U.S. ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND

2020 COMMAND ACCOMPLISHMENTS






USAMRDC CUTTING EDGE SCIENCE AND TECHNOLOGY:

SOLDIER READINESS AND LETHALITY

USAMRDC 2020 Command Accomplishments

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

While the desire to continuously and methodically move forward drives the very purpose of this command, it is also important to review our achievements. Those accomplishments –and trust me, there are many– reveal this command and the Soldiers, Civilians, and contractors who make the wheels turn on daily basis to be worthy of the investment offered by this great Nation.

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, 2020 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

Combat Casualty Care Research Program
CCCRP

Joint Trauma Analysis and Prevention of Injury in Combat
JTAPIC

Blast Injury Research Coordinating Office
BIRCO

Military Operational Medicine Research Program
MOMRP

Biotechnology High Performance Computing Software Applications Institute
BHSAI

Medical Robotics and Autonomous Systems Lab
MEDRAS

Enterprise Information Technology, Project Management Office
EIT, PMO

USAMRDC CUTTING EDGE SCIENCE AND TECHNOLOGY:

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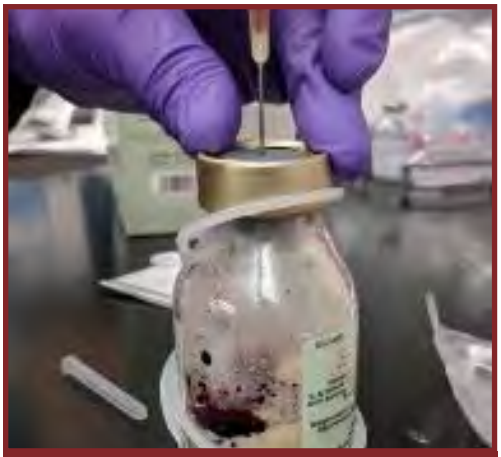
Ensuring the Warfighter's ability to operate at peak physical condition in their efforts to secure operational success in any scenario.

Free, Blood: Progress Toward Elimination of the Cold-Chain Requirement for Blood

The use of hemoglobin-based oxygen carriers *(HBOC)* as a reconstitution solution for freeze-dried plasma *(FDP)* was examined in a model of hemorrhagic resuscitation and found to be superior to a combination of both HBOC and water-reconstituted FDP in-vitro diagnostics. These efforts represent the foundations in the development of an engineered plasma to treat acute traumatic bleeding disorders at-or-near the point of injury. ***CDMRP***



Empowered Braind Sample Modules

Via Funding from the Combat Casualty Care Research Program, USAISR Publishes Burn **Wound Severity Classification** to Support Care Decisions

U.S. Army Institute of Surgical Research scientists published Army-funded novel findings to enable currently unavailable prehospital strategies to assess burn wound depth in the absence of evaluation by a burn care specialist; the same kind of expert evaluation that likely may not be available close to the point of injury. Spatial frequency-domain imaging of burn wound depth is one of several lead technology candidates for burn wound depth determination that may be amenable to forward deployment in multi-domain operations *(MDOs)* to support treatment decisions to keep Warfighters in their units to sustain combat effectiveness in Theater versus decisive determination for need for evacuation ***USAISR***

Via Funding From the Combat Casualty Care Research Program, **USAISR Publishes "Identification** and Description of a Relationship Between Burn Wound Location and Recovery Outcomes"

USAISR scientists published novel findings that demonstrate a relationship between burn wound location and recovery outcomes. These findings are important in describing a correlation that may be utilized in algorithms for triage and prehospital treatment decisions, in addition to the traditional paradigm focused on total body surface area and rudimentary tools for burn wound depth assessment. Such efforts currently rely on burn care specialist providers not available in the prehospital environment. This advancement will contribute to advanced, simplified tools to support care decisions closer to the point of injury by lesser-skilled caregivers. ***USAISR***

Via Funding From the Combat Casualty Care Research Program, USAISR Develops Acute Compartment Syndrome Extremity Animal Model

Scientists at USAISR have developed an animal model of extremity acute compartment syndrome to mimic Acute Compartment Syndrome *(ACS)* in traumatic injured casualties. The model will enable objective comparison of new and emerging devices. These devices will enable the accurate detection of ACS in casualties for early intervention strategies to be employed at the earliest possible echelon of care in a large scale operation environment. ***USAISR***

Kidney Functional Support Capability with Extracorporeal Life Support (ECLS)

Scientists at USAISR, partnering with the Geneva Foundation and funded by the CCCRP, have worked on characterizing ECLS devices to provide kidney support. They have successfully determined the optimal device settings to achieve the best outcomes in preclinical models. This information was successfully transitioned as a knowledge product to the Joint Trauma System. This knowledge product will add to a

growing number of innovative approaches to care for casualties with kidney failure in a large scale combat operation environment.

USAISR

Novel Lung Support Strategies with Extracorporeal Life Support Devices

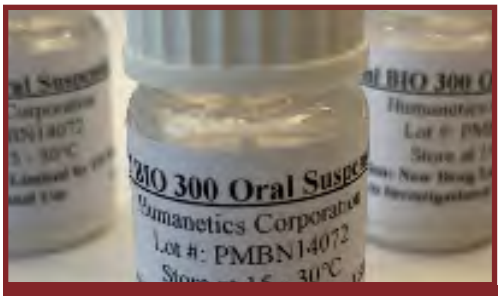
Scientists at USAISR, funded by the Combat Casualty Care Research Program, have initiated clinical trials to assess effectiveness of novel lung support strategies to improve outcomes after trauma. Scientists are currently investigating safety and feasibility measures to employ novel lung strategies in acute respiratory distress syndrome *(ARDS)* patients in lieu of mechanical ventilation. The impact of these novel strategies will provide a modern and innovative approach to the treatment of casualties with lung failure. These strategies will push optimal care to the earliest possible echelon of care to assist in large scale combat operations.

USAISR

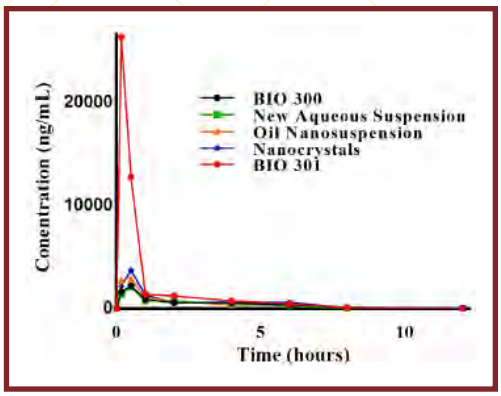
Pre-Clinical Studies Lead to FDA-Approved of Drug to Treat COVID-19, Prevent Pulmonary Fibrosis

With funding from the CDMRP's Peer Reviewed Medical and Joint Warfighter Medical Research Programs, Humanetics Corporation developed an oral suspension drug product *(BIO 300)* containing genistein, a compound that stimulates DNA damage protection and repair, as an effective therapy to prevent the negative health effects of radiation treatment (such as pulmonary fibrosis). Data from the CDMRP-funded pre-clinical and human safety studies supported an additional FY20 PRMRP COVID Expansion Award to evaluate repurposing the BIO 300 oral suspension as a post-COVID-19 therapeutic intended to prevent the development of pulmonary fibrosis in survivors of COVID-19-associated ARDS. These studies highlight the progress toward essential prevention and/or treatment of damage and scarring in the lungs, especially due to emerging respiratory viral threats, and acute radiation exposure.

CDMRP



Empowered Braind Sample Modules

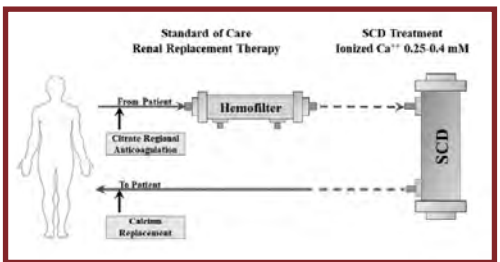


Novel candidate formulation optimized for the warfighter "BIO 301" has been identified under current CDMRP funding. This formulation also appears to dramatically improve the drug exposure (thus likely potency) with identical doses compared to the current.

Successful Treatment of Cytokine Storm in COVID-19 Patients with Extracorporeal Immunomodulatory Therapy

With funding from the CDMRP's Peer Reviewed Medical Research Program, Innovative BioTherapies, Inc. developed the selective cytopheretic device therapy *(SCD Rx)* to reduce inflammation-related disease processes in trauma, pathogen-induced, or other causes of acute respiratory distress syndrome *(ARDS)*. Preclinical studies of a pig ARDS model allowed investigators to obtain an investigational device exemption from the FDA for use in a future clinical trial. Preclinical data were so robust that the SCD Rx was given FDA emergency use authorization for several ICU patients with COVID-19 treated at the University of Michigan with encouraging results recently published in a peer reviewed journal. This is a critical step in developing targeted therapies to treat and improve clinical outcomes in patients suffering from ARDS, which has lacked specific therapeutic treatment.

CDMRP



Selective Cytopheretic Inhibitory Device

Selective cytopheretic inhibitory device used in continuous renal replacement therapy system. SCD, Selective cytopheretic inhibitory device.

SOLDIER READINESS AND LETHALITY

Portable Stimulator Improves Vestibular Function in Veterans

Research funded through CDMRP's Gulf War Illness Research Program developed a portable neuromodulation device to treat vestibular dysfunction (such as dizziness or trouble with balance, hearing or vision) in Gulf War Veterans. Additional development of this technology was supported through a subsequent Traumatic Brain Injury and Psychological Health Research Program award and five 2019 Defense Health Agency Small Business Innovation Research *(DHA SBIR)* Phase 1 awards. In 2020, a Phase 2 DHA SBIR call resulted in a single award to Phase I recipient Vivonics, Inc., for further development of the stimulator, including pilot clinical trials, to move this technology toward commercialization. If successful, this device could potentially enable Service Members to return to duty and restore function for others after suffering injuries that result in vestibular dysfunction.

CDMRP

Major Shift in Assessing Burn Patients' Functional Outcomes for Improved Disability Diagnosis and Physical Therapy Prescription

Goniometry is an accepted clinical practice used to assess post-injury outcomes by measuring a patient's joint range of motion. It has been used for more than 90 years without consideration of patient's injury type or differences between scar-free trauma versus burn scars and currently does not take into account burn scars near or around the joints, which may limit a patient's range of motion or functional outcomes. With funding from the CDMRP's Military Burn Research Program, physical therapists at the University of California, Davis and the USAISR completed a multi-center clinical study that compared the current goniometry method versus a revised goniometry method that positions the measurement to include burn scars in burn patient populations. The data showed that in burn patients with scar contractures, the revised goniometry determined significantly more limitations in joint range of motion than assessments made using the standard goniometry. In FY20, the funded award produced and disseminated several scientific publications and presentations, digital guides, video instructions, and a "Scar Goniometry" app on the Android and iOS platforms to teach other physical therapists at no cost how to implement the revised goniometry method for burn patients. Thus, physical therapists can now appropriately diagnose the severity of disability and functional limitations in burn patients. This provides clinicians a more accurate assessment of how the burn scar affects the burn survivor's daily function, which is important in developing a rehabilitation plan for improved quality of life. The International Society for Burn Injury (ISBI) and American Burn Association (ABA) recognized the importance of these research findings with awards for the published paper and abstracts.

