2021 Command Accomplishments

U.S. ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND

Welcome

Welcome to the USAMRDC 2020 Command Accomplishments, where you will find our defining moments and achievements of the past year.

After a challenging year packed with a number of obstacles, the USAMRDC nonetheless continued its enduring efforts to push the limits of military medicine, and indeed push the very boundaries of what is possible in a global medical sense.

From achievements in the field of infectious disease research to progress in the world of health monitoring, 2021 will be remembered as the year in which the USAMRDC took one step further into the future, and in doing so came one step closer to ensuring the protection and success of our most important asset: the U.S. Warfighter.

Forge the Future!

U.S. Army Aeromedical Research Laboratory
USAARL

U.S. Army Institute of Surgical Research
USAISR

U.S. Army Medical Materiel Development Activity
USAMMDA

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

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

U.S. Army Research Institute of Environmental Medicine
USARIEM

Walter Reed Army Institute of Research
WRAIR

Congressionally Directed Medical Research Programs
CDMRP

Telemedicine and Advanced Technology Research Center
TATRC

Telemedicine and Advanced Technology Research Center

● TATRC Provides Planning, Testing of Nominated Technologies in Support of PC22

TATRC provided initial planning and testing of nominated technologies in support of Project Convergence 22, the Army modernization campaign of learning. Activities that support this effort included: TATRC's Medical Modeling Simulation, Informatics, and Visualization team performing baseline casualty care skills assessments in preparation for prototype technology evaluation and data collection for PC22; a Comparative Effectiveness Study of technologies for PC22 being conducted in TATRC's NEXUS Simulation Lab; and TATRC's NEXUS lab delivering the first Medical Technology Comparative Effectiveness Report for PC22.

● TATRC Expands NETCCN Initiative

Scope and use of the National Emergency Tele-Critical Care Network tool grew substantially in 2021. From lessons learned, we see that NETCCN not only provides a quality response to large-scale disasters, but also provides a model that can be applied to increase medical capability and capacity in future large scale combat operations in the multi-domain environment to enhance medical capability and capacity.

● Project Crimson Takes Flight at MSSPIX Event

TATRC's Project Crimson, an effort from our Medical Robotic & Autonomous Systems Division, took part in the Maneuver Support, Sustainment, and Protection Integration eXperiments 2021 at Ft. Pickett, Virginia. This was an important milestone for long range autonomous resupply of critical Class VIII materiel (such as Blood Products). The goal of Project Crimson is to develop an autonomous unmanned aerial system for "just-in-time" delivery of blood products and other critical medical supplies to remote, contested battlefield environments in order to support prehospital casualty care. To meet the outlined project goals, MedRAS collaborated with Near Earth Autonomy to integrate its cutting edge Peregrine Autonomy System with the L3Harris FVR-90 UAS aircraft.

BELOW: Official logo for TATRC's National Emergency Tele Critical Care Network, an evolving network of clinical care teams that provide expert medical advice to anyone who needs it, wherever they may be, using network-enabled mobile devices like cell phones, tablets and computers.

ABOVE TOP: TATRC researchers test unmanned aerial vehicle technology. (Photo credit: TATRC Public Affairs)

MIDDLE: Soldiers participate in an exercise in the new TATRC Nexus laboratory, a high-tech medical performance measurement laboratory designed to better understand clinical procedural performance. (Photo credit: TATRC Public Affairs)

BOTTOM: Medical personnel test a piece of technology in the new TATRC Nexus laboratory. (Photo credit: TATRC Public Affairs)

U.S. Army Aeromedical Research Laboratory

● USAARL's Load Stability System, More on Display at Project Convergence 21

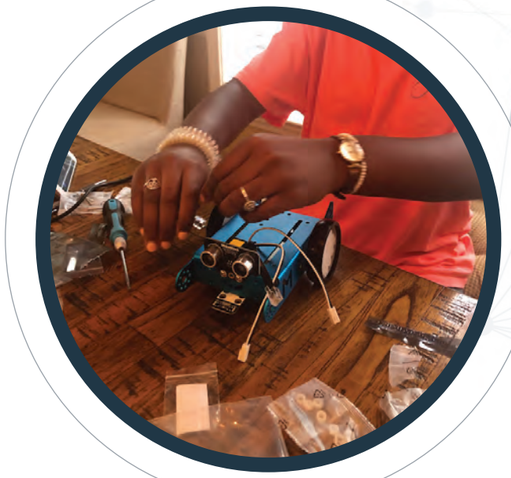
USAARL demonstrated the Load Stability System–Litter Attachment during hoist operations with 82nd Airborne Division's Air Assault teams during Project Convergence 21. The LSS-LA, developed by Vita Inclinata Technologies, Inc., stabilizes hoist and sling loads allowing for faster and safer operations in operationally challenging environments. USAARL and Vita Inclinata Technologies collaborated under a Cooperative Research and Development Agreement to test and evaluate the LSS-LA for rotary-wing aircraft airworthiness prior to the technology being transferred to the Program Executive Office, Aviation for further testing, development, and Soldier touch-point user evaluations. Participation in Project Convergence allowed USAARL the opportunity to demonstrate to senior military and government leaders, academia, industry, and the media how USAARL and USAMRDC contribute to the Joint fight.

● USAARL Researchers Contribute Aircrew Safety, No Matter The Size

USAARL made a significant contribution to the health and safety of rotary-wing aircrews by developing injury assessment reference values for females of a smaller size. Injury assessment reference values provide a mathematical estimate of the chances that an individual will experience specific injuries in an aircraft mishap or accident (e.g., injuries to the neck, head, chest, spine, or pelvis). In the past, rotary-wing aircraft and safety equipment has been designed to provide the safest environment for aircrew of a specific size, generally that of a male occupant. Over the past year, USAARL used human cadavers that were both female and smaller than the average build to develop injury assessment reference values that correlate to the likelihood of injury in spinal regions in case of an accident or mishap. USAARL's contributions include recommendations for changes in the development of safety features and equipment on Future Vertical Lift aircraft. This will allow for a safer operational environment for future aircrews, which are increasingly female.

ABOVE LEFT: USAARL demonstrates the LSS-LA Hoist mechanism during Project Convergence 21.

RIGHT: The Hypbrid III 5th Percentile Female Crash Test dummy sits in the Rigid Seat of USAARL's Vertical Acceleration Tower during a testing exercise.



● USAARL Provides Summer STEM Education to Local Students

USAARL prioritized Science Technology Engineering and Mathematics (or, STEM) education during 2021 through multiple efforts. USAARL mentored 24 college students, post-graduates, post-doctoral fellows, established scientists, and faculty through the Oak Ridge Institute for Science and Education program; one student in the Department of Defense Historically Black Colleges and Universities-Minority Serving Institutions Summer Research Internship program; 150 students (Kindergarten – 6th grade) students in the Camp Invention program; and 207 students (4th grade – 12th grade) in the Gains in Education of Math and Sciences program. In total in 2021, USAARL provided STEM education to 382 students. USAARL's most notable 2021 STEM education achievement was the implementation of the 2021 GEMS program. Students were taught and mentored by high school and college aged students (called "near peer mentors") in a virtual environment due to the ongoing pandemic. Modules taught by USAARL personnel included instruction on simple machines, forensics, and robotics, among others.

● Transcranial Direct Current Stimulation Proves Effective in Aircrew Performance

USAARL made significant progress in evaluating Transcranial Direct Current Stimulation and its potential application to enhance and sustain performance in aviators. Specifically, two studies were completed. One study evaluated performance enhancement, while the other study evaluated sustaining performance during flight tasks. Results from both studies provide evidence supporting the efficacy of tDCS, particularly in sustaining attention of aviators during simulated flight tasks. Minimal to no side effects were reported, thus further supporting the potential incorporation of tDCS into aviation.

● USAARL Makes Strides in Operator State Monitoring

USAARL completed a three-phased project evaluating candidate physiological variables for inclusion in Operator State Monitoring. The goal of OSM involves real-time monitoring of the physiological indicators of aircrew workload and subsequent performance. Candidate sensors evaluated included measurements by electroencephalogram, electrocardiogram, and eye tracking and pupillometry technology. The aim is to predict performance deficits throughout the flight envelope to inform adaptive autonomous systems in the aircraft. Novel methodological approaches were developed and later validated to improve recording reliability. Included in the series of experiments was testing and evaluation of an e-Tattoo in collaboration with the University of Texas at Austin.

ABOVE LEFT: A student builds a robot as part of an exercise during USAARL's summertime GEMS program.

RIGHT: A Soldier outfitted with an e-tattoo. (Photo credit: USAARL Public Affairs)

A test subject receives transcranial direct current stimulation while attempting to complete ceratin tasks in the UH-60 helicopter simulator. (Photo credit: USAARL Public Affairs)

U.S. Army Medical Research Institute of Chemical Defense

● USAMRICD First to Acquire Protective Shelter for CBRN Training

USAMRICD added a unique asset to its training mission capabilities with the installation of a specially-configured Chemical Biological Protective Shelter. Installation of the CBPS marked the completion of a multi-year endeavor to equip the Institute's Chemical Casualty Care Division with this immersive, training-specific system. The CBPS enhances instruction provided to medical professionals, combat medic specialists, and first responders attending the Institute's Medical Management and Field Management of Chemical and Biological Casualties courses. USAMRICD is the one of only two locations — and the first overall — to have a system designed for life-like training purposes.

● ChemDX Test System Scores Milestone B Approval, Entry as Program of Record

The ChemDx Test System was given Milestone B approval, designating it as a program of record and marking its entrance into the Engineering and Manufacturing Development Phase of the Acquisition Pipeline. A chemical diagnostic platform, the ChemDx is a hand-held device that can be carried by forward-deployed personnel to rapidly detect nerve agent intoxication in 20 seconds using a drop of blood. USAMRICD, the pioneer of this technology, is also developing ChemDx modifications to detect opioid intoxication and other chemical threats. Access to this technology mitigates continued injury to patients in the field due to delayed diagnoses.

● USAMRICD Building E2900 Achieves Full Operational Capacity

Upon completion of construction of Building E2900, multiple issues were discovered that prevented the safe use for research in the high hazard chemical containment wing. After many delays and a great deal of work on the part of multiple offices and organizations, these issues have been resolved. USAMRICD achieved Full Operational Capacity in January 2021, six years after initially occupying the current research space in 2015. This milestone marks the first time all institute research and training activities are under one roof. With a mixture of state-of-the-art neat and dilute chemical agent labs and training capability, the facility consists of 526 thousand total square feet of specialized space that delivers state-of-the-art clinical education and medical chemical defense research.

