 (REGIONAL) AND HIV VACCINE INCREMENT 2 (GLOBAL)

REGIONAL AND GLOBAL VACCINE DEVELOPMENT EFFORTS

PARTNERS

- Sanofi Pasteur
  Swiftwater, Pennsylvania
- Crucell (subsidiary of
  Johnson & Johnson)
  Leiden, Netherlands
- Inovio Pharmaceuticals, Inc.
  Plymouth Meeting, Pennsylvania
- The Armed Forces Research Institute of Medical Sciences
  Bangkok, Thailand
- Novartis
  Basel, Switzerland
- Thailand Ministry of Health and Ministry of Science and Technology
  Bangkok, Thailand
- Bill and Melinda Gates Foundation
  Seattle, Washington
- Centers for Disease Control and Prevention, HIV/AIDS
  Atlanta, Georgia
- Center for HIV-AIDS Vaccine Immunology Duke University
  Durham, North Carolina
  Scripps Institute
  La Jolla, California
- Division of AIDS, National Institute of Allergy and Infectious Diseases, National Institutes of Health
  Bethesda, Maryland
- Global HIV Vaccine Enterprise
  New York, New York
- Global Solutions for Infectious Diseases
  San Francisco, California
- 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, New York
- President's Emergency Plan for AIDS Relief
  Washington, District of Columbia
- Major academic partners, including:
  - Harvard University
    Cambridge, Massachusetts
  - Massachusetts Institute of Technology
    Cambridge, Massachusetts
  - Duke University
    Durham, North Carolina
  - New York University
    New York, New York
  - University of Washington
    Seattle, Washington
  - Beth Israel-Deaconess Medical Center
    Boston, Massachusetts

This effort is managed by the U.S. Military HIV Research Program. Centered at the Walter Reed Army Institute of Research, the MHRP conducts research to develop an effective HIV vaccine to protect U.S. and allied troops and to reduce the impact of HIV infection.

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 366 new HIV infections are diagnosed per year in the U.S. military. Currently 1,500 infected individuals serve on active duty. The cost for the treatment and care of HIV infected service members ranges from $21 million to $54 million per year with an estimated lifetime accrued cost of $418 million. The total lifetime cost to the U.S. government of the approximately 5,000 infected service members identified since active force-wide screening was initiated is estimated at $8-$10 billion.

HIV VACCINE INCREMENT 1 (REGIONAL VACCINE STRATEGY)

The Army-led RV144 Thai HIV vaccine trial showed, for the first time, that a preventive HIV vaccine is possible. These results provided scientific data to inform and improve vaccine development and was published in the *New England Journal of Medicine* and *Lancet Infectious Diseases*. A public-private collaborative team, called the Pox-Protein Public-Private Partnership, is planning follow-up efficacy studies using a similar vaccine regimen in Southern Africa and in Thailand. These studies will target the most common HIV subtypes in those regions.

HIV VACCINE INCREMENT 2 (GLOBAL VACCINE STRATEGY)

The MHRP has developed a next-generation Modified Vaccinia Ankara vaccine in collaboration with the Laboratory of Viral Diseases at the NIAID. This vaccine is aimed at global protection and is currently in clinical testing in Africa and Sweden in combination with two investigational DNA vaccines. Together, the vaccines are designed to deliver a diverse mixture of antigens for HIV subtypes A, C, D and E.

Collaborative work between Beth Israel-Deaconess Medical Center and Harvard University, Crucell Corporation/Johnson & Johnson and the MHRP point the way to another novel vaccine combination that will soon be evaluated in clinical studies with the support of the NIAID. This work was published in February 2012 in the journal *Nature*. This regimen entered early clinical trials in 2014.

ACUTE HIV INFECTION RESEARCH

The MHRP has initiated two research studies on acute HIV infections in East Africa and Thailand. The acute, or first stage, of HIV infection immediately follows exposure and occurs before common tests for the diagnosis of HIV are able to identify an HIV infection. Many researchers believe that understanding this early period of infection will help to provide clues to developing an effective vaccine and will provide a platform for cure studies.

ACQUISITION STATUS

- Increment 1 (Regional Vaccine) - Post Milestone B
- Increment 2 (Global Vaccine) – Post Milestone A

MALARIA RELATED PRODUCTS

COUNTERMEASURES AGAINST THE NUMBER ONE INFECTIOUS DISEASE THREAT TO DEPLOYED U.S. FORCES

Malaria is a global health threat, infecting 350-500 million people and causing nearly 600,000 deaths annually, mostly children. Malaria is caused by a parasite of the genus *Plasmodium*. It is transmitted to humans through the bite of infected mosquitoes. Victims experience fever, headaches, chills, nausea and muscle aches. In severe and complicated cases, organ failure with coma or death can occur.

Malaria represents the number one 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 percent (Liberia, 2003). Throughout the past 13 years, approximately 100 cases per year have been diagnosed in deployed U.S. troops. On average, each case results in seven to 10 lost duty days and poses a significant operational risk.

- Afghanistan, 2002: One Army regiment experienced infection by *P. vivax* with 38 cases of relapse
- Liberia, 2003: 44 percent of troops infected by *P. falciparum* over a 10 day period
- Benin, 2009: 15 reported cases of infection by *P. falciparum*
- Haiti, 2010: 13 cases of infection by *P. falciparum* in five months with five evacuations
- Afghanistan, 2012: 16 cases of relapse involving *P. vivax*

The development of malarial vaccines, treatments and diagnostics are product development efforts that heavily leverage external partnerships to achieve results.

MALARIA VACCINE

PARTNERS

- GlaxoSmithKline Biologicals, Belgium
- Sanaria, Inc., Rockville, Maryland
- University of Oxford, United Kingdom
- National Institutes of Health, Rockville, Maryland
- Bill and Melinda Gates Foundation, Seattle, Washington
- Naval Medical Research Center, San Diego, California
- Walter Reed Army Institute of Research, Silver Spring, Maryland

Several vaccine candidates are under development. These are directed towards the two most militarily important species of *Plasmodium, P. falciparum and P. vivax*. One vaccine candidate, a collaborative effort between the DOD, GlaxoSmithKline and the Bill and Melinda Gates Foundation, has completed licensure trials in Africa. This candidate is targeted for use in children. Another vaccine candidate which has completed advanced clinical trials represents a developmental partnership between the DOD, Sanaria, the National Institutes of Health and the Bill and Melinda Gates Foundation. For all of the vaccine candidates in the developmental pipeline, the optimal configurations (formulations, regimens, delivery methods) are yet to be defined.

The USAMMDA's Pharmaceutical Systems Project Management Office is the Advanced Development representative for this effort, which is still considered to be in the technical base.

ACQUISITION STATUS

- Post Milestone A

MALARIA TREATMENTS

These product development efforts seek to improve on current therapies and take a proactive approach to future treatment needs.

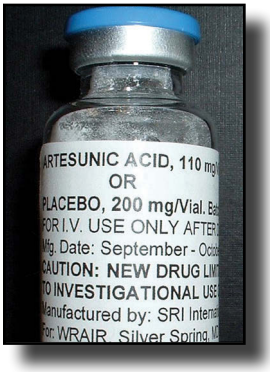
Emerging resistance to current malarial treatments is driving the development of new therapies. Resistance to currently available anti-malarial drugs is now widespread in Africa and Southeast Asia, which are regions where U.S. troops frequently deploy. Untreatable malaria is again emerging in Cambodia.

To protect U.S. troops deployed in this area of the world, product development efforts are targeting new antimalarial drugs, particularly drugs that are effective against drug resistant strains of the malaria parasite.

INTRAVENOUS ARTESUNATE ANTIMALARIAL DRUG

PARTNERS

- Sigma-Tau Industrie Farmaceutiche, Riunite S.p.A., Italy
- Health Canada, Ottawa, Ontario, Canada
- University of Tubingen, Germany
- Centers for Disease Control, Atlanta, Georgia
- Walter Reed Army Institute of Research, 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. However, this drug is in short supply and has significant side effects, such as the potential to induce heart failure.

IV AS is a new drug to treat severe and complicated malaria. AS is a derivative of the compound Artemisinin, an antimalarial compound extracted from the Chinese herb *Artemisia annua.* It has been used in non-U.S. countries and has a well-established safety profile. AS has been endorsed by the World Health Organization as first-line treatment for severe malaria.

This product effort seeks to develop AS in an IV form as a replacement for quinidine. Clinical trials conducted in the U.S. and Canada demonstrated that IV AS was highly effective against severe and complicated malaria. A New Drug Application submission to the FDA is planned for 2015.

The USAMMDA's Pharmaceutical Systems Project Management Office is the Advanced Development lead for this product.