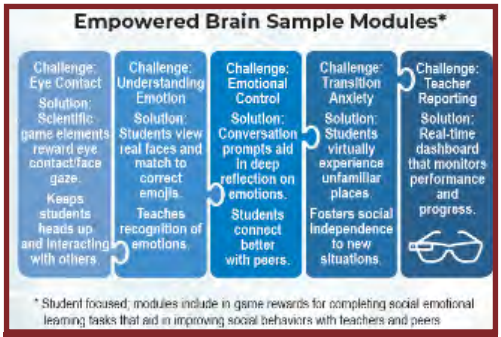
CDMRP

Burn Patient With Scar Contractures That Limit Elbow Flexion

Virtual Reality Platform Improves Employment Skills for Transitioning Adults with Autism

Funded through an Idea Development Award from the CDMRP's Autism Research Program Brain Power LLC developed a virtual reality (VR) technology platform called "Empowered Brain" to improve social interaction and employment skills for young adults with autism. With "Empowered Brain", individuals look through a pair of Google Glasses, which interfaces with VR displays designed to improve skills across several domains and reduce user stress and anxiety. The investigators have published ten peer-reviewed articles on use of this technology and its capacity to aid in developing social and behavioral skills for individuals with autism. The technology platform has already been used in several U.S. school districts.

CDMRP



Empowered Braind Sample Modules

Military Infectious Diseases Research Program Shifts Focus **to MDO to Support Warfighter**

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CDMRP

Development of Mobile Behavioral Health and Sleep Intervention Tools

Intramural investigators at WRAIR have partnered with industry scientists (Design Interactive, Inc, and Rehat, LLC) to develop mobile technology for continuous real-time monitoring of physiological measures of stress response and sleep. This technology includes the Mobile Stress and Anger Management (MSAT) wearable watch, and the NOCTEM sleep intervention mobile application for smart devices. Real-time data is then entered into a patient-provider portal where it can be assessed and behavioral health care and sleep interventions can be administered. These types of mobile solutions can be used in Role of Care (ROC) 4, but are also being piloted for use in far forward settings at ROC 1 where interaction with providers is asynchronous and in-person access to providers is not available.

WRAIR

Role of Care (ROC)

Head-supported Mass (HSM) Guidelines to Prevent Injury Risk and Performance Decrement

Head protection systems are based around the helmet serving as a common mounting platform for Warfighter technologies, such as night vision goggles *(NVGs)* that give our Warfighters

an advantage over the enemy. However, the increased stress placed on the musculoskeletal ligamentous neck can lead to rapid onset of musculoskeletal fatigue, pain, and potential long-term degenerative changes. USAARL is collaborating with the U.S. Army Combat Capabilities Development Command - Soldier Center (*CCDC-SC)* and Program Executive Office *(PEO)* - Soldier to deliver standardized methodology to measure HSM, and working with academic and industry partners to develop acute injury risk criteria for HSM in order to support the Army Public Health Center *(APHC)* Health Hazard Assessment *(HHA)* program. USAARL delivered performance based HSM criteria to PEO-Soldier and to the U.S. Marine Corps Systems Command (PM-Marine Expeditionary Rifle Squad) to support roll out of the next generation of night vision goggles. The APHC used the updated HSM criteria to revise their Health Hazard Assessor's Guide Technical Guide 351, which will support dismounted HHA for new and some existing head borne materiel systems.

USAARL

MOMRP Key Participant in Futures Integration Directorate-led Maximizing Human Potential (MHP) Integrated Concept Development Team (ICDT)

The MHP ICDT's mission will derive critical human experiences from the collection and analysis of insights and vignettes across the Army Modernization Enterprise and both transform and consolidate those insights into "Meta-Insights". This will provide a vision of the human-level future operational environment *(HFOE)*, project vignettes into the future using the HFOE, and then score them to determine the ones that humans must dominate in order to ensure future mission success. MOMRP's participation in the ICDT assists in developing this supporting concept that will be a foundational document for the Army in defining the future operational environment for human potential as well as and one that will have significant impact on MRDC's S&T efforts for the future.

MOMRP

MOMRP, U.S. Army Medical Materiel Development Activity (USAMMDA) and U.S. Army Research Institute of Environmental Medicine (USARIEM) Collaborate and Participate in Arctic Warrior Exercise 21 in Support of (ISO) the Army Arctic Strategy **Development and Refinement** to Regain Arctic Dominance

As the Army continues to define capability requirements for cold region expeditionary medical operations in support of the implementation of the 2019 Department of Defense Arctic Strategy, the MOMRP, USAMMDA's Warfighter Performance and Evacuation Project Management Office *(WHPE PMO)*, and USARIEM collaborated with the U.S. Army Alaska *(USARAK)* Surgeon to demonstrate the Cold Weather Ensemble Decision Aid *(CoWEDA)* during the Arctic Warrior 21 Exercise. The CoWEDA has been designed to provide Service Members with a capability to model and simulate cold protection and its impact on performance, optimize mission planning for cold injury risk mitigation, and to determine clothing and equipment needs specific to mission demands; all of which are currently unavailable. The Arctic Warrior 21 Exercise executed a cold weather training event in order to validate the 4-25 IBCT *(ABN)* cold weather training readiness and capabilities, current equipment cold weather capability, and to provide detailed feedback and observation of current MTOE equipment sets as well as demonstrations of capabilities like the CoWEDA to the USARAK ISO of the Army's further development and refinement and to man, train, equip, and organize to win in the Arctic.

MOMRP

Beyond Reality: New AUGMED Tool Pushes Limits of Medical Simulation

The AUGMED is a multi-platform medical simulation tool designed to prepare Soldiers for the application of medical interventions in stressful or unpredictable situations. Training can be performed on both a standard tablet computer and, also, via a pair of Microsoft HoloLens virtual reality goggles; the latter of which stands the device's main draw and additionally provides for a deeper, more immersive experience. The insertion of the AUGMED into the Combat Lifesaver *(CLS)* course at Fort Indiantown Gap *(FTIG)* was designed as a stress test of sorts – as a way for both scientists and designers to gauge "usability" of the device and to obtain Soldier feedback as well. The long-term goal of the technology is to make Soldiers proficient in key life-saving skills at a faster rate and, also, to allow course participants to retain those skills over a longer period of

Warfighters Utilizing AUGMED Tablets for Virtual Reality Training

time. The team is also working with stakeholders and Program Management Medical Simulation and Training *(J4 PM MST)* to obtain additional end user feedback. Ultimately, MSISRP scientists hope they can help supplement the standard Army training regimen in new and different ways

MSISRP

CyberQuest 2020 Demonstration of the Virtual Medical Portal and Medical Data Cloud

In September, CyberQuest 2020 held demonstrations for Remote Training, Scenario Execution, and Virtual Presentations including the technology derived from joint MSISRP-DHA funded efforts of the Virtual Medical Portal and Medical Data Cloud. The project provides a medical data tactical cloud capability that supports transmission of theater/operational medicine patient data (e.g. physiological vital signs, patient history) as well as the virtual medical portal (Joint Medical Exchange for Combat Casualty Care - JMEDIC3). Team members from the Telemedicine & Advanced Technology Research Center *(TATRC)* lab completed these exercises in South Carolina. These demonstrations were utilized as medical integration and engagement into scenarios for real world application. The technology will also have future implications within the Army Network Cross Functional Team *(N-CFT)* in prolong care environments and additional exercises.

MSISRP

Medical scenario using the Forward Ready Advanced Information Module (FRAIM) prototype. This capability would be initially paired with JPC-1's Medical Data Cloud to collect end user feedback.

Medical scenario simulation using telemedicine capabilities for health status.

" Trauma Care in a Rucksack (TRACIR)": Building Foundations, Building the Future

The University of Pittsburgh, School of Medicine continues to research and develop the Trauma Care in a Rucksack *(TRACIR)* effort. Despite the pandemic restrictions the performer exceeded in collection and analysis of pre-hospital trauma data. These efforts support building an automated resuscitation system to further advance hemodynamic analysis research. Utilizing these datasets and analysis also provides the team strategic planning and advancements necessary to create an automatic artifact detection and censure system critical to future solutions. These efforts will allow the team to build essential models to test accuracy and linkages between trauma patient data and feedback loops that are imperative to implementation of closed-loop trauma resuscitation systems. Lastly, these advances further develop foundational concepts for identification of common biological signatures of STAT Medical Evacuation patients needing life-saving interventions leading to more accurate predictive analytics modeling. These modernization efforts provide iterative solutions and increase the capability and capacity of future caregivers.

MSISRP

RACIR will provide a next generation intelligent cardiopulmonary resuscitation management tool at its core.

System and Method for Reconstruction of Explosion Impact on Humans Using Pressure Sensor Data

Through a DOD Small Business Innovation Research (SBIR) program managed by the DOD Blast Injury Research Coordinating Office *(BIRCO)*, CFD Research Corporation has designed, developed, and demonstrated the CoBi-blast Injury Simulation framework. This modeling framework consists of improved whole body and detailed brain injury models for simulations of explosive blast events, blast

SOLDIER READINESS AND LETHALITY

loading on the human body, and injury prediction. Through coordination with TRADOC Capabilities Manager *(TCM)* Ranges, the CoBi-blast Injury Simulation framework is being considered for integration with the Range Manager ToolKit. This new capability, the Blast Overpressure *(BOP)* Tool, will assist installation range management authorities, master gunners, and commanders in range planning to ensure training is safe and as realistic as possible. Routine use of this tool in planning range exercises for heavy weapons will help sustain lethality of the force while promoting Warfighter health and safety.

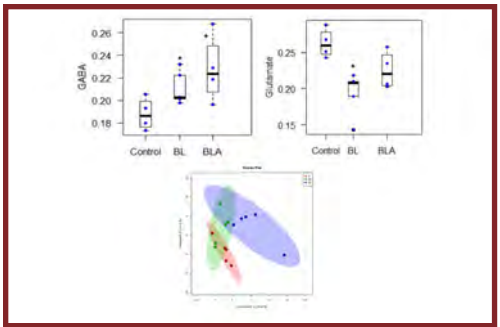
BIRCO

CoBi-Blast Tool

Strategic International Collaboration **for Warfighter Brain Health**

To optimize performance and lethality in he Multi-Domain Operations environment, sustaining Warfighter health is critical. Rapid transition of blast injury prevention and treatment strategies relies on a thorough mechanistic understanding of blast-induced traumatic brain injury *(TBI)*. As part of the strategic international collaboration between the U.S. and India, collaborators performed research to determine the effects of oxidative stress on metabolomics profile changes in blast-induced TBI. Building upon previous work, the team evaluated how oxidative stress affects metabolomics profiles in the brain after blast-induced neurotrauma. Studies such as these build towards a better understanding of the mechanisms of cell and tissue damage after blast exposure. Further research in this area will benefit Service members by accelerating prophylactic or therapeutic approaches to TBI.