LEFT: Image of a Chemical Biological Protective Shelter. (Photo credit: Peter Hurst, USAMRICD)

● USAMRICD Wraps Key Portion of Opioid Countermeasure System Study

USAMRICD concluded experimental work to establish a non-human primate model of opioid intoxication, with an emphasis upon the synthetic opioid carfentanil. Studies elaborated the onset, severity, and duration of carfentanil intoxication to capture functional performance dimensions of militarily relevance. Optimal doses of naloxone for effective treatment were identified, which were higher than those available or easily achievable through existing commercial products. The Rapid Opioid Countermeasure System Translational Team and the ROCS Integrated Product Team worked with experts from the USAMRICD to select a 10 milligram dose for a naloxone auto injector based on these non-human primate data. Additional studies verified the safety of large doses of naloxone in this same model system and defined the pharmacokinetic profile, enabling predictions of efficacy and informing practical medical guidance for existing and future medical countermeasure products to successfully treat opioid intoxication. Presently, the USAMRICD data have formed part of the U.S. Food and Drug Administration supplemental new drug application submitted by the industry partner selected for development of the high-dose naloxone auto-injector. Recently, these same data sets have been shared with another industry partner seeking to develop a multi-use high-dose naloxone vial for intramuscular injection, as part of a larger strategy to mitigate product development risk and provide military personnel with expedient options in the treatment of this growing opioid threat.

ABOVE TOP: A Soldier uses the ROCS during a field test. (Photo credit: Jose Rodriguez, MEDCoE)

LEFT: Image of the ruggedized ChemDX system. (Photo credit: Eric Woltz, USAMRICD) (bottom): Animated image of a Naloxone injector. (Photo credit: USAMRICD Public Affairs)

United States Army Research Institute of Environmental Medicine

● USARIEM Partners with TRADOC-CIMT on Army Comprehensive Body Composition Study

USARIEM scientists designed and initiated data collection on the Army Comprehensive Body Composition (ACBC) study. As subject matter experts in modern anthropometrics and Soldier performance, USARIEM was tasked by the Center for Initial Military Training (TRADOC) to lead the effort in support of their Holistic Health and Fitness (H2F) initiative focused on improved Soldier readiness. The ACBC study will provide measurements on a representative population across all three Army components (active duty, Reserve and National Guard) and then relate these measures to physical performance and injury. The ACBC study has collected data on approximately 2,100 Soldiers at Fort Bragg, North Carolina, and Fort Lee, Virginia, since October 2022. The study is set to be the largest, most modern and comprehensive assessment of body size and composition the Army has completed to date. Sergeant Major of the Army Michael A. Grinston and Brig. Gen. John Kline, commanding general for the U.S. Army Center for Initial Military Training, volunteered to be study participants.

LEFT: U.S. Army Sgt. Maj. of the Army Michael A. Grinston receives a bioelectrical impedance analysis scan at Fort Bragg, N.C. on Oct. 19, 2021. The scan/study is part of a comprehensive body composition study examining the association between body composition and Soldier physical performance and the Army's efforts to optimize Holistic Health and Fitness and improve Soldier readiness. (U.S. Army photo by Spc. Jacob Moir)

● USARIEM Completes Personal Heating Dexterity Device (PHD2) Prototype; Prepares for First Field Study

In 2021, USARIEM developed the Personal Heating Dexterity Device (PHD2) prototype, a forearm-heater used to improve hand dexterity in cold environments. After a series of in-house studies testing the safety and efficacy of the PHD2, the researchers will test the device in real-world conditions. In 2022, the researchers will receive feedback on the PHD2 from warfighters participating in the Arctic Eagle-Patriot exercise in Anchorage, Alaska. Loss of hand function and manual dexterity during cold-weather operations severely compromises essential military tasks such as medical treatment, marksmanship, digital command and control functions, mechanical and electrical repairs, and helicopter gunship activities. The PHD2 reduces the impact of cold-induced degradations on dexterity and Warfighter performance. USARIEM will transition the prototype to the U.S. Army Medical Materiel Development Agency for advanced development in 2022.

ABOVE: Inside the U.S. Army Research Institute of Environmental Medicine's environmental chamber, a study volunteer tests out the Personal Heating Dexterity Device prototype. Known as the PHD2, the forearm heater improves hand dexterity in the cold by increasing blood flow to the hands. (Photo courtesy of Dr. John Castellani, USARIEM)

● USARIEM and MIT Lincoln Laboratory Scientists Develop Novel Ambulatory Measure of Cognitive Fatigue

In fiscal year 2021, USARIEM scientists developed a novel algorithm for detecting and predicting cognitive fatigue based on changes in speech patterns. The scientists isolated changes in speech timing and coordination, enabling them to subjectively and objectively measure a Warfighter's level of fatigue due to high cognitive workload. They developed this method through basic and applied science studies and field validation. By incorporating the algorithm into body-worn sensors or mobile devices, the Army would have an unobtrusive way to capture speech data and monitor cognitive state. The innovation directly supports Army requirements to mitigate shortfalls in protecting, sustaining and optimizing service members' physical and psychological health, readiness and performance in all environments. An initial element of a larger, multi-modal Cognitive State Assessment Tool, this algorithm supports the Alertness and Fitness for Duty and Neuropsychological Status components of the Army's Health Readiness and Performance System initiative.

● USARIEM Study of Musculoskeletal Injury in Trainees Returns to Action

USARIEM's ARIEM Reduction in Musculoskeletal Injury (ARMI) study team restarted data collection after COVID-related travel delays. The researchers increased their total volunteer enrollment to over 3,600 participants. This prospective study uses advanced technologies to comprehensively examine modifiable and nonmodifiable risk factors for musculoskeletal injury during Basic Combat Training (BCT). USARIEM and their partners implemented several new study arms to examine how female reproductive health, oxidative stress, biomechanics, and somatosensory function affected injuries during BCT. The researchers published manuscripts describing how trainees' sleep quality and body composition changed. They will complete their data collection in 2022 and transition an injury risk algorithm to the TRADOC Center of Initial Military Training in 2023.

LEFT TOP: A 5th Engineer Battalion Soldier rucks to the Kachina Peak summit in Taos Ski Valley, New Mexico, at 11,800 feet above sea level. He will spend four days living in the Ski Patrol Headquarters as part of a study the U.S. Army Research Institute of Environmental Medicine is conducting to validate an algorithm that can predict acute mountain sickness in individuals.

BOTTOM: A trainee at Ft. Jackson, South Carolina, receives a bone scan as part of the ARIEM Reduction of Musculoskeletal Injury study. The aim of the ARMI study, led by the U.S. Army Research Institute of Environmental Medicine, is to understand who is more likely to get injured and what can affect injury risk. (Photo credit: Mallory Roussel, USARIEM Public Affairs)

● USARIEM Develops Tool to Predict Acute Mountain Sickness Before Mountain Operations

USARIEM conducted its most extensive field study with 41 active duty Warfighters from the 5th Engineer Battalion at Taos Ski Valley, New Mexico, in the summer of 2021. The research team conducted baseline sea-level testing in Ft. Leonard Wood, Missouri, and altitude testing on Kachina Peak, Taos Ski Valley, for four days at 3,600 meters altitude. The study's purpose was to finalize the AMS-alert, the first Army tool to predict individuals' Acute Mountain Sickness (AMS) risk in real-time. The effort resulted in several breakthroughs in the Army's scientific knowledge of altitude mission planning. In collaboration with the Walter Reed Army Institute of Research, preliminary analysis of study volunteers' saliva suggests that a handful of differently expressed genes can identify individuals at high risk of AMS. Furthermore, the researchers have improved the AMS-alert's accuracy to 88 percent. The researchers plan to conduct another study with 40 female volunteers in Taos Ski Valley in the summer of 2022 to fine-tune the algorithm. The finalized tool will be transitioned to the U.S. Army Medical Materiel Development Agency at the end of fiscal year 2024 to be used by troops deploying to high-altitudes.

ABOVE LEFT: A female Soldier participates in a barbed wire crawl during a training exercise. Research performed by USARIEM scientists ensures Soldiers operate at peak physical capacity.

RIGHT: A Soldiers surveys mountainous terrain during a training exercise. USARIEM scientists use data gathered during such exercises to better understand human physiology, along with physical function and capacity.

Walter Reed Army Institute of Research

● WRAIR Continues Development of COVID-19 Vaccine

WRAIR'S Emerging Infectious Diseases Branch continued its focus on the development of a preventive vaccine that uses a nanoparticle platform and an Army-patented adjuvant. The vaccine, called the Spike Ferritin Nanoparticle (or, SpFN), underwent Phase I clinical testing in 2021. The SARS-CoV-2 vaccine, co-formulated with the Army Liposomal Formulation adjuvant — both developed at WRAIR — was evaluated in a phase I double-blind, placebo-controlled study. This was a first in-human study of the safety, tolerability, and immunogenicity of different doses of the SpFN vaccine against COVID-19 in healthy adults to inform product development efforts for the protection of the Warfighter. A series of pre-clinical studies published in 2021 indicated that SpFN has the potential to protect broadly and proactively against multiple coronavirus species and strains.

● WRAIR, BHAT Continue Focus on Soldier Health, Resiliency

Scientists from WRAIR and the U.S. Army Public Health Center continued their partnership of the Behavioral Health Advisory Team to survey more than 20,000 Soldiers across the globe. The BHAT assessments are currently addressing 3 key needs of Army stakeholders: (1) the impact of COVID-19 on Soldiers, units, and Soldier's families; (2) Operation People First initiatives under III Corps; and (3) resiliency among the AMEDD and JAG Core workforces. The team have collected data concerning vaccine hesitancy and the role of attitudes about the vaccine and leadership engagement as key intervention areas to reduce hesitancy, developed leadership quick guides about ways to manage COVID-19 and maintain unit cohesion.

● Brain Studies Could Lead to Better Sleep, Increased Resilience for Soldiers

The WRAIR Sleep Research Center has a multi-pronged approach to developing and testing cutting-edge brain stimulation technology to enhance both sleep and waking efforts during periods of restricted sleep opportunity. The cornerstone of this program is the use of oscillatory transcranial electrical stimulation during sleep to enhance the restoration of short sleep opportunities. The first half of this study was completed in FY21 with promising results, and the second half of the study will test a variety of stimulation parameters to optimize the restorative effect in FY22-24. The Operational Research Team completed data collection for a study to evaluate habitual sleep as a susceptibility factor for COVID-19 in a high-risk healthcare provider population, and completed three new data collection missions in FY21. Major outcomes to highlight include providing the content for the report to Congressional Armed Services Committees entitled "Study on Effects of Sleep Deprivation on Readiness of Members of the Armed Forces" in March 2021. Further, content on the importance of sleep was added to Recovery MRE cards as a part of the Assembly Contract Requirement for MRE 42 and will be updated in the 2022 year of production. Additionally, three infographics were created for stakeholders, with five separate infographics and other, additional material translated to French in collaboration with the Canadian Armed Forces for broader dissemination.