ACQUISITION STATUS

- Post Milestone B

TAFENOQUINE ANTI-MALARIAL DRUG

PARTNERS

- GlaxoSmithKline, Hanover, Pennsylvania
- 60° Pharmaceuticals, LLC, Australia
- Medicines for Malaria Venture, Switzerland
- Bill and Melinda Gates Foundation, Seattle, Washington
- Walter Reed Army Institute of Research, Silver Spring, Maryland

A new malarial treatment, the drug Tafenoquine, was developed by the Walter Reed Army Institute of Research and is being pursued as both a therapeutic and prophylaxis (disease prevention) drug. It targets the two malarial species responsible for malarial relapse, *Plasmodium vivax* and *Plasmodium ovale.* TQ is being investigated as a single dose treatment to clear the malarial parasites from the blood and liver. It will be administered weekly in a tablet form.

In 2014, 60° Pharmaceuticals, LLC, became the USAMRMC's commercial sponsor for the licensing of TQ through the FDA. GlaxoSmithKline is supporting the effort by providing access to its manufacturer in India for the formulation of tablets. A New Drug Application to the FDA is planned for 2015 for TQ as a treatment drug, and in 2019 for TQ as a prophylactic drug.

The USAMMDA's Pharmaceutical Systems Project Management Office is the Advanced Development lead for this product.

ACQUISITION STATUS

- Post Milestone B

NEXT GENERATION MALARIA DRUG

PARTNERS

- National Institute of Allergy and Infectious Diseases, Bethesda, Maryland
- Walter Reed Army Institute of Research, Silver Spring, Maryland

The goal of the next generation malaria drug effort is a FDA-approved weekly, or less frequent, treatment that targets the liver and/or blood stages of the malarial parasites *P. falciparum* and *P. vivax*. Multiple candidates are being investigated. Data suggests that a class of drug known as the triazines will be safe and efficacious as a weekly treatment of malaria. Three other candidates are in tech watch for potential clinical development. Future malaria prevention efforts will likely be a combination of both drugs and vaccines.

The USAMMDA's Pharmaceutical Systems Program Management Office is the Advanced Development lead for this project.

ACQUISITION STATUS

- Post Material Development Decision

MALARIA DIAGNOSTICS

PARTNER

- Binax, Inc., Portland, Maine

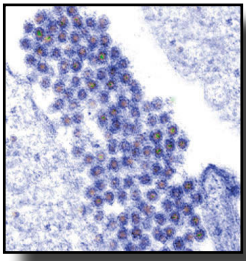
The NOW® ICT Malaria P. Falciparum and P. Vivax for Whole Blood is a device for the rapid diagnosis of malaria.

ACQUISITION STATUS

- Fielded in 2009

DENGUE FEVER-RELATED PRODUCTS

PROTECTION AGAINST DENGUE FEVER AND ITS POTENTIALLY FATAL HEMORRHAGIC VARIANT



The incidence of dengue fever has increased 30-fold over the last 50 years, with half of the world population now at risk.[1,2] 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 percent of Special Operations Command 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 an acute, incapacitating illness characterized by severe head, muscle, joint and eye pain as well as a fever lasting from four to seven days. A second infection with a different dengue serotype is not uncommon and can result in a more severe, often fatal, hemorrhagic form of the disease. As U.S. Forces shift to the Pacific theatre, an endemic area 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 ("tetravalent immunity").

The USAMMDA's Pharmaceutical Systems Project Management Office is the Advanced Development lead for these products.

[1] CDC Website, 2 World Health Organization

DENGUE TETRAVALENT VACCINE (INCREMENT I)

PARTNERS

- Sanofi Pasteur, Rockville, Maryland
- State University of New York, Syracuse, New York
- Armed Forces Institute of Medical Sciences, Bangkok, Thailand
- Walter Reed Army Institute of Research, Silver Spring, Maryland

The first dengue vaccine study aimed specifically at U.S. licensure is currently in Advanced Development. The lead tetravalent vaccine candidate, ChimeriVax™, was developed by Sanofi Pasteur, who is collaborating with the USAMMDA under a Technology Transition Agreement.

In more than 40,000 volunteers vaccinated in Phase Three clinical studies conducted in endemic areas, the ChimeriVax™ vaccine has demonstrated an excellent safety profile. In addition, the first of two pivotal Phase Three vaccine efficacy studies showed a 56 percent reduction in the number of dengue disease cases. Parallel studies at the State University of New York at Syracuse are seeking to identify markers in the blood that will indicate protection against dengue. These studies represent the most comprehensive evaluation of the immunological mechanisms when exposed to dengue conducted to date.

ACQUISITION STATUS

- Post Milestone B

DENGUE TETRAVALENT VACCINE (INCREMENT II)

PARTNERS

- GlaxoSmithKline Biologicals, Belgium
- Hawaii Biotech, Inc., Aiea, Hawaii
- Vical, Inc., San Diego, California
- Naval Medical Research Center, Silver Spring, Maryland
- Walter Reed Army Institute of Research, Silver Spring, Maryland

The Dengue Tetravalent Vaccine Increment II is a risk mitigation effort for new approaches to protect against the disease. Increment II is in Phase One clinical development. Numerous alternate approaches are being pursued globally, with 13 vaccine candidates in various stages of development. These include:

- Investigation of a tetravalent, classically attenuated live virus dengue vaccine (Walter Reed Army Institute of Research in conjunction with GlaxoSmithKline Biologicals)
- Early phase development of a purified inactivated virus dengue vaccine (WRAIR in conjunction with GlaxoSmithKline Biologicals)
- DNA-based vaccine, Phase One clinical trial (Naval Medical Research Center)
- Evaluation of recombinant protein vaccine candidates (WRAIR and NMRC in conjunction with Hawaii Biotech, Inc.)

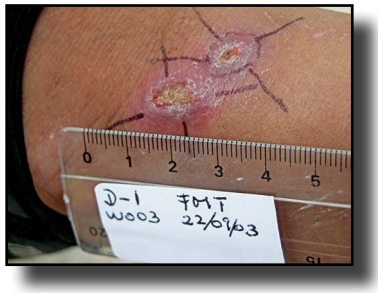
Several of these efforts are being considered as candidates for a “prime-boost” immunization strategy, which may enhance tetravalent immunity. These efforts are still considered to be in tech base development.

ACQUISITION STATUS

- Post Milestone A

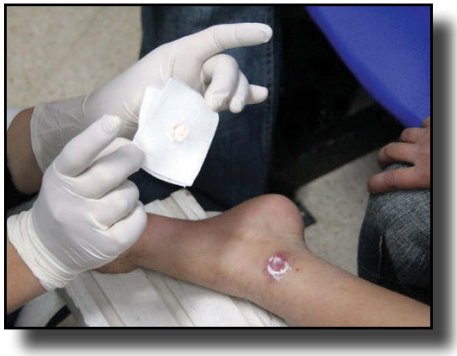
CUTANEOUS LEISHMANIASIS-RELATED PRODUCTS

A POTENTIALLY DISFIGURING SKIN DISEASE AFFECTING DEPLOYED TROOPS



Cutaneous leishmaniasis is a potentially disfiguring parasitic disease presenting as skin lesions. It is caused by protozoa of the genus *Leishmania* and is transmitted to humans through the bite of infected sandflies. Seventeen species of *Leishmania* can cause CL in humans. It has been diagnosed in approximately 98 countries and territories around the world, including portions of both the New World (tropics and sub-tropics of the Americas) and the Old World (primarily South-western Asia, North Africa and Southern Europe). CL has been observed in deployed U.S. Forces since World War I. Since the initiation of large scale deployments to endemic areas (e.g., Iraq and Afghanistan), the number of cases has risen sharply.

Current therapy involves investigational interventions, therapies with patient safety risks or evacuation of affected personnel out of the theatre. Treatment involves daily intravenous administration of toxic, metal-based drugs with potential side effects such as vomiting, diarrhea, inflammation of the liver and/or pancreas and, at higher doses, pulmonary edema. There are currently approximately 50-100 confirmed cases of CL diagnosed per year in the military, with an approximately equal distribution between Old World and New World disease.



LEISHMANIASIS *TREATMENT*

TOPICAL ANTI-LEISHMANIASIS DRUG PAROMOMYCIN + GENTAMICIN

PARTNERS

- Advantar Laboratories, San Diego, California
- Institut Pasteur de Tunis, Tunesia
- Instituto Conmemorativo Gorgas de Estudios de la Salud, Panama City, Panama
- Walter Reed Army Institute of Research, Silver Spring, Maryland

The topical anti-leishmaniasis drug is a topical cream made from two antibiotics. The antibiotic paromomycin (15 percent) kills the *Leishmania* parasite, while the antibiotic gentamicin (0.5 percent) prevents/limits secondary bacterial infections. The cream is applied directly to the lesion once per day for 20 days. It is intended as an early treatment for cases of uncomplicated CL.

The USAMMDA's Pharmaceutical Systems Project Management Office is pursuing FDA approval of this product. It is currently in Phase Three clinical trials in Panama. An Expanded Access Treatment Protocol has been approved by the FDA, which allows for the product to be used in DOD Healthcare beneficiaries to treat uncomplicated CL until the FDA formally approves the product.