BIRCO



Blast Exposure Changes Brain Metabolomics Profiles

Preserving Hearing and Quality of Life through New Auditory Injury Prevention Standards

To address the need for a better auditory injury prevention standard, the DOD Blast Injury Research Coordinating Office *(BIRCO)* led the Military Health System Blast Injury Prevention Standards Recommendation *(BIPSR)* Process. The BIPSR Process is the DOD's first ever stakeholder-driven process that provides in-depth and unbiased assessments of candidate blast injury prevention standards. Through the BIPSR Process, subject matter experts have identified 14 existing candidate auditory injury prevention standards and are evaluating their suitability for use in health hazard assessments, combat platform occupant survivability assessments, and protection system development and testing. The BIPSR Process may allow the DOD to implement new injury prevention standards using existing information, and without costly and time-consuming new research efforts.

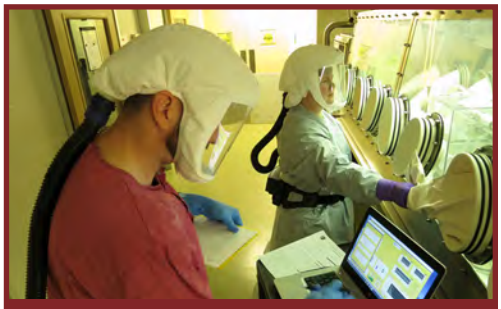
BIRCO

iBIPSR Process

USAMRIID Develops Foundational Animal Models for Testing COVID-19 Medical Products

One of USAMRIID's core competencies is the ability to rapidly develop animal models that successfully replicate human diseases in order to support medical countermeasure development. USAMRIID established several animal models of COVID-19 infection, including the first lethal disease model of COVID-19 (in mice). USAMRIID's Syrian hamster model was selected for use in ongoing Operation Warp Speed studies to rapidly identify effective therapeutics. In addition, USAMRIID was one of the first laboratories in the world to quickly develop and validate imaging techniques to visualize the novel corona-virus in animal tissues, and created highly sensitive assays to assess the efficacy of medical countermeasures in animal models. This body of work is essential for testing vaccines, treatments and diagnostic tools to satisfy Food and Drug Administration requirements for licensing COVID-19 medical products to protect U.S. fighting forces.

USAMRIID



USAMRIID COVID-19 Animal Models

USAMRIID Provides Round-the-Clock COVID-19 Diagnostic Support to U.S. Fighting Forces

As the DOD's only Biosafety Level 4 capable clinical lab in the Centers for Disease Control's Laboratory Response Network, USAMRIID plays a critical role in medical diagnostics for the Warfighter and the Nation. USAMRIID serves as a round-the-clock confirmatory laboratory for the DOD, providing diagnostic testing for mission-critical military personnel to help leaders make informed decisions about Force protection and return to duty. USAMRIID refined and tested multiple laboratory assays to identify COVID-19 positive samples and developed methods for determining protective antibody levels. USAMRIID worked with CCDC to assess lateral flow assays for use in identifying suitable convalescent plasma donors and determining their potential immune status based on prior exposure. In addition, USAMRIID developed a COVID-19 biosurveillance approach combining next-generation sequencing and pooled testing, which has the potential to increase DoD diagnostic capacity while helping to alleviate the logistical burden.

USAMRIID

USAMRIID COVID-19 Diagnostics

SOLDIER READINESS AND LETHALITY

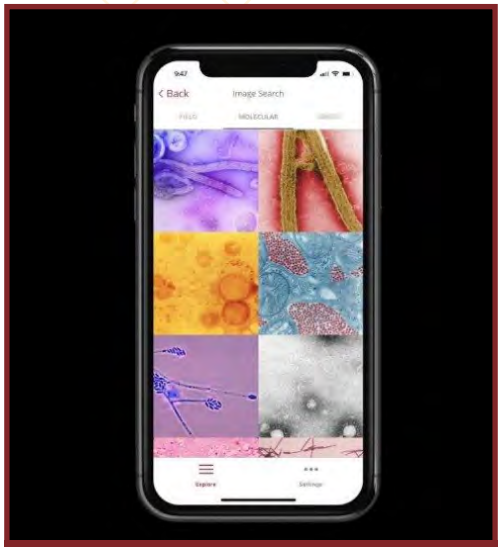
USAMRIID Identifies Key Therapeutic Strategies for Treating COVID-19 Infection

USAMRIID develops medical countermeasures to protect U.S. Service Members against biological threats and emerging diseases. On the therapeutics front, USAMRIID performed pivotal animal studies of the drug remdesivir that laid the foundation for FDA approval as a treatment for COVID-19. USAMRIID also screened multiple drug compounds provided by collaborators, using its high-throughput screening capability to quickly identify candidates with potential activity against SARS-CoV-2. USAMRIID worked with industry partners to assess monoclonal antibodies as a potential treatment for COVID-19, and identified a candidate that showed promise in the hamster model of infection. In addition, USAMRIID and CCDC-ARL took part in a study that linked antibody levels in COVID-19 patients to their ability to control infection, and provided potential benchmarks for the development of convalescent plasma as a treatment for the disease. ***USAMRIID***

USAMRIID COVID-19 Therapeutics

USAMRIID Develops Mobile Application/Pocket Tool for Biological Agents

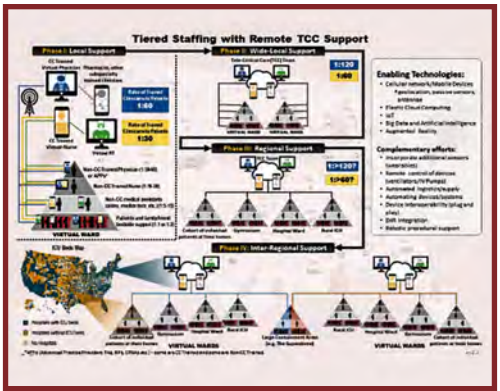
USAMRIID developed the first-ever mobile application that serves as a quick reference guide to biological agents and a tool for matching clinical signs and symptoms to the agent that might be present. In addition to being useful to Service Members, it can be used by any healthcare professional with an interest in learning more about biological agents, as it provides quick access to data and images describing prevention, treatment, and common symptoms. The app was created by the Training and Education Department within USAMRIID's Division of Medicine, which strives to make the scientific and clinical information developed by the Institute readily available to our Service members and partners. TRADOC has reviewed the application and published it to the IOS and Android stores for free download to the public. ***USAMRIID***



USAMRIID App for Bio Casualties Training

Cutting-Edge "National Emergency Telecritical Care Network (NETCCN)" Launches

In support of the ongoing COVID-19 response, the USAMRDC's Telemedicine and Advanced Technology Research Center *(TATRC)* is working with clinical and technical teams to support the rapid development, deployment and testing of the National Emergency Telecritical Care Network *(NETCCN)*. NETCCN is a cloud-based, low-resource, stand-alone health information management system for the creation and coordination of flexible and extendable "virtual critical care wards." These high acuity, virtual wards bring high-quality critical care capability to nearly every bedside, be it healthcare facility, field hospital, or gymnasium. Based on cellular communication networks, mobile technologies and cloud computing, the NETCCN will support



Tiered Staffing with Remote TCC Support

the extension of high-quality intensive care to places, which lack adequate critical care expertise and resources necessary for care of COVID-19-related illnesses.

TATRC

Uncovering Physiological Markers Linking Sleep, PTSD

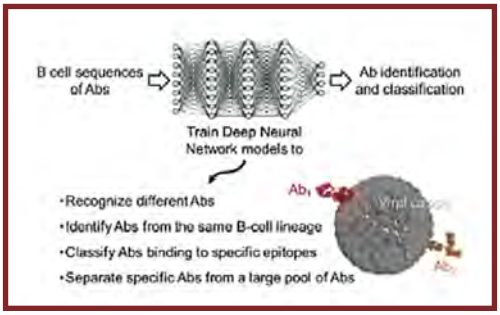
Epidemiological studies have indicated that as many as 10-20 percent of combat veterans returning from conflicts in Iraq and Afghanistan develop post-traumatic stress disorder *(PTSD)*. Sleep disturbances are the hallmark symptoms of PTSD. Going back to the 1970s, multiple studies have shown that among combat veterans with PTSD, between 40-90 percent reported difficulties falling asleep or staying asleep and more than 50 percent reported having recurrent nightmares. While there is unequivocal evidence linking sleep disturbances and PTSD, until now there have been no known quantitative markers of PTSD in combat-exposed Veterans. This research identifies ten objective sleep markers that were altered in PTSD subjects. Notably, these markers were consistent across nights, with reproducible trends across the subsamples of our study population. As such, we now have a quantitative metric to discriminate PTSD from non-PTSD Veterans with moderate classification performance. Additionally, we revealed a linkage between sleep markers and daytime cognitive performance, suggesting that sleep disturbances partially explain the daytime performance deterioration in PTSD subjects

TATRC

Building Artificial Intelligence Capabilities for Antibody Countermeasures

The Army's stated goal to provide treatments before and during deployment that can sustain a 90% medical fitness during deployment has prompted USAMRDC laboratories to prioritize development of prophylactic (preventative treatments) and therapeutic antibodies as a means to provide protection and treatment against a range of bacterial (multidrug-resistant ESKAPE-E pathogens), viral (Dengue, SARS-COV-19), and emerging infectious diseases (unknowns). The ability to take advantage of the rapid progress in artificial intelligence *(AI)* for biological and medical application oftentimes requires looking at the problem from a non-traditional point-of-view. The BHSAI developed an image-based recognition algorithm based on Convolution and Deep Neural Networks that can use the recently developed high-throughput B-cell sequencing data to functionally classify antibodies from a single patient blood sample. The developed AI technology provides the means to efficiently merge advances in high-throughput B cell sequencing with identification of high-value antibodies for countermeasure development against all the high-priority pathogens identified by the Army to maintain medical readiness.

TATRC



The BHSAI has developed Convolution and Deep Neural Network-based AI models to classify antibodies associated with different functional characteristics. The technique has been successfully applied to accurately predict antibody family lineage and epitope specificity against Ebola and HIV-1 viruses as a proof-of-principle concept. The technology will be applied to further identify COVID-19 therapeutic antibodies (Abs).

