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Summer 2018

ADVANCING COMBAT SUPPORT AND MATERIEL READINESS

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[1]Lurie KG, et al. *J Med Soc Toho.* 2012;59(6):304-315.
[2]Convertino VA, et al. *Resp Care.* 2011;56(6):846-857.

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TRANSFORMATION IN FIELD SURGICAL CARE

U.S. Army Forward Surgical Teams (FSTs) are transitioning to Forward Resuscitation and Surgical Teams (FRSTs) for expanded capabilities in vital damage control resuscitation, surgery, and post-operative care.

By Ellen Crown

Features

COMMANDER'S CORNER

COL Ryan Bailey

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

Departments

Cover: SGT Berland Robinson, an 88M motor vehicle operator assigned to the 82nd Airborne Division Artillery, carries a wounded paratrooper to safety after their convoy was hit by an improvised explosive device during tactical convoy training on Fort Bragg, NC. (CPT Joe Bush, 82nd Airborne Division Artillery/Released)

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INSIGHTS

As summer heats up, those charged with mending our wounded warriors must face the heat that comes from global combat zone realities almost daily. From the evolution of forward surgical teams into Forward Resuscitation Surgical Teams to the latest in Air Supported shelters for forward triaging, combat medics bring their procedural expertise to myriad live-fire and non-battlefield casualty scenarios. With an increase in unseen trauma such as traumatic brain and concussion-related injury, the Summer 2018 issue of Combat & Casualty Care offers insight into efforts addressing a proactive approach to wounds not manifested by the outward disruption of flesh and bone.

When a Servicemember does suffer from flesh-and-bone injuries, though, surgical precision is vital. Robotic-assisted surgery provides a level of precision that can be a lifesaver in such circumstances. The U.S. Navy and Military Sealift Command was the first to use this innovative surgery in an operational setting—on the U.S. Navy hospital ship USNS MERCY—using the da Vinci Xi Surgical System. LCDR Kyle D. Gadbois, MD FACS, Director of Surgical Services, describes the system as well as this successful first-time use of the technology.

With increasing U.S. military intervention as part of international relief, mobile medical supply readiness is more important than ever. COL Ryan Bailey, U.S. Army Medical Materiel Development Activity (USAMMDA), spoke with us regarding Army medical product development and acquisition, beginning with the analysis of alternatives through the entire life-cycle process.

Employing a range of capabilities from the materiel that enables proper combat casualty care to the mobile personnel trained to dispense that care, the 745th Forward Surgical Team (FST), a detachment of the 31st Combat Support Hospital, became the U.S. Army's first unit to upgrade into a Forward Resuscitation and Surgical Team (FRST) at Fort Bliss, TX.

From the field to the lab, research being done to unlock the secrets as to why one combat Servicemember displays symptoms of a traumatic brain injury (TBI) differently from another is at the fore of what the Army's Combat Casualty Care Research Program (CCCRP), the Defense and Veterans Brain Injury Center (DVBIC), and the National Intrepid Center of Excellence (NICoE), Walter Reed National Military Medical Center (WRNMMC), are tasked with. A recently organized body called the Neuroscience, Neurotrauma, and Neurodegeneration Working Group (N3WG), U.S. Army Medical Research and Materiel Command (USAMRMC), is working to advance the development of devices to help assess brain injury, improve diagnostic tools, advance clinical trials of TBI-mitigating drugs, and improve personal protective equipment for preventing TBI-related injury.

As always, we welcome your comments and suggestions. Thank you for your continued readership.

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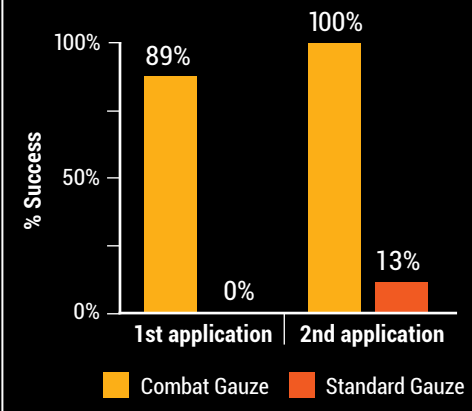

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TRANSFORMATION IN FIELD SURGICAL CARE

U.S. Army Medical Command (MEDCOM) is overseeing the transition of combat medical Forward Surgical Teams (FSTs) to Forward Resuscitation and Surgical Teams (FRSTs), bringing expanded capabilities in vital damage control resuscitation, surgery, and post-operative care to the front line.

By Ellen Crown, U.S. Army Medical Materiel Activity

745th FRST Commander LTC Brian Cooley (second from left) works with unit Soldiers as they inventory new equipment and supplies during medical materiel fielding at Fort Bliss, TX. (U.S. Army photo by Ellen Crown, USAMMA)

Earlier this year, the 745th Forward Surgical Team (FST), a detachment of the 31st Combat Support Hospital, became the U.S. Army's first unit to upgrade into a Forward Resuscitation and Surgical Team (FRST) at Fort Bliss, TX. The unit converted as part of a coordinated medical materiel fielding with the U.S. Army Medical Materiel Agency, a subordinate organization of the U.S. Army Medical Research and Materiel Command (USAMRMC).

Enhancing Forward Surgical Capability

Highly mobile 20-person medical teams that operate close to the front lines, FSTs provide emergency resuscitation and surgery to injured Servicemembers prior to further medical evacuation. The conversion to the FRST restructures the team and resources so they can split into two separate 10-person teams that are both able to provide "damage control" resuscitation, surgery and post-operative care.

"Functionally, FSTs have been splitting up in support of missions for years. However, when we would split up an FST, we would have to decide which team took a certain medical device or personnel," said LTC Brian Cooley, 745th FRST commander. "Now, with the restructure to a FRST, each team can provide complete capabilities. FRSTs are modular and scalable, offering the Army greater mission flexibility."

Cooley, a certified registered nurse anesthetist who has served in the Army for 28 years, worked alongside fellow Soldiers during the fielding. Similar to a FST, the FRST includes Army doctors, nurses, and medics, some of whom are pulled from the Army Professional Filler System, a program that fills deploying units with needed personnel to complete the mission. One change, however, is that FRSTs are no longer slotted to include operating room nurses. Detachment SFC Michael Reisinger, a combat medic with more than 13 years of service, said that change will require some team cross-training prior to deployment.

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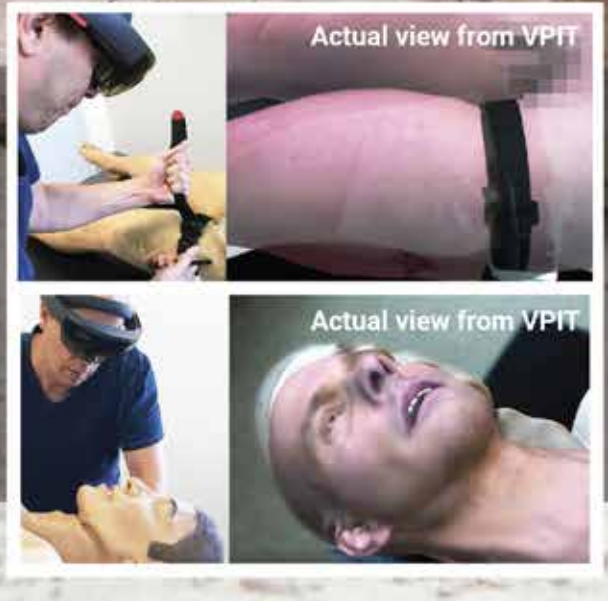

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Soldiers from the 745th Forward Surgical Team, a detachment of the 31st Combat Support Hospital, conduct a joint inventory as they receive medical equipment and supplies in support of conversion into a Forward Resuscitation and Surgical Team at Fort Bliss, TX.
(U.S. Army photo by Ellen Crown, USAMMA)

"I will be focused on making sure my Soldiers are fully trained and mentally prepared for the mission," said Reisinger, who participated in the fielding coordinated by the Army's Medical Materiel Activity (USAMMA) Mid-Western Regional Manager Jude Corpuz, in collaboration with USAMMA colleagues Emma Ashford and Natalie Ingram.