ACQUISITION STATUS

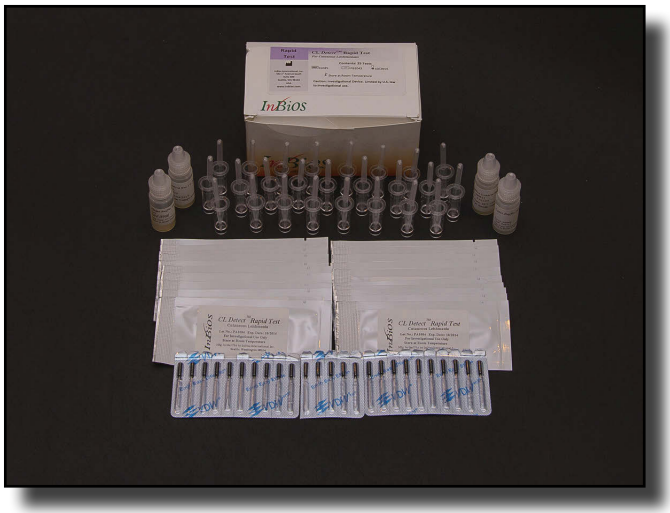
- Post Milestone B

LEISHMANIASIS DIAGNOSTIC

LEISHMANIA RAPID DIAGNOSTIC DEVICE CL DETECT™ RAPID TEST

PARTNERS

- InBios International, Inc., Seattle, Washington
- Institut Pasteur de Tunis, Tunesia
- Icahn Medical School at Mount Sinai, New York, New York
- Walter Reed Army Institute of Research, Silver Spring, Maryland



The *Leishmania* rapid diagnostic device of a field-deployable “dipstick” enabling the rapid diagnosis of CL. The CL *Detect*™ Rapid Test is a disposable, point-of-care test that can detect, within 30 minutes, the presence of *Leishmania* parasites in samples taken directly from skin lesions. Using the kit requires no special training, but test results must be interpreted within the context of relevant clinical and lab findings. This product was developed under a Small Business Innovative Research effort by InBios International, Inc.

This product received FDA approval in November 2014. The USAMMDA’s Pharmaceutical Systems Project Management Office oversaw product development. An Increment 2 study targeting detection of *Leishmania* species found in the New World is currently underway in Peru. The results may be submitted to the FDA as a special 510(k) application to expand the label use on the approved product.

ACQUISITION STATUS

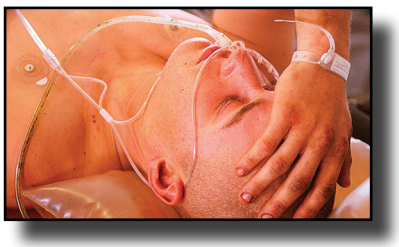
- Post Milestone C

DIARRHEAL DISEASE VACCINES
SHIGELLA, ENTERTOXIGENIC *ESCHERICHIA COLI*, *CAMPYLOBACTER*

PROTECTION AGAINST CAUSES OF BACTERIAL DIARRHEA

PARTNERS

- Sanofi-Pasteur, Lyon, France
- PATH-EVI, Seattle, Washington
- Naval Medical Research Center, Silver Spring, Maryland
- Walter Reed Army Institute of Research, Silver Spring, Maryland



Incapacitation from diarrhea caused by bacterial infections impacted the duty performance of 30-50 percent of deployed troops per month in Iraq and Afghanistan. It is estimated that diarrheal disease caused more than one million lost duty days over the course of OIF/OEF (2001-2007) at a cost estimated up to $2.2 billion.[1]

The goal of this effort is to produce FDA-licensed vaccine(s) that will prevent infection by the three most common bacterial causes of diarrhea in deployed U.S. Forces. These are: enterotoxigenic *E. coli*, *Shigella* and *Campylobacter*. Vaccines would be administered by either oral, intranasal, intradermal or intramuscular routes in a two-to-three dose series, preferably given at least two weeks before deployment.

- *Shigella* vaccines: Phase One clinical trials are underway. A Phase One trial of a subunit vaccine (artificial InVaPlex) will start in mid-2015.
- ETEC vaccine: Phase One clinical trials have been completed. A Phase Two B challenge trial is underway.
- *Campylobacter* vaccine: A Phase One clinical trial is complete, and data analysis is underway.

The USAMMDA's Pharmaceutical Systems Project Management Office is the Advanced Development representative for this effort, which is still in development in the technical base.

ACQUISITION STATUS

- Post Milestone A (ETEC, Shigella)
- Pre Milestone A (Campylobacter)

[1]*Riddle et al.: Development of a travelers' diarrhea vaccine for the military: How much is an ounce of prevention really worth? Vaccine 2008; 26(20): 2490-2502*

HEMORRHAGIC FEVER WITH RENAL SYNDROME (HANTAVIRUS) VACCINE

PROTECTION AGAINST A VIRAL DISEASE TRANSMITTED BY INFECTED RODENTS

PARTNERS

- National Institute for Allergy and Infectious Diseases, Bethesda, Maryland
- U.S. Army Medical Research Institute of Infectious Diseases, Fort Detrick, Maryland

Hantaviruses are a group of viruses that are carried by some rodent species. Human infections occur through the bite of infected rodents or through contact with their urine or droppings. Hantaviruses can cause a rare, but deadly, respiratory disease that affects the lungs, spleen and gall bladder called Hantavirus Pulmonary Syndrome or a similar condition affecting the kidneys known as Hemorrhagic Fever with Renal Syndrome.

HFRS is characterized by massive internal bleeding and severe kidney damage. HFRS has been ranked number 15 on the list of infectious disease threats to deployed military troops.[1]

No vaccine or anti-viral treatment exists for HSFRS or HPS. A vaccine for HFRS is in early clinical trials. This is a DNA vaccine that will be delivered through the skin and/or muscle by electroporation (electric pulses). Once vaccinated with two doses, the individual will be protected against infection within 14 days, with the protection lasting up to five years. For military personnel, the initial vaccination would occur prior to deployment to endemic areas.

The USAMMDA's Pharmaceutical Systems Project Management Office is the Advanced Development representative for this effort, which is still in development in the technical base.

ACQUISITION STATUS

- Post Milestone A

[1]*Infectious Disease Threats to U.S. Military Prioritization Panel Results, 23 Apr 2010 memo from the Infectious Disease Consultant to the U.S. Army Surgeon General.*

RAPID HUMAN DIAGNOSTIC DEVICES

RAPID DIAGNOSIS OF INFECTIOUS DISEASES IMPACTING MILITARY OPERATIONS

Infectious disease epidemics can incapacitate troops and significantly impact military operations. During OEF, for example, 50 percent of deployed troops reported at least one episode of bacterial diarrhea.[1] During Operations Desert Shield and Desert Storm, OEF and OIF, norovirus epidemics were often widespread, with 11 patients requiring evacuation from theatre in 2002.[2] Because conditions such as these are not commonly found within the continental U.S., it is difficult to find a commercial entity interested in developing diagnostic devices.

The development of rapid human diagnostic devices is a high priority for the U.S. military. Currently, there is only one FDA-cleared device meeting the requirements of a RHDD.[3]

The goal of this effort is to develop RHDDs 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). They will be FDA-cleared for use by laboratory technicians at the Level of Care Role Two and Role Three facilities.

RHDD assays have been prioritized for development. Acquisition and contracting strategies are being formulated. The business case for each individual RHDD assay must be considered before a significant investment is made. The development/implementation of commercial sustainability plans (e.g., foreign sales in endemic countries and regions) are a prerequisite for RHDD program success.

The USAMMDA's Pharmaceutical Systems Project Management Office is the Advanced Development lead for this project.

ACQUISITION STATUS

- Post Material Development Decision

[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.
[2] Centers for Disease Control and Prevention: Historical perspective: Norovirus gastroenteritis outbreaks in military forces. MSMR 2011; 18(11):7-8.
[3] There is a FDA-cleared RHDD for Shiga toxin producing E. coli.

VECTOR SURVEILLANCE
ENHANCED SURVEILLANCE AND DETECTION OF DISEASE-CARRYING INSECTS IN THE FIELD

Historically, combat effectiveness and Soldier health are impacted more by disease than by injury sustained as a direct result of combat. Some of the most significant diseases affecting deployed troops (e.g., malaria, yellow fever, dengue and leishmaniasis) are transmitted through the bites of flying arthropods (e.g., mosquitoes and sand flies).

In the absence of vaccines and preventive drugs, the most effective means of addressing these threats is the identification of the arthropod vector through environmental surveillance. In the field, Preventative Medicine personnel routinely conduct surveillance for disease transmitting flying arthropods. Once identified, this is followed by either killing the arthropod vectors and/or rigorously implementing the use of personal protective measures.

VECTOR TRAP CARBON DIOXIDE (CO^2) GENERATOR

PARTNERS

- TDA Research, Inc., Denver, Colorado
- CUBE Technology, Inc., Chandler, Arizona
- U.S. Navy Entomology Center of Excellence, Jacksonville, Florida
- Armed Forces Research Institute of Medical Sciences, Thailand
- Armed Forces Pest Management Board, Silver Spring, Maryland
- Walter Reed Army Institute of Research, Silver Spring, Maryland

Field surveillance programs rely on trapping flying arthropods and then testing them for the presence of disease-causing pathogens. The standard tool for conducting arthropod surveillance, the Centers for Disease Control miniature light trap, was developed in 1962. This device uses light to attract flying insects. However, not all flying insect vectors are attracted to light.