Forward Operating Base Expert Telemedicine Resource Utilizing Mobile Application for Trauma (FOXTROT) receives a FedHealthIT Innovation Award and publication in JAMA Opthamology in August of 2020

FOXTROT is an operationally secure, HIPAA-compliant mobile application for remotely treating combat-related injuries involving the eye. The application currently features triage surveys, image capture, secure chat, remote health monitoring, and is compliant with the Joint Trauma Systems Clinical Practice Guidelines. The application works in conjunction with

FOXTROT Operational View

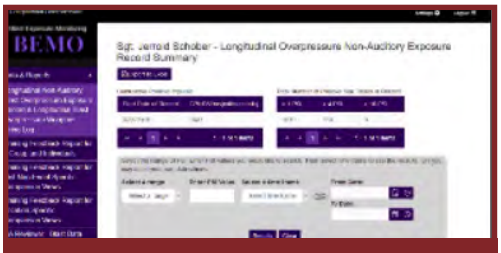
access to a secure web portal where providers can view detailed reports, manage users and have another method by which to communicate with those at the point of injury. With additional future developments, FOXTROT will ultimately provide comprehensive teleophthalmology care to deployed service members and augment access to ocular specialists at clinics and emergency rooms in the CONUS environment. In August of 2020, findings from the deployment of FOXTROT in Afghanistan were published in the JAMA Ophthalmology edition. In brief, the researchers concluded that teleophthalmology mobile phone apps in a combat environment may improve and extend ophthalmic care. Further, FOXTROT was named a 2020 FedHealthIT Innovation Award winner.

TATRC

TATRC DHIC Develops Project BOOM using the mCare Mobile App & Mobile Health Care Environment Web Portal

Project BOOM aligns with recent guidance mandating the study of the effects of blast overpressure on armed services members and longitudinal recording of exposures. TATRC DHIC's Project BOOM is an element of the Joint Health Risk Management Enhanced Capability Demonstration *(JHRM ECD)* program, (which is a research collaboration between Defense Health Agency, the Joint Program Executive Office for Chemical Biological Radiological and Nuclear Defense and U.S. Special Operations Command). The mCare Blast Exposure Monitoring *(BEMO)* Weapons Firing Log app enables an operator, or an observer of a group of operators, to rapidly record information such as weapon system, munition type, body positon, and crew position after firing heavy weapons or explosives. This information, when combined with blast overpressure gauge measurements within the MHCE BEMO web portal, provides a complete picture of blast overpressure exposures. Commanders and environmental health professionals will use this information to reduce and mitigate repetitive and potentially excessive blast overpressure exposures, which may adversely affect Warfighter performance.

TATRC

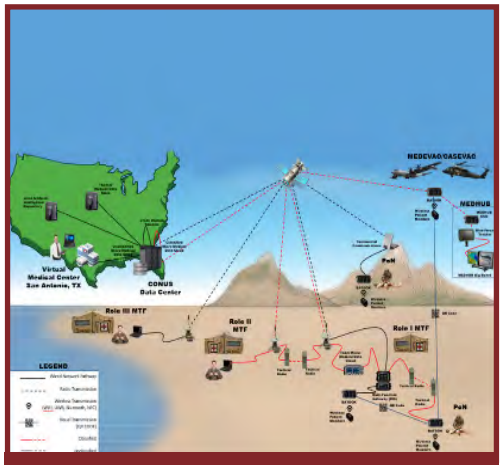


BEMO Website Portal

TATRC Transitions Two Research Projects in Support of Virtual Medicine on Tactical Networks

These Joint Program Committee-1 funded research prototypes are designed to address capability gaps identified in approved capability development documents. The Theater Medical Information Requirements *(TMIR)* Information System *(IS)* Capability Development Document *(CDD)* states, "These research prototypes address gaps by providing medical situational awareness from the battlefield to care providers anywhere in the world through cloud-based web capability hosted in DoD Cloud Environments serving as both a virtual health portal and as a clinical data aggregation point providing information to other medical systems, such as the Electronic Health Record." These capabilities will enable expert medical support to operational units in remote austere environments and dispersed operations by providing access to specialty consultation according to the immediacy of need and, also, can provide operational commanders the medical situational awareness on chosen battlefields required to clear casualties. These research prototypes provide the capability to extend clinical expertise resident in Role IV Military Treatment Facilities to the point of need through synchronous consultative systems for urgent, specialty care consultation and emergent, critical care consultation during military operations in prolonged field care and austere environments. This will offer the potential to reduce evacuations to higher level care for non-urgent illnesses and injuries; and also the ability to support medical care remotely when casualties cannot be evacuated due to operational constraints. These projects have been transitioned to the Special Operations PM – Survival Support and Equipment Systems at the U.S. Special Operations Command.

TATRC

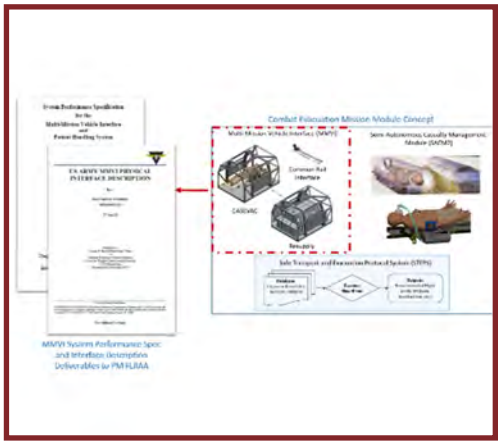


MEDVAC CASEVAC

Combat Evacuation Mission Module – 1st Technology Transition Deliverable to PM Future Long Range Assault Aircraft (PM FLRAA)

The USAMRDC Telemedicine and Advanced Technology Research Center *(TATRC)* joined forces with the USAMRDC U.S. Army Aeromedical Research Lab *(USAARL)* and Naval Air System Command (NAVAIR) on a new S&T effort entitled "Combat Evacuation Mission Module" *(CEMM)* – a Medical Robotic and Autonomous Systems *(MedRAS)* S&T Task Area project. The CEMM project is designed to explore methods of increasing casualty evacuation capability and capacity during Multi-Domain Operations by using non-traditional evacuation platforms to expedite transport of combat casualties while still providing required en-route care in high-risk or resource constrained environments. This concept includes future-use cases involving both "autonomous transport" onboard unmanned or optionally-piloted vehicles and "autonomous treatment" through a remotely monitored and controlled treatment and patient management system.

TATRC,MEDRAS



Year 1 CEMM Products Successfully Delivered to PM FLRAA per Technology Transition Agreement

SOLDIER READINESS AND LETHALITY

USAARL Tests Respiratory Protection and Patient Isolation Units for use during Rotary-Wing Flight in Response to COVID-19

Scientists from the USAMRDC DRU U.S. Army Aeromedical Research Laboratory *(USAARL)* responded to an urgent need from the U.S. Army Aviation Center of Excellence *(USAACE)* for an evaluation of respiratory protection for aircrew during rotary-wing flight due to the COVID-19 pandemic. USAARL conducted three evaluations using Black Hawk helicopter aircrew, Air Traffic Controllers, and CH-47 aircrew. The evaluations assessed aircrew performance and safety using the 3MTM Model 1860 N95 respiratory protection mask, two aviation-specific cloth mask prototypes, and a commercial off-the-shelf aviation-specific cloth mask during flight operations. Results showed that speech intelligibility was within an acceptable range as defined by MIL-STD-1474E, Design Criteria Standard Noise Limit although volunteers reported higher perceived workload while communicating. USAARL also performed rapid testing and Airworthiness Review (AWR) on three patient isolation units *(PIUs)* needed to treat and transport COVID-19 positive patients as well as the King Vision Laryngoscope. PIUs tested included the ISOPOD PIU, MILPOD PIU, and the ISOVAC CAPSULS PIU. USAARL ensured those PIUs were safe and effective for the transport of COVID-19 positive patients, ensuring the safety of both patients and medical staff. USAARL's collective efforts in ensuring aeromedical preparedness for the COVID-19 pandemic increased the nation's readiness and greatly enhanced the nation's response to the virus.

USAARL

USAARL Tests Respiratory Protection in Rotary-Wing Flight in Response to COVID-19

USAARL Contributes Research Products in Support of Future Vertical Lift Science and Technology

Ongoing research at the USAMRDC U.S. Army Aeromedical Research Laboratory directly supports the mission of Future Vertical Lift *(FVL)*. A study on polytrauma patients under delayed care is providing future combat medical systems developers information on shock and vibration criterion important to the allowable tolerances of new platform mission equipment packages. Another science and technology *(S&T)* contribution to FVL is the on-going work for the Load Stability System - Litter Assembly *(LSS-LA)*, with our cooperative research and development agreement *(CRADA)* partner Vita Inclinata. This unique technology and beneficial impact for the current and future fleet gained senior leader visibility and is now set to be included in the Project Convergence 2021 *(PC21)* demonstration. It is the predecessor to the Load Stability System - Fly to Target *(LSS-F2T)*, which has beneficial implications for the utility and cargo aviation communities as a novel capability for hoist and sling-load operations. Collaborative work with organizations such as Holistic Situational Awareness-Decision Making *(HSA-DM)* create the basis for intuitive human-systems integration by creating man-machine interfaces designed to reduce the cognitive workload of the pilot and increase safety in flight situations such as Degraded Visual Environment *(DVE)*. USAARL translated the information gained on gaps and future needs to create studies on psychophysiological (i.e., the interaction between psychological states and physiological responses) and cognitive workload, transcranial direct current stimulation (i.e., low-level electrical current applied to the scalp intended to help the brain be more responsive to cognitive tasks), and operator state monitoring studies to further future cockpit development progress.

USAARL

USAARL Pilots in Rotary-Wing Aircraft

USAARL Assesses Effectiveness of Virtual Reality Rotary Wing Flight Training

In support of the Army Innovation Strategy *(AIS)*, the United States Army Aviation Center of Excellence *(USAACE)* and its executive agency, the Directorate of Simulation *(DOS)*, launched the Aviator Training Next *(ATN)* program. USAARL's

efforts were initially concentrated on a literature search of the physiological effects of VR exposure, on collection and analysis of demographic data in order to describe the student populations in the 2 groups, to determine whether the groups were split equitably with respect to various traits and experiences and whether certain traits or experiences were associated with performance. A team from the Warfighter Performance Group designed a demographic questionnaire using a secure, locally hosted online tool (SelectSurvey.NET v5.0), processed the extensive data using USAARL-designed custom Python code, and undertook comparative statistical analysis of the group demographic responses, alongside individual performance scores. A total of 296 students were included in the analysis. The results showed that the 2 student groups were generally split equitably with respect to demographic characteristics and that prior rotary wing flying experience was positively correlated with performance, albeit this association declined as training progressed. Motion sickness propensity scores showed a non-significant correlation with performance but this also declined as training progressed, suggesting adaptation to the provocative aviation environment. Female gender was associated with a higher propensity to motion sickness but performance scores were comparable with their male counterparts. The detailed performance results from ORCEN, which showed no significant difference in performance between the 2 groups, and the results of USAARL's demographic analysis were detailed in a Technical Report (ORCEN-TR-2004, USAARL-TECH-TR-2020-035) that was delivered to DOS and the Commanding General of USAACE. This report has been published on DTIC.

