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# JASUAITY CARE



#### **LEADERSHIP PERSPECTIVE**



BG George Appenzeller Commanding General Brooke Army Medical Center BAMC



COL Scott W.
McIntosh
Joint Project
Manager
Medical Modeling
& Simulation
PEO STRI



RADM Colin Chinn

Joint Staff Surgeon
Chief Medical Advisor
to the Joint Chiefs of Staff

- MC4 Cellular-Level TBI
- Austere MEDEVAC Viral Vaccine
- Medical Hands-free Unified Broadcast/MEDHUB



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# HONING SIMULATION TO ADVANCE REAL-WORLD READINESS

JPM for Medical Modeling and Simulation (MMS), PEO Simulation, Training and Instrumentation (STRI), provides total lifecycle systems management.

By Christian Sheehy

#### **Features**



# LEADERSHIP PERSPECTIVE ACHIEVING GLOBAL MEDICAL INTEGRATION ACROSS A TOTAL FORCE

#### **RADM Colin Chinn**

Joint Staff Surgeon Chief Medical Advisor to the Joint Chiefs of Staff

#### Departments

2

Insights

22

MedTech

28

Advertisers Index/ Calendar of Events

## COMMANDER'S CORNER PROMOTING FORCE READINESS THROUGH HEALTH MANAGEMENT



**BG George Appenzeller**Commanding General

Brooke Army Medical Center

12



CSM Thomas R. Oates

Command Sergeant Major Brooke Army Medical Center Cover: Chemical, Biological, Radiological, and Nuclear Marines with Headquarters Company, 3rd Marine Division, and Cadre with 554 Redhorse Squadron, Pacific Forces, put a makeshift tourniquet from a belt on a Marine with a simulated injury as the rest of their team bring a stretcher, while conducting a low angle rescue drill on Camp Courtney, Okinawa, Japan. (U.S. Marine Corps photo by Lance Cpl. Marcus Allen)





#### ENSURING TRAUMA-CRITICAL CONNECTIVITY

The U.S. Army Medical Hands-free Unified Broadcast, or MEDHUB, enhances fluidity in field trauma care.

By Carey Phillips



MC4: Bridging A Capability Gap U.S. Army's Med Comms for Combat Casualty Care (MC4) Health Assessment Lite Ops (HAL0) when network down. By Paul Clark



BRAIN CELL CARE AFTER TBI An immunosuppressant under test for the prevention of advanced cell death following traumatic brain injury or TBI. By Steve Campbell



#### MANAGING AUSTERE EVACUATION

The latest in medical litter technology offers versatile mobility for complex extraction. By John Voinche



#### PITTING MODERN GENETICS AGAINST VIRAL DISEASE

U.S. Army Medical Research Institute of Infectious Diseases develops specialized vaccines. By Connie Schmaliohn FOLLOW US ON SOCIAL MEDIA 中Tactical Defense media





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# **COMBAT&**

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#### INSIGHTS

Communications are critical to bridging the gap between life and death at point of trauma. Although technology enables greater treatment efficiency sooner, no amount of technology can replace the essential information exchange during trauma care, particularly in the absence of clinical-level capability. This issue of Combat & Casualty Care sheds light on the need for advanced data movement to and from those who hold lives in their hands.

From simulation to integration, what drives higher standards in casualty care is accurate and timely data sharing across the care continuum. The recent refocus by DoD on global integration of health services from operational trauma care to standard healthcare is something that RADM Colin Chinn, Joint Staff Surgeon and Medical Advisor to the Joint Chiefs of Staff champions every day. Much of this integration across the Military Health System (MHS) is in the digitization of electronic health record (EHR) information, however, a critical operations-oriented integration mission can be seen in work being done by the Medical Communications for Combat Casualty Care (MC4) program. A key part of MC4 efforts is the enhancement of the U.S. Army's first electronic software application Theater Medical Information Program, or TMIP, today giving way to the Joint Operational Medicine Information Systems (JOMIS) intended to further streamline the packaging, delivery, and accessibility of operational personnel medical data. On the technology front, testing of the Army's Medical Hands-Free Unified Broadcast, or MEDHUB, comms device is in its final pre-fielding phase.

With the continual drive to sustain readiness in combat medicine, the U.S. Department of Defense relies on Joint coordination of medical assets from Pentagon leadership to field corpsman. Rapid advances in medical simulation have made training behind the lines more reliable in preparing those with little or no combat experience for the realities that even the best simulation cannot duplicate. In a focused feature to C&CC, readers get a look into current and ongoing efforts by the Joint Project Manager for Medical Modeling & Simulation (JPM MMS), COL Scott McIntosh and how PEO Simulation, Training and Instrumentation (STRI) is advancing the selection and utilization of medical training aids, devices, simulators, and simulations (TADSS) for increased clinical and operational readiness across the Army and Joint DoD.

Be sure not to miss a look at the newest in vaccine development at the Army's Medical Research Institute for Infectious Diseases (USAMRIID) as well as this issue's industry spotlights on the latest in austere-ready litter medical evacuation and cellular-level traumatic brain injury (TBI) care.

Your comments and suggestions are welcome. Thank you for the continued readership!

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#### HONING SIMULATION TO ADVANCE REAL-WORLD READINESS

The Joint Project Manager for Medical Modeling and Simulation, Program Executive Office for Simulation, Training and Instrumentation, is chartered by the Defense Health Agency Component Acquisition Executive to provide total lifecycle systems management including sustainment of medical acquisition across the Military Health System. By Christian Sheehy, Editor



Seaman Brandon Taylor, a corpsman with Combat Logistics Detachment 34 (CLD-34) attached to Special Purpose Marine Air-Ground Task Force Crisis Response-Central Command (SPMAGTF-CR-CC), inserts a decompression needle into an essential care simulator manikin during shock trauma section drills held in the U.S. Central Command area of responsibility. (U.S. Marine Corps photo by Sgt. Justin Huffty)

The Office of Joint Project Manager for Medical Modeling and Simulation (JPM MMS) was created by the Assistant Secretary of Defense for Health Affairs (ASD (HA)), in partnership with the Program Executive Office for Simulation, Training and Instrumentation (PEO STRI), in September 2013. The selection and utilization of medical training aids, devices, simulators, and simulations (TADSS) directly affects the cost of health care as well as clinical and operational readiness. That said, the acquisition and management of medical TADSS, over their life cycle, should be accomplished by a Defense Acquisition organization in order to ensure quality,

availability, and economy while satisfying user requirements. The term "lifecycle management" is key in that the JPM MMS is working to change the culture of medical simulation procurement from one that is medical logistics centric (a one-time commodity purchase) to a mindset the includes centralized funding, commercial off-the-shelf (COTS) or modified COTS procurement, training, sustainment and disposal (i.e. lifecycle management).

#### **Transition to Multi-Domain Care Delivery Mindset**

The traditional dogma of Roles of Care I-IV is being challenged by multi-domain operations. Scenarios such as isolated troops in



counterinsurgency (COIN) operations, large conventional formations in the Pacific and combat in large urban areas require medical care based on physiology instead of the geography of a traditional battlefield. Therefore, medical modeling and simulation must continue to evolve and replicate the complexities of our modern threat scenarios.

"Today's simulation capabilities are limited in that we use manneguins and other surrogates (i.e., live tissue, cadavers, role players) that do not realistically portray the medical complexity of a human patient requiring initial life-saving and/or prolonged field care, "said COL Scott McIntosh, Joint

Project Manager, Medical Modeling & Simulation. "Furthermore, today's medical simulation is limited in training and assessing the individual and team collective tasks required during large scale patient triage, treatment and evacuation (i.e., mass of troops in the Pacific)."

As alluded to earlier, one of our focus areas is to change the culture of medical simulation procurement from one that is medical logistics centric to more of a lifecycle management mindset. The Army currently uses a lifecycle management approach for its Medical Simulation Training Center (MSTC) and Tactical Combat Casualty Care Exportable (TC3X) programs of record. However, MSTC and TC3X represent a very small subset of overall Army purchases of medical simulation. As mentioned, we're chartered by DHA to perform lifecycle management

functions for the entire MHS. Once medical simulation requirements are generated by the Services and validated by DHA; our office stands ready to accomplish our lifecycle management mission in support of both tactical and hospital-based medical simulation customers. "Key to our organization realizing the ASD (HA) vision is the concept of trust," said McIntosh. "Today, organizations within the Services and DHA perform the medical simulation procurement function which is merely one element of lifecycle management. Our organization needs to earn the title "provider of choice" which is found in our mission statement: Provider of choice committed to developing, acquiring and sustaining medical simulation capabilities to optimize Warfighter readiness and improve healthcare. Our approach to earning the trust of the Services and DHA is multi-faceted and something we focus on every day."