The improved vector surveillance system uses the CDC light trap plus a device that generates CO^2. This combination allows for trapping flying arthropods during daylight hours, as well as at night. Once a threat is identified, troops can be alerted to use appropriate personal preventive measures (e.g., bednets and insect repellents).

Through the U.S. Army's Small Business Innovative Research program, two technologies have been identified that show promise of meeting this capability gap. One uses an acid-base reduction technology (TDA Research, Inc.) to produce CO^2 while the other uses a fuel combustion technology (CUBE Technology, Inc.). Field assessments of the systems are ongoing (Afghanistan in 2013 and Thailand in 2014).

The USAMMDA's Material Support Systems Program Management Office is the advanced developer for this effort.

ACQUISITION STATUS

- Post Milestone A

ARTHROPOD VECTOR RAPID DIAGNOSTIC DEVICES

PARTNERS

- Various Small Business Innovative Research Partners
- Armed Forces Pest Management Board, Silver Spring, Maryland

The Arthropod Vector Rapid Diagnostic Devices are a means of testing captured arthropods (vectors) for the presence of disease-causing pathogens. These are hand-held detection devices that can provide a result within 30 minutes. They are used by far-forward preventive medicine personnel.

Previously, through Army SBIR funds, several Arthropod Vector Rapid Diagnostic Devices were developed, awarded National Stock Numbers and fielded. These devices test for malaria, dengue, leishmania, West Nile virus, Rift Valley fever virus, WNV/St. Louis encephalitis/western equine encephalitis and WNV/SLE/eastern equine encephalitis.

The current effort continues to leverage the SBIR program to develop additional Arthropod Vector Rapid Diagnostic Devices. Of highest priority is the development of devices testing for vectors carrying chikungunya and rickettsial diseases.

The USAMMDA's Pharmaceutical Systems Project Management Office is the Advanced Development lead for this product.

ACQUISITION STATUS

- Post Material Development Decision

VECTOR PERSONAL PROTECTIVE MEASURES
PROTECTION FROM THE BITES OF DISEASE-CARRYING INSECTS

Protecting deployed troops from the bites of disease-carrying insects is a critical component of force health protection. The use of personal protective equipment, such as bednets, insect repellents and insecticide treated military uniforms, reduces disease vulnerability and helps to ensure that deployed troops remain healthy.

DUAL INSECTICIDE-IMPREGNATED BEDNET

PARTNERS

- Triton Systems, Inc., Chelmsford, Massachusetts
- Armed Forces Pest Management Board, Silver Spring, Maryland
- Walter Reed Army Institute of Research, Silver Spring, Maryland

The bednet is a self-supporting mesh screen enclosure designed to protect a sleeping occupant from the bites of disease-carrying mosquitos and sand flies. Currently deployed bednets are sprayed with the insecticide permethrin to repel insect vectors. However, various mosquito species have shown resistance to permethrin, potentially exposing Soldiers who are deployed to endemic regions such as Korea and Afghanistan to disease.

The USAMMDA's Medical Support Systems Program Management Office worked with the Walter Reed Army Institute of Research and Triton Systems, Inc., under an Army Small Business Innovative Research Program Phase Three contract to develop a new prototype bednet, known as Egret. Egret is designed to be carried in a small pouch attached to a Soldier's backpack. It can be set up and broken down in less than five minutes, weighs little more than three pounds, fits a standard or oversized cot while allowing for standing room and provides better ventilation than the currently deployed bednet.

Egret has a fine, airy mesh netting that is impregnated with two potent long-lasting insecticides (deltamethrin and permethrin). When used together, these insecticides have been shown to provide protection against mosquitoes transmitting the most common infectious diseases found in theatre – malaria, dengue and leismaniasis. Due to the dual insecticides impregnated on the mesh, the Egret bednet must be registered by the Environmental Protection Agency. Safety and efficacy testing have been completed and the registration packet is currently under review by the EPA.

ACQUISITION STATUS

- EPA registration expected by December 2014
- Once registered, a National Stock Number will be obtained through the Armed Forced Pest Management Board to enable procurement

NEXT-GENERATION UNIFORM REPELLENT APPLICATION

PARTNERS

- Armed Forces Pest Management Board, Silver Spring, Maryland
- Walter Reed Army Institute of Research, Silver Spring, Maryland
- Program Executive Office Soldier, Fort Belvoir, Virginia
- Project Manager Soldier Protection and Individual Equipment, Fort Belvoir, Virginia

Current military uniforms are treated with the insecticide permethrin to protect the wearer against the bites of disease-carrying mosquitos and sand flies. Recently, however, various mosquito species have shown resistance to permethrin. The USAMMDA's Medical Support Systems Program Management Office is evaluating new insecticide/repellent formulations and new uniform application technologies. The goal of these technologies is to reduce the concentration of the active insecticide ingredient used to treat the uniforms, while maintaining the same level of protection.

ACQUISITION STATUS

- Fielding expected in 2019

ALTERNATIVE ARTHROPOD INSECT REPELLENT

PARTNER

- Armed Forces Pest Management Board, Silver Spring, Maryland

During OIF and OEF, 51.2 percent of deployed troops never used topical skin repellents, particularly those containing DEET, to deter flying insects. These products were readily available, but product odor, consistency, irritation on the skin and perceptions of ineffectiveness impacted their widespread use.

The goal of this project was to identify commercially available topical skin repellents containing an active ingredient other than DEET. These were assessed for effectiveness and other defined military-specific criteria, and for good user acceptability.

As result of this effort, two non-DEET products, SkinSmart® (Coleman, Wichita, Kansas) and Natrapel® (Tender Corporation, Littleton, New Hampshire) were assigned a National Stock Number. These products provide a "pump spray" topical repellent alternative to the standard lotion formulations. They meet the Armed Forces Pest Management Board research requirement to develop non-DEET topical repellents with good user acceptability.

An additional DEET-based compound, Ultra 30™, has been added to the contingency pesticide list. The USAMMDA's Pharmaceutical Systems Project Management Office serves as the Advanced Development lead for this product.

ACQUISITION STATUS

- National Stock Number assigned
- Operations and Support Phase

COMBINED CAMOUFLAGE FACE PAINT

PARTNER

- Iguana, LLC, Thomasville, Georgia

Camouflage face paint has long been used in training and in operational settings in environments that carry the risk of exposure to biting insects. This product combines a five-color Combined Camouflage face paint with the insect repellent, DEET. Previously, these products were only available separately (compact or stick).

USAMMDA's Pharmaceutical Systems Project Management Office is the Advanced Development lead for this product.

ACQUISITION STATUS

- National Stock Number assigned
- Operations and Support Phase

SKIN SUBSTITUTES FOR BURN INJURY AND SKIN REPAIR

RESTORING WARFIGHTER FORM AND FUNCTION

StrataGRAFT®
PARTNERS

- University of Wisconsin, Madison, Wisconsin
- Stratatech Corporation, Madison Wisconsin
- U.S. Army Institute of Surgical Research, San Antonio, Texas

ReCell® Spray-On Skin™
PARTNERS

- Wake Forest University, Winston-Salem, North Carolina
- Avita Medical, Northridge, California
- U.S. Army Institute of Surgical Research, San Antonio, Texas

The risk of skin injury due to burns is significantly increased in a combat environment. The Armed Forces Institute of Regenerative Medicine sponsors research to improve burn and wound healing management, minimize acute complications and decrease chronic functional impairment. The end goal of this research is to restore to the affected Service Member high-quality, long-lasting, durable skin that is elastic, appropriately pigmented and complete with hair follicles and sweat glands. Two major efforts are being sponsored.

StrataGraft® (L) and Autograft (R) Three Months after skin-grafting for severe burn

ReCell® Spray-on Skin™

StrataGraft® is a full-thickness, biologically-active, universal donor skin tissue that reproduces many of the structural and biological properties of normal human skin. StrataGraft® provides immediate wound coverage while promoting tissue regeneration.

ReCell® Spray-On Skin™ is a stand-alone, rapid, autologous cell harvesting, processing and delivery technology that enables treatment of skin defects using the patient's own cells in a regenerative process. When applied in conjunction with an autologous donor meshed skin graft, ReCell® Spray-On Skin™ accelerates wound healing, minimizes scar formation and eliminates the risk of tissue rejection.

These projects are managed by the USAMMDA's Tissue Injury and Regenerative Medicine Project Management Office.