"Overall, this was a smooth fielding, due in great part to the unit for its support with the pre-planning and participation during the actual fielding and joint inventory," said Corpuz.

Corpuz also noted that the unit's property book officer participated during the fielding to ensure property accountability in the Global Combat Support System-Army (GCSS-A), the Army's single system for logistics management and property visibility. "USAMMA is working closely with GCSS-A and the Army Enterprise Systems Integration Program (AESIP) to define the interface process between our systems, applications and products (SAP), including the Theater Enterprise-Wide Logistics Systems (TEWLS). TEWLS is an information technology system within the Defense Medical Logistics – Enterprise Solution (DML-ES) portfolio. The goal is to streamline asset visibility within these systems so we can maintain full accountability of fielded medical equipment, including equipment that requires routine maintenance and calibration," she mentioned. "To keep FRSTs lean and agile, they do not include medical maintainers as part of the core team. This means that FRSTs depend on brigade-level support for medical maintenance and medical resupply."

Sustaining High-Level Equipment Readiness

Medical maintenance directly affects readiness. Medical equipment must be routinely serviced on schedule and calibrated in order to work properly. In order to plan for these maintenance cycles, brigade-level medical maintainers must have system visibility of the unit's medical equipment within GCSS-A.

"Accurate accountability in GCSS-Army is essential," stressed Corpuz. "There are many steps to the fielding process, but our goal when we're finished is to leave the unit ready to complete its mission."

The USAMMA plans to field the rest of the Army's FSTs, including 17 active units and 22 reserve units, to support their conversions to FRSTs within the next six years.

More info: http://www.usamma.army.mil/Pages/Main01.aspx

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PIONEERING USE OF ROBOTIC-ASSISTED SURGERY AT SEA

The U.S. Navy recently performed a first-of-its-kind maritime, operational, robotic-assisted surgery on board the USNS MERCY (T-AH 19) during its deployment in support of Pacific Partnership 2018. The initial operation on 04May2018 and the three others following it were executed flawlessly—the historic and innovative surgical endeavor was completely successful..

By LCDR Kyle D. Gadbois, MD FACS, Director of Surgical Services, USNS MERCY (T-AH 19)

Hospital Corpsman Third Class Dyllon Canady observes from the patient's side during an operation. As the primary surgical technician, he remains next to the patient and scrubbed-in at all times. (Photo by MC2(SW/AW) Kelsey Adams)

Stanford Research Institute, under a U.S. Army contract, first developed the original prototype for a robotic surgical system in the late 1980s. Although the initial goal was to develop a system for remote surgery on the battlefield, it gradually became clear that commercial applications were more viable during the early stages of the robotic surgical system's development. Approximately two decades later, the goals and purposes of the U.S. Army's investigational expenditure were ultimately realized with the first operational use of robotic-assisted surgery aboard the USNS MERCY (T-AH 19) during Pacific Partnership 2018.

LCDR Kyle D. Gadbois

Intuitive Surgical, an American corporation that develops, manufactures, and markets robotic products designed to improve clinical outcomes of patients through minimally invasive surgery, was founded in 1995. In January 1999, Intuitive launched the da Vinci system, and in 2000, it became the first robotic surgical system cleared by the U.S. Food and Drug Administration (FDA) for general laparoscopic surgery. In the following years, the FDA cleared the da Vinci system for thoracoscopic (chest) surgery, cardiac procedures performed with adjunctive incisions, as well as urologic, gynecologic, pediatric, and transoral otolaryngology procedures. As of September 30, 2017, there were 4,271 da Vinci surgical robots in use worldwide—2,770 in the United States, 719 in Europe, 561 in Asia, and 221 in the rest of the world.

Facility-Networked Capability

Currently, the U.S. Department of Defense has a number of continental United States military Medical Treatment Facilities (MTFs) that routinely use the da Vinci robotic-assisted surgical system. An example would be Naval Medical Center San Diego (NMCSD), which owns and operates two da Vinci Xi systems; each has dual-console operating ability, which facilitates more collaborative surgeon interaction and enhanced teaching. This is important as NMCSD is an academic teaching hospital that trains fellows, residents, and medical students from all over the United States.

Commander Tamara Worlton views a patient's internal anatomy on the robotic surgery console. Her hand movements on the console are directly translated to the robot's surgical instruments, resulting in extremely precise surgical dissection. (Photo by MC2(SW/AW) Kelsey Adams)

Pacific Partnership 2018 provided a unique setting for the first use of robotic-assisted surgery on an operational, maritime platform—the USNS MERCY (T-AH 19). This effort has been made possible through collaboration between multiple government organizations and industry: Military Sealift Command, Medical Treatment Facility USNS MERCY (T-AH 19), NMCSD, the Uniformed Services University of the Health Sciences, and Intuitive Surgical.

Current benefits of robotic-assisted surgery compared to open and conventional laparoscopic surgery include:

- Efficient access throughout the pelvis, abdomen, and chest, using small incisions (8mm) that enable reach into multiple areas of the body (pelvis, abdomen, and chest).

Dr. Vyramuthu Varanitharan (a Sri Lankan surgeon) placing one of four total trocars into the patient's abdomen. Each of the four trocars requires only an 8 mm incision to perform this particular minimally invasive surgical procedure (cholecystectomy). (Photo by MC2(SW/AW) Kelsey Adams)

- Advantages over open surgery, which can include all the benefits of minimally invasive surgery (MIS): shorter hospitalization, faster recovery, less pain, fewer wound complications (infection, hernia), and fewer adverse cardiac/respiratory events.

Novel technological features that distinguish robotic-assisted surgery as compared to conventional laparoscopic surgery include:

- Wristed instruments, allowing for technically enhanced exposure of tissue planes and more precise tissue dissection.
- Immersive three-dimensional (3D), high-definition (HD) visualization with magnified view ability.
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- Firefly™ Fluorescence Imaging System: real-time visualization and assessment of blood vessels, bile ducts, and tissue perfusion.
- "Intangibles"—A diverse operative experience that exemplifies a spirit of discovery and an energizing, educational atmosphere that enhances and heightens the desire and drive to learn new technologies.

Partnering for Progress

The nations involved in Pacific Partnership 2018 are both familiar with and very interested in the rapidly growing field of minimally invasive, robotic-assisted surgery. The da Vinci Xi surgical system replaces large-incision surgery (open surgery) with a minimally invasive approach. The system can be used across a wide spectrum of minimally invasive surgical procedures and has been optimized for complex, multi-quadrant thoracic, abdominal and pelvic operations—specifically for use in gynecologic, urologic, cardiothoracic and general surgery.

The U.S. Navy and Military Sealift Command is the first to use robotic-assisted surgery in an operational setting (fulfilling the initial goals and purposes of the U.S. Army's investigational expenditure in the late 1980s). Broadly, we hope that this research will allow us to advance the Military Health System's goal of increasingly integrating advanced medical and surgical technology into forward operating areas.

One example of how we might be able to do that is through improved remote training and "tele-mentoring" capabilities. The surgeon consoles of the da Vinci Xi surgical system currently can also function as training simulators. However, future research with regard to the imaging technology could facilitate distant viewing of an operation in real time, enabling another consulting surgeon to provide guidance and advice intra-operatively from a remote location. Furthermore, looking even further into the future, it is possible that coupling robotic-assisted surgery with telemedicine will eventually allow real-time interface between surgeons thousands of miles away, perhaps even facilitating active and direct participation in an operation from a remote location. The capabilities to allow deployed surgeons to improve or practice their surgical skills via simulation and/or seek real-time advice from other surgeons back in the U.S. are the kinds of capabilities that can help us bring expertise and support closer to our deployed Servicemembers in austere locations around the world..

However, it is important to note that this is foundational research and the current robotic surgery systems are not designed to treat combat injuries nor are they manufactured for active combat environments.

Augmented Reality: Improving Austere Surgical Care

While robotic surgical systems strive to take surgery beyond the limits of conventional, endoscopic, minimally invasive surgery using technologies like wristed instruments and improved vision, it's better to think of this as "augmented reality" rather than artificial or virtual reality. The current robotic surgery system seamlessly translates a surgeon's hand movements into precise movements of the surgical instruments, allowing for superior visualization, enhanced dexterity, greater precision, and improved ergonomic comfort.