Medical treatment in the current fight focuses on TC3 and the

based evaluation with feedback. Training without these components leaves competency largely up to chance. Given the high-risk nature of medical practice, and that the outcomes directly impact the Warfighters' health and livelihoods, this is less than acceptable."

"The effectiveness of medical simulation, like all educational modalities, depends on how well it is used," said McIntosh. "Medical simulation should be utilized as an adjunct to patient care experiences across the continuum of health care, and its integration into the curriculum should be well-planned and outcome driven."

In combat or battlefield scenarios, simulation is increasingly being used in tactical field medical education to teach cognitive, psychomotor, and affective skills to individuals and teams. It is important to first determine the outcomes of using simulation and utilize these to guide its integration into the combat medical curriculum. Feedback is critical

"Medical simulation should be utilized as an adjunct to patient care experiences across the continuum of health care, and its integration into the curriculum should be well-planned and outcome driven."

Golden Hour due to robust medical evacuation (MEDEVAC) systems. Providing quality medical simulation for the modern threats identified above (prolonged field care, large-scale mass casualties, etc.,) demands capabilities not available today. Although current medical simulation capability allows medics and providers to practice isolated aspects of prolonged field care, we cannot provide the realism of a dynamically changing trauma patient. For example, a significantly burned trauma patient will require initial interventions for circulation, airway and breathing. Imagine a scenario and simulator that "evolves" over time in accordance with natural progression of the injury and the interventions rendered-both positive and negative. Tissue swelling requiring escharotomy, actual "urine" output driving further fluid management decisions, incorporating telemedicine and appropriate after action review capability (AAR). Currently, a scenario such as this requires piecemealing different technologies and notional physiologic cues.

#### **Measuring Design through Simulation**

The JPM MMS is working to further medical simulation development in the areas of instructional design, and outcomes measurements. Translation and implementation of more realistic medical simulators and simulated volatile, uncertain, complex, and ambiguous (VUCA) environments will provide for a better trained Joint Force.

A confluence of recent events has led to increased growth in the use of medical simulation across the healthcare education continuum. These factors include an increased focus on patient safety, the call for a new training model not based solely on apprenticeship, a desire for standardized educational opportunities that are available on-demand, and a need to practice and hone skills in a controlled (hospital-setting) and operational environments. In addition, the benefits of clinical simulation are increasingly reported in the literature, adding further validity to its use in healthcare education.

"Over the past decade, it has become increasingly clear that exposure to trauma patients in a clinical and operational environment with ad hoc educational sessions is not sufficient to create competent healthcare practitioners," noted McIntosh. "Furthermore, it is evident that there is a need for curriculum and simulation standardization, deliberate skills practice, structured exercises, and outcomes-

to effective learning using medical simulation and should be guided by individual learning needs as they prepare for combat deployments. Simulation allows for training in realistic, combat environments, with opportunities for deliberate practice and assessment of critical skills needed to save lives in VUCA environments. Simulation-based mastery learning significantly improves skills for all participants, and also leads to a high level of skill retention.

#### **Driving Acquisition through Lessons Learned**

JPM MMS is working closely with the DHA J7 Defense Medical Modeling and Simulation Office, which serves as the joint service organization that manages medical simulation requirements. The goal is to put in place a functioning Defense Acquisition Management System that operates based upon need/threat-driven requirements, the DoD 5000 series, and principles of the Planning, Programming, Budgeting and Execution System. Additionally, JPM MMS has an enduring partnership with the Veterans Administration (VA) and has successfully executed multiple projects in support of the VA National Simulation Learning initiative.

"Leveraging this partnership, JPM MMS has connected executives within the DHA and VA in an attempt to capture lessons learned; applying best practices to both organizations — which is important considering the similar missions of the two organizations," McIntosh emphasized. "Many other examples exist ranging from medical aspects of the Synthetic Training Environment to patient safety initiatives sponsored by the National Training and Simulation Association. I would like to also highlight an example of close collaboration with our NATO partners as evidenced by the co-chairing of an International Military Medical Simulation Symposium with the Bundeswehr Medical Corps in May 2018. All examples are efforts we've undertaken to save lives and improve healthcare through simulation." ■



## **ENSURING TRAUMA-CRITICAL CONNECTIVITY**

The U.S. Army's newest medical communication device, the Medical Hands-free Unified Broadcast, or MEDHUB, is poised to enhance the fluidity of field trauma care, from point of injury assessment to accelerated evacuation. By Carey Phillips, USAMMDA



Cpt. Sean McCoy, 541st Forward Surgical Team ER physician, conducted patient evaluations on each simulation of a combat casualty during a recent MEDHUB operational test. Evaluators denoted whether or not test participants completed specific critical actions in order for each patient treatment to count as criteria successes. (Photo by Ashley Force, USAMMDA)

It was two years ago, that Jay Wang, Product Manager for the U.S. Army Medical Materiel Development Activity (USAMMDA), was in Fort Rucker, Alabama. He was demonstrating the latest U.S. Department of Defense medical software called the Battlefield Airmen Trauma Distributed Observation Kit, or BATDOK, to the U.S. Army School of Aviation Medicine and Medical Evacuation Proponency Division, based on recommendations from the medics. Returning two years later, he co-facilitated the final medical study of the Medical Hands-free Unified Broadcast (MEDHUB) at the U.S. Army Aeromedical Research Laboratory (USAARL).

These past two years, Wang and his team of Medical Support Systems and Evacuation Project Management Office engineers have been hyper-focused on developing this product because of its important purpose: to help save the lives of injured Soldiers.

"In 2017, I was visiting paramedics in Fort Rucker. At the time, when they were transporting a patient to a hospital, they had to type all the patient's medical information letter by letter into the old system," said Wang. "They just didn't have time for that."

That's when the idea for MEDHUB sparked. It was designed to improve the communication flow between patients, medics and receiving field hospitals. MEDHUB features smart automation technology, so

medics can send patient information with the click of a button on a handheld tablet versus typing in thousands of characters. It shortens the medic's time completing a Tactical Combat Casualty Care card and increases accuracy in completeness by about two-to-three times versus pen and paper.

After the data is captured, the device automatically forwards that message to the hospital through existing long-range tactical communication systems used by the DoD and prepares the hospital for the patients arriving.

"Every minute counts here," said Wang. "There are certain things like defrosting blood that takes 20 minutes, so an early warning versus a five-minute-notice radio call makes a world of a difference."

#### **Putting Capability to the Test**

To assure the best possible product, MEDHUB must be tested by Soldiers for effectiveness, and that is what took place at USAARL.

The purpose of the study was to find out how a field hospital staff reacts to using the device in a mass casualty environment. USAARL provided the facility for the study, lab equipment, technical support, Sim-man 3G manikins, which are life-size mannequins used in

medical education, and Soldier support. A moulage team, a team with mock injuries for training purposes, makes test scenarios more realistic.

The test participants being studied were six members of the Forward Resuscitative Surgical Team with the 44th Medical Brigade from Fort Bragg, NC.

"USAARL was honored to host the 44th Medical Brigade, USAMMDA and the U.S. Army Institute for Surgical Research (USAISR). I'd like to first thank the study participants," said Army Col. Jonathan Taylor, commander of USAARL. "These medical experts brought enthusiasm and realism to our test scenario that made it work. Next, the study team, led by Ms. Rachel Kinsler, created a realistic and relevant study design that allowed our medical experts and the test team from USAMMDA to effectively evaluate the technology."

During the mass casualty simulations, randomized manikins were mocked-up to resemble combat injuries like burns,

gunshot wounds and amputations. The 44th test participants were tasked with treating those victims and additional stress was added by giving the clinicians eight patients during the course of each scenario.

Evaluators, who were mostly research clinicians from the U.S. Army Medical Research and Materiel Command, captured every single medical procedure that the 44th test participants performed.

The 44th test participants treated patients in two circumstances. The first was based on standard of care where the doctors and nurses received a radio call from the medics five minutes before patient arrival. The second circumstance was with the use of MEDHUB, which provided patient information 20 minutes ahead of time in addition to the standardof-care call.