ACQUISITION STATUS

- Post Material Development Decision

StrataGRAFT®	ReCell® Spray-On Skin™
Regulatory Category: Biologic (Orphan Drug) Clinical Sponsor: Stratatech Corporation Current Development Phase: Phase One b/ Tw b Intellectual Property Holder: Stratatech Corporation	Regulatory Category: Medical Device Clinical Sponsor: Avita Medical Current Development Phase: Phase Three Intellectual Property Holder: Avita Medical

EXTREMITY INJURY REPAIR

PROSTHETICS

EXCELLENCE IN EXTREMITY AMPUTEE CARE

Improvised explosive devices and high-energy explosions cause severe extremity trauma, including fractures, soft-tissue loss and vascular injuries. Approximately 79 percent of reported trauma cases from theatre were extremity injuries.[1] Between 2001-2011, 2,295 Service Members suffered limb amputation, with 70 percent being battle-related.[1,2,3]

The typical military prosthetic user is, on average, a 26-year-old male (98 percent). This represents a different demographic from that of the civilian community.

During the early years of Operation Iraqi Freedom and Operation Enduring Freedom, injured military members quickly outperformed the rudimentary prosthetics available on the market. Today's prosthetic technology revolution has been driven by the demands of Service amputees for higher-functioning prosthetics.

The efforts described below are supported by the Clinical and Rehabilitative Medicine Research Program, Fort Detrick, Maryland, for technical base development. The USAMMDA's Tissue Injury and Regenerative Medicine Project Management Office is the Advanced Development lead for the products.

[1] 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.

[2] Belmont et al.: Combat wounds in Iraq and Afghanistan from 2005 to 2009. J Trauma Acute Care Surg 2012; 72(1): 3-12.

[3] Armed Forces Health Surveillance Center Medical Surveillance Monthly Report, 2012; 19(6): 2-6.

ADVANCED UPPER EXTREMITY PROSTHETICS

PARTNERS

- DEKA, Manchester, New Hampshire
- Johns Hopkins Applied Physics Laboratory, Laurel, Maryland
- Defense Advanced Research Projects Agency, Arlington, Virginia
- Extremity Trauma and Amputation Center of Excellence, Bethesda, Maryland; San Diego, California; San Antonio, Texas
- Walter Reed National Military Medical Center, Bethesda, Maryland

Recent upper extremity prosthetic research has focused on improved device control through myoelectrics, microsensors and the addition of multiple degrees of freedom. Currently, myoelectric upper extremity prosthetics are commercially available from several companies.

The CRMRP is supporting several studies examining improved control of upper extremity prosthetics through implantable electrodes. The USAMMDA's Tissue Injury and Regenerative Medicine Project Management Office is managing the clinical testing of the advanced myoelectric, multiple degree of freedom upper extremity prosthetic devices such as the DEKA arm, currently under development at the Advanced Physics Laboratory, Johns Hopkins University.

ACQUISITION STATUS

- Post Material Development Decision

ADVANCED LOWER EXTREMITY PROSTHETIC

PARTNERS

- BiOM, Bedford, Massachusetts
- Spring Active, Tempe, Arizona
- KCF Technologies, State College, Pennsylvania
- Massachusetts Institute of Technology, Cambridge, Massachusetts
- Extremity Trauma and Amputation Center of Excellence, Bethesda, Maryland; San Diego, California; San Antonio, Texas
- Walter Reed National Military Medical Center, Bethesda, Maryland

Recent lower extremity prosthetic research has focused on the development of microprocessor additions to restore a more realistic function to lower extremity prosthetics, and on efforts to ruggedize these microprocessor devices. The first ruggedized microprocessor knee prosthetic from Otto Bock, a German prosthetics company, became available in 2012. Currently, one microprocessor ankle prosthetic is commercially available.

The CRMRP is supporting several projects aimed at improving the durability of the microprocessor ankle and associated energy harvesting devices, as well as improving the battery life of lower extremity prosthetics. The USAMMDA's TIRM Project Management Office is providing Advanced Development support.

ACQUISITION STATUS

- Post Material Development Decision

INNOVATIONS IN HAND AND FACIAL RECONSTRUCTION

PARTNERS

- Tufts University, Medford, Massachusetts
- University of Pittsburgh, Pittsburgh, Pennsylvania
- Wake Forest University, Winston-Salem, North Carolina
- Vanderbilt University, Nashville, Tennessee
- Ohio State University, Columbus, Ohio
- Massachusetts General Hospital, Boston, Massachusetts
- Northwestern University, Evanston, Illinois
- Massachusetts Institute of Technology, Cambridge, Massachusetts
- Rutgers University, New Brunswick, New Jersey
- Rice University, Houston, Texas
- Radboud University, Nijmegen, Netherlands
- Johns Hopkins University, Baltimore, Maryland
- University of Michigan, Ann Arbor, Michigan
- Brigham and Women's Hospital, Boston, Massachusetts
- Cleveland Clinic, Cleveland, Ohio
- New York University, New York City, New York
- University of Maryland, College Park, Maryland

Forty-two percent of wounded service members evacuated from theatre between 2001 and 2011 sustained injuries to the face.[1] The goal of this research effort is to better enable major reconstruction of the lower face and mouth following a traumatic injury.

Historically, more than 70 percent of combat facial injuries involve the lower face, including the mouth and lips.[2] Current reconstructive procedures fail to achieve a satisfactory esthetic and functional outcome because of the lack of tissue to replace lips or the lining of the mouth (or oral mucosa). Tissue engineering/regenerative medicine technologies may offer unique opportunities to address this surgical challenge. Skin substitutes for the treatment of burns and chronic wounds are available, and the development of a similar product for the lips and mouth is underway. Investigators at the University of Michigan have successfully fabricated a laboratory produced oral mucosal equivalent to repair intraoral defects. Building upon this technology, investigators have produced the EVPOME, a 3-D tissue structure containing all of the features of a lip (epidermal skin, the vermillion border and oral mucosa).

The Armed Forces Institute of Regenerative Medicine sponsors more than $20M in regenerative medicine research related to facial injury. These efforts are managed by the USAMMDA's Tissue Injury and Regenerative Medicine Project Management Office.

ACQUISITION STATUS

- Human clinical trials for the EVPOME graft for reconstruction of intraoral defects are underway. Human clinical trials for use of the EVPOME graft for reconstruction of lips is expected in the next two years

[1] Chan RK, Siller-Jackson A, Verrett AJ et al.; Ten years of war: A characterization of craniomaxillofacial injuries incurred during operations Enduring Freedom and Iraqi Freedom. J Trauma Acute Care Surg 2012; 73(6 Suppl 5): S453-8.

[2] Taher AA: Management of weapon injuries to the craniofacial skeleton. J Craniofacial Surg 1998; 9(4): 371-382.

PARTNERS

- Brigham and Women's Hospital, Boston, Massachusetts
- Cleveland Clinic, Cleveland, Ohio
- Duke University, Durham, North Carolina
- Johns Hopkins University, Baltimore, Maryland
- Massachusetts General Hospital, Boston, Massachusetts
- New York University, New York, New York
- University of Louisville, Louisville, Kentucky
- University of Maryland, Baltimore, Maryland
- University of Pittsburgh, Pittsburgh, Pennsylvania

Vascularized composite allotransplantation is the transplant of intact vascularized body parts. The science of VCA extrapolates the considerable knowledge gained over the past five decades of solid organ transplantation (e.g., kidney, liver, heart and lungs). It is applied here as a novel strategy to the catastrophic loss of vital composite tissues, particularly those of the face and hands.

The DOD support for VCA is currently more than $30M and growing, reflecting the DOD's commitment to make revolutionary approaches to the treatment of catastrophic injuries available to affected Service Members.

The goal of the hand and face transplantation program is the restoration of aesthetic, sensory and motor functions following severe injury, amputation or irreversible traumatic functional loss. Fourteen U.S. institutions are capable of performing VCAs; of these, nine receive DOD funding. As of January 2014, 28 VCAs have been performed in the U.S.; of these, 20 were hand transplants and eight were face transplants.

The USAMMDA's Tissue Injury and Regenerative Medicine Project Management Office is the manager for this Advanced Development effort.

ACQUISITION STATUS

- Two clinical trials for face transplantation are open to enrollment; one additional trial is pending human subjects review board approvals
- Two clinical trials for hand transplantation are open to enrollment; two additional trials are pending human subjects review board approvals

VASCULAR REPAIR FOR EXTREMITY TRAUMA

SAVING INJURED LIMBS

PARTNERS

- Humacyte, Inc., Morrisville, North Carolina
- Yale University, New Haven, Connecticut
- Johns Hopkins University, Baltimore, Maryland
- University of Maryland, Baltimore, Maryland
- University of Washington, Seattle, Washington
- Walter Reed National Military Medical Center, Bethesda, Maryland

VasTech® Vascular Graft

This effort is focused on new regenerative medicine therapies to "bridge" vascular injuries in order to save and rebuild injured limbs.

Extremity injury accounts for up to 79 percent of reported trauma cases from theatre.[1] Improvised explosive devices and high energy explosions cause severe extremity trauma involving fractures, soft tissue loss and vascular injuries.

The use of tourniquets to control bleeding in these cases has saved countless lives. However, the ability to re-establish blood flow through a damaged artery in order to keep the injured limb functional remains a challenge.