The robotic surgical systems are not autonomous. In fact, the robot is completely controlled by the surgeon. The robot should be best described simply as an advanced surgical tool—the same as a surgical microscope or surgical instrument. The robot facilitates and allows technically complex procedures to be done using a minimally invasive surgical approach, but it is always under the direct control of the credentialed, privileged, experienced surgeon.

Fifteen to 20 years ago, minimally invasive surgery (particularly laparoscopy) revolutionized surgery throughout the world. Some countries adopted the technology sooner than others, and initially

The 8mm diameter fiber-optic laparoscope has two separate high-definition (HD) cameras – one for each eye. This allows for true three-dimensional (3D) depth perception when viewing the internal anatomy on the robotic surgery console. (Photo by MC2(SW/AW) Kelsey Adams)

there may have been resistance, but the benefits of minimally invasive surgery are proving increasingly valuable. In fact, on Pacific Partnership 2018 laparoscopy was common and routine in every country that we visited. This is reflective of laparoscopy's eventual universal acceptance by surgeons and its common use in surgical procedures every day throughout the world. Similarly, robotic surgery is still relatively early in its clinical development, but this revolutionary technology has great potential to improve surgery in the future.

As the U.S. military continues to meet the needs of combatant commanders who require forward deployed medical assets in austere environments, surgical expertise is an extremely valuable but scarce resource that requires judicial placement of deployed surgical assets. Servicemembers in harm's way know that surgeons and military medicine are present nearby to care for their wounded—this is a force multiplier. In the same way, in the future the ability to have real-time consultation and assistance in the form of telemedicine and robotic surgery will augment forward surgical presence and capability.

Moving Forward

One obstacle to wide-scale acceptance and implementation of robotic surgery includes the initial cost of the robot and its maintenance. The Pacific Partnership 2018/RIMPAC 2018 robotic surgical system was provided free of charge to the U.S. Navy under the terms of a Limited Purpose Cooperative Research and Development Agreement (LP-CRADA). Currently, the robot is specifically for minimally invasive surgery and not for major trauma surgery as seen in combat. However, the imaging system and telemedicine components of the robot could have very beneficial roles in combat surgery.

The robotic surgery system requires a secure operational maritime platform or non-mobile fleet surgical hospital. It is not designed for maneuver warfare as it is not portable and has specific power requirements. Furthermore, a robotic surgical system may require industry (Intuitive Surgical in this case) technician support. However, for PP18/RIMPAC18 there has been no equipment faults during more than five months of continuous use. Finally, the robotic equipment requires both surgeons and a surgical staff that are trained and comfortable with the technology.

ADDRESSING FULL-SPECTRUM PRODUCT LIFE CYCLE

COL John "Ryan" Bailey graduated from North Georgia College in Dahlonega, Georgia, with a Bachelor's Degree in Business Administration in Marketing. In June 1993, he was commissioned as a Second Lieutenant in the Army Medical Service Corps. He earned his Master of Business Administration Degree in Supply Chain Management from the Naval Postgraduate School, Monterey, California in 2004.

COL Bailey recently served as the Deputy Program Manager of the Joint Operational Medicine Information Systems Program Management Office, where he provided leadership and guidance for two ACAT I programs on acquisition, planning, and execution of the Department of Defense's new electronic health record, MHS GENESIS, for operational forces. The mission included the sustainment of Theater Medical Information Program-Joint and developing or acquiring any new capabilities to meet evolving operational requirements.

COL Bailey served in numerous acquisition and medical logistics positions at the tactical, operational, and strategic levels of the Army. His previous assignments include Platoon Leader; Property Book Officer; Division Medical Supply Officer; Operation and Plans Officer; Battalion Supply Officer; Company Commander; and Medical Logistics Plans Officer, Multi-National Corps Iraq. In 2014, COL Bailey served as Senior Joint Medical Logistics Officer for the Joint Staff Surgeon's Office. In 2011, he was Command-selected to serve as Joint Product Manager for the Chemical, Biological, Radiological, Nuclear, and Explosive Analytics and Response Systems within the Joint Program Executive Office for Chemical and Biological Defense. He completed a tour from 2006 to 2011 in Germany, where he led both the Materiel Management Division and the Distribution and Transportation Division, and served as Deputy Commander for Operations at the United States Army Medical Materiel Center, Europe. He also deployed in support of the Implementation Force in Bosnia-Herzegovina with the 1st Armored Division, and Operation Iraqi Freedom with V Corps/Multi-National Corps Iraq.

COL John "Ryan" Bailey

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

C&CC: What are some primary responsibilities of the U.S. Army Medical Materiel Development Activity (USAMMDA)?

COL Bailey: As a subordinate command of the U.S. Army Medical Research and Materiel Command (USAMRMC), Fort Detrick, MD, USAMMDA is tasked with developing and delivering quality medical capabilities to protect, treat, and sustain the health of Servicemembers throughout the world. The breadth and depth of our command offer distinct exposure to a wide range of medical materiel solutions, so from a military perspective, an assignment at USAMMDA offers an opportunity to be part of an organization that is focused on medical product development and acquisition, beginning with the analysis of alternatives through the entire lifecycle process of a product. While Army acquisition usually involves various types of defense equipment, such as tanks and weapons, USAMMDA focuses on military medical products, devices, pharmaceuticals, vaccines, and other medical solutions for our Servicemembers.

Among the numerous critical items that USAMMDA is currently developing for our troops, three of our primary focus areas are traumatic brain injury (TBI) solutions, hemorrhage control, and malaria countermeasures. Our product development in these key areas is certainly helping to support the continued readiness of our military forces worldwide.

C&CC: What is USAMMDA doing to help prevent, evaluate, and treat TBI in Servicemembers?

COL Bailey: Brain health falls under the Neurotrauma and Psychological Health (NPH) Project Management Office (PMO) at USAMMDA. The mission of the NPH PMO is to transition, develop, and field materiel solutions that assess, protect, treat, and care for Servicemembers suffering from TBIs and psychological health illnesses. The NPH PMO is focused on product development to take pre-clinical ideas and create

clinically relevant product solutions that support the DoD medical community. As such, we fund areas of potential solutions that are mature enough for clinical development, typically clinical trials sufficient to support submission to the U.S. Food and Drug Administration (FDA) for approval and eventual fielding.

Additionally, the NPH PMO interfaces with the Science and Technology (S&T) field to provide product development expertise for all of the TBI studies that are potential solutions in pre-clinical development, to ensure any successful efforts are ready for transition to the NPH PMO portfolio. As such, we are monitoring and shaping efforts for alternative therapies for TBI, such as stem cells and hypothermia, future biomarker and device efforts to diagnose mild TBI and understand mild TBI prognosis, and for potential treatments for mild TBI.

C&CC: What product(s) do you have available for the prevention, evaluation, and treatment of TBI in Servicemembers, and what is the effect on readiness?

COL Bailey: Currently, the NPH PMO has two funded product development efforts. One is the Laboratory Assay for TBI (LATBI), which is the first-ever blood marker of brain injury to help in the evaluation of Servicemembers who have acutely experienced a potential head injury. The second one is the drug treatment for TBI, where the goal is to redesign Phase 2 clinical studies for TBI drug development using a proven TBI clinical network to perform adaptive clinical trials on multiple candidate drugs, to ultimately achieve FDA approval and field a new capability.