The observers were watching to see how the extra minutes of preparation potentially helped the patient outcomes or provided better care.

"What I've witnessed is the test participants are getting to the patient quicker," said Lt. Col. Chris VanFosson, Study Evaluator and Chief for Trauma Outcomes and Systems Research at the USAISR. "They are triaging. As evaluators, we have sat in the hallway for 20 minutes waiting for the triage officer to get to our patient. But with the MEDHUB system, it seems like they are getting there guicker."

The 44th test participants needed to complete a few critical things in order for each patient treatment to count as criteria successes. They were not graded on how well they treated the patient, rather, if they completed the critical actions. For example, a critical action could be putting in a new airway or checking tourniquets.

"Evaluators denoted the time it took for procedures to be done, and we are logging all data points so we can see which procedures were done faster. Which were better organized so they were done earlier in the study? Was communication improved? Those are things that were looked at," said Kinsler.

Each manikin was staffed with a clinician to tell the 44th test participants how the manikin would react to their treatments. Each manikin also had an operator in charge of adjusting its health status. The realistic environment provided valuable practice for the 44th test



U.S. Army Paratroopers from the 1st Brigade Combat Team, 82nd Airborne Division, train on a Troop Combat Casualty Care Exportable kit manikin at Ft. Bragg, NC. The training provided data to the Army Training Support Center to improve the effectiveness of the TC3X kit manikin during combat-focused medical training. (U.S. Army photo by Sgt. Michelle U. Blesam)

participants as the study aimed to resemble a true mass casualty situation.

"We appreciate the opportunity for this training," said Cpt. Sean McCoy, 541st Forward Surgical Team ER physician. "Our main goal is damage control resuscitation. We don't have CAT scans, X-ray or ultrasound machines. We basically plug holes, give blood, start antibiotics and keep the patient warm. For some patients, the 'Golden Hour' is ultimately too long, these patients need to be treated within minutes."

#### No Substitute for Real-World Application

Wang believes watching the Army clinicians in action allowed the research team to understand their gaps.

"As researchers, we can build new equipment for things that maybe we don't understand or don't work with as much," said Wang. "We all have different roles, but a study like this expands our knowledge of how well we can all work together to provide a better Army."

This hospital scenario test was MEDHUB's final developmental test. The data from this study allows for the proper planning of an end-to-end Operational Test scheduled for March 2019. At that time, the use of MEDHUB will be tested from point of injury — to the ground medic - to the ground vehicle medic - to the air and ambulance - to the hospital.

After the data from this field hospital study is analyzed, USAMMDA and USAARL will take their findings and publish a joint paper and report. That data will serve to push MEDHUB along into the user's hands, inspire user confidence in the device and continue to make MEDHUB better and stronger. •



## **ACHIEVING GLOBAL MEDICAL INTEGRATION ACROSS A TOTAL FORCE**

Rear Admiral Colin Chinn is the Joint Staff Surgeon at the Pentagon, Washington, D.C. He serves as the chief medical advisor to the Chairman of the Joint Chiefs of Staff, providing advice to the Chairman, the Joint Staff, and the Combatant Commanders. He coordinates all issues related to Health Services to include operational medicine, force health protection, and readiness among the Combatant Commands, the Office of the Secretary of Defense, and the Services.

A native of San Francisco, Rear Adm. Chinn graduated from Johns Hopkins University in 1979 with a bachelor's degree in public health and received a master's degree in epidemiology from Johns Hopkins University School of Public Health in 1982. After his commissioning as an ensign in 1981, he attended the Medical College of Virginia through the Armed Forces Health Professions Scholarship Program and earned a Doctor of Medicine in 1985. He completed an internal medicine internship and residency at Naval Hospital Oakland, serving as chief medical resident in 1990. Chinn completed gastroenterology fellowship training at Naval Medical Center San Diego in 1993.

Since completing his medical training, Chinn has served his country both domestically and overseas in a number of roles, including as director of TRICARE Region West/Pacific, chief of the Navy Medical Corps, United States Pacific Command surgeon, and as the dual-hatted Director of the Research & Development Directorate (J9) of the Defense Health Agency and U.S. Army Medical Research and Materiel Command (USAMRMC) Deputy Commander. His most recent assignment was as the Acting Deputy Director of the Defense Health Agency. His accomplished career as a doctor and leader with the U.S. Navy makes him a vital asset as he strives to help the Military Health System deliver an integrated system of readiness and health.

Chinn is a Fleet Marine Force qualified officer. His personal decorations include the Defense Superior Service Medal (three awards), Legion of Merit (three awards), Meritorious Service Medal (three awards), Navy and Marine Corps Commendation Medal (three awards), Navy and Marine Corps Achievement Medal and various unit and service awards.

Combat & Casualty Care spoke recently with the Joint Staff Surgeon and Medical Advisor to the Joint Chiefs RADM Colin Chinn regarding current focus on a smooth transition of Defense Health Agency oversight of all Military Health System function in support of greater effectiveness in cross-Service healthcare needs.



#### **RADM Colin Chinn**

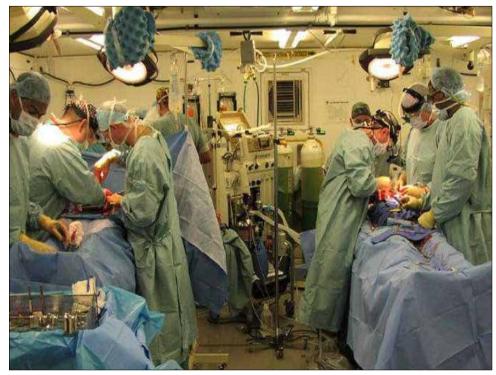
Joint Staff Surgeon Chief Medical Advisor to the Joint Chiefs of Staff

C&CC: Please speak to your role as Joint Staff Surgeon and what your current priorities are in support of the Joint Force.

**RADM Chinn:** My role as the Joint Staff Surgeon is to serve as the senior medical advisor to the Chairman of the Joint Chiefs of Staff. Among many things, my primary responsibility to the Chairman is to ensure that health services are globally integrated in support of enabling joint force operations. My staff and I do this through overseeing medical requirements and capabilities, as well as education, evaluations, and assessments. Additionally, we (along with our stakeholders across the DoD) ensure that the Military Health System (MHS) is synchronized across the Services and combat support agencies to support Combatant Command requirements.

C&CC: We've recently become aware of the Chairman's (Chairman of the Joint Chiefs of Staff) responsibilities as they relate to globally integrating the Joint Force. How are you applying this concept from a joint medical perspective?

RADM Chinn: The speed and complexity of modern warfare demands a different approach (than that of years past) to meet Combatant Command requirements involving all military domains cutting across multiple geographic regions. Global Integration describes the Chairman's authority to respond to these global requirements using military options. The Chairman, by law, serves as the integrator for the entire Joint Force, by extension, The Joint Staff Surgeon has a responsibility to globally integrate the Joint Medical Force. Through Global Force Management, the Joint Staff meets daily requirements around the world maintaining readiness and flexibility to respond to the unexpected. In essence, as the Medical Global Integrator, I ensure the Joint Force is resourced and operationally aligned to meet strategic priorities and integrated globally with medical sustainment capabilities. My office reviews plans, contributes to estimates, and participates in discussions across Combatant Commands to communicate



Department of Defense healthcare professionals in a deployed setting provide life-saving surgical care to trauma patients. (DoD)

medical integration requirements globally. In an era of constrained resources, I also have to be prepared to make hard recommendations to change global medical positioning of capabilities to meet emerging threats. Therein lies the heart of the matter. What occurs in one theater may have an impact in other theaters and we the Joint Staff, need to ensure that we have done everything in our power to account for that in our planning. It's about being prepared for the unexpected. Finally, while we are focused on Combatant Command's executing theater plans, my staff and I work with the Services and the Defense Health Agency (DHA) to provide focused medical capabilities tailored to meet healthcare challenges in contingency operations across all Combatant Command areas of responsibility.

#### C&CC: In terms of the challenges unique to producing and maintaining medical readiness in today's military, what are some priorities you are focusing on?