Current methods to reconstruct blood vessels often rely on transferring veins or arteries from another part of the body to the injured area. Unfortunately, the nature of combat injuries is such that severely wounded Service Members may not have those tissues available. Additionally, other materials used as substitutes may not be sufficiently durable to withstand decades of high-demand use, considering the young age of affected Warfighters.

VasTech® (Humacyte, Inc.) is a tissue engineered circular vascular graft. It is made up of a biodegradable polymer scaffold whose inner surface is an extracellular matrix coated with banked allogeneic cells. Prior to use, the allogenic cells are removed to prevent an immune reaction to the patient graft. The underlying extracellular matrix then serves as a substrate for the colonization of patient cells. This product offers an "off-the-shelf" solution to address vessel replacement.

The USAMMDA's Tissue Injury and Regenerative Medicine Project Management Office is the Advanced Development lead for this effort.

ACQUISITION STATUS

- Regulatory Category: Biologic
- Clinical Sponsor: Humacyte, Inc.
- Current Development Phase: Investigational New Drug application to the FDA in preparation

[1] 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.

OUR PARTNERS

PARTNER	PRODUCT	PAGE
Assistant Secretary of Defense (Health Affairs)	Adenovirus Type 4 and 7 Vaccine, Live, Oral	41
60° Pharmaceuticals, LLC Australia	Tafenoquine Antimalarial Drug	47
Abbot Point of Care Princeton, New Jersey	Laboratory Assay For Traumatic Brain Injury	37
AcelRX Pharmaceuticals, Inc. Redwood City, California	(Battlefield) Pain Management Sufentanil Nano Tabs®	40
Active Signal Technologies, Inc. Linthicum Heights, Maryland	Noise-Immune Stethoscope	39
Advantar Laboratories San Diego, California	Topical Anti-Leishmaniasis Drug, Paromomycin and Gentamicin	53
Agave, Biosystems Ithaca, New York	Environmental Sentinel Biomonitor	20
ANP Technologies, Inc. Newark, Delaware	Environmental Sentinel Biomonitor	20
AnthroTronix Silver Spring, Maryland	Physiological Nuerodiagnostics/ Noninvasive Nuerodiagnostics	34
Armed Forces Blood Program Office Falls Church, Virginia	• Whole Blood Pathogen Reduction Device • Red Blood Cell Extended Life • Cryopreserved Platelets	13 15 17
Armed Forces Pest Management Board Silver Spring, Maryland	• Dual Insecticide-Impregnated Bednet • Vector Trap Carbon Dioxide Generator • Alternative Arthropod Insect Repellent • Arthropod Vector Rapid Diagnostic Devices • Next Generation Uniform Repellent Application	60 58 61 59 61
The Armed Forces Research Institute of Medical Sciences Bangkok, Thailand	• Dengue Tetravalent Vaccine (Increment One) • HIV Vaccine Incremental One (Regional) • HIV Vaccine Incremental Two (Global) • Vector Trap Carbon Dioxide Generator	50 42 58

PARTNER	PRODUCT	PAGE
Arcos Medical San Antonio, Texas	Burn Resuscitation Decision Support System – Mobile	24
Avita Medical Northridge, California	ReCell® Spray-on Skin™/Skin Substitutes For Burn Injury and Skin Repair	63
Banyan Biomarkers Alchua, Florida	Laboratory Assay For Traumatic Brain Injury	37
Barr Laboratories Inc., of Teva Pharmaceuticals USA Forest, Virginia	Adenovirus Type 4 and Type 7 Vaccine, Live, Oral	41
Beth Israel-Deaconess Medical Center Boston, Massachusetts	HIV Vaccine Increment 1 (Regional) and HIV Vaccine Increment 2 (Global)	42
Bill and Melinda Gates Foundation Seattle, Washington	• HIV Vaccine Increment 1 (Regional) and HIV Vaccine Increment 2 (Global) • Malaria Vaccine/*Plasmodium falciparum* and *Plasmodium vivax* species • Tafenoquine, Antimalarial Drug	42 45 46
Binax, Inc., Portland, Maine	• Malaria Diagnostics	48
BiOM Bedford, Massachusetts	Advanced Lower Extremity Prosthetics/Extremity Injury Repair	65
Biomedical Advanced Research Defense Authority, U.S. Department of Health and Human Services Washington, D.C.	Platelet Derived Hemostatic Agent	18
Biosentinel, Inc. Austin, Texas	Environmental Sentinel Biomonitor	20
BrainScope Bethesda, Maryland	Physiological Nuerodiagnostics/ Noninvasive Nuerodiagnostics	34
Brigham and Women's Hospital Boston, Massachusetts	Hand and Face Transplantation	67
Cellphire, Inc. Rockville, Maryland	Platelet Derived Hemostatic Agent (PDHA)	18
Centers for Disease Control and Prevention Atlanta, Georgia	• HIV Vaccine Increment 1 (Regional) and HIV Vaccine Increment 2 (Global) • Intravenous Artesunate, Antimalarial Drug	42 46

PARTNER	PRODUCT	PAGE
Chart Industries Ball Ground, Georgia	• Deployable Oxygen Generator, Small, 15 Liters per Minute • Oxygen Generator, Field Portable	27 26
Cleveland Clinic Cleveland, Ohio	Hand and Face Transplantation	67
Clinical Research Management, Inc. Hinckley, Ohio	Cryopreserved Platelets	17
Coleman Wichita, Kansas	SkinSmart®	59
Contect, University of Notre Dame South Bend, Indiana	Physiological Neurodiagnostics/ Noninvasive Neurodiagnostics	34
Crucell (Subsidiary of Johnson & Johnson Leiden, Netherlands	• HIV Vaccine Increment One (Regional) • HIV Vaccine Increment Two (Global)	42
CUBE Technology, Inc. Chandler, Arizona	Vector Trap Carbon Dioxide Generator	58
Dartmouth-Hitchcock Medical Center Hanover, New Hampshire	Cryopreserved Platelets	17
The Defense Advanced Research Projects Agency Arlington, Virginia	Advanced Upper Extremity Prosthetics/Extremity Injury Repair	65
The Defense Health Agency, Medical Logistics Division Fort Detrick, Maryland	XSTAT-30™	19
Defense Logistics Agency Fort Belvoir, Virginia	Adenovirus Type 4 and Type 7 Vaccine, Live, Oral	41
DEKA Manchester, New Hampshire	Advanced Upper Extremity Prosthetics/Extremity Injury Repair	65
Duke University Durham, North Carolina	• Hand and Face Transplantation • HIV Vaccine Increment One (Regional) • HIV Vaccine Increment Two (Global)	67 42
Entegrion Inc. Triangle Park, North Carolina	Platelet Derived Hemostatic Factor	18

PARTNER	PRODUCT	PAGE
Extremity Trauma and Amputation Center of Excellence Bethesda, Maryland; San Diego, California; San Antonio, Texas	• Advanced Upper Extremity Prosthetics/Extremity Injury Repair • Advanced Lower Extremity Prosthetics/Extremity Injury Repair	65
Fast-Track Drugs and Biologics, Inc. North Potomac, Maryland	Cryopreserved Platelets	17
Flashback Technologies Boulder, Colorado	Advanced Physiological Monitor	23
Fort Defiance Industries Loudon, Tennessee	Steam Sterilizer, Field Portable	28
Future Diagnostics Wijchen, Netherlands	Laboratory Assay For Traumatic Brain Injury	37
GlaxoSmithKline Biologicals Belgium Hanover, Pennsylvania	• Dengue Tetravalent Vaccine (Increment 2) • Malaria Vaccine/*Plasmodium falciparum* and *Plasmodium vivax* species • Tafenoquine Antimalarial Drug	50 45 47
Global HIV Vaccine Enterprise New York, New York	• HIV Vaccine Increment One (Regional) • HIV Vaccine Increment Two (Global)	42
Global Solutions for Infectious Diseases San Francisco, California	• HIV Vaccine Increment One (Regional) • HIV Vaccine Increment Two (Global)	42
Haemonetic Corporation Braintree, Massachusetts	Red Blood Cell Extended Life	15
Harvard University Cambridge, Massachusetts	• HIV Vaccine Increment One (Regional) • HIV Vaccine Increment Two (Global)	42
Hawaii Biotech Inc. Aiea, Hawaii	Dengue Tetravalent Vaccine (Increment Two)	50
Health Canada Ottawa, Ontario, Canada	Intravenous Artesunate, Antimalarial Drug	46
Hemerus Medical LLC St. Paul, Minnesota	Red Blood Cell Extended Life	15
Henry M. Jackson Foundation for the Advancement of Military Medicine, Bethesda, Maryland	• HIV Vaccine Increment One (Regional) • HIV Vaccine Increment Two (Global)	42