● WRAIR Leads International Effort to Train the Human Brain

U.S. Army Medical Research Directorate-West engaged in research to determine the effectiveness of pairing strenuous physical fitness training with cognitive training to improve Soldier lethality and performance on operationally-relevant tasks such as dynamic marksmanship. This research project is called the Brain Physical Optimization Conditioning (or B-POC) study. In June 2021, a CRADA between USARMD-W/WRAIR and The Arctic University of Norway was approved in support of the study. Data collection on the B-POC study is ongoing at Joint Base Lewis McChord, in Washington, and work will continue into future fiscal year periods. Moreover, USAMRD-W also developed a joint proposal with the Brazilian Army Physical Training Center to execute a B-POC study with the Brazilian army to determine the effectiveness of B-POC in improving Soldier performance and lethality in hot and humid climates. This proposal was submitted to the U.S. Department of Defense Coalition Warfare Program and is currently under review.

● WRAIR Takes Lead On International Health Diplomacy

U.S. Army Medical Research Directorate-Africa, headquartered in Nairobi, Kenya, is WRAIR's forward platform in Africa for infectious disease surveillance, countermeasure research, development, testing and evaluation, and health diplomacy. USAMRD-A plays a key role in maintaining active relationships between host nation Defence Forces Medical Services and the U.S. Department of Defense through longstanding partnerships with the defense forces of each of its host countries. In April 2021, USAMRD-A/K staff members of the Malaria Drug Resistance and Microbiology Hub Kericho laboratories initiated a two-week malaria and enteric surveillance event at the KDF Recruit Training School, which tested 3,993 recruits — 27 of which tested positive for malaria and were proactively treated to prevent malaria outbreaks in the barracks. This annual event strengthened the U.S. DoD-KDF relationship, generated unique malaria prevalence data, and enabled USAMRD-A's KDF partners to mitigate the malaria threat within its forces.

ABOVE LEFT: Army Capt. Aaron Sanborn injects Staff Sgt. Daniel Ellis during clinical testing for WRAIR's spike ferritin nanoparticle (SpFN) vaccine at the WRAIR Clinical Trials Center. soldier to take part in the study. (Photo credit: Mike Walters/ WRAIR)

RIGHT: A soldier participates in a sleep study at the Center for Military Psychiatry and Neuroscience Research at Walter Reed Army Institute of Research. (Photo credit: Arlen Caplan/WRAIR)

U.S. Army Institute of Surgical Research

● USAISR Develops Tablet-Based, Mobile Burn Navigator Tool

USAISR finalized development of the new tablet-based and mobile based burn navigator system to support the Air Force CCATT teams and Army deployed clinical teams that provide care for acute burn combat casualties. This effort occurred in partnership with the U.S. Air Force and Arcos medical). The system has been deployed as an application that is currently available for civilian burn providers in both the Android and Apple stores. It is also available for military providers in the DISA app store.

● USAISR Ensures Characterization of Automated Critical Care System

USAISR ensured characterization of the Automated Critical Care System fluid infusion module to support development of new fluid resuscitation algorithms for automated transport and evacuation of combat casualties. The MSISRP program took over development of the ACCS platform from the Office of Naval Research. USAISR further continued funding the development of the system to support various automation capabilities for combat casualties.

● USAISR Develops Slew of Augmented Reality Apps for HoloLens

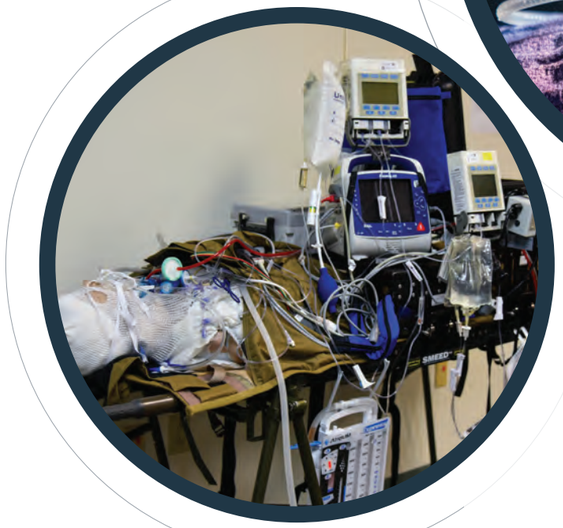
USAISR led the development of several augmented reality applications for use on the Microsoft HoloLens System. These applications were developed to support the MSISRP Virtual Health program, which is focused on development of technologies that can be used in multi-domain operations with limited or no connectivity. The applications were developed to test the concepts of using advanced augmented reality in a field environment for the care of a severely burned combat casualty requiring multiple critical care interventions. Applications included an automated burn estimation system, an electronic application for displaying the Joint Trauma System clinical practice guidelines, application for supporting burn resuscitation, pain management, sedation, drug calculations, and escharotomy guidance.

● USAISR Develops Clinical Decision Support System for CPGs

USAISR developed a clinical decision support system for use by medics using advanced rule-based engine based on converted clinical practice guidelines. The purpose of the system is to provide users at the point of injury with an intelligent assistant that provides clinical decision support capabilities based on the standard of care guidelines. The system uses a CLIPS engine to implement a set of rules stored as a knowledge base encompassing the current standard of care for several injury types. Clinical practice guidelines were converted from a free text form to a rules-based set to provide the required knowledge driving the CLIPS engine.

● USAISR Finalizes, Tests Initial Iteration of the Burn Patient Transfer System

In collaboration with TATRC, Chenega, and St. Barnabas Medical Center, USAISR finalized and tested the initial iteration of the Burn Patient Transfer System, which is designed to manage burn patients in a mass casualty environment. The goal of the system is to provide a national military (or even civilian) emergency management system for burn patients. The system underwent successful validation for full expected deployment in the next year.



ABOVE TOP: A surgeon operates using bioengineered blood vessels. This next-generation technology uses human cells to generate blood vessels that may function in people without prompting an immune reaction.

MIDDLE: Medical support equipment sits atop a wheeled litter carrier during the 2022 USAMRDC Capability Days. (Photo credit: Gloriann Martin, USAMRDC Public Affairs)

BOTTOM: Brig. Gen. Tony McQueen, Commanding General of USAMRDC and Fort Detrick, tests a virtual reality headset. (Photo credit: USAMRDC Public Affairs)

Congressionally Directed Medical Research Programs

MeMed BV test and MeMed Key platform

● MeMed Obtains 501(k) FDA Clearance for Diagnostic Test and Platform to Distinguish Bacterial Versus Viral Infections.

MeMed scientists have developed a device capable of distinguishing bacterial from viral infections in just 15 minutes at the point of care with a simple blood test. The technology measures the body's immune response to the pathogen by detecting three different proteins in the patient's blood. PRMRP funding supported the scale-up of the materials production, including the cartridge for running the MeMed BV® test and the MeMed Key® Platform. In September 2021 MeMed received 510(k) clearance from the FDA indicating the MeMed BV and MeMed Key are as safe and effective as other devices already on the market and that the device can be sold in the United States. The high accuracy and compact size of this breakthrough technology could allow the device to travel for use in military environments. Importantly, it could address limitations in identifying and treating infections in the Warfighter when medical diagnostics tools and treatment supplies are limited.

● OsteoAdapt Receives FDA Breakthrough Device Designation

Past and current funding from three CDMRP programs (Joint Warfighter Medical, Peer Reviewed Medical, and Peer Reviewed Orthopaedic) supported the development and pre-clinical validation of OsteoAdapt (Theradaptive, Inc.), a synthetic bone scaffold used to promote bone regrowth and healing for musculoskeletal injuries (MSKIs). MSKIs affect the bones, joints, and muscles and collectively comprise ~50% of all combat wounds in recent conflicts (1). OsteoAdapt technology is a promising new device that harnesses the body's own regenerative mechanisms to support bone regrowth for the treatment of these debilitating injuries. In November 2021, OsteoAdapt was granted Breakthrough Device designation by the FDA for the treatment of degenerative disc disease, a type of MSKI affecting nearly one third of all Americans (2). The FDA's Breakthrough Device designation is intended to help patients have more timely access to medical devices by facilitating the development and expediting the review of breakthrough technologies.

● Development of Bacteriophage for Treatment of Bacterial Infections

Military personnel, including both those operating on land or at sea, are at heightened risk of infection from Staphylococcus aureus, including methicillin-resistant S. aureus (MRSA), due to habitation in close quarters and shared equipment for extended periods. Combat injuries can disrupt the skin barrier and put military personnel at increased risk of S. aureus blood infection (bacteremia). Despite conventional antibiotics, S. aureus bacteremia represents a major threat in terms of increasing morbidity, mortality (up to 40% of all cases) and health care utilization.

With almost $7M in Joint Warfighter Medical Research Program funding for a project managed by the Navy

through the USAMRDC-established Medical Technology Enterprise Consortium, Armata Pharmaceuticals has developed a novel bacteriophage therapeutic, AP-SA02 to combat bacteremia. AP-SA02 demonstrates potent antimicrobial activity against 95% of S. aureus isolates tested, including MRSA, and penetrates biofilms. The company received FDA clearance in November 2021 for its Investigational New Drug (IND) to initiate the "diSArm" study, a Phase 1b/2a clinical trial assessing the safety, tolerability, and efficacy of intravenous AP-SA02 as an adjunct to best available antibiotic therapy for the treatment of S. aureus bacteremia.

ABOVE: Development of a Novel Bacteriophage Therapeuti for Targeted Treatment of Staphylococcus aureus Bacteremia, Including Drug Resistant Forms - MTEC (mtec-sc.org)

● Repurposing FDA-approved Drug to Treat Cornea Trauma, Burns and Infections

Scientists have developed a novel topical treatment for corneal injury and validated its effectiveness in a large animal (rabbit) model.* The treatment focuses on the prevention of scarring that often occurs after trauma, burns and infections in the cornea. By repurposing an FDA-approved drug, losartan, that targets a prominent signaling pathway in scar formation into the novel treatment, scientists are accelerating a potential product for the battlefield with high relevance for treating all severe corneal injuries from blunt trauma, blast injuries, thermal burns, chemical injuries, bioweapons such as smallpox virus that infect the cornea, and complications of surgery where the cornea's structure are injured or destroyed.

*There are 12 peer reviewed publications, including 3 in 2021, and 3 within the first 3 months of 2022.

● Significant Employment Rates in Transition-Aged Military Dependents with ASD After 9-Month Internship

With funding from Autism Research Program through a Clinical Trial Award, Dr. Paul Wehman and his team at Virginia Commonwealth University investigated the impact of a job internship program on transition-aged military dependents with autism spectrum disorder (ASD). In this study, high school seniors with ASD were embedded in an intensive 9-month job training program within large community businesses, while receiving ASD specific support during the internship period. Of the military beneficiaries that completed the program, over 76% gained competitive integrated employment (compared to only about 4% of the control group completers). Because of the success of the Fort Eustis Project SEARCH + ASD support study, the Naval Air Station, Oceana has already implemented the intervention. Additionally, the U.S. Army Garrison, at Fort Lee is planning to implement the intervention in the coming year. As the ASD community struggles with high percentages of unemployment and underemployment (over 50%), findings from this intervention could provide caregivers the necessary tools to help improve employment outcomes as ASD youth transition into adulthood.