RADM Chinn: As the Joint Staff Surgeon, my highest priority is ensuring the Joint Medical Force remains highly proficient and effective in supporting the lethality of the operating force across all domains. Medical skills proficiency, joint operational capability and capacity, and interoperability are among the top challenges to integrate across the Joint Force. Each Service has unique requirements that are essential for Joint Force execution and effectiveness across the Range of Military Operations. However, there is a core set of medical capabilities that transcend Service requirements. We continue to identify and refine Joint Knowledge, Skills and Attributes (KSAs) to address common gaps in clinical/ surgical skillsets across the services in an effort to improve operational proficiency and interoperability. Additionally, addressing equipment standardization and interoperability poses a significant challenge, related to, but separate from, the KSAs but also impact readiness. Using technology to develop systems to build and monitor readiness assist in understanding a common operating picture and

assists in defining a modular, expeditionary medical force that can be employed across a variety of operational domains. All of this must be worked within a resource-constrained (both personnel and financial) environment. Finally, I seek to be the honest broker in addressing the Combatant Commands' unique requirements to the Services and DHA, ensuring that the operational readiness needs are met and DHA is able to deliver within its Combat Support Agency role. Meeting readiness goals is no small challenge while simultaneously executing health system reforms and changes being addressed by the Services and DHA. The Joint Staff stands at the ready to meet these challenges with our key and valued stakeholders.

#### C&CC: Could you expand on the intent for developing a Joint Medical Estimate? What are the main outcomes associated with this? How will you measure progress?

RADM Chinn: My vision is a medical enterprise capable of supporting a military conflict continuum at the speed of war - from the tip of the spear, through theater hospitalization and patient movement back to military treatment facilities providing definitive care. The Joint Medical Estimate (JME) provides a framework to assess key medical capabilities in support of joint operations and is similar to how the J1 uses its Joint Personnel Estimate or the J2 uses its Joint Intelligence Estimate to assess their communities, respectively. The assessment includes capabilities such as: medical force generation, environmental medicine, medical logistics, Global Health Engagement (GHE), patient management, patient movement, forward resuscitative care, hospitalization, definitive care and medical countermeasures. The JME is directed by Congress in the National Defense Authorization Act (NDAA) 2019 and drives dynamic innovation that rapidly builds, projects, and sustains life-saving and life-sustaining capabilities for the joint force. This allows targeted investments in capabilities in line with future warfighter formations across ground, air, sea, cyber and space domains.

#### **■ LEADERSHIP PERSPECTIVE**



Military personnel load a patient onto an Air Force C-17 aircraft as part of an aeromedical evacuation mission. (DoD)

C&CC: With Military Health System reform on the forefront and in full swing, how is your office involved in this effort? What are your equities in support of reform? Do you have any concerns?

RADM Chinn: As the Chairman's senior medical advisor, my primary responsibility is to ensure that the Joint Warfighting force has what it needs to execute their Globally Integrated Campaign Plans, from a

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medical perspective. With that in mind, my office is strategically engaged with our partners within the Military Health System (MHS) to ensure that the Chairman's equities are not being compromised and that the end state remains support to the Joint Warfighter. I firmly believe that if we keep this end state at the forefront of every discussion and every decision, reform will have positive outcomes for all parties involved. In the military, there is this concept of supporting and supported commands or organizations. My view is that the deployed Soldier, Marine, Sailor, and Airman on the ground, at sea, or in the air is the supported entity. At the end of the day, MHS reform must conform to this very basic principle. If we can focus on this, everything else will fall into place. This is an excellent opportunity to take advantage of the economic principle of division of labor. With the DHA assuming authorities, direction, and control of all Military Treatment Facilities (MTFs), as well as lead for Combat Support areas that support all Services, this will free up ready medical forces in the Army, Marine Corps, Navy, and Air Force to do what they do best-sustaining their line counterparts in fighting battles and winning wars.

C&CC: As global health engagements grow in importance with the interconnected sharing of worldwide health research outcomes, what are some of your priorities for boosting alliances with partnering national medical entities?

RADM Chinn: Global health engagements help to build military medical interoperability while fostering current partnerships, attracting new DoD partners, and is a strategic enabler for the Combatant Commander. Health engagements also contribute to the readiness of our own Joint Force. Integrating global health engagement within The Chairman's global integration priorities is crucial for attaining security cooperation objectives. Diseases know no boundaries and ensuring health as a means of security is vital for both the United States and our partner nations. A prime example of fostering military medicine interoperability is supporting multilateral military medical platforms with our NATO partners. Furthermore, global health engagement facilitates achieving capacity building with partner nations with a shared goal of bi-lateral security cooperation. Such engagements range from health systems strengthening, research, and disaster response, all which provide sustainment, learning opportunities, and readiness training for DoD personnel. Research, for example, promotes partner nation interoperability with such tools as epidemiological surveillance for infectious diseases which directly contributes to force health protection both for DoD service members and our partner militaries.

C&CC: In terms of the Chairman's focus areas, what are your thoughts on developing the next generation of joint medical leaders? Where should the services focus their professional development efforts?

**RADM Chinn:** It starts with acknowledging that we (medical) probably have not done as good a job at this, when compared to our line counterparts. Do not get me wrong, we have produced excellent leaders throughout the years, but the focus has been primarily on growing and developing medical leaders who understand and know how to run a healthcare system, not necessarily a military organization that happens to provide healthcare. This has to change if the Services expect to have medical leaders capable of producing and managing ready medical forces whose primary focus and duty is to support Combatant Command requirements. To be certain, we will need leaders who have experience and have excelled in both the operational and healthcare delivery



Staff Sgt. David Hernandez and Tech. Sgt. Joseph Vergona, 332nd Expeditionary Aeromedical Squadron contingency aeromedical staging facility medical technicians, load a trauma patient onto an Iragi Air Force Huey II. The patient was flown to U.S. Army 86th Combat Support Hospital in Baghdad. This mission marked the first medical evacuation mission to be flown by the Iragi Air Force. (USAF)

arenas. The DHA has and will continue to have uniformed medical personnel requirements to fulfill its mission. This will require innovative approaches to balance Joint Professional Military Education (JPME), along with the clinical and administrative management KSAs that many of our specialties will require long term. It also involves proactive talent management through the development of a human capital strategy for medical leaders. It is imperative that we identify capable leaders early and design professional development and career assignment pipelines aimed at not only developing specialists, but also leaders who are capable of managing ready medical forces in a joint environment. 06 or 05 command should not be the first time we've assessed whether or not an individual is cut out for these types of roles, where authority, responsibility, and accountability is at its peak.

#### Please feel free to address other goals and challenges moving forward.

RADM Chinn: As discussed, reform within the MHS is providing us opportunities that have not existed in the past. Having spent time as a Combatant Command Surgeon, as well as multiple assignments with the U.S. Marine Corps—I am convinced that the more closely integrated a medical department is with the line, the more attuned we are to the needs of the Warfighter and the better we can define and communicate medical resource and capability development requirements to program sponsors at the Pentagon and our leaders in Congress. Military medicine has achieved amazing results with respect to survivability rates in combat over the past 17 years due to well-documented advantages over our adversaries in the Middle East. I believe that may not be the case moving forward and as a result, we must posture and integrate medical in a way that ensures we are completely aligned with the commander and his or her intent for sustaining the fighting force and preventing early culmination in pursuit of the objective (s). I believe this is an opportunity for each of the Services to conduct a thorough assessment of its medical department, how it is currently structured, resourced, and organized, and begin the process of developing models that best fit and are aligned with Warfighting priorities. Organized correctly, I believe military medicine can and will continue to deliver high-quality care in both the operational and healthcare delivery setting.

# Tactical Defense



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**Tactical Defense Media** 

## PROMOTING FORCE READINESS THROUGH **HEALTH MANAGEMENT**



Brigadier General George (Ned) Appenzeller currently serves as the Commanding General, Brooke Army Medical Center; Deputy Commanding General. Regional Health Command-Central; and Market Manager for the San Antonio Military Health System. He attended Tulane University with a Reserve Officer Training Corps Scholarship. Upon graduating with a Bachelor's Degree in biology, he was commissioned

a 2LT in the Medical Service Corps. BG Appenzeller attended the Medical University of South Carolina under the Health Professions Scholarship Program, and after completing an Internal Medicine Internship at the Medical University of South Carolina, he spent two years at Fort Sill, OK, as the Chief of the David B. Bleak TMC serving the U.S. Field Artillery Training Center.