Soldiers from the 75th Ranger Regiment, Ft. Benning, GA, use the French freeze-dried plasma on a simulated injury in a training exercise. (SOCOM, 75th Ranger Regiment, Ft. Benning, GA)

Although both of these programs are critical for helping to treat affected Servicemembers, the most influential and groundbreaking one may be LATBI, which has been a primary focal point. In conjunction with our commercial partner, the NPH PMO recently received FDA approval for the Banyan BTI™ (Brain Trauma Indicator)—the first-ever blood test used to evaluate instances of mild TBI. Within 12 hours of injury, the test analyzes two particular brain biomarkers to determine

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FDA TAKES ACTION TO SUPPORT AMERICAN MILITARY PERSONNEL BY GRANTING AN AUTHORIZATION FOR FREEZE-DRIED PLASMA PRODUCT TO ENABLE BROADER ACCESS WHILE THE AGENCY WORKS TOWARD APPROVAL OF THE PRODUCT

For Immediate Release |July 10, 2018

The U.S Food and Drug Administration announced that an emergency use authorization (EUA) has been granted to the U.S. Department of Defense (DoD) to enable the emergency use of Pathogen-Reduced Leukocyte-Depleted Freeze-Dried Plasma manufactured by the Centre de Transfusion Sanguine des Armées (referred to in the EUA as French FDP).

"Earlier this year, we reaffirmed our commitment to the Department of Defense (DoD) and to the dedicated men and women protecting our country, by expediting the development and availability of safe and effective, priority medical products that are essential to the health of our military servicemembers. This is especially true when it comes to products used to treat injuries in a potential battlefield setting," said FDA Commissioner Scott Gottlieb, M.D. "Through our collaborative program with the DoD, they've made clear the importance of access to freeze-dried plasma in initial efforts to control hemorrhage from battlefield trauma. Granting this authorization will support access to this important product in the event it's needed." Under this EUA, the use of French FDP is authorized for the treatment of hemorrhage or coagulopathy of U.S. Military personnel during an emergency involving agents of military combat (e.g., firearms, projectiles, and explosive devices) when plasma is not available for use or when the use of plasma is not practical. Hemorrhage, sometimes accompanied by coagulopathy (a condition that affects the blood's ability to clot), is the leading cause of preventable deaths among combat trauma casualties. Plasma contains proteins that help clot blood and can be used for the management of hemorrhage and coagulopathy, but its use in combat settings is severely limited by logistical and operational challenges such as the need for refrigeration and—in the case of frozen plasma—a long thawing period. This French FDP is a powdered, freeze-dried product that can be used following reconstitution in settings where refrigeration is not available, thus enabling the rapid availability of plasma for use at the point of injury.

The FDA issued this EUA in response to a request from DoD and after receiving the required determination by DoD and a declaration by the Secretary of the Department of Health and Human Services. This action is the result of the close collaboration between the FDA and the DoD to prioritize the efficient development of safe and effective medical products intended to help save the lives of American military personnel.

The FDA outlined its approach to advancing the development and availability of medical products to help save the lives of American military personnel in a work plan it developed in close collaboration with DoD earlier this year. The FDA remains committed to working to address the medical needs of military personnel. The FDA is also providing its highest level of attention to helping expedite the development and review of medical products that are a priority for DoD, to aid in the rapid development and manufacturing of safe and effective medical products for use by the U.S. military.

Laboratory Assay for TBI (LATBI) devices enable blood marking for traumatic brain injury (TBI) monitoring. (Photo by USAMMDA Public Affairs)

if a computed tomography scan of the head is necessary or may be ruled out. Not only will this test be useful in determining a mild TBI event, but it will also help to eliminate many unnecessary CT scans for military—and eventually civilian—patients.

This past winter, we held a training session at Fort Detrick to demonstrate the LATBI assay, and this was very helpful for everyone involved. Although we currently use a large benchtop unit for the assay, the ultimate goal is to develop a small handheld device that could be used practically anywhere, including on the battlefield, to provide test results quickly. While the assay currently uses only two specific brain biomarkers, we hope to uncover many other biomarkers in the future that can be used to identify and classify novel indications for other types of brain injury research.

C&CC: What is freeze-dried plasma, and how will it benefit Servicemembers?

COL Bailey: As blood loss from catastrophic injuries remains a major factor in deaths on the battlefield, USAMMDA's Pharmaceutical Systems PMO has been focused on the development of a freeze-dried plasma (FDP) product for our military. FDP is the dry, powdered form of fresh-frozen plasma (FFP), from which water has been removed by the process of lyophilization.

Regarding the product itself, each unit of FDP corresponds to one unit of FFP and is supplied in a flexible plastic bag container. The FDP is packaged in a portable kit that contains the FDP, sterile water for injection in a separate bag, a sterile transfer set, and a separate infusion set. A key attribute of this system is that it can be utilized very quickly by the medic in the field, as rehydration to a full transfusable unit (approximately 250 ml) takes less than a minute.

For the Servicemember, the benefit of FDP is that it can be deployed further forward on the battlefield, at or close to the point of injury. It also reduces the logistical burden associated with frozen versus thawed FFP. The goal of this program is to save as many lives as possible, and our Pharmaceutical Systems PMO hopes to gain U.S. FDA approval by 2019 so that it can be readily available for our military throughout the world.

C&CC: Would combat medics or surgeons be delivering FDP and under what conditions (in a hospital, during MEDEVAC, or in the field at point-of-injury)?

COL Bailey: Today, we are closely involved with supporting the U.S. Special Operations Command with a French version of freeze-dried

The USAMMDA Pharmaceutical Systems Project Management Office Tafenoquine program team members, from left to right: Dr. Moshe Shmuklarsky; Mr. Gerry LoSardo; Ms. Kathy Simpson; MAJ Victor Zottig; MAJ Katherine Carr; Dr. Frank Klotz; Mr. John Clarke; and Dr. Selva Murugesan (USAMMDA Public Affairs)

plasma, and it is being used successfully in remote areas by both medics and surgeons as an expanded-access investigational new drug.

Ultimately, U.S.-sourced FDP will be available for use by military medical professionals whenever there is a requirement for plasma transfusion. In the short term, prior to full approval, when FDP is given limited approval by the FDA for use under austere conditions, it will be available in hospital emergency rooms when FFP cannot be provided, and outside of the hospital at the point-of-injury. For the deployed military, it will be available at all care levels (Roles 1–3) during MEDEVAC and at Role 4 as necessary.

C&CC: What is tafenoquine, and how will it benefit Servicemembers?

COL Bailey: Tafenoquine is our newest antimalarial drug. A new drug application has recently been submitted to the U.S. FDA for approval. Tested for use in adults, tafenoquine has been developed as both a treatment and a prophylactic (preventative) drug for malaria, which is a very serious and sometimes fatal disease transmitted by the Anopheles mosquito. The chemical structure of tafenoquine is similar to primaquine, which is the only FDA-approved antimalarial drug for the radical cure (prevention of relapse) of P. vivax malaria. Primaquine has been in clinical use in the United States for more than 60 years, since its FDA-approval in 1952.

Military personnel deployed to malaria-endemic areas are at high risk for contracting malaria. Therefore, the DoD has great interest in ensuring the safety and full operational capability of personnel during missions in malaria-endemic areas. The weekly dosing of tafenoquine will provide a highly convenient, safe, and effective option as an anti-malarial prophylactic drug for our Servicemembers throughout the world.

C&CC: What are the advantages of tafenoquine over other antimalarial drugs?

COL Bailey: As a large number of antimalarial drugs have shown decreased efficacy due to resistance or are of limited use because of known side effects and/or inconvenient drug-dosing schedules, the DoD has been a critical partner in the development of past and present FDA-approved antimalarial drugs in the United States. We've found that tafenoquine has many advantages over other types of similar drugs, such as its high efficacy against all malaria parasites that infect humans, including the deadliest species, P. falciparum. Additionally, it acts against all stages of the malaria parasite life cycle, including the liver-stage of relapsing forms of malaria, such as P. vivax. Tafenoquine reduces the spread of malaria by preventing malaria transmission from an infected person to mosquitoes.

Whereas most antimalarial drug treatments or prophylaxis require daily dosing, tafenoquine will have a convenient, once-a-week dosing schedule. Primaquine, the current drug to protect against relapsing malaria, requires up to 14 days of dosing following departure from a malaria-endemic area. As an anti-relapse agent, tafenoquine requires only a single terminal prophylaxis dose, offering a much more convenient option for Servicemembers returning home. Collectively, tafenoquine offers a safe, effective, and convenient option to protect against the top infectious disease threat to Servicemembers deployed overseas.