ABOVE: Greater than 75% of transition-aged military dependents with autism spectrum disorder gained competitive integrated employment following a novel study funded by CDMRP and conducted by researchers at Virginia Commonwealth University.

U.S. Army Medical Research Institute of Infectious Diseases

● USAMRIID Assesses the Effectiveness of Pesticide-Treated Uniforms

Arthropod-borne viral diseases, such as the mosquito-transmitted dengue fever, continue to pose a significant health threat to U.S. forces during deployments to austere environments. As part of an ongoing study into components of the DoD Insect Repellent System, U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) scientists conducted the first independent study to examine the effectiveness of repeatedly washed pesticide-treated flame resistant Army combat uniforms to repel arthropod vectors. They found a significant decrease in quantity of two pesticides after 10 and 25 launderings, which could reduce the ability of the uniform to protect personnel from vectors. Using scanning electron microscopy, they also found damage to the uniform fabric after repeated washings. A breakdown in the integrity of the uniform could increase the risk of exposure to arthropod-borne diseases among deployed forces by allowing vectors to bite through the fabric. These findings and additional ongoing studies are providing the critical data needed to continuously improve repellent systems and mitigate arthropod-borne disease threats to the Warfighter.

● Synthetic Biology Helps USAMRIID Stay One Step Ahead of Disease Variants

Synthetic Biology provides powerful tools for understanding emerging biological threats. Acquiring sequences of interest for rapid characterization during outbreaks can be difficult for logistical, safety, and political reasons. USAMRIID's Center for Genome Sciences (CGS) maintains a full suite of synthetic biology tools and has developed methods to obtain viral sequences of interest when clinical samples cannot be obtained. This technology also enables scientists to identify the major determinants of virus transmission, pathogenesis and human adaptation, while allowing them to examine the efficacy of medical countermeasures against the evolving virus. In addition to providing operational support for outbreak response, the CGS conducts and supports training, basic research, advanced development, and testing & evaluation for any pathogen(s) encountered, whether naturally occurring, modified, or weaponized. USAMRIID is the Department of Defense's only Biosafety Level 4 (BSL-4) research and clinical laboratory, with extensive BSL-2 and BSL-3 assets as well. Its Special Pathogens Laboratory is fully accredited and can provide definitive diagnostic support and characterization for any pathogen. The CGS has leveraged these in-house capabilities to support outbreak response across the globe for over a decade, using state-of-the-art whole genome sequencing expertise to support investigations of Ebola virus, Andes virus, Zika virus, and many others. In 2021, USAMRIID supported the Defense Health Agency (DHA) Global Emerging Infections Surveillance (GEIS) network, performing variant characterization in support of COVID-19 pandemic response.

● USAMRIID Collaboration with AstraZeneca Leads to COVID-19 Treatment

Recognizing the unique capabilities of the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), the pharmaceutical company AstraZeneca teamed up with the Army lab to assess an existing panel of SARS-CoV-2 monoclonal antibodies (mAbs). The overall goal of the work was to develop mAbs against the SARS-CoV-2 viral spike protein. Monoclonal antibodies have the potential to both prevent COVID-19 and reduce the risk of severe disease and death in infected individuals. USAMRIID scientists evaluated the neutralizing activity of AstraZeneca mAbs in a high-throughput neutralization assay that had been developed by USAMRIID just a month prior. In addition, USAMRIID further supported product development efforts by testing samples from nonhuman primate studies and human clinical trials conducted elsewhere. The collaborative efforts of AstraZeneca, USAMRIID, and others culminated in the Food and Drug Administration's granting an Emergency Use Authorization for Evusheld™, a combination of two long-acting monoclonal antibodies, in December 2021—less than two years from project initiation. This medication is currently available to prevent COVID-19 in military personnel and civilians who may not produce antibodies following vaccination.

ABOVE LEFT: Brig. Gen. Tony McQueen, Commanding General of USAMRDC and Fort Detrick (second from left) meets with scientists at USAMRIID to discuss current and upcoming research projects. (Photo credit: USAMRIID Public Affairs)

RIGHT: A scientist uses a pipette during a synthetic biology experiment at USAMRIID. (Photo credit: USAMRIID Public Affairs)

A scientist collects data during an ongoing experiment at USAMRIID. (Photo credit: USAMRIID Public Affairs)

● USAMRIID Serosurveillance Reveals COVID-19 Infections Among U.S. Forces

During the COVID-19 pandemic, fast and reliable serosurveillance conducted by the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) helped the DoD to understand exposure and vaccination levels in the force and to determine additional force protection measures. In collaboration with the Armed Forces Health Surveillance Branch (AFHSB) Global Emerging Infections Surveillance (GEIS) program and the Defense Health Agency (DHA), USAMRIID conducted COVID-19 serosurveillance of the U.S. military population using samples from the DoD Serum Repository. USAMRIID scientists used a high-throughput assay to assess antibody levels from routinely collected and stored sera. This was followed by a virus neutralization test on all positive tests to confirm the results. Within seven days of receiving a batch of 4,000 samples, USAMRIID reported results to GEIS; in total, USAMRIID analyzed over 28,000 samples through the end of 2021. Serosurveillance is considered the gold standard for measuring population immunity due to past infection or vaccination. The methods that USAMRIID developed for COVID-19 are now being used in many OCONUS locations, in collaboration with international partners, to screen for arthropod-borne viral diseases and viral hemorrhagic fevers.

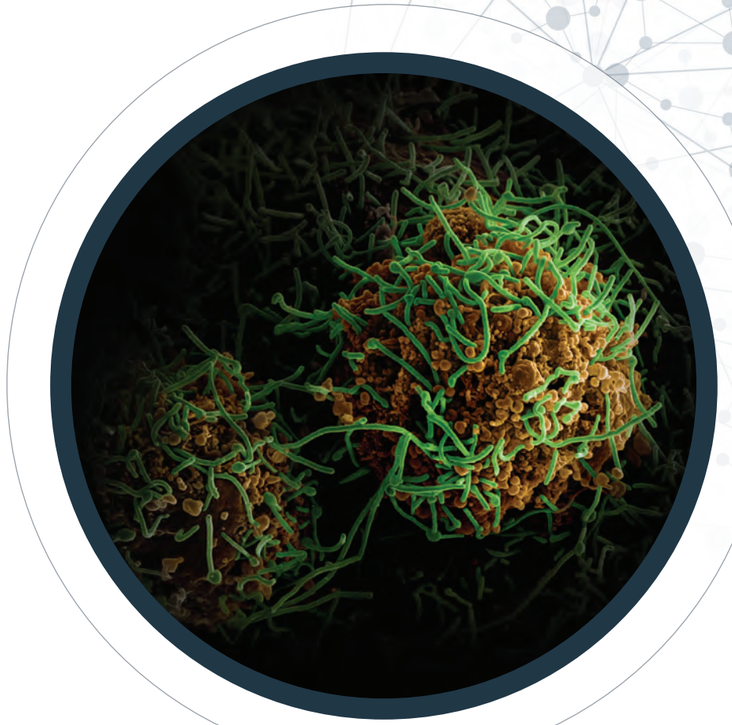
● USAMRIID Develops BMASS Method for Large-Scale Disease Testing in Warfighters

Large-scale testing is necessary to accurately track respiratory infections in Warfighters. The Biodefense Mass Sequencing and Surveillance (BMASS) method developed by the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) can combine and test over 40,000 saliva samples within 24 hours in a single test tube. A unique genetic barcode is attached to each sample, allowing any positive result to be directly tracked to its individual sample. USAMRIID initially developed BMASS to improve COVID-19 surveillance, but it can be used to detect a broad array of biological threats to the Warfighter. BMASS combines large-scale sample pooling, PCR testing, and a technique called Next Generation Sequencing, or NGS. The method uses readily available materials and runs on instruments already present in many DoD research and public health laboratories. Data analysis is performed on a standard-issue laptop in under 30 minutes using software created at USAMRIID. BMASS has a small enough footprint to provide operational units and strategic assets with vulnerable populations a way to access large-scale surveillance testing. BMASS provides commanders with a cost-effective method to rapidly screen groups of service members for potential disease in order to maintain overall force readiness.

● USAMRIID Conducts Specialized Medical Training for Polish Special Forces

At the request of the Defense Threat Reduction Agency, the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) Training and Education Branch facilitated a custom-tailored biological threat agent short course for a select group of Polish Special Operations Forces in October 2021. USAMRIID teamed up with other DoD agencies to provide a broad overview of the topic that included agent recognition, treatment of casualties, and emerging medical countermeasures. Twenty Polish nationals attended the course, which was actively translated from English to Polish. The course was very well received and additional courses are planned. Each year, USAMRIID partners with the USAMRICD Chemical Casualty Care Division to host several courses on the medical management of chemical and biological casualties. Hundreds of personnel from all branches of the U.S. military, other Federal agencies, and partner nations attend the resident courses annually. Including international partners in CBRNE training can lead to stronger alliances and a more prepared allied fighting force.

ABOVE: Training Polish Special Forces



● USAMRIID Studies Ebola Virus Disease Relapse to Prevent New Outbreaks

Highly effective therapeutics have been developed and tested against acute Ebola virus disease, both in humans and in experimentally infected nonhuman primates. However, the risk of viral persistence and associated disease recurrence in survivors receiving these therapeutics, including monoclonal antibodies, has been unclear. In a groundbreaking study, USAMRIID researchers discovered that Ebola virus, despite being cleared from all other organs, persisted in the brain ventricles of rhesus monkeys that received monoclonal antibody treatment and recovered from infection. Two of the monkeys that initially recovered from Ebola virus disease after the treatment had a recurrence of clinical signs associated with Ebola virus infection prior to their death. Several recent Ebola virus disease outbreaks in Africa have been linked to persistent infection in patients who had survived previous outbreaks. A 2021 Ebola outbreak in Guinea was started by a persistently infected survivor of the 2013-2016 West African Ebola outbreak, the largest in human history. Outbreaks of Ebola virus occur naturally in regions of Africa where military personnel could be deployed. Understanding the risk of persistent infection is necessary to guide post-recovery monitoring and management of infected Warfighters.

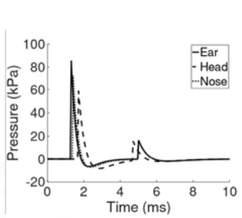
ABOVE: Image of Ebola Persistence

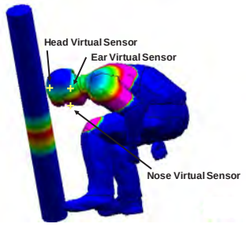
Blast Injury Research Coordinating Office

● Scientists Describe a System and Method for Determining Blast Injury Metrics Using Model-Based Calculations

Through a DOD Small Business Innovation Research (SBIR) program managed by the DOD Blast Injury Research Coordinating Office (BIRCO), researchers from CFD Research Corporation and Walter Reed Army Institute of Research developed a system and method that will improve the accuracy of calculating blast load on the human body and specific organs. The system and method will minimize potential harmful effects from blast exposure during military training and combat.