USAARL

USAARL Supports ATN VR Flight Training Initiative by USAACE

USAARL Researchers Develop Head-Supported Mass Performance Guidance for Dismounted Soldier Environments

Research conducted by USAMRDC U.S. Army Aeromedical Research Laboratory *(USAARL)* researchers establishes weight thresholds for helmet mounted devices *(HMDs)* – such as night vision goggles or communication gear – and informs materiel developers and program managers of safety risks and dismounted Soldier effectiveness decrement, which is experienced as a result of excessive head-supported mass *(HSM)*. This information, provided early in the materiel development process, will help ensure safety and maximum performance of Soldiers conducting long-duration missions in the highly kinetic Joint Domain Operations *(JDO)* environment. Without such analysis, information, and guidance, decision makers may inadvertently procure HMDs that produce acute or chronic head/neck injury or hinder Soldier performance. USAARL generated preliminary threshold guidance for HSM and provided this guidance to materiel developers and health hazard assessors. This guidance was based on characterization of dismounted environments and operational exposures; however, the guidance as presented does not currently address wear duration, a future research objective. Additional efforts in this field of research will provide HSM threshold guidance for Future Vertical Lift aircraft and Next Generation Combat Vehicles. Further, a standard was recently proposed for testing and measuring HSM properties and was published in September of 2020 as USAARL-TECH-TR--2020-052.

USAARL

USAARL Researchers Conduct Aviation Survivability and Tactics (ASDAT) Combat-Related Injury Retrospective Study

The Survival Analysis Team *(SAT)* within the Injury Biomechanics and Protection Group *(IBPG)* at the U.S. Army Aeromedical Research Laboratory *(USAARL)* performed retrospective studies for two rotary-wing aircraft platforms (Black Hawk and Apache) to address occupant casualties in combat damage events between 2003 and 2014. The assessment reviewed more than 200 Black Hawk and Apache events each. The assessment found that injuries from penetrating objects in the head and extremities are most likely to occur in the Black Hawk platform, (which may be due to the lack of ballistic armor in the cabin area) while injuries related to indirect events including blunt force trauma that result from hard landings or crashes are most likely to occur in the Apache platform. The research team recommends that increased structural crashworthiness and cabin armor systems be considered in future rotorcraft designs similar to the Black Hawk platform and in platforms intended for medical evacuation. The research team also recommends that future designs of Black Hawk similar platforms sustain the crashworthy and ballistic tolerant fuel system. In the

SOLDIER READINESS AND LETHALITY

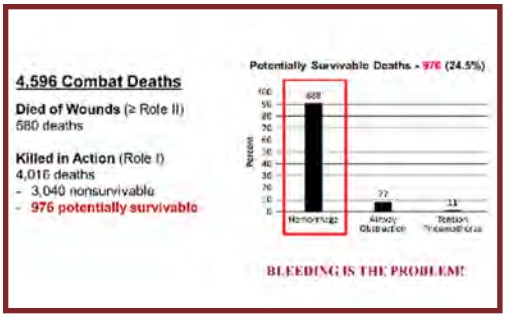
Apache platform, the research team recommends that protective armor systems and crash-worthy capability be sustained in future rotorcraft designs as well as additional protective measures for flight critical systems to protection from weapons threats. Multiple publications have resulted from this effort including USAARL Technical Report 2018-01 and USAARL Technical Report 2020-01a, as well as a number of classified reports.

USAARL

Researchers Embark on Phase III Study examining safety and **efficacy of cold stored platelets**

In collaboration with Washington University in St. Louis, USAISR researchers initiated a multicenter, randomized study to evaluate platelet storage duration in cardiac surgery patients with active bleeding. The Chilled Platelet Study *(CHIPS)* allows for up to 21-day cold storage of platelets. In-vitro work at the USAISR will evaluate all platelet collection platforms, storage solutions, and pathogen reduction. CHIPS study outcomes are expected to extend platelet shelf life, increasing the inventory and availability when conventional platelet products are not available or their use is not practical. Ultimately, these impacts will lead to improvement in care and increased survival of our service members on the battlefield.

USAARL



Uncontrolled blood loss was the leading cause of death in 90 percent of the potentially survivable battlefield cases and in 80 percent of those who died in a military treatment facility. This trend is expected to continue into future conflicts and highlights the need for more advanced blood products going forward.

Tech. Sgt. Federico Arriaga, 379th Expeditionary Medical Group Blood Transshipment Center (BTC) logistics craftsman, scans barcodes on blood containers in the BTC Jan. 9, 2019, at Al Udeid Air Base, Qatar. The BTC is comprised of a four-person team that orchestrates the flow of blood and platelet products to 72 forward operating locations and eight mobile field surgical teams throughout U.S. Central Command's area of responsibility. (U.S. Air Force by Tech. Sgt. Christopher Hubenthal)

Progress Toward Elimination of the Cold-Chain Requirement for Blood

Hemorrhage is the leading cause of preventable death on the battlefield. Blood availability limitations include shelf life constraints and cold-chain requirements. USAISR researchers identified alternative strategies to improve the availability of critical blood products. The use of hemoglobin-based oxygen carriers *(HBOC)* as a reconstitution solution for freeze-dried plasma *(FDP)* was found to be superior to a combination HBOC-plus-water reconstitution of FDP in a pre-model of hemorrhagic resuscitation. These efforts represent the foundation towards development of an engineered plasma to treat hemorrhage and shock at or near the point of injury.

USAISR

USAISR hosts the inaugural Joint Medical Effects of Directed Energy Injury: State of the Science Meeting

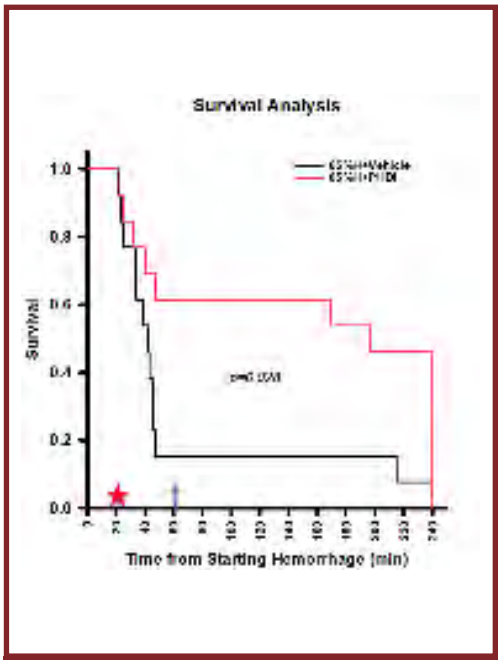
In FY20, the Army Institute of Surgical Research, in collaboration with key leaders from Navy Medical Research Unit - San Antonio, the USAF 711th Human Performance Wing, and the USAF 59th Medical Wing hosted an inaugural Joint Medical Effects of Directed Energy *(DE)* Injury meeting. The meeting was designed to bring together lead scientists and key stakeholders to discuss the medical effects of DE and identify critical knowledge gaps in DE-related Warfighter sustainment and readiness. The event laid the groundwork to develop a joint DE research program focused on creating and delivering innovative medical capabilities needed to combat injuries from the application of DE technologies in future battlespace.

USAISR

USAISR Researchers Use Breakthrough Drug as Anti-Shock Therapy to Improve Acute Survivability of Lethal Hemorrhagic Shock

Shock is the underlying pathophysiology that drives complications from hemorrhage leading to multiple organ dysfunction and ultimately death. USAISR researchers discovered that acute administration of Prolyl Hydroxylase Domain Inhibitors *(PHDi)* significantly improved survival in rats with lethal hemorrhagic shock. PHDi improves oxygen sensing (hypoxic adaptation) by regulating oxygen sensors during hemorrhagic shock. These studies suggest that PHDi is a promising anti-shock candidate that can be used independently or potentially bundled with other drugs and resuscitation strategies to treat hemorrhagic shock under Multi Domain Operations and PFC scenarios. critical research support functions to meet Federal and DOD requirements for research programs that use animals. In Fiscal Year 2019, 5 out of 6 (83%) of Army officers taking the ACLAM Diplomate examination for their first time passed, for a pass rate well above the national pass rate of 54%. All of the officers who successfully passed the exam had been assigned to MRDC subordinate commands for their residency.

USAISR



SURVIVAL ANALYSIS

SOLDIER READINESS AND LETHALITY

USAISR Supports Operation Warp Speed in Collection, Testing of COVID-19 Convalescent Plasma

During the COVID-19 pandemic, medical laboratory specialists (68Ks – or, "kilos") at the Institute of Surgical Research *(ISR)* played a unique role in support of Operation Warp Speed *(OWS)*; a multi-agency, federal initiative to facilitate and accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutic treatments, and diagnostic tests. Patients recovering from COVID-19 generate antibodies to the SARSCoV-2 virus, which circulate in their blood plasma. This plasma, called COVID Convalescent Plasma *(CCP)*, can provide a life-saving therapy for other infected patients. On order from the U.S. Secretary of Defense, and at the request of the U.S. Secretary of Health and Human Services, ISR deployed twelve "kilos" to the Texas Blood and Tissue Center *(STBTC)* in San Antonio for 30 days to assist in the collection and distribution of CCP from volunteers who recovered from COVID-19 Infections. Due to efforts, donor recruitment increased by 400%, and collection by 150% during a two-week period. Further, in collaboration with Biomedical Advanced Research and Development Authority *(BARDA)*, these efforts paved the way for the collection, distribution and storage of a national stockpile.

USAISR

ISR Operatives assiting in COVID-19

USAMMDA Fills Nationwide Need for Safe, Effective Treatment of Severe Malaria

In May 2020, the U.S. Food and Drug Administration *(FDA)* granted marketing approval for Artesunate for Injection, an initial treatment for severe malaria. The drug was developed under current Good Manufacturing Practices by the USAMRDC (Walter Reed Army Institute of Research, USAMMDA's Warfighter Performance and Acute Care Project Management Office) and with the industry partner Amivas USA, LLC., who submitted the New Drug Application for Artesunate for Injection. With a lack of alternate FDA-approved therapies to treat life-threatening severe malaria, Artesunate for Injection fills a critical gap for the military and the larger U.S. population. The only other FDA-approved treatment option, intravenous quinidine, was discontinued in 2019. The marketing approval of Artesunate for Injection will allow military and civilian hospitals the ability to commercially obtain the drug to treat this deadly disease.