BATTLEFIELD TRIAGE: BUILDING MODULARITY AND MOBILITY

By Jonathan Doyle, USAMMDA Medical Support Systems Project Management Office

Soldiers set up Temper Air-Supported shelters for a U.S. Army Medical Research and Materiel Command product demo at Fort Polk. (Photo by Carey Phillips, USAMMDA public affairs)

One of the core building blocks for the modern military is capable field hospitals. To fill that need, the TEMPER (Tent, Extendable, Modular, Personnel) Air Supported shelter (TAS), developed by the U.S. Army Medical Materiel Development Activity (USAMMDA), a subordinate command of the U.S. Army Medical Research and Materiel Command (USAMRMC) and part of the U.S. Army Medical Department (AMEDD), was recently adopted by the Product Manager Force Sustainment Systems for general Army shelter requirements. These shelters are expeditionary in that they allow for mission dependent modularity, are lightweight, and are faster to deploy than current TEMPER aluminum shelters.

Steve Hawbecker

Advanced Capability to Address Real Need

The new and improved TAS replaces the original TEMPER shelter, composed of a tent made of fabric placed over a metal A-frame with a shelf life of 10 years. The majority of the current stock is older than 10 years and in dire need of replacement.

"As late as 2014, TEMPER testing showed that the old shelters were not passing fire-resistant requirements and were potentially unsafe to patients and staff," said Steve Hawbecker, project manager for the USAMMDA Medical Support Systems Project Management Office.

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"These were bulky and heavy systems, which took 10 to 12 Soldiers one to two hours to assemble," he continues. "Soldiers were prone to injuries from having their fingers pinched in the frames and from heat exhaustion in extreme temperatures while assembling the shelters."

Soft-wall shelters are typically replaced after 10 years, and since the majority of Combat Support Hospital (CSH) TEMPER shelters are older than 10 years, with most exceeding 20, replacement is of critical importance. To replace 74 percent of the Force Design Update tenting with new TEMPER Air Supported shelters would require a significant amount of funding, with remaining assets modernized in future budget planning.

The process to inflate a 64-foot section of a TEMPER Air-Supported shelter takes about 15 minutes. (Photo by Ashley Force, USAMMDA public affairs)

Increased Strength and Decreased Weight

The newer shelters comprise a self-healing fabric, are 50 percent lighter, and deploy 50 percent faster than TEMPER shelters currently in use. The new field hospitals are comprised of modular units, starting with a 32-bed early entry section, which provides hospitalization and outpatient services in support of deployed forces. Next, either the surgical capabilities are expanded with a 24-bed surgical augmentation, capability or intensive and intermediate medical care augmentation which increases by an additional 32 beds. Finally, a 60-bed intensive care capability is added, depending on what is required.

The TAS incorporates four high-pressure air-filled arches to provide the framework for the shelter. The interior of the shelter has a 10-foot height, 20-foot width, and 32-foot length. It will withstand wind gusts of up to 65 miles per hour and a snow load of 10 pounds per square foot. With a shelf life of 15 years, these shelters also include a thermal liner to improve energy efficiency, which provides a more comfortable environment for the staff and patients during hot and cold extremes.

Weighing less than the legacy TEMPER, the TAS is streamlined for shipping purposes, which also makes it easier for Soldiers to maneuver. The TAS weighs about 1,600 pounds, which is about 50 percent lighter than the old TEMPER.

"Reducing the weight of the new field hospital by approximately 17 tons, while deploying 50 percent faster, is a real game-changer to be more expeditionary for the AMEDD," said Jaime Lee, product manager for the MSS PMO at USAMMDA. "It takes four personnel eight minutes to roll out the shelter for deployment, and a compressor, diesel or electric, does the rest. The shelter can be erected in about 15 minutes."

Putting TAS to the Test

In 2016, the 115th Combat Support Hospital hosted the USAMMDA-sponsored equipment verification event at Fort Polk, Louisiana, to review the new field hospital design. USAMMDA led the exercise in coordination with the Army Medical Department Center and School/Health Readiness Center of Excellence, Capabilities Development Integration Directorate, the AMEDD Board, and the U.S. Army Medical Materiel Agency. During this two-week event, new products were evaluated, such as the configuration of the water and wastewater systems, TEMPER Air Supported shelters, and the new M400 digital power distribution system, as well as a new power design for the computed tomography scanner system.

The 10th Field Hospital at Fort Carson, Colorado, made history in September 2017 by becoming the first active-duty unit to set up and test the new field hospital, a modular modernization update to the well-known Combat Support Hospital.

During these exercises and throughout trainings, lessons have been learned. Lee explains there is a constant cycle of training and turnover at combat support hospitals. Anytime you are fielding a new system you have to expect mistakes and lessons learned. To address inflation issues, additional diesel compressors were added to provide flexibility for inflation of multiple TAS. Other lessons learned involved shelters damaged as a result of improper shipping, incorrect loading and offloading of the shelters, and not laying the proper foundation to deploy the shelters. These situations can damage the shelters, causing costly repairs and even making them unusable. In response to this, and as a companion to the physical training, USAMMDA developed a secure, Common Access Card-accessible training site for the TAS shelters, complete with vendor manuals and training videos.

"The TAS shelters serve a very important role in the combat support hospital infrastructure," said Lee. "The TAS shelter online training site offers tools to help properly train our Forces as they deploy the TAS shelters."

The improvements to the shelter, physical training of CSH, and access to the online training site are steps towards a prepared and ready Force.

As the premier developer of world-class military medical capabilities, USAMMDA is responsible for developing and delivering critical products designed to protect and preserve the lives of Warfighters across the globe. These products, such as the TAS shelters, are intended to maximize survival of casualties on the battlefield.

Combat & Casualty Care recently spoke with Mr. Jaime Lee, Product Manager, Medical Support Systems Project Management Office of the U.S. Army Medical Materiel Development Activity (USAMMDA), regarding early implementation of the TEMPER Air Shelter (TAS) capability and projected use and evolution of TAS across a global battlespace.

C&CC: From a combat medical shelter capability evolutionary perspective, please speak to primary variations in shelter systems the Army/Joint DoD have used and challenges driving decision-making to the present-day solution set.

Jaime Lee

Lee: The new TEMPER (Tent, Extendable, Modular, Personnel) Air Supported shelters are expeditionary versus the older aging TEMPER shelters that no longer pass fire-retardant requirements and have been determined by Product Manager, Force Sustainment, to need replacement. These new shelters are 50 percent lighter. They save an estimated 17 tons for each 148-bed field hospital. They can be erected by four Soldiers in about 15 to 30 minutes, which is 85 percent quicker than the older medical tents that can take more than an hour to set up. Just one 64-foot section takes about 15 minutes to inflate. So, care happens faster than with the current system.

C&CC: As recent decades of combat operations in austere environments have made clear, terrain and climate have posed challenges to mobility and operation of medical tent application for more than basic triage and pre-evacuation prep. Can you tell us about the asset of transportability and constructability offered by Air Supported sheltering that offers greater support of critical triaging needs than past shelter options?

Lee: The new field hospitals with TAS are lightweight and transport easily and can deploy anywhere and "withstand diverse climate challenges." For example, based on TAS destroyed at Fort Carson during a training scenario where winds exceeded 65 mph, sandbags were added so TAS could be deployed safely in high wind conditions and were waterproof so they could withstand high-water rain areas. The sandbags will keep the shelters in place in gusts up to 55 to 65 mph and prevent water intrusion into the TAS. Also, installing a floor tarp protects the floor from sharp

objects if not removed before deploying the TAS. In addition, since the shelters are modular in concept, lighter and faster to deploy, patient triage support is faster, providing lifesaving capabilities sooner.

C&CC: From an environment challenges perspective, please discuss ways Air Supported sheltering meets climate adversity even in situations where lighter-weight systems might seem less robust than heavier, more permanent solutions.

Lee: The new TAS have a thermal liner in them that decreases thermal loading by 40 percent. This works in cold and warm environments to make the working area more usable for the patients and staff and saves energy by being more efficient. Solar shades are also being used in hot environments, and these shades decrease solar loading by 90 percent.

C&CC: In terms of adaptability for changing triaging needs, how are Air Supported shelters addressing greater prolonged field care needs of mobile combat forces, often Joint or coalition in nature?