PARTNER	PRODUCT	PAGE
HIV Vaccine Trials Network Seattle, Washington	• HIV Vaccine Increment One (Regional) • HIV Vaccine Increment Two (Global)	42
Hoxworth Blood Center Cincinnati, Ohio	• Cryopreserved Platelets • Whole Blood Pathogen Reduction Device	17 12
Humacyte Inc. Morrisville, North Carolina	Vascular Repair for Extremity Trauma	69
Icahn Medical School at Mount Sinai New York, New York	Leishmania Rapid Diagnostic Device, CL *Detect*™ Rapid Test	54
Iguana, LLC Thomasville, Georgia	Combined Camouflage Face Paint	61
InBios International, Inc. Seattle, Washington	Leishmania Rapid Diagnostic Device, CL *Detect*™ Rapid Test	54
Indiana University Oral Health Research Institute Indianapolis, Indiana	Anti-Plaque Chewing Gum	25
Inovio Pharmaceuticals, Inc. Plymouth Meeting, Pennsylvania; San Diego, California	• HIV Vaccine Increment One (Regional) • HIV Vaccine Increment Two (Global)	42
Institut Pasteur de Tunis Tunesia	• Topical Anti-Leishmaniasis Drug, Paromomycin and Gentamicin • Leishmania Rapid Diagnostic Device, CL *Detect*™ Rapid Test	53 54
Instituto Conmemorativo Gorgas de Estudios de la Salud Panama City, Panama	Topical Anti-Leishmaniasis Drug, Paromomycin and Gentamicin	53
International AIDS Vaccine Initiative New York, New York	• HIV Vaccine Increment One (Regional) • HIV Vaccine Increment Two (Global)	42
JBC Corp Virginia Beach, Virginia	Oxygen Generator, Field Portable	26
Johns Hopkins Applied Physics Laboratory Laurel, Maryland	Advanced Upper Extremity Prosthetics/Extremity Injury Repair	65
Johns Hopkins University Baltimore, Maryland	• Innovations in Hand and Facial Reconstruction • Vascular Repair for Extremity Trauma	67 69
KCF Technologies State College, Pennsylvania	Advanced Lower Extremity Prosthetics/Extremity Injury Repair	65
Massachusetts General Hospital Boston, Massachusetts	Hand and Face Transplantation	67

PARTNER	PRODUCT	PAGE
Massachusetts Institute of Technology Cambridge, Massachusetts	• Advanced Lower Extremity Prosthetics/Extremity Injury Repair	65
	• HIV Vaccine Increment One (Regional) • HIV Vaccine Increment Two (Global)	42
	• Innovations in Hand and Facial Reconstruction	67
Medicines For Malaria Venture Switzerland	Tafenoquine Antimalarial Drug	47
Medmira, Inc. Nova Scotia, Canada	Transfusion Transmitted Disease Rapid Diagnostic Device	14
Military Vaccine Agency Falls Church, Virginia	Adenovirus Type 4 and Type 7 Vaccine, Live, Oral	41
Nanohmics Austin, Texas	Environmental Sentinel Biomonitor	20
National Institutes of Health Bethesda, Maryland	• HIV Vaccine Increment One (Regional) • HIV Vaccine Increment Two (Global)	42
	• Malaria Vaccine/*Plasmodium falciparum* and *Plasmodium vivax* species	45
National Institute of Allergy and Infectious Diseases Bethesda, Maryland	• HIV Vaccine Increment One (Regional) • HIV Vaccine Increment Two (Global)	42
	• Hemorrhagic Fever with Renal Syndrome (Hantavirus) Vaccine	56
	• Next Generation Malaria Drug	48
Naval Health Research Center San Diego, California	• Adenovirus Type 4 and Type 7 Vaccine, Live, Oral	41
Naval Medical Research Center Silver Spring, Maryland	• Dengue Tetravalent Vaccine, Increment 2	50
	• Diarrheal Disease Vaccines: *Shigella*, Entertoxigenic *Escherichia coli*, *Campylobacter*	55
	• Malaria Vaccine/*Plasmodium falciparum* and *Plasmodium vivax* species	45
Navistar Defense Madison Heights, Michigan	Maxxpro Plus Long Wheel Base Ambulance	30
Neuren Pharmaceuticals LTD Bethesda, Maryland	Drug Therapy for Traumatic Brain Injury	36

PARTNER	PRODUCT	PAGE
Neuro-Habilitation Corporation Philadelphia, Pennsylvania	Portable Neuromodulation Stimulator	35
Neurokinetics Pittsburgh, Pennsylvania	Physiological Neurodiagnostics/ Noninvasive Neurodiagnostics	34
NeuroWave Cleveland Heights, Ohio	Physiological Neurodiagnostics/ Noninvasive Neurodiagnostics	34
Nevada National Guard Reno, Nevada	Transport Telemedicine	21
New York University New York, New York	• Innovations in Hand and Facial Reconstruction • HIV Vaccine Increment One (Regional) • HIV Vaccine Increment Two (Global)	67 42
Nonin Medical Plymouth, Minnesota	Intercompartmental Pressure Relief	22
Northwestern University, Evanston Illinois	Innovations in Hand and Facial Reconstruction	67
Novartis Basel, Switzerland	• HIV Vaccine Increment One (Regional) • HIV Vaccine Increment Two (Global)	42
Ohio State University, Columbus Ohio	Innovations in Hand and Facial Reconstruction	67
PATH-EVI Seattle Washington	Diarrheal Disease Vaccines: *Shigella*, Entertoxigenic *Escherichia coli*, *Campylobacter*	55
Phillips Group Innovation Eindhoven, Netherlands	Laboratory Assay For Traumatic Brain Injury	37
President's Emergency Plan for AIDS Relief	• HIV Vaccine Increment One (Regional) • HIV Vaccine Increment Two (Global)	42
Project Manager, Armored Brigade Combat Team Fort Benning, Georgia	Armored Multi-Purpose Vehicle Medical Treatment/Evacuation Variants	29
Project Manager Soldier Protection and Individual Equipment, Fort Belvoir, Virginia	Next Generation Uniform Repellent Application	61
Program Executive Office Soldier, Fort Belvoir, Virginia	Next Generation Uniform Repellent Application	61
Product Manager, Armored Multi-Purpose Vehicle Warren, Michigan	Armored Multi-Purpose Vehicle Medical Treatment/Evacuation Variants	29

PARTNER	PRODUCT	PAGE
Project Manager, Mine-Resistant Ambush Protected Warren, Michigan	Maxxpro Plus Long Wheel Base Ambulance	30
Puget Sound Blood Center Seattle, Washington	• Cryopreserved Platelets • Whole Blood Pathogen Reduction Device	17 13
Radboud University, Nijmegen, Netherlands	Innovations in Hand and Facial Reconstruction	67
Rice University, Houston, Texas	Innovations in Hand and Facial Reconstruction	67
RevMedx, Inc. Portland, Oregon	XSTAT-30™	19
Rutgers University, New Brunswick, New Jersey	Innovations in Hand and Facial Reconstruction	67
Sanaria, Inc Rockville, Maryland	Malaria Vaccine/*Plasmodium falciparum* and *Plasmodium vivax* species	45
Sanofi Pasteur Swiftwater, Pennsylvania (U.S. HQ) Rockville, Maryland Lyon, France	• Dengue Tetravalent Vaccine, Increment 1 • Diarrheal Disease Vaccines: *Shigella*, Entertoxigenic *Escherichia coli*, *Campylobacter* • HIV Vaccine Increment One (Regional) • HIV Vaccine Increment Two (Global)	50 55 42
Scripps Institute La Jolla, California	• HIV Vaccine Increment One (Regional) • HIV Vaccine Increment Two (Global)	40
Sierra Nevada Corporation Las Vegas, Nevada	Transport Telemedicine	21
Sigma-Tau Industrie Farmaceutiche Riunite S.p.A., Italy	Intravenous Artesunate, Antimalarial Drug	46
Sotera Wireless, Inc. San Diego, California	Advanced Physiological Monitor	23
Spring Active Tempe, Arizona	Advanced Lower Extremity Prosthetics/Extremity Injury Repair	65
State University of New York Syracuse, New York	Dengue Tetravalent Vaccine (Increment One)	50
Stratatech Corporation Madison Wisconsin	StrataGRAFT®/Skin Substitutes For Burn Injury and Skin Repair	63
Sync-Think Boston, Massachusetts	Physiological Neurodiagnostics/ Noninvasive Neurodiagnostics	34
TDA Research, Inc. Denver, Colorado	Vector Trap Carbon Dioxide Generator	58