USAMMDA

USAMMDA Selected to Manage Tier 1 Acquisition Program Funding for Three COVID-19 Response

USAMMDA's Warfighter Protection and Acute Care *(WPAC)* Project Management Office *(PMO)* is managing three projects selected by the Defense Health Agency to receive Tier 1 acquisition program investments in support of the COVID-19 effort. The acquisition program investments are aimed at supplying capabilities that can improve existing testing capabilities and treatments. The first project, the secreted phospholipase A2, or sPLA2, Inhibitor (Varespladib) for SARS-CoV2 treatment, is a small-molecule drug that blocks inflammation and the degradation of lung function seen in Acute Respiratory Distress Syndrome *(ARDS)*. ARDS can be caused by several diseases, including COVID-19. Together with the industry partner, Ophirex, Inc., the WPAC PMO is working to develop Varespladib as an ARDS preventative and for treatment in COVID-19 patients. It was previously tested against sepsis and acute coronary syndromes as part of an evaluation for snakebite treatment, and shown to be safe and well-tolerated in patients.

The second project selected contributed to the regulatory progression of BioFire Defense's COVID-19 test. Authorized by the U.S. Food and Drug Administration for Emergency Use, the test is performed on the BioFire® FilmArray® instrument, which is present in many Department of Defense facilities. The instrument provides a "detected" or "not detected" report about 50 minutes after a sample, a nasopharyngeal swab in transport medium, is loaded for analysis. This project capitalizes on the work of colleagues at the Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear

BioFire® FilmArray

Defense, who partnered with BioFire Defense on the development of a COVID-19 test on the FilmArray®.

The third project, the SARS-CoV-2 Rapid Diagnostic Lateral Flow Test for direct antigen detection and serology, includes two point-of-care diagnostic tests that will be able to identify persons infected with SARS-CoV-2. The SCOV-2 Ag Detect™ is a direct antigen-based test that uses a proprietary "dip-stick"-like test to detect several SARS-CoV-2 antigen targets present in respiratory samples collected by nasopharyngeal swab. The SCoV-2 Ab Detect™ is a serology "dip-stick"-like test that will use blood collected by finger stick to detect SARS-CoV-2-specific antibodies in individuals who meet either clinical and/or epidemiological criteria to infer recent or prior infection.

Improved detection and drug treatment options are important tools to our Warfighters and the Nation in the fight against SARS-CoV-2. These three tools for diagnosis and treatment will help prevent the further spread of SARS-CoV-2 and potentially save the lives of those infected. They represent the "whole-of-government" approach to fighting the worldwide COVID-19 pandemic.

USAMMDA

SCOV-2 Ag Detect™

DOD Utilizes Additive Manufacturing to Address Critical Supply Shortages During the COVID-19 Public Health Emergency

In response to the COVID-19 global pandemic, the U.S. Army Medical Materiel Development Activity *(USAMMDA)* Warfighter Expeditionary Medicine and Treatment Project Management Office formed the USAMRDC Additive Manufacturing Working Group *(AM WG)* to address critical supply shortages within the Department of Defense. The multidisciplinary AM WG acts as a force multiplier across the enterprise to include programmatic, regulatory, agreements, clinical, legal, and intellectual property expertise. The AM WG ensures that the DOD is supplying materiel in compliance with Food and Drug Administration *(FDA)* guidance where existing FDA compliant commercial solutions are unavailable. The group coordinates in instances where the DOD is requesting to use an alternative supplier to an FDA compliant product, or when the DoD Industrial base may be needed to manufacture materiel that is FDA regulated.

The AM WG streamlined processes and testing capabilities to expedite the delivery of medical products such as 3D printed swabs, viral transport media *(VTM)*, face masks, face shields, and N95 respirators. For over 10 months, the team assisted with over 120 inquiries from Army, Navy, Air Force, Marine Corps and Coast Guard Organic Industrial Base *(OIB)* partners, and Services and Defense Logistics Agency acquisition organizations. All were unfamiliar with medical product development and Food and Drug Administration regulations, and this newly formed team assisted in providing specialized support to fill these critical shortages.

The outputs from these efforts include receiving FDA Enforcement Discretion for 3D printed swabs manufactured by the DoD for use in Military Treatment Facilities. This approval is the first instance of FDA granting Enforcement Discretion for DoD additively-manufactured swabs. Participating sites include: Air Force 59th Medical Wing, Army's Rock Island Arsenal, Portsmouth Navy Shipyard, Fort Gordon Dental Lab, Fort Polk Dental Lab, and the U.S. Coast Guard Academy. These DoD produced swabs enabled the U.S. Coast Guard Academy to continue their surveillance testing program when commercial swabs became back-ordered, allowing in-person learning to continue.

As part of the N95 respirator prototype effort, the AM WG established agreements with the CCDC – Chemical Biological Center *(CBC)* to conduct developmental testing and the National Institute for Occupational Safety and Health (NIOSH) to perform confirmatory testing. Thus far, this process has facilitated testing of over 22 prototypes from government organizations and alternative manufacturers. Three commercial prototypes have since passed initial developmental testing and CCDC CBC and are pursing NIOSH certification. This contribution has expanded the commercial industrial base expansion for the production of critical Personal Protective Equipment within the United States.

To facilitate the distribution of critical supplies from alternative vendors, the AM WG engaged when the only available items were not in compliance with FDA regulations or enforcement policies. The AM WG was able to request and receive FDA Enforcement Discretion for the use of 2 alternative sample collections kits, and one alternative VTM that enabled accession training to resume for new Soldiers at U.S. Army Training and Doctrine Command locations and for the United States Forces, Korea 8th Army

to maintain their operational readiness. Additionally, with the coordination and approval of the Deputy Surgeon General, the AM WG directly enabled a $40M cost avoidance to the Army, by either bringing critical PPE in compliance, or assisting in the return of non-compliant PPE.

USAMMDA

N95 Respirator Prototype

USAMMDA Increased All Critical Equipping On-Hand Readiness for Activated Units in Response to COVID-19

As COVID-19 continued to affect the nation, USAMMDA ensured enhanced mission capability through the procurement and rapid equipping of six activated Army medical units with critical care equipment, oxygen capabilities, sterilization equipment, water management systems, and medical materiel sets specific to post-operative and intensive care unit wards. The effort was managed by USAMMDA's Warfighter Deployed Medical Systems Project Management Office *(WDMS PMO)*, an experienced team of equipment maintainers, clinicians, product managers and contractors. The effort resulted in more than 500 oxygen-D cylinders being delivered to some of the hardest hit areas within the U.S., ensuring the availability of healthcare capabilities to areas where they desperately required. USAMMDA's response to the call allowed Warfighters throughout the U.S. to engage in the COVID-19 response with a war-type mentality, and contributed to the overall success and implementation of military hospitals in both New York and Seattle.

USAMMDA

Medical Materiel Sets

USAMMDA's Force Health Protection Division Implements COVID-19 Treatment Protocol across Multiple Sites

USAMMDA's Force Health Protection *(FHP)* Division is at the forefront of a treatment protocol being utilized in an effort to combat the COVID-19 pandemic. In May 2020, the U.S. Food and Drug Administration *(FDA)* authorized FHP to implement an Expanded Access Protocol for COVID-19 Convalescent Plasma. COVID-19 Convalescent Plasma *(CCP)* is blood plasma taken from patients who have recovered from COVID-19 who have developed antibodies naturally against the illness. As convalescent plasma has been used successfully to treat other respiratory viruses, the effort is intended to assess whether plasma from people who have recovered from COVID-19 is an effective treatment for people with severe, or risk of severe COVID-19 disease, and whether this treatment causes any unwanted effects. This treatment can be combined with other treatments for COVID-19 illness, such as corticosteroids, anticoagulants or other medications that have FDA emergency use authorization, including remdesivir, which is also available through USAMMDA's FHP Division. Approved protocol sites include both CONUS and OCONUS Army, Air Force and Navy sites as well as sites in Bagram, Afghanistan, and Baghdad, Iraq. In mid-July 2020, the Navy's USS Nimitz was the first ship in its fleet to be approved to administer CCP per the treatment protocol. The FHP team has built a network of joint medical facilities globally that are participating in this life-saving treatment protocol.

USAMMDA

Medical Materiel Sets

USAMMDA's Force Health Protection Division's stood up the COVID-19 treatment protocol for remdesivir in 21 days from signing the **agreement to first patient treated**

USAMMDA's Force Health Protection *(FHP)* Division in anticipation of the emerging pandemic's impact on the warfighter, stood up an FDA-approved COVID-19 treatment protocol using Gilead's remdesivir under an investigational new drug *(IND)* application. The Cooperative Research and Development Agreement *(CRADA)* with Gilead was signed on 5 March, 2020, FDA and IRB approvals received on 17 & 18 March, product received/shipped, and first patient treated at Landstuhl Regional Medical Center *(LRMC)*, Germany on 26 March, 2020. This highlights FHP's mission and capability to strategically early equip investigational products, through rapid operationalization, in response to high consequence threats when there are no FDA approved or feasible solutions available. This treatment protocol was available at 26 sites worldwide to include CENTCOM and AFRICOM locations and 40 hospitalized COVID-19 patients were provided this treatment option. This effort set the stage for the expansion and success of the FHP COVID-19 convalescent plasma treatment protocol.

USAMMDA

USAMMDA's Force Health protection Division selected by DHA to be the DoD centralized distribution, storage, and tracking hub for EUA remdesivir

Due to the efficient processes and procedures to distribute and resupply sites worldwide under the expanded access treatment protocols, DHA selected FHP to be the DoD centralized distribution, storage, and tracking hub for remdesivir under FDA emergency use authorization *(EUA)*. To this effort, FHP has provided product to over 64 locations to include aircraft carriers, amphibious ships, and austere locations within CENTCOM and AFRICOM. Over 95% of all shipments arrived within 24 hours of supply requests. For 2020, FHP has provided treatment to over 1090 patients and have filled 195 resupply requests to locations worldwide. Due to the continued success of this mission, FHP was also selected to be the OCONUS distribution hub for two EUA approved monoclonal antibody products – Eli Lily's Bamlanivimab and Regeneron's combination (Casiribimab/Imdevimab).