Lee: TAS shelters that make up the new field hospital, which is modular in design, allow for prolonged field care once deployed to an operational environment. Since the TAS provides one of the key components to the new field hospital, it allows for maximum hospital services in a much faster and more flexible fashion. It does this by being easier to deploy and easier to take down and move somewhere else in a more timely manner. The new field hospital provides modularity by being comprised of a 32-bed early entry hospital, 24-bed surgical augmentation, 32-bed medical augmentation, and 60-bed intensive care ward addition. This can provide prolonged care anywhere in the world, once deployed.

C&CC: Looking ahead to changing Army/DoD force strategy in meeting combat casualty needs in more austere, extended range scenarios, what modularity do you see Air Supported shelters bringing and what potential improvements do you see for this solution in meeting unpredicted future challenges?

Lee: The new TAS is genuinely expeditionary by being lighter and faster to deploy. The new field hospital can deploy anywhere a lot faster and can be taken down and redeployed to a new area. By using this new system of shelters, the Army Field Hospital has been made lighter and faster to deploy in any combat situation.

The TEMPER Air Supported shelters serve an essential purpose as part of the crucial infrastructure of the new field hospital. This modernization effort replaces the current metal frame TEMPER shelters, which are no longer safe to use, with a much-improved expeditionary shelter system that is faster to deploy, lighter to use, and more energy-efficient for prolonged field care.

ADDRESSING TBI CAUSE AND EFFECT

Recent efforts by the Neuroscience, Neurotrauma, and Neurodegeneration Working Group (N3WG), U.S. Army Medical Research and Materiel Command (USAMRMC), Ft. Detrick, MD, are shedding light on biological markers helping to measure the severity of traumatic brain injury and the need for long-term care.

By Christian Sheehy, Editor

A soldier performs tactical field medical care on a mock patient during Expert Field Medical Badge testing at Fort Bragg, NC. (Army photo by PFC Sadie Martinez)

Since the turn of the century, significant strides in therapeutic approaches to aid clinicians in the diagnosis and treatment of traumatic brain injury (TBI) have been made, including the FDA approval of multiple devices to help assess brain injury, ongoing efforts to develop improved diagnostic tools, clinical trials of TBI-mitigating drugs, and improvements to personal protective equipment for preventing injury. Recognizing the importance of maintaining brain health, the DoD has focused ongoing efforts in multiple facets of TBI research, such as the development of a stratification system of TBI severity, the cellular causes of injury, medical device development, therapeutic approaches, and finally, drug-discovery efforts intended to mitigate mortality and morbidity resulting from injury.

According to representatives of the Combat Casualty Care Research Program (CCCRP), Ft. Detrick, MD, reports are that the DoD has made significant investments in TBI research in recent years. As ongoing conflicts continued to result in an elevated number of Soldiers suffering TBI, this increased occurrence, while partially due to an increase in combat-related injuries, also reflects the medical field's improved ability to diagnose and provide therapy for TBIs.

Post-Initial Diagnosis

Both CCCRP and Congressionally Directed Medical Research Programs report that the following long-term efforts have been initiated to understand and potentially minimize the negative long-term effects of TBI:

- **The Transforming Research and Clinical Knowledge in TBI** (TRACK-TBI; see https://tracktbi.ucsf.edu/). This study is collecting and analyzing detailed clinical data on subjects at 18 U.S. sites, across the TBI spectrum, along with CT/MRI imaging, blood biospecimens, and detailed clinical outcomes. The goal of this study is to improve TBI classification, improve outcome assessments, and identify the health and economic impact of TBI patient disposition. TRACK-TBI is primarily funded by the National Institutes of Health with additional DoD funding managed by CCCRP.
- **The Chronic Effects of Neurotrauma Consortium** (CENC; see https://cenc.rti.org/) focuses on the long-term effects of combat-related and military-relevant TBI. CENC identifies and

characterizes the anatomic, molecular, and physiological mechanisms of chronic injury from TBI, such as potential neurodegeneration, and investigates the relationship of comorbidities.

- **Targeted Evaluation, Action, and Monitoring of Traumatic Brain Injury** (TEAM TBI; see http://www.team-tbi.com/) focuses on precision medicine with targeted strategies based on specific TBI phenotypes for individual patients. This study evaluates the extent of everyone's injury with comprehensive assessments, including cognitive/neuropsychological testing, vestibular/oculomotor testing, cervical evaluation, sleep evaluation, high-definition fiber tractography MRI, MR spectroscopy, magnetoencephalography, and biomarker profiles.
- **TBI Endpoints Development initiative** (TED; see https://tbiendpoints.ucsf.edu/) works to identify and validate clinically relevant endpoints to accelerate FDA approval of TBI diagnostic tools and therapeutic agents to improve patient stratification, better inform TBI clinical trial design for targeted outcomes, and improve regulatory readiness of both diagnostic biomarkers (blood based and neuroimaging) and clinical outcome measures (e.g., cognition endpoints).
- **The Federal Interagency Traumatic Brain Injury Research** (FITBIR; see https://fitbir.nih.gov/) was developed through a collaborative effort between the USAMRMC and the National Institute of Neurological Disease and Stroke (NINDS) to advance neurotrauma research to include diagnosis and treatment capabilities of TBI patients. FITBIR contains a large amount of high-quality and reproducible TBI data spanning from neuroimaging, clinical assessments, genomics, and other TBI data types, enabling researchers to utilize a common platform for standardization of data elements, definitions, tools, and outcome measurements; apply bioinformatics solutions to data collection, storage, access, and analysis; and share de-identified data and collaborate on scientific research studies including comparative effectiveness research studies, on optimal treatments and diagnostic tools.
- **The International Traumatic Brain Injury Research initiative** (In TBIR; see https://intbir.nih.gov/) provides a framework for fostering international collaborations to "improve health care and lessen the global burden of TBI by 2020 through the discovery of causal relationships between treatments and clinically meaningful outcomes."
- **The NCAA-CARE Grand Alliance CARE Consortium** (CARE Consortium; see http://careconsortium.net/) conducts large-scale studies of sports-related concussion, such as those from impacts, at NCAA sites to prospectively characterize the full spectrum of concussion using standardized clinical measures at baseline and post-concussion. Participating institutions include military service academies such as the U. S. Military Academy (West Point) and the U.S. Air Force Academy. Within the CARE Consortium, there is a smaller study under an advanced research core, which utilizes several advanced sensors, neuroimaging techniques, and biomarkers to better understand recovery trajectories of concussion from head impacts.
- **Exploring the Natural History of Traumatic Brain Injury within a Military Cohort — A Longitudinal Database and Blood Banking Study** (commonly referred to as the DVBIC 15-year study; http://dvbic.dcoe.mil/research/exploring-natural-history-traumatic-brain-injury-within-military-cohort-longitudinal) examines the effects of TBI incurred by Servicemembers during Operations Iraqi Freedom and Enduring Freedom. Annual Servicemember evaluations included as part of the study will allow the DoD to determine the type of healthcare and rehabilitation services needed to address the ongoing symptoms of Servicemembers. Presently, there are no FDA-approved pharmaceutical interventions to treat TBI. Researchers and clinicians are working to be able to examine and continually improve existing clinical practice guidelines for treatment of chronic TBI to better treat the symptoms experienced by patients.

Monitoring Psychological Variations

MOMRP reports that DoD is using IT solutions to make psychological monitoring more effective. By regularly monitoring the psychological health of Servicemembers through online tools like the Behavioral Health Data Portal, which prompts Servicemembers to answer questionnaires about physical/psychological health, it is hoped that the psychological sequelae associated with TBI (e.g., cognitive problems, PTSD/anxiety, depression, anger, and difficulty with sleep) can be detected and treatments/interventions administered sooner.

In 2015, the Ahead 200 smartphone technology was cleared by the FDA to help clinicians assess mildly presenting head trauma patients. The device, which was developed by the U.S. Army Medical Research and Materiel Command's Combat Casualty Care Research Program and the BrainScope Company, Inc., uses commercial smartphone

technology to analyze a patient's brain activity for signs of a TBI within 24 hours of the injury.