BG Appenzeller then completed a three-year residency in Emergency Medicine at the San Antonio Uniformed Services Health Education Consortium in 1999. Subsequently, he was assigned as the Chief, Department of Emergency Medicine, USA MEDDAC, Heidelberg, GE. In 2002, he was assigned to the Army Medical Department Center and School, Fort Sam Houston, TX, as the Chief, 91W IET. Upon completion of the Command and General Staff Officer's Course at Fort Leavenworth, KS in 2004, BG Appenzeller was assigned as the Assistant Chief of Emergency Medicine at Winn Army Community Hospital, Fort Stewart, Georgia. In January 2006, he assumed duties as the Division Surgeon, Third Infantry Division, and then Multi- National Division-Center during a 15-month deployment to Baghdad, Irag. In

In June 2008, he was assigned as the Deputy Commander for Clinical Services at Winn Army Community Hospital, Fort Stewart, Georgia. He commanded U.S. Army Medical Activity-Alaska from June 2010 to June 2012, prior to attending a U.S. Army War College Fellowship at the U.S. Department of Veterans Affairs in July 2012. He assumed command of U.S. Army Medical Activity-Ft. Campbell, KY, and Blanchfield Army Community Hospital in July 2013, and served as Command Surgeon, AFRICOM, in June 2015. Prior to this assignment to BAMC, BG Appenzeller served as Deputy Commanding General, Regional Health Command-Pacific, JBLM, WA. BG Appenzeller is board certified in Emergency Medicine.



Command Sergeant Major Thomas R. Oates currently serves as Command Sergeant Major, Brooke Army Medical Center. He has served in a of assignments variety including: Womack Army Medical Center 2 tours; 558th Ground Ambulance Company (Camp Humphrey's Korea); Victory Brigade Fort Jackson SC; 3rd BN 7th Infantry Division (Fort Stewart GA); Fox Army Health Center

(Redstone Arsenal); Headquarters and HQ Detachment 56th Multifunctional Medical Battalion, 602nd Area Support Medical Company, Headquarters and Headquarters Detachment 1st Infantry Division, Reynolds Army Community Hospital Fort Sill OK, and 32nd MED BDE, JBSA.

His operational and combat tours include Kosovo in support of KFOR 7A, Multinational Force and Observers, Sinai Egypt; Operation Iragi Freedom and Operation Enduring Freedom. CSM Oates has served with distinction in all enlisted leadership positions from Squad Leader through Command Sergeant Major. His positions of increased responsibility include Line Medic, Team Leader, Squad Leader, Platoon Sergeant, Detachment Sergeant, NCOIC of Primary Care Clinic, Plans and Operations Sergeant, First Sergeant, Senior Medical NCO, Chief Medical NCO, and Command Sergeant Major.

CSM Oates military education includes but is not limited to Warrior Leader Course, Instructor Trainer Course, Advanced Leader Course, Senior Leader Course, First Sergeants Course, Basic Healthcare Administrator Course, Master Resilience Trainer Course, AMEDD Executive Skills Course, the Joint Medical Executive Skills Institute and The United States Army Sergeants Major Academy.

His civilian education includes an Associate of Arts degree in General Studies and a Bachelor of Science degree in Business Administration from Columbia College of Missouri. He also holds a Master of Arts Degree in Human Resource Management from Webster University.

Combat & Casualty Care had the opportunity to speak with the Commanding General and Command Sergeant Major of Brooke Army Medical Center (BAMC), Ft. Sam Houston, TX, regarding BAMC efforts to facilitate the DoD medical community's transition to Defense Health Agency oversight of an integrated healthcare network.

C&CC: Please speak to your roles as BAMC Commander and Command Sergeant Major, and present mission focus.

**BG Appenzeller:** CSM Oates and I are blessed to be allowed to serve the patients and staff of Brooke Army Medical Center. Brooke is a premier joint medical "live fire" training platform that exercises our medical battlefield operating systems daily. The nearly 9,000 Army, Air Force, Navy, Public Health Service and civilian staff are focused on the high-quality, safe, accessible care all our beneficiaries deserve, while ensuring our service members are ready to deploy and we are ready to care for them both at home and abroad.

We believe 2019 will be a year of change as we look to transition to the Defense Health Agency. This transition is mandated by the 2017 National Defense Authorization Act to improve access to quality care for beneficiaries while enhancing readiness. Our focus will be on leveraging the opportunities these changes bring to enhance our core mission: supporting the warfighter and caring for our patients.

**CSM Oates:** Maintaining our mission and vision is a vital part of our future. We protect the nation by ensuring Total Force Readiness through innovative, safe, accessible, high-quality healthcare and the development of elite healthcare professionals. By doing this, we will be the pinnacle of military healthcare, anytime, anywhere.

C&CC: From a current day trauma care treatment perspective, can you discuss some focus areas at BAMC?

**CSM Oates:** BAMC is the DoD's only Level I trauma center. Our trauma capability is vital to the clinical and operational readiness and training of our doctors, nurses, and other medical professionals. We deliver high-quality trauma care to 22 counties in southwest Texas. Without this mission, it would be difficult for our active duty medics, nurses, blood bank, radiology, surgeons, etc., to maintain readiness for the deployed mission.

The premier military research institute, the U.S. Army Institute for Surgical Research (USAISR), is literally next door and there is a lot of cross-pollination between the two institutions. The resuscitation strategy for bleeding patients changed about 10 years ago because of work that was done at the USAISR and carried out by BAMC surgeons. We are now one of a few hospitals in the country that are transfusing low titer group O whole blood (LTOWB) to trauma patients as our deployed battlefield facilities do the same.

**BG Appenzeller**: The BAMC Trauma Center is a key player in melding the lessons of battlefield surgical care with civilian surgical treatment. BAMC Ortho Trauma is involved in over 12 multicenter studies in conjunction with the Major Extremity Trauma and Rehabilitation Consortium (METRC). METRC is a 43-hospital research organization that has brought groundbreaking treatment to the orthopedic community for the treatment of infection, mangled limbs, blood clot prevention and pre-hospital stabilization.

BAMC is the lead military treatment facility for the San Antonio Uniformed Services Health Education Consortium SAUSHEC, which

trains over 600 physicians (from Army, Air Force, Navy, and the Public Health Service) across 37 medical specialties, including the only surgical critical care fellowship in the DoD. Graduates from these programs take the lessons learned here and go on to serve as staff physicians at other military treatment facilities across the Military Health System and in operational units. BAMC is a leader in combat casualty care research, with 48 peer-reviewed publications from our Graduate Military Education (GME) faculty and residents on the topic in the last year alone.

GME is the lifeblood of military medicine and our programs ensure appropriate clinical, educational and didactic exposure to trauma care in all GME specialties, promoting multidisciplinary readiness.

C&CC: Can you highlight some efforts BAMC is undertaking to advance care for combat veterans with chronic or long-term rehabilitation challenges?

BG Appenzeller: Our Center for the Intrepid (CFI) team is actively conducting research to advance care for returning combat veterans. Some examples include: participating in groundbreaking rehabilitation of patients with amputations using osseointegration; the formation of a direct interface between an implant and bone, without intervening soft tissue. The ability to "test drive" prosthetic feet with a simulator prior to fitting; using advanced tissue regeneration techniques to toughen residual limb skin and reduce sweating; improving the training of myoelectric upper extremity prostheses; employing novel trip training techniques to minimize falls after patients leave rehab; leveraging new technologies to enable the rapid collection of clinical outcome measures; defining the effect of new treatments for chronic pain.

Physical therapy is implementing the Military Orthopaedics Tracking Injuries and Outcomes Network (MOTION) database to track outcomes of care. Rehabilitation professionals will be able to use the MOTION database to develop best practices and improve quality of care, improve outcomes, and create value.

Concussion, or mild traumatic brain injury has been a common injury in returning combat veterans. The BAMC Brain Injury Rehabilitation Service (BIRS), in partnership with the Defense and Veterans Brain Injury Centers, completed the largest randomized controlled trial to date evaluating cognitive rehabilitation interventions for service members following in-theatre concussion. This study, the Study of Cognitive Rehabilitation Effectiveness (SCORE), included the development of nearly 1,000 pages of publicly available manualized treatment interventions.

C&CC: In terms of specific program areas addressing robotic-assisted and other technological enhancements to procedural care, can you discuss any advances at BAMC?