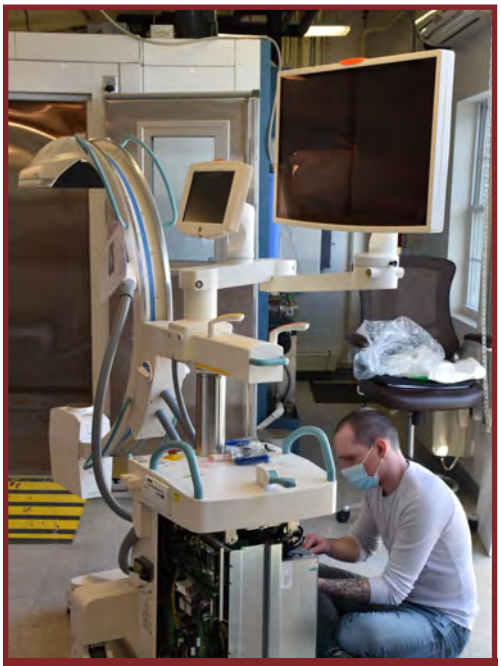
USAMMDA

SOLDIER READINESS AND LETHALITY

USAMMDA's Innovative "C-Arm" Device to Help Save Lives

In November 2020, the Warfighter Deployed Medical Systems Project Management Office, USAMMDA received the state-of-the-art "C-Arm" high-capacity radiographic and fluoroscopic unit. The innovative tool is essentially a mobile, self-contained X-ray machine that uses non-invasive real-time fluoroscopic imaging in the operating room during examination, diagnosis and surgery. Primarily used during surgery to locate and treat vascular injuries such as uncontrolled bleeding, the "C-Arm" also can be used to locate and remove foreign bodies and to triage patients. The successful implementation of the unit at military treatment facilities will help to reduce the fatality rate of Warfighters who have suffered vascular injuries. During multi-domain operations, the "C-arm" will help to reduce morbidity and mortality due to these injuries.

USAMMDA



C-Arm

USAMMDA Working to Bring Lactated Ringer's Solution Generator to the Frontline of Army Medicine

The Warfighter Deployed Medical Systems Project Management Office, USAMMDA has teamed with a commercial partner in the development of a novel medical device that may prove to be a "game-changer" in the frontline treatment of wounded Warfighters. The Lactated Ringer's *(LR)* Solution Generator was developed by TDA Research, Inc., and funded through the Defense Health Agency's Small Business Innovation Research program. This device is a lightweight, portable unit that can produce sterile LR solution in austere locations from locally available freshwater sources, including ditch water. The device utilizes proprietary technology to produce one liter-size intravenous bags from a concentrated LR salt solution. The LR solution is used primarily to treat dehydration, deliver medication, and restore fluid balance following bodily injury. It is also used to treat moderate hemorrhagic shock, as it has been shown to increase initial survival rates among patients and decrease the chances of organ damage. The unit weighs less than 11 pounds and is stored in a hard-shell case that is approximately 10 inches wide by 18 inches long, and only 6 inches deep. The purification device runs on a rechargeable lithium-ion cell that can produce more than 30 bags of LR solution per single charge. This small device could dramatically reduce the Army's logistical footprint of having to ship and store LR solution, which is the fluid-of-choice for resuscitation if blood is not available on the battlefield. The unit is pending FDA cleared/approved.

USAMMDA

Lactated Ringer's (LR) Solution Generator

USAMMDA Modernizes Deployable CT Scanner to Provide Top-Notch Images in Deployed Settings

The joint deployable computerized tomography scanner is a non-invasive, cross-sectional imaging system that enhances the field surgeon's ability to diagnose wounded Warfighters in a deployed setting at the field hospital. USAMMDA's Warfighter Deployed Medical Systems Project Management Office *(WDMS PMO)* is overseeing the replacement of previously-fielded CT models that have become non-procurable. The CT scanner uses computer-processed combinations of several x-ray images taken from a variety angles to produce cross-sectional images focusing on specific areas of the scanned patient. In a deployed setting, this improves the surgeon's ability to diagnose trauma patients in a non-invasive manner at the field hospital; particularly trauma injuries related to the head, abdomen, spine and eyes. With this effort, the WDMS PMO will ensure that technologically advanced, state-of-the-art deployable CT scanners are avail-

able for diagnostic use in austere environments, ensuring the best possible battlefield medical care for the Warfighter.

USAMMDA

USAMMDA Converts, Modernizes Hospital Centers and Forward Resuscitative Surgical Teams for Mobility, Security

The U.S. Army has a worldwide medical mission. Lessons learned from over a decade of combat has reinforced the Army's need to have forward-based medical capabilities that are advanced, yet also agile and logistically scalable. Thus, the ability to organize tailorable medical support packages with ease and agility is critical to supporting men and women in a multi-domain battlefield. This conversion reconfigures the 248-bed Combat Support Hospital *(CSH)* into a smaller, more modular 32-bed Field Hospital (FH) with three additional augmentation detachments, including a 24-bed surgical detachment, a 32-bed medical detachment, and a 60-bed Intermediate Care Ward detachment. The FH and the augmentation detachments will all operate under the authority of a headquarters hospital center. This conversion allows Commanders flexibility to respond to medical emergencies with a capability that is sized according to the requirement. This effort, involving the conversion of three legacy Combat Support Hospital to the HC and the conversion of Forward Surgical Teams to Forward Resuscitative Surgical Teams is being managed by USAMMDA's Warfighter Deployed Medical Systems Project Management Office.

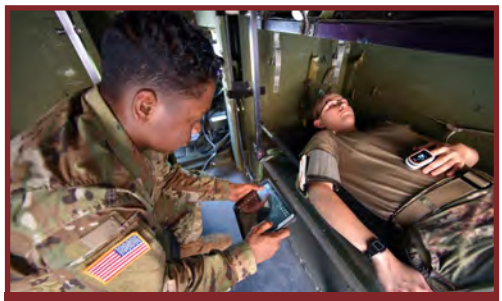
USAMMDA

Forward Surgical Teams

USAMMDA Uses MEDHUB to Give Deployed Units Key Situational Awareness Capabilities

The Medical Hands-free Unified Broadcast *(MEDHUB)* system is a hands-free, voice-free, wire-free, automated medical device that utilizes a handheld electronic tablet to share patient information between medics and hospitals during medical evacuations. MEDHUB does not replace the way medics triage a patient, or how they conduct rapid trauma assessments. It changes the way medical intervention is documented by replacing the traditional Tactical Combat Casualty Care Card with a touch screen tablet to electronically document any administered drugs, or any lifesaving interventions. Managed by USAMMDA's Warfighter Health, Performance, and Evacuation Project Management Office, MEDHUB integrates U.S. Food and Drug Administration-approved wearable medical devices to seamlessly collect, store and transmit non-personally identifiable patient information from point-of-injury to the receiving military treatment facility or hospital and later scanning into the patient's Electronic Health Record. The use of the MEDHUB system will help to alleviate the burden and stress of medical documentation and drug treatment during patient evacuation, both on and off of the battlefield.

USAMMDA



MEDHUB Monitoring Vital Signs

USAMRICD Develops Diagnostic (Dx) System to Detect Chemical, Toxin Exposure

The chemical diagnostic platform Chem Dx is a hand-held, easy-to-use device (similar to a glucometer) that can be carried by forward-deployed personnel to rapidly detect nerve agent intoxication using a drop of blood. The USAMRDC's U.S. Army Medical Research Institute of Chemical Defense, the pioneer of this technology, is also developing Chem Dx modifications to detect opioid intoxication. Access to this technology mitigates continued injury to patients in the field from medical mistreatments and delayed diagnoses.

USAMRICD

ChemDx Ruggedized

Chem Dx

SOLDIER READINESS AND LETHALITY

USAMRICD Establishes Directed Energy Capability to Study Unconventional Brain Injuries

Directed energy *(DE)* exposure has the potential to produce long-term cognitive impairments as well as physiological changes in the brain and in parts of the inner ear that control balance. DE is a newly recognized threat for service member brain injury, and methods to properly diagnose, assess and treat DE injuries are critically needed. The USAMRICD DE research program is the result of academic, industry, inter-agency, and Joint collaborations that will better inform and direct patient care by assessing the physical and behavioral health problems caused by DE.

USAMRICD

USAMRICD Develops Online Courses to Keep Select Staff Trained, Ready During COVID-19 Pandemic

With the ongoing health risks and travel restrictions related to the COVID-19 pandemic, the USAMRICD developed and delivered virtual programs of instruction for its three advanced courses in the medical management of chemical and biological casualties. The virtual courses are approved and accredited by the U.S. Army Medical Center of Excellence to meet the certification requirements of graduating occupational medicine residents and medical practitioners – 81 of whom attended the course. Additionally, the online courses are approved by the U.S. Army Training and Doctrine Command. An online Mobile Training Team *(MTT)* was further created and delivered to 150 students to meet the Joint Readiness Training Center and deployment training and competency requirements. Both the MTT and the Medical Management of Chemical and Biological Casualties *(MCBC)* virtual courses will be used as a template to develop additional online courses. The new online courses will ensure, despite COVID-19-imposed limitations that Warfighters are trained and ready to operate in chemically contested environments.

USAMRICD

USAMRICD Clinical Laboratory Receives Reaccreditation

Despite the COVID-19 pandemic, members of the USAMRICD prepared for and successfully achieved reaccreditation of the only U.S. Department of Defense clinical laboratory, registered with the Center for Laboratory Medicine Services, that is engaged in analyzing human samples for the presence of chemical warfare agents *(CWAs)*. The team spent countless hours evaluating documents, confirming equipment, performing proficiency and competency assessments, and evaluating methods. In addition to the time required to prepare for this multi-day inspection, the team had to perform real-time analysis with the inspectors and answer questions. The ability of this research facility to meet these clinical standards is above and beyond the norm. The efforts of the team help ensure that our service members receive appropriate diagnostic evaluation for CWA exposure with placement of the findings in their permanent medical record to facilitate lifelong care requirements.

USAMRICD

USARIEM Forges Ahead With First-Ever Study on Elite **Female Warfighters**

USARIEM became the first laboratory to embark on an exploratory study to classify the defining physical, mental, and metabolic characteristics of female elite Warfighters *(FEW)*; an emerging demographic of females who have been the first in history to successfully graduate from the most physically and mentally challenging training courses in the military. Research findings from the FEW study will help modernize biomedical studies aimed at developing and applying new methods to understand how body composition, fitness, nutrition and exercise influence fuel metabolism and performance in extreme training and operational environments. Through a deeper understanding of the innate and modifiable characteristics of elite Warfighters – not just those who are female – the U.S. military can enhance their fighting potential through ensuring that the right individuals are placed in appropriate specialties to match their capabilities. Study findings will be provided to Army Senior Leaders and policy-makers to inform policies related to female physical training, physical assessments, and body composition standards.