BELOW: Image showing the impact of blast overpressure loading on different anatomical regions of a virtual Soldier model. (Image credit: BIRCO)





● Human Factors and Medicine-341 Research Technical Group (HFM-341 RTG)

Blast Injury Research Coordinating Office (BIRCO) will continue to chair the NATO Human Factors and Medicine (HFM)-341 Research Technical Group (RTG), Validation of Modeling and Simulation Methodologies for Human Lethality, Injury, and Impairment from Blast Related Threats. The objective of HFM-341 RTG is to develop standardized methodologies and metrics to validate computational models and simulation approaches established in the HFM-270 blast-related injuries prediction framework. The HFM-341 RTG will utilize the latest scientific, experimental, and combat theater data to include, but not limited to, prediction of the performance of protective equipment in blast explosions, as well as combat scenario predictions. The outcome will be approach, criteria, and metrics to validate such a framework as well as its component computational models and simulation techniques.

● Researchers Develop a System and Method for Reconstruction of Blast and Blast Loading Using Pressor Sensor Data

Blast Injury Research Coordinating Office in collaboration with researchers from CFD Research Corporation developed a method that uses pressure sensor data as input to an inverse problem solver to calculate the location and charge mass of an explosive device and detailed pressure loads on the human body exposed to blast wave. The results of such blast loading reconstruction simulations on soldiers can be used to correlate these with blast injury probability using experimentally collected “dose-response” data, thus predicting injuries to various organs, such as the brain, etc. In addition, information can then be used for a myriad of purposes ranging from designing better protective equipment, determining whether or not the soldier should receive rest without exposure to blasts, determining medical treatment, and improving emergency response to blast events.

A soldier registers and calibrates the M777A2 howitzer weapon system in Syria in 2021. (Photo credit: U.S. Army Public Affairs)

U.S. Army Medical Research and Development Command

● USAMRDC Partnership with Medical Technology Enterprise Consortium (MTEC) Advances Wearable Sensor

In the spring of 2021, LifeLens Technologies, a small biotechnology company, successfully demonstrated its Ascent Platform in a field-testing environment at the Army Expeditionary Warrior Experiment (AEWE) at Fort Benning. The U.S. Army Medical Materiel Development Activity (USAMMDA) funded LifeLens through the MTEC. The event proved to be a good first demonstration of the Ascent Platform and provided the LifeLens team with a wide range of tasks and targets to prepare its system for longer use cases. The Ascent Platform captured 48 soldier-missions over the course of the AEWE 2021 event, and pulled 60 metrics from each soldier during their events. There were zero field failures. The LifeLens team will use the insights gathered from this event to plan for subsequent fielding with USAMMDA. In August 2021, the U.S. Food and Drug Administration approved the 510k.

During training and operations, we need real-time status information about our nation's Warfighters to provide Commanders with actionable information to mitigate non-battle injuries, and to maintain overmatch and maximize human potential; as well as, to mitigate injuries caused by high-risk training events. The Ascent Platform, a wearable sensor with proprietary, hypoallergenic, and stretchable microelectronic components and bioadhesives in a patch configuration, is the solution. The platform can remotely monitor and wirelessly transmit to a receiving device to provide physiological data (such as heat strain, cardiac stress, cognitive readiness, respiration, and alertness) for assessing Warfighter health readiness and performance in real-time training and operations environments. The total system weighs less than a penny and is extremely comfortable to wear.

The USAMRDC partners with the MTEC, a 501(c)(3) biomedical consortium, through an Other Transaction Agreement. There are currently 531 members in the consortium, consisting of small businesses, academia, large industry, and non-profit organizations. To date, the MTEC has funded 175 prototype projects totaling $637.5M. In addition to the USAMRDC, The Uniformed Services University of the Health Sciences, Naval Medical Research Center, Office of Naval Research, Joint Operational Medicine Information Systems, and National Guard Bureau also use the MTEC.

● Command Wide Laboratory Information Management System (LIMS)

The USAMRDC eIT PMO initiated USAMRDC LIMS Information Technology solutions by defining high-level capabilities and awarding a new contract to LabVantage Solutions, Inc. The eIT PMO is actively documenting core laboratory business processes to be included in the Enterprise Core LIMS. Working with the Functional Sponsor, the Principal Assistant for Research and Technology, the eIT PMO continues to facilitate lab standardization to be included in Increment 1 with Walter Reed Army Institute of Research Multidrug-Resistant Organism Repository and Surveillance Network as the initial lab to use the U.S. Food and Drug Administration validated command-wide capability. User workshops are underway to refine the requirements for specific labs throughout the command. Data and process standards are being coordinated with the Functional Sponsor's office, throughout the LIMS implementation and as each new lab/user group is engaged by the eIT PMO. The LIMS efforts have encouraged collaboration throughout the command to add value to the DoD to resolve an identified need for standardization in labs' business processes and for better integrated capabilities supporting all USAMRDC laboratories.

● Test Branch Evaluates Auto-Injectors for Chemical/Biological Response

The U.S. Army Medical Research and Materiel Command (USAMRDC) Test Branch conducted developmental testing of six Auto-Injectors in support of the Joint Project Manager Chemical/Biological/Radiological/Nuclear – Medical. Test Branch findings contributed to substantial re-designs to enhance the operational effectiveness of these critical lifesaving devices on a chemical battlefield.

LEFT: Soldiers use the Ascent platform as part of a fielding exercise during the 2021 Army Expeditionary Warrior Experiment at Fort Benning, Georgia. (Photo credit: Willima Norris, U.S. Army Training Support Center)

BOTTOM: A chest sensor applied to the body of a soldier. USAMRDC continues to make substantial investments in sensor technology. (Photo credit: USAMRDC Public Affairs)

● Test Branch Enhances Medical Device Modernization

In support of the U.S. Army Medical Materiel Development Activity Medical Modernization Project Management Office, the USAMRDC Test Branch evaluated multiple devices including both Human and Veterinary Ultrasounds, Portable Oxygen Generators, and several focusing on diagnosis and treatment of eye trauma. Test Branch Developmental Testing supported multiple successful procurement decisions for modernized medical equipment. Army healthcare providers use the modernized medical devices, listed below, to support Warfighters in deployed environments, maintain operational readiness and save lives.

- Ziehm Solo FD C-Arm Mobile System
- Lens Edging System
- Candidate X-Ray Calibration Systems
- B Braun Infusomat® Space 6.0 Infusion Pump
- ENDOLIGHT Flex LED
- Aseptico AEU-525CF Transport III Portable Dental System
- CataRhex 3 Anterior Ophthalmic Surgical System
- GE Venue Go Portable Ultrasound System
- Kowa Model SL-17 Ophthalmic Slit Lamp
- SonoSite Edge II Ultrasound System
- Field Oxygen Generator
- Philips PageWriter TC50 Electrocardiogram Case
- Doak MK4 Portable Surgical Table
- AcuTemp® AX56L Refrigerator/Freezer
- VuPad™ Ophthalmic Ultrasound System
- Fluke Biomedical VT900A Gas Flow Analyzer, VAPOR Anesthesia Tester
- Vaporizer Anesthesia Drawover General Anesthetic Services, Inc.

USAMMDA Warfighter Brain Health Program Management Office

● WBH PMO Initiates Clinical Implementation and Operational Assessment of FDA-approved i-STAT Traumatic Brain Injury Plasma Test (Army funded)

In deployed operations there are approximately 2,200 traumatic brain injuries (TBI) per year, the majority that are mild TBI casualties that are evacuated to higher roles of care for advanced imaging to rule out brain bleed. The implementation of the Analyzer, Traumatic Brain Injury (ATBI) capability would avoid 33% of these evacuations, which would preserve the fighting force, reduce risk to MEDEVAC crews, and conserve resources for more severe TBI casualties. The WBH PMO initiated the Clinical Implementation and Operational Assessment (CIOA) of the i-STAT Traumatic Brain Injury (TBI) Plasma test for the Analyzer, Traumatic Brain Injury (ATBI) Program in October 2021. The i-STAT Alinity and the TBI Plasma Test were fielded to Womack Army Medical center and five deployed operational medical units in CENTCOM where the providers will utilize the Joint Trauma Systems Clinical Practice Guideline for the capability that was published in September 2021. The goals of the CIOA are to provide data to support clinical utility of the test, increase user/provider familiarity, and ensure proper integration into the practice of medicine. Womack AMC tested the first patient on 9 November 2021 and 24 patients were tested as of December 2021 using this new capability.

ABOVE LEFT: The i-STAT Alinity handheld analyzer, base station and printer.

RIGHT: A laboratory officer prepares a TBI Plasma Test Cartridge for analysis.

● Developments in the Concussion Dosimeter Program (DHA funded)

Blast overpressure is a leading cause of traumatic brain injury (TBI) however, the Joint Force lacks sufficient capabilities to mitigate blast, ballistic, blunt and directed injury threats to Service Members. Sensor based-indicators of blast overpressure such as concussion dosimeters will help maintain warfighter readiness by mitigating the risk of TBI. Furthermore, the Concussion Dosimeter will help the DOD meet section 717 of the 2020 NDAA, which requires the documentation of blast exposure history in the medical record of each Service Member that sustains a TBI, including the measure blast pressure experienced if available. The WBH PMO's Concussion Dosimeter program is accelerating their schedule by leveraging over the past year; WBH PMO has transitioned the Concussion Dosimeter Program from WHPE PMO to WBH PMO. The program is also leveraging the SOCOM Blast Exposure Monitoring Program to procure prototypes for operational testing and evaluation collecting end-user feedback. This effort will accelerate development by at least 18 months, reducing Warfighter risk of unnecessary injury, and save over $2 million in taxpayer funds.

● Developments in the Post-Traumatic Stress Disorder- Screening Tool (PTSD-ST) Program (DHA funded)

The PTSD-ST Program has initiated collaboration between WBH and the Walter Reed Army Institute of Research (WRAIR) to collect end-user feedback to refine the capability gap. Within this effort, the focus group guide is complete and we have started to identify unit points of contact for the focus groups.

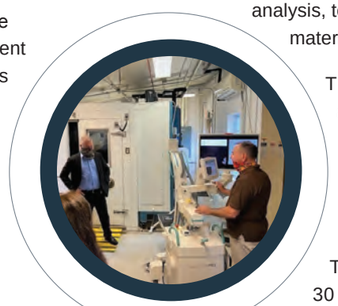
ABOVE LEFT: A laboratory officer reads the result of a test sample analysis delivered via the i-STAT Alinity handheld analyzer.

RIGHT: Developing solutions for Soldiers suffering from PTSD is a key goal of the USAMMDA Brain Health Program Managment Office.

USAMMDA Warfighter Deployed Medical Systems Project Management Office

● The Warfighter Deployed Medical Systems PMO Serves as the Focal Point for Medical Materiel Lifecycle Management in the Army, with a Mission to Develop, Deliver, and Sustain Deployable Medical Capabilities for the Warfighter. Within WDMS There are Two Divisions, Medical Devices Assemblage Management (MDAM) and Medical Modernization (MedMod)

The MDAM Product Management Office provides acquisition lifecycle management of medical equipment, unit assemblages (UA), devices and ancillary medical items to support human and animal patient care, ensuring that the Warfighter has the necessary equipment and materiel to meet their assigned missions.