PARTNER	PRODUCT	PAGE
Tender Corporation Littleton, New Hampshire	Natrapel®	59
Terumo BCT Lakewood, Colorado	Whole Blood Pathogen Reduction Device	13
Thailand Ministry of Health and Ministry of Science and Technology Bankok, Thailand	• HIV Vaccine Increment One (Regional) • HIV Vaccine Increment Two (Global)	42
Triton Systems, Inc. Chelmsford, Massachusetts	Dual Insecticide-Impregnated Bednet	60
Twin Star Medical Minneapolis, Minnesota	Intercompartmental Pressure Relief	22
Ultra Electronics Lanham, Maryland	Oxygen Generator, Field Portable	26
University of Cincinnati Cincinnati, Ohio	Red Blood Cell Extended Life	15
University of Louisville Louisville, Kentucky	Hand and Face Transplantation	67
University of Maryland Baltimore, Maryland	• Hand and Face Transplantation • Vascular Repair for Extremity Trauma	67 65
University of Michigan Ann Arbor, Michigan	Innovations in Hand and Facial	67
University of Oxford United Kingdom	Malaria Vaccine/*Plasmodium falciparum* and *Plasmodium vivax* species	45
University of Pittsburgh Pittsburgh, Pennsylvania	Innovations in Hand and Face Reconstruction	67
University of Tubingen Germany	Intravenous Artesunate, Antimalarial Drug	46
University of Washington Seattle, Washington	• HIV Vaccine Increment One (Regional) • HIV Vaccine Increment Two (Global) • Vascular Repair for Extremity Injury	42 69
University of Wisconsin Madison, Wisconsin	• PoNS™ • StrataGRAFT®/Skin Substitutes For Burn Injury and Skin Repair	35 63

PARTNER	PRODUCT	PAGE
Uniformed Services University of Health Sciences Bethesda, Maryland	• HIV Vaccine Increment One (Regional) • HIV Vaccine Increment Two (Global)	42
U.S. Air Force Life Cycle Management Command Wright-Patterson Air Force Base, Ohio	Deployable Oxygen Generator, Small, 15 Liters per Minute	26
U.S. Air Force Medical Support Agency Falls Church, Virginia	XSTAT-30™	19
U.S. Army Aeromedical Research Lab Fort Rucker, Alabama	• Transport Telemedicine • Advanced Physiological Monitor • Noise-Immune Stethoscope • Oxygen Generator Field Portable	21 23 39 26
U.S. Army Blood Program San Antonio, Texas	Cryopreserved Platelets	17
U.S. Army Center for Health Promotion and Preventive Medicine Aberdeen Proving Ground, Maryland	Environmental Sentinel Biomonitor	20
U.S. Army Edgewood Chemical Biological Center Aberdeen Proving Ground, Maryland	Environmental Sentinel Biomonitor	20
U.S. Army Institute of Surgical Research San Antonio, Texas	• Burn Resuscitation Decision Support System – Mobile • Cryopreserved Platelets • Whole Blood Pathogen Reducation Device • Advanced Physiological Monitor • ReCell® Spray-On Skin™/Skin Substitutes For Burn Injury and Skin Repair • StrataGRAFT®/Skin Substitutes For Burn Injury and Skin Repair	24 17 12 23 63 63
U.S. Army Maneuver Center of Excellence Fort Benning, Georgia	• Armored Multi-Purpose Vehicle Medical Treatment/ Evacuation Variants • Joint Light Tactical Vehicle Casualty Evacuation	29
U.S. Army Natick Research, Development & Engineering Command/ Shelter Technology, Engineering & Fabrication, Directorate Natick, Massachusetts	• Soft-Wall Shelter Modernization • Rigid-Wall Shelter Modernization	31-32
U.S. Army Research Institute of Infectious Diseases Fort Detrick, Maryland	Hemorrhagic Fever with Renal Syndrome (Hantavirus) Vaccine	56

PARTNER	PRODUCT	PAGE
U.S. Army Center for Environmental Health Research Fort Detrick, Maryland	Environmental Sentinel Biomonitor	20
U.S. Navy Entomology Center of Excellence Jacksonville, Florida	Vector Trap Carbon Dioxide Generator	58
U.S. Special Operations Command MacDill Air Force Base, Florida	XSTAT-30™	19
Vanderbilt University, Nashville, Tennessee	Innovations in Hand and Facial Reconstruction	67
Vascular Solutions, Inc. Minneapolis, Minnesota	Freeze-Dried Plasma	16
Vical Inc. San Diego, California	Dengue Tetravalent Vaccine, Increment 2	50
Wake Forest University Winston-Salem, North Carolina	ReCell® Spray-On Skin™/ Skin Substitutes For Burn Injury and Skin Repair Innovations in Hand and Facial Reconstruction	63
Walter Reed Army Institute of Research Silver Spring, Maryland	• Adenovirus Type 4 and Type 7 Vaccine, Live, Oral • Anti-Plaque Chewing Gum • Dengue Tetravalent Vaccine, Increment One • Dengue Tetravalent Vaccine, Increment Two • Diarrheal Disease Vaccines: *Shigella*, Entertoxigenic *Escherichia coli*, *Campylobacter* • Drug Therapy for Traumatic Brain Injury • Dual Insecticide-Impregnated Bednet • Intravenous Artesunate Antimalarial Drug • Laboratory Assay For Traumatic Brain Injury • Leishmania Rapid Diagnostic Device, CL Detect™ Rapid Test • Malaria Vaccine/*Plasmodium falciparum* and *Plasmodium vivax* species • Next Generation Malaria Drug • Next Generation Uniform Repellent Application • Tafenoquine Antimalarial Drug • Topical Anti-Leishmaniasis Drug, Paromomycin and Gentamicin • Vector Trap Carbon Dioxide Generator	41 25 50 55 36 60 46 37 54 45 48 47 53 58

PARTNER	PRODUCT	PAGE
Walter Reed National Military Medical Center Bethesda, Maryland	• Advanced Upper Extremity Prosthetics/Extremity Injury Repair • Advanced Lower Extremity Prosthetics/Extremity Injury Repair • Vascular Repair for Extremity Trauma	65 69
Yale University New Haven, Conneticut	Vascular Repair for Extremity Trauma	69

THE USAMRMC PRODUCT ACQUISITION STATUS AS OF 30 SEPT 2014							
	Army-Managed Products in Decision Gate	**Post Milestone Development Decision**	**Post Milestone A**	**Post Milestone B**	**Post Milestone C**	**Full-Rate Production**	**Sustainment**
1	Adenovirus (Types 4 & 7) Vaccine, Live, Oral						●
2	Anti-Plaque Chewing Gum	●					
3	Advanced Physiological Monitor	●					
4	Arthropod Vector Rapid Diagnostic Device(s)	●					
5	Burn Resuscitation Decision Support System-Mobile					●	
6	Cyropreserved Platelets			●			
7	Dengue Tetravalent Vaccine (Increment 1)			●			
8	Dengue Tetravalent Vaccine (Increment 2)		●				
9	Diarrheal Disease Vaccine		●				
10	Drug Treatment for Post Traumatic Stress Disorder		●				
11	Drug Therapy for Traumatic Brain Injury		●				
12	Environmental Setinal Biomonitor			●			
13	Extremity Injury Repair	●					
14	Freeze Dried Plasma			●			
15	Future Medical Shelter/ Force Provider Rigid Wall Shelther Modernization			●			
16	Future Medical Shelter/ Force Provider Soft Wall Shelther Modernization	●					

THE USAMRMC PRODUCT ACQUISITION STATUS AS OF 30 SEPT 2014

	Army-Managed Products in Decision Gate	Post Milestone Development Decision	Post Milestone A	Post Milestone B	Post Milestone C	Full-Rate Production	Sustainment
17	Hemorrhagic Fever w/ Renal Syndrome (Hantavirus) Vaccine		●				
18	HIV Vaccine Increment 1 (Regional Vaccine)			●			
19	HIV-1 Vaccine Increment 2 (Global Vaccine)		●				
20	Intravenous Artesunate Antimalarial Drug			●			
21	Intercompartmental Pressure Relief	●					
22	Junctional Hemorrhage Control Agent		●				
23	Laboratory Assay for Traumatic Brain Injury			●			
24	Leishmania Rapid Diagnostic Device				●		
25	Malaria Vaccine		●				
26	Neurocognitive Assessment Test	●					
27	Next Generation Malaria Drug	●					
28	Noise Immune Stethoscope					●	
29	Oxygen Generator Field Portable (3 Liters Per Minute)				●		
30	Pain Management Sufentanil NanoTabs®		●				
31	Platelet Derived Hemostatic Agent	●					
32	Physiologica/Nonivasive Neurodiagnostics		●				

USAMRMC DECISION GATE PRODUCT STATUS AS OF 30 SEPT 2014							
	Army-Managed Products in Decision Gate	**Post Milestone Development Decision**	**Post Milestone A**	**Post Milestone B**	**Post Milestone C**	**Full-Rate Production**	**Sustainment**
33	Physiological Status Monitor		●				
34	Portable Neuromodulation Stimulator	●					
35	Red Blood Cells Extended Life				●		
36	Rapid Human Diagnostic Devices	●					
37	Skin Substitutes for Burn Injury and Skin Repair	●					
38	Tafenoquine Antimalarial Drug			●			
39	Topical Anti-leishmanisis Drug Paromomycin + Gentamycin			●			
40	Transfusion Transmitted Disease Rapid Diagnostic Device		●				
41	Transport Telemedicine		●				
42	Vector Trap CO2 Generator		●				
	Whole Blood Pathogen Reduction Device			●			
	TOTALS	**13**	**14**	**11**	**3**	**2**	**1**