The device works by measuring the brain's electrical activity via a disposable headset that is placed on the forehead. Once recorded, the Ahead 200 uses algorithms that quantify and characterize activity associated with TBIs. Used in conjunction with other tools, the Ahead 200 medical device will assist clinicians in the real-time screening and care of Warfighters with head injuries.

Other psychological monitoring efforts being explored, specifically for stress, include biomarkers for PTSD/pathological stress levels in the form of blood-based molecules; voice analysis; imaging; and wearable monitors that can capture, measure, and report to providers high levels of stress and/or anger or sleep problems.

Looking Out

The National Research Action Plan responding to a Congressional Executive Order entitled "Improving Access to Mental Health Services for Veterans, Servicemembers, and Military Families" speaks to improving the coordination of agency research into TBI to reduce the number of affected men and women through better prevention, diagnosis, and treatment. The Plan describes overall strategy to translate research findings into clinical practice and other activities.

Future efforts to improve assessment and management of post-concussive dysfunction must include focused calls to characterize subtle, duty-limiting impairments that may address a Servicemember's ability to perform their wartime mission. The area of ecological assessment, which focuses on multimodal, operational assessment of Servicemembers seeking to return to duty following TBI, is of importance given the emphasis on maintaining unit lethality and operational readiness.

The Ahead 200, cleared by the FDA in May 2015 to help clinicians assess mildly presenting head trauma patients, uses commercial smartphone technology to analyze a patient's brain activity for signs of a traumatic brain injury within 24 hours of injury. The device works by measuring the brain's electrical activity via a disposable headset placed on the forehead. Once recorded, algorithms quantify and characterize activity associated with traumatic brain injuries. (USAMRMC Public Affairs)

ENHANCING INTEROPERABILITY AND PROLONGED FIELD CARE

ZOLL, a provider of comprehensive solutions for military medical care from monitoring and airway management to enhanced perfusion, focuses on providing lifesaving technologies that are portable and effective for all roles of care throughout the life cycle of DoD's en route care system.

By Brenda Butler, Vice President Global Military Sales

This past January, after extensive evaluation, ZOLL® received a sole-source contract from the Defense Logistics Agency (DLA) Troop Support to supply Propaq M deployable, vital-signs monitors to the U.S. Air Force and U.S. Army. The Propaq M vital-signs transport monitor, with advanced monitoring parameters, includes an integral printer and is available with an optional integrated defibrillator and pacer for critical lifesaving mission readiness. This small and lightweight device, known as the Propaq MD, eliminates the need to carry a separate monitor and defibrillator, improving operational and cost efficiencies. Although not frequently used during deployed missions, the Propaq MD, with integrated, evidence-based, lifesaving ZOLL Resuscitation Technologies, ensures improved survival outcomes when seconds count.

The Propaq M joins several other ZOLL airworthy products selected by the military services as their standard critical care transport medical device. This further enhances Defense Healthcare's goal for interoperability throughout all roles of care from Medevac to strategic critical care airlift and humanitarian missions worldwide. As requirements change, the Propaq will continue to evolve with additional capabilities and algorithms incorporated.

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ZOLL remains committed to developing leading-edge resuscitation technologies for the military as it has for more than 25 years. From vital signs monitoring and defibrillation to critical care ventilation, ZOLL continues to be the standard of care chosen by military health-care providers of NATO, NATO partners, and U.S. agencies. Whether on the battlefield, during aeromedical transport, or in the Continental United States or a VA hospital, ZOLL has solutions to help provide the highest-quality casualty care.

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SLOWING THE "CLOCK" TO EXTEND GOLDEN HOUR

Soldiers with the 115th Brigade Support Battalion, 1st Brigade Combat Team, 1st Cavalry Division practice rendering first aid in Hohenfels, Germany, during Combined Resolve III. Combined Resolve III was a multinational training exercise designed to reinforce our nation's commitment to ally and partner nations. (U.S. Army photo by SPC Marcus Floyd, 7th Mobile Public Affairs Detachment)

When a Servicemember suffers a traumatic injury or acute infection, the time from event to first medical treatment is usually the single most significant factor in determining the outcome between saving a life or not. First responders must act as quickly as possible, first to ensure a patient's sheer survival and then to prevent permanent disability. The U.S. Department of Defense refers to this critical, initial window of time as the "golden hour," but in many cases the opportunity to successfully intervene may amount to much less than 60 minutes, which is why the military invests so heavily in moving casualties as rapidly as possible from the battlefield to suitable medical facilities. However, due to the realities of combat, there are often hard limits to the availability of rapid medical transport and care.

Leveraging Biology to Maximize Recovery

The Defense Advanced Research Projects Agency (DARPA) created the Biostasis program to develop new possibilities for extending the golden hour, not by improving logistics or battlefield care but by going after time itself, at least how the body manages it. Biostasis will attempt to directly address the need for additional time in continuously operating biological systems faced with catastrophic, life-threatening events. The program will leverage molecular biology to develop new ways of controlling the speed at which living systems operate and thus extend the window of time following a damaging event before system collapse. Essentially, the concept aims to slow life to save life.

Sailors assigned to Expeditionary Resuscitative Surgical System (ERSS) Team 15 conduct a medical survival-training scenario in an open-spaced storage warehouse. While forward deployed to U.S. 5th Fleet area of operations, ERSS Team 15 provides tailored, mission-specific medical capabilities in support of military operations afloat and ashore. (U.S. Navy photo by Mass Communication Specialist 1st Class Kenneth R. Hendrix/Released)

"At the molecular level, life is a set of continuous biochemical reactions, and a defining characteristic of these reactions is that they need a catalyst to occur at all," said Tristan McClure-Begley, the Biostasis program manager. "Within a cell, these catalysts come in the form of proteins and large molecular machines that transform chemical and kinetic energy into biological processes. Our goal with Biostasis is to control those molecular machines and get them to all slow their roll at about the same rate so that we can slow down the entire system gracefully and avoid adverse consequences when the intervention is reversed or wears off."

The program will pursue various approaches to slowing down biochemical processes in living cells. Ideally, these approaches will scale from simple biological treatments such as antibodies to more holistic treatments applicable to whole cells and tissues, eventually scaling all the way up to the level of a complete organism. Successful approaches will meet the conditions that the system be slowed across all measurable biological functions and that it do so with minimal damage to cellular processes when the system reverts and resumes normal speed.

"Our treatments need to hit every cellular process at close to the same rate and with the same potency and efficacy," McClure-Begley said. "We can't focus treatments to interrupt just a subset of known critical processes."

Targeting Individual Cell Processes

As an example, cellular respiration is critical for many cellular processes, but those other processes do not shut down in tandem if respiration is blocked. The maladaptive responses from such an intervention would ultimately kill the cell. DARPA is also looking for biochemical approaches that control cellular energetics at the protein level. Proteins are the workhorses of cellular functions, and nature offers several examples of organisms that use proteins to help them survive extreme environmental conditions. Creatures such as tardigrades and wood frogs exhibit a capability known as "cryptobiosis," a state where all metabolic processes appear to have stopped, yet life persists. In the case of tardigrades—microscopic invertebrates colloquially known as "water bears"—they can survive freezing, near total dehydration, and extreme radiation. Wood frogs, meanwhile, can survive being frozen completely solid for days on end. And while the specific molecular mechanisms involved in these animals are very different, they share a common biochemical concept: They selectively stabilize their intracellular machinery.

"Nature is a source of inspiration," McClure-Begley said. "If we can figure out the best ways to bolster other biological systems and make them less likely to enter a runaway downward spiral after being damaged, then we will have made a significant addition to the biology toolbox."

Intended Capability Aim

Biostasis is initially meant to generate proof-of-concept benchtop technologies for testing their application in simple living systems in experimental validation settings. To support eventual transition to patients, DARPA will work with federal health and regulatory agencies as the program advances to develop a pathway for potential, future human medical use. By the end of the five-year, fundamental research program, DARPA hopes to have multiple tools for reducing the risk of permanent damage or death following acute injury or infection.