**BG Appenzeller:** Blood flow restriction (BFR) rehabilitation was developed at the CFI and is being used to help expedite recovery. BFR training involves decreasing blood flow to working skeletal muscles in order to promote hypertrophy and prevent disuse atrophy. Reduced blood flow creates a local hypoxic event which results in the accumulation of metabolites that regulate the anabolic response system during exercise.

Rehabilitation experts and researchers utilize the Computer Assisted Rehabilitation Environment (CAREN) system to provide functional rehabilitation. The CAREN immerses patients in a

#### **■ COMMANDER'S CORNER**



U.S. Army Spc. William Waggoner, assigned to the Brooke Army Medical Center emergency room, and Domingo Guerrero, Schertz emergency medical technician, prepare to move Shannon Murphy, an emergency medical service student role-playing a patient, into the ER during a no-notice mass casualty exercise with the city of Schertz, TX. The exercise was a collaborative effort between BAMC and Schertz emergency services. (U. S. Army photo by Robert A. Whetstone)

versatile, multi-sensory virtual reality platform used for treatment and rehabilitation of human locomotion, or walking, as well as pain, posture, balance spinal stability and motor control integration.

The prosthetic emulator project is a robotic prosthetic foot system that can be programmed to emulate any commercially available prosthetic foot and enable the patient to "test drive" a prosthetic foot before committing. Also, treadmill training exposes patients to trips and slips and trains them on techniques to avoid falls, is technically a robotic therapy.

CSM Oates: The Firearms Training Simulator (FATS) provides rehab patients the opportunity for realistic firearms training without the external factors such as weather and limited resources. FATS puts wounded warriors through a series of dangers, testing their ability to swiftly react and fire on threats. FATS not only trains their hand-eye coordination, but also keeps patients current with weapons systems common to the military. As use of firearms is an integral part of military soldier tasks, using shooting as part of the care plan allows for both physical and psychological rehabilitation.

BG Appenzeller: BIRS frequently incorporates technology into our rehabilitation programs, with resources including commerciallyavailable smart phone apps, eye-tracking diagnostic tools, SmartHome technology, and a driving simulator. Soon, the BIRS will incorporate virtual reality into our programs, including its use in the management of post-traumatic stress disorder.

C&CC: From a Joint partnering perspective, how is BAMC working with other Army/DoD medical entities in helping advance standard of care across the spectrum?

CSM Oates: Our command is working across the MHS doctrine, organization, training, materiel, leadership and education, personnel, facilities, and policy spectrum to ensure quality trauma education, training and management. BAMC is spanning/organizing the numerous commands/training programs (i.e. BAMC, USAISR, AMEDD, Joint Trauma System, Defense Medical Readiness Training Institute, and Joint Trauma Education Training Directorate) into a centralized readiness training platform for all deploying military personnel. BAMC has the key components, most important being the trauma patient volume and acuity, and experienced medical personnel, to be the military's premier training and readiness platform for deployment readiness and to prepare providers at all levels to support the operational units.

Operating Room (OR) personnel are rotating through USAISR ORs for training. The goal is to have Air Force and Army rotate both nurses and technicians to USAISR ORs. We are directly partnering with the Air Force to integrate training opportunities and provide more cohesion between services. This helps standardize processes and gives some linearity to the chain of command and overall decision-making.

BG Appenzeller: The MOTION, Pain Assessment Screening Tool, Outcomes Registry databases, and Activity and Mobility Promotion, are initiatives that will help standardize patient care throughout DHA.

The BAMC BIRS routinely collaborates with experts from DoD, academia, and VA, both clinically and in research. All but one of our active research protocols include partners from places including VA medical centers in San Antonio, Tampa, and Utah; universities including Vanderbilt, Iowa, Delaware, and McMaster; and DoD medical treatment facilities around the world. One exciting study, Optimizing Rehabilitation Interventions for Cognition following Complex Traumatic Brain Injury (ORION), will leverage the large numbers of patients seen by multiple DoD institutions and the depth of expertise from the treating providers in order to advance the science more quickly than can be done in randomized controlled trials. This study uses advanced statistical modeling through the VA's Utah data center in order to develop practice-based evidence (i.e. evaluating what we do with hundreds of patients in thousands of encounters to see what really works pragmatically rather than trying one idealized intervention on a couple of dozen patients at a time as is generally done in Random Controlled Trials).

The Extremity Trauma and Amputation Center of Excellence (EACE) continues to coordinate efforts between BAMC, Walter Reed National Military Medical Center, and Naval Medical Center San Diego to advance care and incorporate outcome measures into daily clinical practice. Some EACE personnel work in the CFI.

#### C&CC: Can you discuss other areas of achievements/focus?

CSM Oates: Our MEDIC utilization program is designed to ensure that medical enlisted personnel assigned to BAMC are prepared at a moment's notice to deploy and execute their wartime/combat medic [68W] skills. For many years medical personnel working in fixed facilities have not been utilized to their fullest potential. We implemented this program to establish a culture change. Our way forward is to utilize both the clinical environment as well as the simulated environment to ensure that medical personnel are prepared to perform their clinical skills in both the hospital and combat environment.

The medical personnel are awarded a different colored proficiency badge for each level of competency they achieve and maintain. This badge serves as a visual cue to the BAMC healthcare team on the medical personnel's level of proficiency:

- Black badge basic skills not validated on direct patient care knowledge.
- Silver badge proficiency in knowledge and skills in direct
- Gold badge proficiency in all knowledge and skills in the direct patient care setting, MEDIC Table VIII training, and the High Stakes Simulation training.

BG Appenzeller: January 4, 2019 marked the one-year anniversary of the opening the military's first Virtual Medical Center (V-MEDCEN) at BAMC. The V-MEDCEN began as a strategic concept in 2017 followed by hiring personnel and creating administrative structure to support operational and garrison virtual health. Key VH programs include the Advanced Virtual Support for Operational Forces (ADVISOR) phone line with a single phone number to support service members with eight specialties [including veterinary care] at the point of need when they have exhausted local military medical resources. ADVISOR also has a training line to support real world training in preparation for contingency operations.

An operational program called 'Mobile Medic' enables 68Ws to screen and care for patients in field by connecting with a role II provider through VH platforms. The 68W presents patients using a tele-presenting kit and algorithm director troop medical care to reduce patient movement and to keep SMs in the field. The V-MEDCEN is working with the National Training Center and the Joint Readiness Training Center to integrate the Mobile Medic Program into rotational unit training scenarios, for real-world medical care, and to improve 68W competency. The V-MEDCEN, in collaboration with RHC-C, stood up a Virtual Health Care Coordination Application (VHCAA) to connect patients to providers at Military treatment facilities across the enterprise. VHCAA provides time-zone appropriate notifications to ensure the patient and the provider are in the right location at the right time for video appointments.

BIRS has been providing telemedicine speech language pathology services since October 2009. Over that period, we've supported four distant installations, Forts Leavenworth, Sill, Redstone, and Leonard Wood; at one time or another, allowing patients to receive these services without having to travel away from their jobs and families.

**CSM Oates:** Our main focus is to see our patients and provide them the best possible medical treatment. The ill and wounded do not care what uniform you wear. They require a service and we aim to give them the best possible healthcare experience here at BAMC. We truly live by the mantra "Our Family taking care of yours." There is no other medical treatment facility at which I would rather work.



# **MANAGING AUSTERE EVACUATION**

By John Voinche, Skedco Correspondent



Medical technicians carefully monitor vital signs of a victim with life support equipment on-board the PJ Sked. (Skedco)

Bud Calkin, founder of Skedco, Portland, OR, recalls first hearing of the Thailand cave rescue a couple of days after 13 young boys, members of a junior football team, had gone missing on Saturday June 23, 2018. Their bicycles were abandoned at the cave's entrance. The cave, known as Tham Luang Nang Non, in Chiang Rai Province, has the longest known tunnel system in Thailand, measuring 7 ½ miles. During the rescue effort, which began about a week after the boys were found by two British divers, the PJ Sked, one of several different Sked stretchers manufactured by Skedco, was used to ferry the boys out of the cave.