During FY21, the MDAM team accomplished the following to update the force and increase unit readiness:

- Executed $40.2 million of FY21 OPA funds to purchase authorized medical equipment for Army deployable forces and regional training sites.
- Executed $3.6 million of FY21 EDI OCO OPA funds to purchase authorized medical equipment and sets for the Medical Center of Excellence to conduct warfighter training.
- Processed 30 amendments to Basis of Issue Feeder Data to align with authorizations.
- Coordinated vendor training and certification for the USAMMA Medical Maintenance Operations Division in order to allow manufacturer-approved repairs and maintenance at the depot-level.
- Executed a Divestiture Roadshow pilot program to address the issue of excess equipment in the field. The team divested approximately $500k of excess equipment, and lessons learned will carry over to additional pilot efforts planned for FY22.

The MEDMOD Product Management Office provides and manages required medical capabilities through continuous analysis, test and evaluation, and acquisition of medical materiel.

The Medical Modernization team was assigned a total of 55 products that were in need of some form of modernization. Contracts were awarded for twelve equipment modernizations through both local contracting and DLA.

The Medical Modernization team led over 30 active Working Groups for modernization projects, to include various stakeholders from across the Enterprise. The Medical Modernization team pulled together a Joint Service Medical Modernization team to bring all Services together to discuss ongoing modernizations, upcoming actions, and how the group could come together to form partnerships and share ideas.

ABOVE: Kenneth Hutchinson, senior biomedical engineer (radiology) at Tracy Defense Depot, provides an overview of the C-Arm system to USAMMDA leadership and staff, including Army Col. Gina E. Adam (left), USAMMDA commander, and Dr. Tyler Bennett (center), project manager, Warfighter Deployed Medical Systems Project Management Office, USAMMDA.

RIGHT: USAMMDA's new C-Arm device undergoes final assembly prior to environmental testing at the U.S. Army Medical Research and Development Command's Test Branch at Fort Detrick, Maryland. (Photo by Jeffrey Soares, USAMMDA public affairs)

USAMMDA Warfighter Expeditionary Medicine & Treatment Project Management Office

● Prototype Development for a Temporary Treatment for Suspected Severe Eye Injuries (Army funded)

There were 1,732 total cases of ocular battlefield injuries reported in a retrospective study of Ocular Battle Injuries among US Military Personnel between 2002 – 2011 (Lo.M et al. USAARL Report No. 2013-12). Our current standard of care for ocular injuries in the far forward environment is to place a rigid piece of material, like the Fox Eye Shield, over the eye and evacuate the casualty directly to Ophthalmic care or eye specialists. No stabilization or treatment exists for non-eye specialists to apply to injuries. Injuries to the eye that cause fluid to leak out and lose pressure need to be treated within 24 hours or the probability of vision deficits and blindness increase.

The Temporary Corneal Repair (TCR) acquisition program at the U.S. Army Medical Materiel Development Activity awarded three Other Transaction (OT) agreements through the Medical Technology Enterprise Consortium to develop a device that can temporarily stabilize suspected severe eye injuries extending the time between injury and surgical repair by an Ophthalmologist.

The awards were made to Critical Innovations, LLC for Eye-Aid™, GelMEDIX for GelPATCH™, and University of Southern California for HEydrogel Sealant System. Eye injuries will be difficult to treat when there are delays in medical evacuations and limited access to surgeons. If successful, the proposed technology will benefit military medicine to stabilize eye injuries and preserve ocular tissue in the attempt to promote better vision outcomes after trauma or surgical repair.

● USAMRDC Stands up Additive Manufacturing Working Group (AMWG) to Address COVID-19 Supply Shortages

Due to the COVID-19 Public Health Emergency, the Department of Defense faced supply shortages for materiel that was critical in the diagnosis and prevention of COVID-19. In response, the USAMRDC created the AMWG in April 2020 to use their expertise in regulatory affairs, project management, legal affairs, and contracting to address these issues. Specifically, the AMWG demonstrated an organic industrial base proof of concept for sterile 3D-printed nasopharyngeal swabs, so in the event of a future need the DoD can rapidly stand up a capability to produce swabs and increase diagnostic capability. The swabs production also supplemented the U.S. Coast Guard Academy's supply shortage, allowing the institution to maintain a safe educational environment. The AMWG also is currently demonstrating an organic industrial base proof of concept for N-95 respirators by partnering with the Naval Undersea Warfare Center – Keyport (NUWC) and Combat Capabilities Development Command - Chemical Biological Center (CCDC – CBC) to manufacture an N95 Elastomeric Half Facepiece Respirator. The AMWG also helped to facilitate the manufacturing and distribution of personal protective equipment to the DoD. As a result, the AMWG served as a one-stop shop for DoD entities to create a unified response for non-FDA approved or 3D printed medical items to COVID-19.

● "Succor Combat Foam for Large Burn Wounds" was awarded to Critical Innovations, LLC through the Medical Technology Enterprise Consortium (MTEC), valued at $2M (Army funded)

In December 2021, the Burn Treatment and Skin Repair (BTSR) program awarded an agreement to Critical Innovations, LLC, titled "Succor Combat Foam for Large Burn Wounds", through the MTEC. The work covered under this agreement is valued at $2M and will further develop the Succor Combat Foam product, a candidate solution under the BTSR program. If successful, this product would satisfy two of the Family-of-Systems (infection prevention and temporizing cover) within the BTSR program with a single, easy-to-use product that provides many benefits over currently fielded products. Medics can easily apply this product as far forward as the point of injury, and can leave it on the wound for prolonged periods. It is also transparent so providers can assess the wound without removing the product, but can easily and painlessly remove it by flushing the product with cold water, if need be. Succor Combat Foam would also be useful in civilian settings for first responders, in emergency departments, and during burn treatment. Application of a burn treatment product closer to the point of injury will decrease mortality and morbidity rates.

ABOVE LEFT: Image of the Eye-Aid System for Acute Ocular Injuries. Eue-Aid is designed to spread topically over eye tissues. (Photo credit: Critical Innovations, LLC)

RIGHT: Bottle of Succor Combat Foam developed by Critical Innovations, LLC. Product is designed to rapidly conform to wound surfaces, reduce wound pain and prevent bacterial adhersion and biofilm formation. (Photo credit: Critical Innovations, LLC)

● The Burn Treatment and Skin Repair (BTSR) Program Released Solicitation for its Family-of-systems Titled “Far Forward Burn Treatment” Through the Medical Technology Enterprise Consortium (MTEC) (Army funded)

In February 2021, the Burn Treatment and Skin Repair (BTSR) released a solicitation for the consumable products under its family-of-systems that will provide a capability to begin treatment of burns on the battlefield. Early intervention of burn injuries in theater will be critical in the future fight, where delayed evacuation and prolonged care could be fatal for the severely burn injured Warfighter. These solutions will provide earlier burn treatment than is currently available in theater, and decrease mortality and morbidity rates. The solicitation, titled “Far Forward Burn Treatment” sought products that can address one or more capabilities in the areas of burn conversion prevention, non-surgical debridement, infection prevention, and temporizing cover. The solicitation was released through the Medical Technology Enterprise Consortium (MTEC) and generated 32 responses from MTEC members. Of those 32 responses, the program invited 12 to submit full proposals. The number of responses provided a wide range of technology options for the BTSR program to evaluate and demonstrated the robust competitive space in burn treatment solutions. The program will make awards from this solicitation in Fiscal Year 2022.

ABOVE: Image of an injectable sponge used to potentially treat deep, penetrating wounds and funded in part by USAMMDA. (Photo credit: USAMMDA Public Affairs)

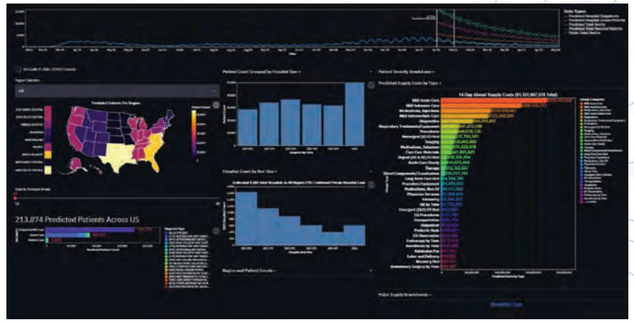
● Phase 2 (Efficacy Human Trial) Clinical Trial to Test Efficacy of Zonisamide, an Anti-Seizure Drug, to Treat Acute Hearing Loss (DHP funded)

The Veterans Benefits Administration Disabilities Report rank hearing loss as the #2 total service-connected disability and #6 of new service-connected disability in FY20. In the same year, 14.5% of Service Members (SMs) enrolled in the Hearing Conservation Program exhibited hearing loss. Currently, there is no FDA-approved drug that treats sensorineural hearing loss. Future conflicts anticipate greater numbers of SMs exposed to acoustic trauma. In future Joint All Domain Operations there is a need for maneuverability and the capability to treat SM hearing impairments in-theater will be critical to sustaining the fighting force.

Washington University at St. Louis is conducting a Phase 2 clinical trial to test the efficacy of Zonisamide, an anti-seizure medication, to treat acute hearing loss after acoustic trauma. The first participant was enrolled in October 2021 and there are two study sites actively recruiting subjects. The randomized and blinded study is in support of the Pharmaceutical Intervention for Noise-Induced Hearing Loss (PINIHL) acquisition program at the U.S. Army Medical Materiel Development Activity. If successful, a pharmaceutical to treat sensorineural hearing loss after acoustic trauma will greatly improve hearing outcomes for the military.

● BioFabUSA Develops a National Demand Forecasting Dashboard to Forecast Supply Shortages during Emergency Scenarios Such as the COVID-19 Pandemic

This project, funded by the 2020 CARES Act and executed by the DOD-sponsored Manufacturing Innovation Institute BioFabUSA in partnership with Neurite, developed and tested a Demand Forecasting Dashboard to help hospital and other treatment facilities forecast supply shortages during emergency scenarios such as the COVID-19 pandemic. This addresses a critical supply chain problem: the lack of real-time inventory tracking data infrastructure and analytics for hospitals, national stockpiles and other medical systems. The supply chain currently lacks transparency with very few reliable, real-time data sets



and consequently medical systems lack visibility of their own needs, leading to supply hoarding during crises. The developer of this Dashboard, Neurite, has partnered with the largest Group Purchasing Organization (GPO) in the US to gain access to 15% of all US medical hospital data (representing hundreds of thousands of patient visits) and has used this data to generate a national level dashboard capable of predicting numbers of patients and future death counts out to two weeks, allowing policymakers to optimize logistics during a crisis. This predictive capacity can be national or regional and can predict patient demand by diagnosis and severity, thereby extrapolating costs of medical supplies needed to treat such patient surges. It can then use that data to generate reports and requisition forms. This National Demand Forecasting Dashboard could revolutionize the way in which hospitals and National Stockpiles could forecast critical supply shortages, predict patient outcomes and mitigate supply chain risks. While developed utilizing a Florida hospital system, future plans include engaging with the Veterans Administration, who is a BioFabUSA member, to demonstrate a real world scenario in a unified and contained health system.