USARIEM

USARIEM Biophysics and Biomedical Modeling Division

USARIEM's Environmental Medicine Solutions Pave Way for the Modern Soldier

USARIEM's expertise in environmental medicine continues to help modernize the Soldier and optimize their ability to perform in multiple extreme environments, including: the humid tropics, the staggering altitudes, the frigid Arctic, and more. Several of the Institute's inventions have been awarded patents; this includes the Estimated Core Temperature (ECTemp) algorithm, which can accurately calculate changes in core body temperature based on heart rate, and the Carbon dioxide/Oxygen Breath and Respiration Analyzer *(COBRA)*, a breathalyzer that tracks a person's metabolism. USARIEM's cold-weather solutions – including a Cold Weather Ensemble Decision Aid and a patented forearm heating device to improve hand dexterity – are advancing in their stages of development, the latter being involved in three SBIR awards. The institute, in partnership with the U.S. Army Medical Material Development Agency's Warfighter Health, Performance and Evacuation Project Management Office, has also transitioned two mission planning tools to the TRADOC App Gateway; these include the Altitude Readiness Management System (ARMS), a mission planning app for mitigating altitude illness, and the Soldier Water Estimation Tool *(SWET)*, a mission planning app for calculating the amount of water needed for troops during operations. These collective efforts will make USARIEM's science more accessible to every Soldier, ensuring the future force will have the tools and medical readiness needed to fight, win, and survive in any MDO environment. Results from future field and laboratory studies will be used to improve the accuracy, usability, and accessibility of these leader tools. Key partners in these efforts include the MIT Lincoln Laboratory, Fort Benning Maneuver Center of Excellence, and the Training and Doctrine Command.

USARIEM

USARIEM Biophysics and Biomedical Modeling Division

SOLDIER READINESS AND LETHALITY

USARIEM's Massive Study of Musculoskeletal Injuries Yields Early, Impactful Results

In 2020, the USARIEM's ARIEM Reduction in Musculoskeletal Injury *(ARMI)* study team saw their participation pool swell to 3,000 people. The goal of this longitudinal study on Army trainees is to provide evidence-based solutions to the TRADOC Center for Initial Military Training to reduce musculoskeletal injuries, such as stress fractures, and build resilient musculoskeletal systems. This multi-year investigation has yielded early demonstrations of powerful results using cutting-edge technology to capture how bones change on a microstructural level during Basic Combat Training. The study team has reported that the average amount of new bone deposited after only eight weeks of BCT is similar to the amount that would occur with two years of drug therapy in older osteoporosis patients. These results have important implications for how physical training can help mitigate risk for stress fractures in military personnel and can prevent bone fragility and osteoporosis in the general population; as ARMI researchers uncover what factors most promote this healthy new bone formation, results will help guide delivery of solutions to prevent stress fractures and other injuries in military personnel. Results from USARIEM's ARMI study will help future Soldiers build resilient musculoskeletal systems needed to overmatch adversaries and dominate in future battlefields. The research team plans to resume their data collections at additional sites in 2021. Results from this study will be used to provide evidence-based recommendations to the TRADOC Center for Initial Military Training to reduce musculoskeletal injuries and build resilient musculoskeletal systems in military trainees.

USARIEM

USARIEM Military Performance Division

WRAIR Pivots to Combat COVID-19

Building upon its ability to rapidly respond to outbreaks and develop diagnostics, vaccines and treatments, WRAIR is playing a key role in the ongoing COVID-19 response. WRAIR ensures readiness by supporting the Army's efforts to accurately test, track and monitor soldiers and their beneficiaries. Our scientists developed and evaluated diagnostic technologies to determine when individuals are no longer infectious, to track those who are infected without symptoms and to support epidemiological and vaccine studies. WRAIR is also advancing a novel vaccine platform that aims to address the COVID-19 pandemic and counter future corona-virus threats. WRAIR researchers have screened millions of compounds to identify novel therapies for COVID-19 and is evaluating potential treatments. In addition to these efforts, WRAIR provides extensive support for Operation Warp Speed in the form of logistics, technical expertise and clinical research sites.

WRAIR

Tracking Behavioral Health During the COVID-19 Pandemic

Scientists from the Walter Reed Army Institute of Research and the U.S. Army Public Health Center joined forces to organize the Behavioral Health Advisory Team or BHAT, a study to measure the behavioral health impact of the COVID-19 pandemic on Soldiers. Surveying more than 20,000 Soldiers across the globe in the spring of 2020, the BHAT identified specific trends about perceptions of COVID-19 and leadership response, behavioral health concerns and use of risk mitigation strategies, providing leaders actionable data and recommendations to bridge communication gaps and address concerns. Follow-up studies are planned through 2021 to continue providing accurate data and relevant solutions to leadership and stakeholders across the Army.

Reference Material:

- https://www.army.mil/article/239460
- AUSA video with Dr. Quartana and Dr. Adler (already with MRDC PAO)

WRAIR

WRAIR Continues Fight Against Drug-resistant Bacteria and Wound Infections

WRAIR continues its support for the Combatting Antibiotic Resistant Bacteria national action plan, a whole-of-government approach to overcome multidrug-resistant *(MDR)* bacteria in the U.S. MDR bacteria remain a significant threat to the public as well as Service Members, on and off the battlefield. WRAIR's Multidrug-resistant organism Repository and Surveillance Network serves as the primary surveillance organization to track antibiotic-resistant bacteria across the military healthcare system and beyond. WRAIR is also leading efforts to transition an antibiotic

drug candidate from discovery to advanced development—as well as other product development efforts also including bacteriophage, or viruses that inactivate specific strains of bacteria. WRAIR-developed bacteriophage cocktails were used in three emergency cases to clear infections not responding to antibiotics.

Reference Material:

- https://www.wrair.army.mil/node/544
- https://www.health.mil/News/Articles/2020/10/19/GEIS-Program-collaborates-to-combat-antibiotic-resistance?type=Reports&page=3#pagingAnchor

WRAIR

Warfighter Fatigue Management Strategies Maintain Unit Readiness

Sleep is a requisite component of high-quality, mentally tough Soldiers, and further plays a critical role in cognitive performance, learning, the immune system and other building blocks of successful Multi-Domain Operations. However, particularly during high operational tempo missions in far-forward environments, Soldiers are often unable to get the recommended seven-to-nine hours of sleep. To overcome this, WRAIR has developed a range of operationally-relevant resources to help Soldiers get better sleep when they can and manage the impacts of sleep loss when they cannot, including portable field cards for use in deployed settings or field training exercises. WRAIR provided direct support to the 7th Infantry Division, dramatically increasing awareness of and access to fatigue management strategies amongst leaders and the unit at-large; the 75th Ranger Regiment, providing guidance for nocturnal operations as well as individual and unit sleep reports and the Uniformed Services University, delivering shiftwork guidance for medical providers and leaders.

Refernce Material:

https://www.wrair.army.mil/node/349

WRAIR

Operationalizing the Pilot Bioproduction Facility Amidst a Global Pandemic

The Pilot Bioproduction Facility *(PBF)* is a cGMP-compliant pharmaceutical manufacturing facility at WRAIR and specializing in the rapid development of vaccines and biologics for military-relevant infectious disease threats. Since 2016, the PBF has undergone extensive renovations to expand and improve its state-of-the-art capabilities including the ability to manufacture vaccines to meet a DOD-wide need. During the SARS-CoV-2 pandemic, the PBF has worked to complete its post-overhaul regulatory certification and rapidly pivoted to work with researchers and contract manufacturing organizations to produce WRAIR's corona-virus vaccine candidates in support of clinical trials scheduled to begin in 2021.

WRAIR

Test Branch Evaluates Traumatic Brain Injury (TBI) Prevention and Diagnostic Products

Developmental testing conducted at the USAMRDC Test Branch supported the U.S. Army Medical Materiel Development Activity *(USAMMDA)* Warfighter Brain Health PMO by evaluating Traumatic Brain Injury *(TBI)* prevention and diagnosis products to determine suitability for rapid deployment to support the Warfighter. The Test Branch assessed three devices: the Abbott i-STAT Alinity, the Infrascanner Model 2500 Traumatic Brain Injury Diagnostic Device, and the Q30 Innovations Q-Collar for suitability and survivability in operational environments.

USAMRDC

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 Scopolamine and Atropine auto-injectors in support of the Joint Project Manager Chemical/Biological/Radiological/ Nuclear – Medical (JPM CBRN-Medical). Test Branch findings contributed to substantial re-designs to enhance the operational effectiveness of these critical lifesaving devices.

USAMRDC

Test Branch Enhances Medical Device Modernization

In support of the USAMMDA Medical Modernization PMO, the USAMRDC Test Branch evaluated multiple devices including Automated External Defibrillators *(AEDs)*, Electrocardiograms *(ECGs)*, a C-Arm x-ray system, and several focusing on diagnosis and treatment of eye trauma to support Warfighters in deployed environments.

Test Branch Developmental Testing supported multiple successful procurement decisions for modernized medical equipment.

USAMRDC

SOLDIER READINESS AND LETHALITY

Clinical Operations Management System

A. Electronic Data Capture *(EDC)* – Provides the capability to electronically manage clinical trial data in support of medical research activity across USAMRDC. During 2020, the eIT PMO rapidly assisted Office of Regulated Activities' *(ORA)* in deploying and configuring two COVID-19 clinical trials across all environments of the EDC Inform application.

i. P_REM: Trial for IND Remdesivir went live in July 2020. Provided support for coding configuration and creation of multiple new user accounts

ii. P_CCP: Trial for IND ASCoV2CP Convalescent Plasma deployed to the Production in August 2020. Provided support for coding configuration

B. Serious Adverse Event Reporting System *(SAE)* - Provides electronic storage and automation in the area of serious adverse event management and safety reporting at USAMRDC. During 2020, ORA's Product Safety team utilized SAE for FDA reporting on adverse events for COVID-19 related drugs such as Remdesivir and ASCoV2CP. The eIT PMO also initiated research on a new FDA requirement for electronic submission of Individual Case Safe Reports directly to the FDA Adverse Event Reporting System.

C. Medical Dictionaries – Provides a repository of medical terms and codes, used by the USAMRDC. In May 2020, emergency upgrades for new COVID19 specific codes were made available

EIT PMO

Regulatory Operations Management System

Electronic Document Management System *(EDMS)*, is an electronic content management and electronic signature capability for FDA-regulated and non-regulated activities. EDMS allows USAMRDC to collaborate across commands and with external partners within the medical research community. During 2020, the eIT PMO supported the following major efforts:

i. USAMRDC Office of Principal Assistant for Acquisition *(OPAA)*: Created collaborative area for Additive Manufacturing Efforts and Resources for COVID-19.

ii. The Office of Principal Assistant for Research Technology *(OPART)*: Developed and deployed EDMS project templates and structure as an interim solution for the Research Project File Management Strategy.

iii. OPART utilized EDMS to provide weekly lab updates and proposals in support of COVID-19 efforts.

iv. USAMRDC Telemedicine and Advanced Technology Research Center *(TATRC)*: Utilized EDMS to report TATRC Technology in Disaster Environments *(TIDE)* Project Files & Virtual Hospital Sub-Project Files related to COVID -19.

v. Assistant Secretary of the Army for Acquisition, Logistics, and Technology Joint Program Executive Offices: Utilized the Other Transaction Authority Tool within EDMS to streamline contract awards for COVID-19. Collaborating with all directorates on COVID-19 Protocol, Treatment and Clinical Reports.

vi. Released EDMS Enterprise Document Routing Workflow enhancements for all users to aid in collaborative medical research efforts across the command and mission partners.

EIT PMO