Like all Sked stretchers, the PJ Sked is made of medium density E-Z glide polyethylene plastic. The nylon webbing included has a tensile strength of 9,000 lbs., while the rope (3/8") used in the Sked for hoisting is rated at 6,000 lbs. The minimum breaking strength (MBS) of the Cobra® quick-release buckles is 3,000 lbs. Deployed, the PJ Sked measures eight (8) feet long X 28 inches wide. Rolled up in the backpack, it is 36 inches long and nine (9) inches in diameter. The PJ Sked weighs 14 lbs., complete with accessories. The PJ Sked is designed to do everything a standard Sked SK-200 will do. The only difference between the two is the standard Sked is 36 inches wide and the PJ Sked is 28 inches wide. This allows for an 8-inch shorter pack and it makes it much easier to go through a door with it across a ruck-sack. Cobra® quick release buckles are included for faster and safer patient packaging. Because of its ruggedness, reliability and resiliency, many of the original Skeds produced nearly 40 years ago are still in service.

#### **Terrain-Challenged Rescue**

Locating the boys was hampered by rising water levels with strong currents inside the cave which resulted in a massive international rescue effort. Among the contingent of military and civilian teams were U.S. Air Force Pararescuemen from the 31st Rescue Squadron located at Kadena AFB, Japan. Part of the equipment cache brought by the 31st were PJ Skeds which were designed specifically for the pararescue mission.

"Because of the versatility of the Sked Stretcher, divers were able to package both the patient and air tanks inside the Sked", according to Calkin. This rescue plan was necessary because many of the boys couldn't swim. Many points along the rescue route were underwater



The Sked in use during pararescue training in Afghanistan. (Skedco)



The Sked litter provided protection along the way as patients were extracted individually from the cave. (Skedco)

and in order to protect the boys both physically and emotionally they were administered an anesthetic for the journey out of the cave. The boys wore a wetsuit, buoyancy jacket, harness and a positive pressure full face mask. When not in the water, the PJ Sked provided ease of transport and protection over rocks and sand hills.

In all, the rescue effort involved more than 10,000 people, over 100 divers, about 100 government agencies, 900 police officers, 2,000 soldiers, and 700 diving cylinders. Australia, Belgium, Canada, Denmark, Finland, Ireland, India, Israel, Japan, Laos, The Netherlands, Russia, The United Kingdom, and the United States all provided personnel and equipment.

Calkin also says in the many years he's manufactured untold quantities of Skeds, he has heard stories of many unique ways in which his product has been used. But this scenario he says was one-of-a-kind. "The caving industry has used Sked Stretchers for decades", says Calkin, but when I heard that it was used in this particular fashion and that all 13 victims had been rescued, that was very rewarding indeed".

In the days leading up to the rescue operation, officials and

family members alike were fearful that due to rising waters and the length of time the boys were in the cave, no one would come out alive. Although all 13 boys were saved, tragically on July 5, Saman Kunan, a 37-year old retired Thai Navy Seal, who showed up as a volunteer, died when he lost consciousness under water.

As Calkin reflected on the rescue effort some days after it was over, he realized that he was celebrating his birthday on or about the day when the last 5 boys were brought out of the cave. "The real heroes", says Calkin, "are the brave men and women who risked their lives for others. I just provided one of the tools".

#### Ahead

Skedco is currently developing a new Sked for the Army called the Folding Sked for use in the "hell hole" in armored vehicles and other places around armored vehicles.

Skedco is also in the final development of a new combat litter that will be ready for fielding before the end of 2019. Final testing will occur within the next few months. .



## MC4: BRIDGING A CAPABILITY GAP

The Medical Communications for Combat Casualty Care (MC4) Program Management Office (PMO) has developed a software application called Health Assessment Lite Operations (HALO) designed to allow medical providers to electronically document critical health information on injured or sick patients, even when connectivity is unavailable.

By Mr. Paul Clark, MC4, PEO Enterprise Information Systems



Army Physician Assistant Maj. Melissa Hodges and Spc. Jesse Medina, a medic, provide Maj. Gen. Brian Lein feedback on HALO during the MC4 Limited User Tests conducted at Joint Base San Antonio, Camp Bullis, Texas. (Photo by Paul Clark, MC4)

After treating an injured Soldier at the point-of-injury (POI), a medic's primary job is to get the Soldier and the medical treatment data to the next level of care. That is often a Role 1 Battalion Aid Station, but can also be the closest Role 2 Medical Treatment Facility or Role 3 hospital.

During a period of no connectivity, the HALO application allows medical providers to continue to digitally capture the Soldier's medical treatment data and when network communications return, the data entered in HALO will be automatically transmitted to AHLTA-T, which in turn links to the Theater Medical Data Store

(TMDS) and the Clinical Data Repository (CDR). Combined, these repositories make-up the electronic medical system which stores data and becomes part of the patient's electronic health record (EHR). This health record follows the Soldier throughout his/her career and beyond, even into the Veteran's Administration system. If a medical provider is unable to electronically capture a Soldiers' treatment data, they must revert to paper in order to capture vital health information. This often results in the loss of data which in turn poses a potential risk to the patient's safety and neglects the transfer of that medical encounter to the Soldier's lifelong EHR.

#### Filling the Data Gap

One of the reasons HALO was created was to fill this critical gap. HALO is a Windows-based application that provides the user with an electronic SF 600 form, the standard form used in the military to chronologically record a Soldier's medical care such as symptoms, diagnosis and treatment. "HALO is a simple, electronic, medical documentation application intended for use when connectivity is down," according to Jay Patnaude, a Senior Engineer with MC4. With the ability to continue

recording health data in HALO, medical providers can focus more of their time on saving lives.

The MC4 engineering team wanted to ensure medical personnel could perform the same health data documentation functions in HALO as they would in AHLTA-T, albeit a pared down version. Engineers eliminated unnecessary functions and provided the user with a simple documentation application that includes capabilities like printing sick call slips, laboratory reports and pharmacy prescriptions. HALO comes pre-installed on current MC4 systems and is "easy to install, configure, update, and maintain," Mark Gregory, MC4's Technical Management Division Chief, says. In order to make HALO more intuitive, the engineering team provides easy to follow instructions and a training demo video.

Tracy Ellis, Product Director of MC4, explains, "HALO is not an EHR, it is essentially an electronic SF 600 that uploads to AHLTA-T



when communications are restored. The intent of HALO is not to replace AHLTA-T, in fact, just the opposite". There are other benefits according to Ellis. "HALO can greatly reduce, if not eliminate, the number of paper encounters, making it much more likely the data will be included in the Soldier's record and allow that data to be searchable via Medical Situational Awareness in the Theater (MSAT) for future treatments, research, etc.," he explains.

#### **Keeping Information Real Time**

HALO also provides a capability that allows providers to share and synchronize patient encounter data in real-time within each aid stations. The hub capability enables the ability to share medical data between two facilities in real time, thereby relaying information to the next level of care, and the ability for providers to oversee and co-sign their medic's notes when they are in different facilities, both which are not available in AHLTA-T.

HALO can also be disconnected from the network then reconnected when the provider returns to the clinic. At certain times and places in operational environments, credentialed clinicians (e.g. physicians assistants, physical therapists and behavioral health clinicians) can be in short supply, and often have to travel to multiple facilities within an area of operation to see patients.

In a recent pilot test completed in Europe in January, this point was demonstrated by a physical therapist (PT). The PT visited patients at



#### MED COMMS INTEGRATION STREAMLINING THE CARE CONTINUUM



Army medical personnel work to perform patient administration tasks on software including HALO during MC4 Limited User Tests conducted at Joint Base San Antonio, Camp Bullis, Texas. (Photo by Paul Clark, MC4)

multiple clinics using HALO in a disconnected environment and upon returning, she was able to transmit all of the medical encounters to AHLTA-T.

When using AHLTA-T, if the laptop is taken offline and to different facilities, the system needs to be reconfigured, which can take several hours and requires system administrator support. A major advantage to HALO is that is does not require reconfiguring after disconnection from the server, which saves a lot of time.

#### **Highly Accurate Data Tracking**

HALO also allows providers the ability to document a Military Acute Concussion Evaluation (MACE), document encounters using ICD-10 diagnosis codes and templates, access references, run standard reports to track, append, and sign patient encounters.

The first HALO application was tested in 2017 during MC4's limited user test (LUT) of EHR software release of the Joint Operational Medicine Information Systems (JOMIS) Theater Medical Information Program-Joint (TMIP-J) at Joint Base San Antonio at Camp

Bullis, Texas. Although the LUT was set up to evaluate TMIP-J, MC4 testers noticed a lot of interest around HALO. Feedback from Soldiers was positive. Maj. Melissa Hodges of Moncrief Army Health Clinic, Ft.