ABOVE: Screenshot of the Supply Forecasting Dashboard developed by BioFabUSA.

USAMMDA Warfighter Health, Performance and Evacuation Project Management Office

● Health Readiness and Performance System (HRAPS) Demonstrated Heat Injury Monitoring Capabilities (DHP funded)

Health Readiness and Performance System (HRAPS), in coordination with the U.S. Army Research Institute of Environmental Medicine (USARIEM), provided heat injury monitoring to over 3,000 Warfighters across the Sapper Leader Course and Best Sapper Competition with the 169th Engineering Battalion, the Ranger Assessment and Selection Program with the 75th Ranger Regiment, and at Crucible Events with the U.S. Marine Corps Recruit Depot (JUN-SEP 2021). The HRAPS' Heat Injury Prevention System (HIPS) was utilized to provide real-time monitoring of Warfighters' core body temperature during rigorous, high-risk training events across the Department of Defense (DoD) in a successful effort to reduce heat injuries. Physiological data was collected and used to inform improvements and evaluate accuracy of USARIEM's heat injury prediction algorithm. Further heat injury monitoring will be conducted in 2022 in an effort to implement widespread adoption of the HIPS system in high risk training events. 12,361 heat-related illnesses were diagnosed from 2015-2019.* First increment will predict when a Service Member is in danger of heat injury during training events , providing actionable information to Cadre and Medical Staff.

In operations, HRAPS provides Commanders with actionable information to minimize non-battle injuries of their Warfighters, maintain overmatch, and maximize human potential to compete and rapidly return to competition.

*Medical Surveillance Monthly Report, Armed Forces Health Surveillance Center, 27(4), pp4-9, April 2020.

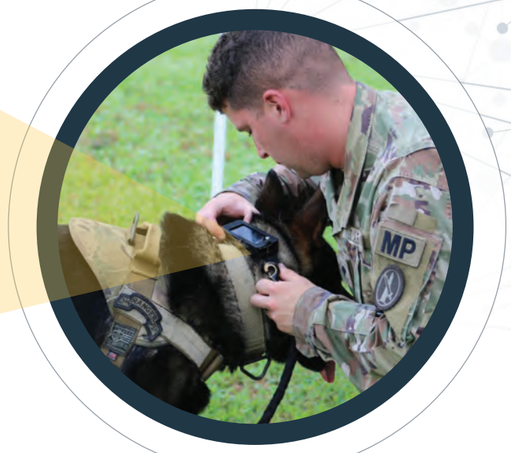
HRAPS also aims to provide a solution to mitigate heat injuries during operations. HRAPS' LifeLens configuration participated in Army Expeditionary Warrior Experiment (AEWE) 2021 using an ultra-miniature, wearable system that monitored the heat risk of sixteen Soldiers each day for forty-eight soldier-mission events. The system provided real-time physiological and geolocation data and demonstrated its ability to calculate heat strain, number of shots fired by each Soldier, overpressure exposure, and gait analysis. Soldiers unanimously did not notice the presence of the device while wearing it. In 2019, there were 507 incident cases of heat stroke and 2,174 incident cases of heat exhaustion among active component service members.*

The first increment will predict when a Service Member is in danger of heat injury during a mission and provide mitigation strategies, solving 90% of the gap.

*References: Medical Surveillance Monthly Report, Armed Forces Health Surviellance Center, 27(4), pp 4-9, April 2020.

ABOVE TOP: LifeLens Technology's harnded gateway tool. designed to facilitate off-body communication.

BOTTOM: Charging station developed by LifeLens Technology.



● Completed Operational Assessment of Canine Thermal Model and Monitor (CTMM)

USAMMDA's WHPE PMO successfully completed an Operational Assessment (OA) of the CTMM at Fort George S. Meade for Military Working Dogs (MWD) in August 2021. The CTMM collar monitor and mobile app software application, a state-of-the-art heat strain decision aid, was provided to MWD handlers, trainers and veterinary staff to be used as a mission planning tool as well as a real time monitor to reduce MWD heat injuries during the test. Eight handlers with their MWDs assessed the CTMM technology over the course of five days where the temperatures and humidity were quite elevated. The OA identified issues for the collar which are being worked. The app worked exceedingly well as noted in the OA to predict and warn of potential heat related issues for the canines.

CTMM mobile app and collar monitor is a state-of-the-art heat strain decision aid for military working dog (MWD) handlers, trainers and veterinary staff. The mobile app works as a mission planning tool to reduce heat injury and safely acclimatize the MWD whereas the collar monitor will assist to provide sensory alerts of the MWD's wellbeing. An Operational Needs Statement (ONS) was developed by the Army Veterinary Command in July, 2015, and validated by the Department of Defense Military Working Dog Veterinary Service (DoDMWDVS) via a Capability Needs Statement (CNS) in June 2020 to address critical heat injuries in Military Working Dogs.

ABOVE: The Canine Thermal Monitor Collar displays a Core Temperature Status Alert. Here, the MWD's core temperature is higher than the CTMC alert status (seen in green) abnd overall predicted temperature. (Image courtesy: Johns Hopkins APL)

● Joint Light Tactical Vehicle (JLTV) Ambulance Kit Received

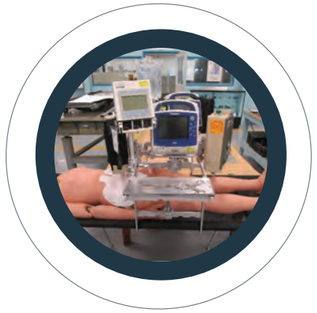
Currently the JLTV program is in production without an ambulance variant. This JLTV prototype was developed for safe medical evacuation of casualties using the existing JLTV utility vehicle. The JLTV Ambulance Kit will have the same mobility and survivability as the other JLTV variants. The kit was completed and delivered to MRDC in November 2021 with demonstrations and assessments planned in April 2022 for US Army Special Operations Command (SOCOM) and 82nd Airborne at Fort Bragg and Army Medical Department (AMEDD) senior leaders at Fort Rucker.

ABOVE FROM LEFT: Image of a JLTV ambulance; Image of a dedicated JLTV ambulance kit inside a JLTV; PMISD frame assembly in folded transport configuration.

● Patent Awarded for Patient Movement Items Support Device (PMISD)

The PMISD is designed to attach to a North Atlantic Treaty Organization (NATO) compliant litter and provide a structure to securely mount required medical patient movement items. The frame of the PMISD has been designed utilizing a common medical mounting rail as its frame thereby providing maximum configuration versatility. This system approach enables medical personnel to use individual medical devices on various medical platforms.

Warfighter WHPE PMO Team, comprised of Mark Brown, Jay Bartlett, Mark Easterday and Scott Walters from the Medical Prototype Development Lab and our Product Manager, Mr. Jaime Lee, received a patent for the Patient Movement Item Support Device. The Patient Movement Item Support Device was designed, developed and prototyped for an Air Force reimbursable project. This project started out as an Air Force reimbursable project that wasn't selected. Due to the unique functional design, interchangeability of medical devices/accessories and interest within the MRDC we applied for and received a patent for the PMISD. Additionally, the technology was transferred to Morzine Medical to produce along with their other related patient movement products.



● Transport Telemedicine System (TTS) Medical Hands-free Unified Broadcast (MEDHUB) PC21 (Congressional and Army Funded)

Transport Telemedicine Systems Medical Hands-free Unified Broadcast (TTS MEDHUB) successfully participated in Army Futures Command's (AFC) Project Convergence '21 (PC21, 04 – 10 November 2021) and the Live Showcase Day at Yuma Proving Grounds (YPG), AZ. PC21 validated TTS MEDHUB's capabilities to integrate, send, and receive data with other systems on the DoD tactical network and demonstrated system compatibly, usability, and safety while on the network and in a degraded network environment. The system demonstrated the ability to function without fail on the Army's future tactical network, consisting of the Integrated Tactical Network (ITN) using Tactical Scalable Mobile (TSM) radios.

This program:

- Provides tactical connectivity across existing tactical network, facilitating expeditionary treatment designed to rapidly stabilize and clear casualties from the battlefield to improve patient outcomes
- Enables quicker patient handoff and re-supply, faster MEDEVAC turnarounds, and a greater quantity of patients evacuated off the battlefield during Large Scale Combat Operations

TTS MEDHUB Patient Awareness Support System (PASS) alerts the field hospital to prepare for incoming casualties based upon receiving multiple patient data such as ETA, Vital Signs (VS), VS trends, and aircraft call sign without engaging the EUD, further reducing medic burden.

ABOVE LEFT: Deployed PMISD Assembly on standard NATO litter.

RIGHT: TTS MEDHUB consists of vital signs monitors and fielded End User Devices to automatically alert, rally, and prepare Army leaders and clinicians of incoming patients. (Photo courtesy: USAMMDA Public Affairs)

USAMMDA Warfighter Protection and Acute Care Project Management Office

● PFIZER Fills Nationwide Need for Safe, Effective Vaccine For Prevention of Tick-Borne Encephalitis (TBE)

Tick-borne Encephalitis virus poses a high risk to United States and allied forces supporting the North Atlantic Treaty Organization alliance in Eastern Europe. TBEV is the fifth most operationally significant infectious disease in US European Command. US Service members had no means to counter the threat other than personal protective measures and supportive care. In August 2021, the U.S. Food and Drug Administration (FDA) granted marketing approval for TicovacTM, a vaccine to help reduce the risk of TBE for people traveling to TBE endemic areas. The vaccine is recommended for persons one year of age and older who are traveling or moving to a TBE-endemic area and will have extensive tick exposure based on their planned outdoor activities and laboratory workers with a potential for TBE virus exposure. TBE vaccination may be considered for persons traveling or moving to a TBE-endemic area who might engage in outdoor activities in areas where ticks may be present. The decision to vaccinate should be based on a shared clinical decision-making assessment of planned activities, risk factors for poor outcome, and personal perception and tolerance of risk. The marketing approval of this vaccine will allow both military and civilians the ability to receive this vaccine to help prevent this deadly disease.

● Next Generation Diagnostics System – Infectious Disease Panel FDA Approval

The FDA granted marketing approval in November 2020 for this diagnostic device used in conjunction with the BioFire FilmArray to test blood samples for the agents that cause Chikungunya Fever, Dengue Fever, Leptospirosis, and Malaria. These four diseases are endemic to geographic areas in which U.S. military forces are or may be deployed. Diagnosis of infections provides information essential to understanding of individual medical readiness, selection of appropriate treatment, and documentation of health status pertinent to long-term health. This product provides actionable information in one hour, rather than days or weeks. Coordination with logistics partners enabled DOD and other customers to begin ordering the Infectious Disease Panel, marketed as the Global Fever Panel, in July 2021. These rapid, sensitive, and specific tests support health care and medical readiness worldwide.