Similar Biostasis technologies could also extend the shelf life of blood products, biological reagents, and drugs by reducing reaction times. Early program research is aimed at identifying approaches that can be tested in simple biological systems such as enzyme complexes or cell lines. If this aspect of the program is successful, these technologies would help to reduce the Defense Department's logistical burden of transporting biological products into the field.

More info: darpa.mil

ADDRESSING TRENDS WITH PROACTIVE CARE

According to Defense and Veterans Brain Injury Center (DVBIC), more than 370,000 Servicemembers have experienced a traumatic brain injury (TBI) since 2001. The National Intrepid Center of Excellence (NICoE) at the Walter Reed National Military Medical Center (WRNMMC) in Bethesda, Maryland, is tasked with improving the lives of patients and families living with TBI and associated conditions. Within the Military Health System's TBI Pathway of Care is the assessment and treatment of injured Servicemembers, spanning screening and identification to community reintegration.

By Dr. Treven Pickett, Department Chief, Research, NICoE

Photo courtesy of NICoE

I arrived at the National Intrepid Center of Excellence (NICoE) in August 2017 from the Richmond Veterans Affairs Medical Center to assume the role of Department Chief, Research. When I assumed responsibilities, there were a number of efforts underway to build—and share—promising clinical, informatics, and research initiatives as part of an overall effort to support TBI patients and families in the Military Health System.

Dr. Treven Pickett

Confronting Increased TBI Incidents in the Military Community

A board-certified rehabilitation psychologist by specialty, I have always been inspired to work with patients to harness their strengths and abilities when they are challenged the most. A common thread in my research interests is to explore ways to optimize rehabilitation for any number of medical and psychiatric conditions. My research has spanned stroke, dementia, and TBI. Regarding the latter, I have always had an interest in the assessment and treatment of TBI and how true interdisciplinary care can help return injured Servicemembers to meaningful participation in their lives, in the ways that they value.

When I joined the Defense and Veterans Brain Injury Center (DVBIC) in 2004, and then the Richmond Polytrauma Rehabilitation Center in 2005, there was a pressing need to sharpen clinical, programmatic, and research initiatives. We were beginning to see increasing numbers of injuries coming back from the battlefield in Afghanistan and Iraq, and in my judgment our system of care was not where it needed to be to provide the care that these injured Servicemembers and their families deserved. We needed to evolve to meet those needs.

Changing Landscapes in TBI Care and Research

The volume of TBI and blast injuries climbed sharply during OEF/OIF (Operation Enduring Freedom/Operation Iraqi Freedom), and the complex nature of life-threatening injuries we were seeing in addition to TBI such as severe blood loss, burns, infections, multiple fractures, and limb amputations were unlike the stateside injuries we were seeing before the OEF/OIF conflicts. On the rehabilitation unit, no one was hitting the snooze button: People were committed to finding solutions to improve care. We needed to cultivate and bring all of the necessary health-care disciplines to the table in an efficient, expedited way, from physiatry, to neurology, to infection control, to psychology, to social work, and beyond. This was a time of extraordinarily rapid program development, and soon after, a full network of polytrauma and TBI care was rolled out.

Over the past decade, our sophistication surrounding TBI diagnosis and treatment has increased at an extraordinary pace and scope, and the importance of strategic partnerships and collaborations to support the lifelong care of injured Servicemembers became evident. Early on when I was at the Richmond Polytrauma Rehabilitation Center, we began developing stronger relationships with military treatment facilities, including the previous Walter Reed Army Medical Center and National Naval Medical Center, before they merged to become the current WRNMMC. These relationships enabled us to see Servicemembers who had been injured in theater more efficiently, and with that, there was an increased need to train future health-care providers to treat and study TBI, psychological health concerns, and other associated conditions. Developing those training programs and supervising cohorts of students and providers who were training to be the next generation of military health providers have been some of the most gratifying parts of my career to date.

Continuing TBI Innovation

Many questions remain about the assessment and treatment of TBI. NICoE TBI experts are asking questions such as "Why do some people get better after TBI, and others don't?" and "How do certain treatments make

TARGETING DEPRESSION THROUGH STIMULATION

In collaboration with NICoE, the Center for Neuroscience and Regenerative Medicine (CNRM) at the Uniformed Services University of Health Science (USUHS) is conducting a multi-site collaborative study aimed at treating depression associated with concussion in military Servicemembers using repetitive transcranial magnetic stimulation (rTMS).

The severity of depression following concussion is strongly correlated with global disability, rate of recovery, and quality of life. There are currently no Level I evidence-based treatments for depression related to concussion. Though it is FDA-approved for Major Depressive Disorder (MDD), rTMS is a relatively novel therapy, and debate continues to exist regarding the optimal stimulation parameters and magnitude of its effect. Some of the key parameters for rTMS are frequency, intensity, and location. The optimal treatment location, which can be determined by imaging or by test stimulations, depends on the targeted disorder and theory on the brain regions involved in this disorder. rTMS for MDD is most commonly targeted at a region of the brain within the dorsolateral prefrontal cortex (DLPFC), which, in clinical practice, is operationally defined as a region that is 5 cm anterior to the motor cortex.

Mapping the Brain's Network

However, this "one size fits all" treatment may not be the most effective. The recent advent of individualized fMRI-based brain network mapping enables the use of fMRI for selection of subject-specific rTMS targets. There is a great deal of inter-individual variability of how and to what extent the various functional brain networks are impacted in a given individual with concussion. Therefore, it is likely that the brain circuitry underlying depression is disrupted in a unique way for each individual following one or multiple concussions. To this end, we have implemented this fMRI-based rTMS targeting approach in a series of civilian patients with depression and a history of concussion and randomized them to Individualized Connectome Targeting (ICT)-rTMS or sham rTMS. In our pilot study, ICT-rTMS substantially improved depression (based on the Montgomery-Asberg Depression Rating Scale, MADRS) in seven out of nine patients with a history of concussion (Mean=56% reduction), whereas one out of five has improved after sham treatment (Mean=27% reduction). While promising, this pilot study was a small, single center, short-term study and clearly needs to be replicated in a larger, longer-term, multi-center study.

Pushing Capability to the Field

With the support and collaboration of NICoE investigators, we are now investigating the efficacy of ICT-rTMS for depression in military Servicemembers with a history of concussion and intend to expand to a broader network of sites soon. We also intend to expand to other concussion-related sequelae that may be amenable to novel drug and device-based interventions.

patients better?" Fundamental to answering these questions, the NICoE collaborates with federal institutions such as DVBIC and the Uniformed Services University, academic and private/nonprofit organizations, and our Intrepid Spirit Center Network to drive TBI evaluation and treatment forward through technical and clinical research protocols. The relationship between the NICoE and the Intrepid Spirit Centers across the country is developing on a larger scale to look at progressive diagnostic and treatment methods. This year, we're looking forward to the implementation and continuation of some promising research protocols, including a multi-site transcranial magnetic stimulation (TMS) study done. Exploring the impact of TMS for depression in TBI patients is both exciting and important because it could one day represent a viable treatment for a condition that can be extraordinarily difficult to treat.

Navigating systems of care delivery for TBI and bringing groups together to support research have the promise to turn around the lives of people who make the ultimate sacrifice for their country. The NICoE research agenda is an important piece of the NICoE's strategic plan. To translate research into real outcomes for patients that can be put directly into practice in our hospitals and clinics, including here at the NICoE, researchers need to support the translation of findings from longitudinal studies, treatment-based protocols, and the use of technologies into clinical care.

Disclaimer: The views expressed in this article are those of the author and do not reflect the official policy of the Department of Army, Navy, Air Force, Department of Defense, or U.S. Government.

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Next Generation DX Summit
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Nextgenerationdx.com

AUG 20 – 21
Enabling Point of Care Diagnostics
Washington, DC
Nextgenerationdx.com/point-of-care-diagnostics

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Army Science and Technology Symposium
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Ndia.org

AUG 21 – 22
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AUG 23 – 26
PA Haz Mat Tech Conference
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Pahazmat.com

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Interdrone.com

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SEP 12 – 13
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Tacticalcommunications.dsigroup.org

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Globalidsummit.iqpc.com

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Cpoa.org/event/copswest-training-expo-2018/

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