ABOVE LEFT: Box containing the Tick-Borne Encephalitis Vaccine. (Image courtesy: Pfizer, Inc.)

RIGHT: Image of the Global Fever Panel by BioFire Defense. (Image courtesy: BioFire Defense, LLC)

● USAMMDA Achieves Full Operational Capability for Malaria Treatment Drug – Intravenous Artesunate (MTD-IVAS)

Malaria remains a threat to military operational readiness. The need for MTD-IVAS is critical because malaria remains one of the top infectious disease threats to Service Members deployed to tropical and subtropical regions. In March 2021, the MTD-IVAS program had a successful Milestone C Decision Review, which was followed by the commercial launch of the product and inclusion into the Defense Logistics Agency's Pharmaceutical Prime Vendor (PPV) Contract. The program also achieved all the Production and Deployment Exit Criteria as specified in the Milestone Decision Authority approved Acquisition Decision Memorandum. After achieving Full Operational Capability, with successful shipments to European Command, Indo-Pacific Command, and U.S. Forces Korea, the program entered the Operations and Support (O&S) acquisition Phase. The fielding and commercialization of MTD-IVAS and inclusion into the Pharmaceutical Prime Vendor contract will allow medical treatment facilities the ability to commercially obtain the drug to treat this deadly disease. The Defense Logistics Agency's Pharmaceutical Prime Vendor program will be the procurement vehicle to execute supply chain activities in the O&S Phase.

ABOVE LEFT: Image of the antimalarial drug Artesunate for Injection (Image courtesy Amivas)

RIGHT: Varespladib tablets.

● USAMMDA and Partner Ophirex, Inc. Initiate Phase 2 Clinical Trial to Investigate PLA2 Inhibitor Varespladib for Treatment of Acute Respiratory Distress Syndrome (ARDS) Caused by SARS-CoV2

WPAC partner Ophirex, Inc kicked off a Phase 2 clinical trial in patients hospitalized with moderate to severe COVID-19, with the first patients being screened and enrolled in July 2021. Patients were randomized to receive investigational drug oral varespladib 1x, 2x or 3x daily, or placebo and followed for outcomes related to the progression or abatement of symptoms related to ARDS, including disease severity score, need for supplemental oxygen, and time hospitalized. This trial may yield a new and powerful way to treat a primary cause of death in COVID-19 patients and could give insight into combating ARDS from other causes.

● Whole Blood Pathogen Reduction Technology Program Termination

Whole blood collection for transfusions in an operational environment occur when stored blood is not available or is depleted. There is a real risk of transmitting infections via whole blood from contingency collections, due to the lack of comprehensive testing ability. Whole blood pathogen reduction was intended to mitigate this risk. Despite significant efforts to develop an effective and fieldable technology, the program office concludes the technology requires further maturation before further investment is warranted. The development program was terminated in September 2021, and new solutions sought to fill the capability gap. The rapid donor screening program, a replacement for WBPRT, aims to pre-test donors with FDA-approved donor screening assays. These assays will provide an important tool for medical providers that mitigates blood transfusion risks.

● SCoV-2 Rapid Diagnostic Lateral Flow Tests

The WPAC PMO's partner, InBios International Inc., received Emergency Use Authorization (EUA) from the Food and Drug Administration (FDA), for their point-of-care (POC) assays detecting SARS-CoV-2 direct antigen (SCoV-2 Ag DetectTM Rapid Test) and antibodies (SCoV-2 Ab DetectTM Rapid Test) on 6 May 2021 and 24 August 2021, respectively. These tests are among the simplest SARS-CoV-2 rapid tests available on the market. They require no instrumentation or transport media and performed on-site with results delivered in less than 30 minutes. Development of these rapid tests has been a "whole-of-government" effort in collaboration with and funding from Defense Health Agency CARES ACT and the Biomedical Advanced Research Development Agency (BARDA) in response to the global COVID-19 pandemic.

ABOVE FROM LEFT: SCov-2 Ab Detect Rapid Test (Serology POC); SCoV2 Ag Detect Rapid Test (Antigen POC); SCoV2 Ag Detect Self-Test (Antigen OTC). (All images courtesy InBios International, Inc.)

● BioFire Defense COVID-19 Test 2 510(k) Submission and Sample Type Expansion for BioFire Defense COVID-19 Test EUA

BioFire Defense submitted a request to the FDA for full regulatory approval, in the form of 510(k) clearance for this rapid, highly sensitive and specific, test for COVID-19 in nasopharyngeal swab (NPS) specimens in April 2021, to reduce the risk that changes in the FDA's regulatory approach might adversely affect the utility of this test. In March 2021, the FDA authorized the addition of the following sample types to the emergency use version of the BioFire COVID-19 Test: Oropharyngeal, mid-turbinate and anterior nasal swab specimens, induced or expectorated sputum, endotracheal aspirates, bronchoalveolar lavage, and mini-bronchoalveolar lavage. The FDA also authorized the use of normal saline and phosphate-buffered saline as transport media types. Collectively, these actions increased the probability of detection of SARS-CoV-2 and decreased the impact of shortages in materials used to collect and transport specimens.

ABOVE: A Soldier administers a vaccine dosage during the height of the novel coronavirus pandemic. (Photo credit: U.S. Army Public Affairs)

USAMMDA Force Health Protection Directorate

● FHP Global Distribution of Monoclonal Antibody Therapeutics.
In November 2020, FDA authorized the use of the Eli Lily monoclonal antibody (mAb) therapeutic, Bamlanivimab, for treatment of patients with mild to moderate COVID-19. FHP assisted with DoD-wide distribution of the intravenous therapeutic for use in outpatient settings, to both U.S. continent (CONUS) and outside the U.S. continent (OCONUS) MTFs. Additional monoclonal antibodies, Casirivimab/Imdevimab, Etesevimab, and Sotrovimab were added to the distribution during 2021. FHP distributed 1, 360 treatment courses of EUA Monoclonal Antibodies to 42 MTFs. The receipt of mAbs, allowed the MTFs to establish protocols and treatment sites at their facilities to treat patients with mild to moderate COVID-19 symptoms and prevent progression of symptoms and prolonged hospitalization.

ABOVE: Packaging for REGEN-COV (casirivimab and imdevimab, administered together), a monoclonal antibody therapy for post-exposure prophylaxis (prevention) for COVID-19, which was authorized by the FDA in mid-2021. (Image credit: Regeneron Pharmaceuticals Inc.)

● FHP Provides Treatment for the Military's COVID-19 Patients Using Remdesivir in an Expanded Access Treatment Protocol (EAP) and Global Distribution Under Emergency Use Authorization During the Pandemic.
FHP along with regulatory support from U.S. Army Medical Research and Development Command (USAMRDC), established an Investigation New Drug (IND) Expanded Access Protocol (EAP) for Remdesivir in March 2020. The protocol established 26 DoD Medical Treatment Facilities (MTF) worldwide and shipped 1,100 vials that allowed 40 patients to receive life-saving treatment for moderate to severe symptoms of COVID-19. The EAP closed for patient enrollment when the manufacturer, Gilead Life Sciences, received Food and Drug Administration (FDA) approval for Veklury® on October 22, 2020. The IND was officially closed on April 7, 2021.

ABOVE: Packaging for etesevimab, an antibody therapy approved by the FDA for emergency use in COVID-19 patients under the age of 12 in late 2021. (Image credit: Eli Lilly and Company)

The FDA granted an Emergency Use Authorization (EUA) to Gilead Life Sciences to use remdesivir for treatment of hospitalized patients diagnosed with severe COVID-19. Defense Health Agency (DHA) delegated EUA remdesivir distribution to FHP as the centralized DoD hub for storage, distribution, and shipping to authorized medical treatment facilities (MTF) in order to meet regulatory requirements for distribution of investigational products. FHP shipped 22,000 vials of liquid and 800 vials of lyophilized Remdesivir to 72 MTFs worldwide through 400 shipments, which allowed the treatment of 3,304 COVID-19 patients.

● FHP Provides Treatment for the Military's COVID-19 Patients Using COVID-19 Convalescent Plasma (CCP) in an Expanded Access Treatment Protocol (EAP) During the Pandemic.
FHP received USAMRDC Headquarters Institutional Review Board (HQ IRB) approval for the protocol "Expanded Access Protocol for Treatment of Coronavirus Disease 2019 (COVID-19) with Anti-SARS-CoV-2 Convalescent Plasma (ASCoV2CP)" in 2020. In 2021 FHP continued to actively set up sites and enroll patients. Treatment indication was expanded to make available up to 2 units of high titer CCP to any hospitalized COVID patients throughout the Military Health System. Globally, 37 sites were established including Army, Air Force, and Navy MTFs and ships including air craft carriers. There were 110 patients enrolled by 1 June 2021 when the protocol was closed to enrollment as sites had access to Emergency Use Authorization compliant high titer CCP through the Armed Services Blood Program (ASBP). The protocol was closed by HQ IRB on 2 November 2021.

RIGHT: Patient receives monoclonal antibody treatment for COVID-19.

USAMMDA Force Sustainment Directorate

● FSD Supports Each USAMMDA Program Management Office (PMO), Executing the Procurement and Assembly of Medical Equipment Sets (MES), and Executes Medical Materiel Fieldings Providing Medical Assemblages and Associated Equipment Globally to the Operational Forces.

FSD executed the procurement, assembly and fielding of over $100 million worth of medical equipment requirements for the operational forces globally. They procured 794 medical equipment sets through the Theater Enterprise Worldwide Logistics system or through local contracting. FSD executed equipment Stock Transport Orders (STOs) in TEWLS issuing 6986 pieces of medical equipment. FSD executed 229 fielding missions throughout FY21, including four Hospital Centers and two Forward Resuscitative Surgical Detachment (FRSD) conversions allowing commanders and planners to employ specific capabilities to meet specific mission requirements and provides the deployability and flexibility required to support projected patience workload Additionally, FSD continued to field units through innovative measures during COVID travel restrictions that impacted scheduled missions both locally and abroad. Through the use of technology and incorporation of virtual-based fieldings, the Materiel Fielding Team was able to execute fieldings to more than 500 units enabling the Army to deploy with increased medical readiness and capabilities.

ABOVE: Dave Wirtz, Jr., product manager for USAMMDA's Medical Devices Assemblage Management team within the Warfighter Deployed Medical Systems Project Management Office, briefs the 3rd Special Forces group from Fort Bragg, North Carolina, during the team's Hospital Center conversion project in November 2021. One aspect of the hospital conversion program involves divestiture of older equipment. (Photo courtesy of USAMMDA WDMS PMO)

Soldiers and contractors clear an area in order to make way for the establishment of a temporary medical facility. (Photo credit: U.S. Army Public Affairs)

U.S. ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND

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