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Sgt. Mackenzie Rhubart, a patient administration specialist provides feedback to Maj. Gen. Brian Lein, Commanding General, Army Medical Department Center and School, Army Health Readiness Center of Excellence, during a Medical Communications for Combat Casualty Care (MC4) limited user test. The Health Assessment Lite Operations (HALO) application was tested during the exercise conducted at Camp Bullis, Joint Base San Antonio in Texas. (Photo by Paul Clark, MC4)

Jackson, SC stated, "You can type a lot and write more in HALO about the patient, so in Role 1 and in combat situations it's easy to use... and for loading health information it's great."

Spc. Jesse Medina, combat medic, stated, "HALO was a good choice and just made more sense. There are a lot of pre-selected boxes you can check off and so it makes it faster and simpler."

#### **Testing Moves Forward**

After a brief deployment and more testing of HALO in Afghanistan in 2018, MC4 engineers were able to continue user tests during the pilot in Europe. MC4 hopes this will give the engineering team more feedback on future improvements and requirements.

Ultimately, with an operational health IT application like HALO, MC4 continues to explore ways that fulfill the Department of Defense's mission of providing Service members with a modernized EHR. MC4 sees HALO as a vital digital communication solution that can quickly be fielded to operational units, providing an important capability for medical personnel in their efforts to save more lives.

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#### **Accelerating Post-Trauma Tissue Repair**

Blast injuries, burns, and other wounds experienced by warfighters often catastrophically damage their bones, skin, and nerves, resulting in months to years of recovery for the most severe injuries and often returning imperfect results. This long and limited healing process means prolonged pain and hardship for the patient, and a drop-in readiness for the military. However, DARPA believes that recent advances in biosensors, actuators, and artificial intelligence could be extended and integrated to dramatically improve tissue regeneration. To achieve this, the new Bioelectronics for Tissue Regeneration (BETR) program asks researchers to develop bioelectronics that closely track the progress of the wound and then stimulate healing processes in real time to optimize tissue repair and regeneration.

The envisioned BETR technology would represent a sharp break from traditional wound treatments, and even from other emerging technologies to facilitate recovery, most of which are passive in nature. Under current medical practice, physicians provide the conditions and time for the body to either heal itself when tissues have regenerative capacity or to accept and heal around direct transplants. Most people are familiar with interventions that include casts to stabilize broken bones or transplants of healthy ligaments or organs from donors to replace tissues that do not regenerate.

Passive approaches often result in slow healing, incomplete healing with scarring, or, in some unfortunate cases, no healing at all. Blast injuries, in particular, seem to scramble the healing

processes; 23 percent of them will not fully close. Moreover, research shows that in nearly two-thirds of military trauma cases - a rate far higher than with civilian trauma injuries these patients suffer abnormal bone growth in their soft tissue due to a condition known as heterotopic ossification, a painful experience that can greatly limit future mobility. Although recent experimental treatments offer some hope for expedited recovery, many of these new approaches remain static in nature. For instance, some "smart" bandages emit a continuous weak electric field or locally deliver drugs. Alternatively, hydrogel scaffolds laced with a drug can recruit stem cells, while decellularized tissue re-seeded with donor cells from the patient help avoid rejection by the host's immune system. These newer approaches may indeed encourage growth of otherwise non-regenerative tissue, but because they do not adapt to the changing state of a wound, their impact is limited.

By the conclusion of the four-year BETR program, DARPA expects researchers to demonstrate a closed-loop, adaptive system that includes sensors to assess wound state and track the body's complex responses to interventions; biological actuators that transmit appropriate biochemical and biophysical signals precisely over space and time to influence healing; and adaptive learning approaches to process data, build models, and determine interventions.

More info: darpa.mil

#### **Surgical Skill Virtual Training**

The Air Force is working with sister services to study a virtual training platform called Crowd-Sourced Assessment of Technical Skills, or C-SATS. C-SATS provides specialized training for surgeons to further improve their specialized skills.

According to Air Force Maj. Joshua Tyler, director of robotics at Keesler Air Force Base, Mississippi, C-SATS lets surgeons receive virtual feedback on an objective, third-party platform. This unbiased feedback helps improve their skills. "Basically, a panel of expert surgeons virtually reviews a case you submit, and [then] provides feedback," said Tyler. "This helps our surgeons learn the most advanced surgical techniques they would otherwise have less exposure to."

While C-SATS shows promising results in studies with civilian surgeons, it has not yet been studied with military surgeons. "The Department of Defense's trained surgeons are talented and qualified, but it takes experience and time to become proficient," said Army Col. Robert Lim, chief of Minimally Invasive Surgery at Tripler Army Medical Center, Hawaii. "The C-SATS platform provides additional opportunities to ensure skills are maintained and perfected."

To assess C-SATS's use on improving the skills and capabilities of military surgeons, Lim and his team, including Tyler, received a grant from the Telemedicine and Advanced Technology Research Center at the U.S. Army Medical Research and Materiel Command in December of 2017. "The grant will look at military surgeons recently back from deployment," said Lim. "We are looking at surgeons at Keesler Air Force Base, Naval Base San Diego, William Beaumont Army Medical Center, and Tripler Army Medical Center."

Using C-SATS, surgeons submit a recording of a case they have completed, after removing any identifiable patient information. The development team at C-SATS will then edit the video file into key steps of the procedure and send it to expert reviewers familiar with the procedure. "Not only do we take great care to ensure patient privacy, but we also ensure the surgeon that performs the operation and the reviewers remain anonymous," said Tyler. "The expert surgeons will then score the video on key areas such as how well the surgeon used their hands, how well they manipulated the tissue, or assess their pace. The surgeon gets feedback on a very granular level, specifying the exact second where a surgeon could improve their technique."

More info: health.mil

#### CHEAT THE REAPER

A hospital in Kabul, Afghanistan critical to NATO and other Joint servicemembers is implementing skills in U.S. Special Operations Forces tactical combat and casualty care to answer a great need.

By MSgt. Felix Figueroa, NATO Special Operations Component Command-Afghanistan

Tactical Combat Casualty Care was designed in the mid-1990s for the Special Operations medical community and created custom guidelines for preventable causes of death on the battlefield, such as hemorrhaging and airway obstruction based on injury patterns from previous conflicts. Adopted by U.S. Special Operations Command in 2005, TCCC is now used widely throughout the U.S. military, the civilian sector and allied nations.

According to the National Association of Emergency Medical Technicians (NAEMT), almost 90% of American service members who die from combat wounds, die before arriving at a medical treatment facility. While the number is staggering, it illustrates the vital importance of first responders (medics, corpsmen, and other medical practitioners) on the battlefield today.

#### **Specialized Training for Proactive Response**

U.S. and NATO servicemembers assigned to Hamid Karzai International Airport (HKIA) Role 2 hospital sacrificed their spare time to train Force Protection service members in the art of Tactical Combat Casualty Care (TCCC). The phrase "Cheat the Reaper," which refers to saving lives, is found on an unofficial patch sewn onto the medical bags the 224th Area Support Medical Company, Maryland Army National Guard (ANG) medical team carries. HKIA's Role 2 hospital is a NATO hospital, based on a U.S. framework, providing routine and preventative medical care and emergency surgery. Hospital management and patient care is the primary mission. "Military medics are in high demand and limited. Therefore, TCCC training for non-medical personnel is not only important; it's critical," said Captain Michelle Levesque, a U.S. Army TCCC training officer from the 224th assigned



Capt. Michelle L. Levesque, a Tactical Combat Casualty Care trainer from the 224th Medical Company, Maryland National Guard, explains the importance of rechecking tourniquet placement after moving a casualty during TCCC training. (MDNG)

to the HKIA hospital. Levesque, a hand surgery specialty physician's assistant in Baltimore, MD, has dealt with a wide range of medical emergencies, from gunshot wounds to complete amputations and other upper extremity traumas.

During her time at HKIA's Role 2 hospital, Levesque and her team provided TCCC training every month to local service members, along with diverse groups such as Force Protection. Train Assist Advise Command-Air (TAAC-Air), and Security Force Assistance Brigade (SFAB). Those participating in the third iteration of TCCC training learned and were tested on: treating severe bleeding (hemorrhaging), tourniquet application, clearing and protecting the airway, treatment for penetrating chest wounds and on-scene safety. After two days of classroom hands-on learning and step-by-step instructions, students donned body armor and tested their skills in a short field exercise, moving as a tactical unit through a training village within the

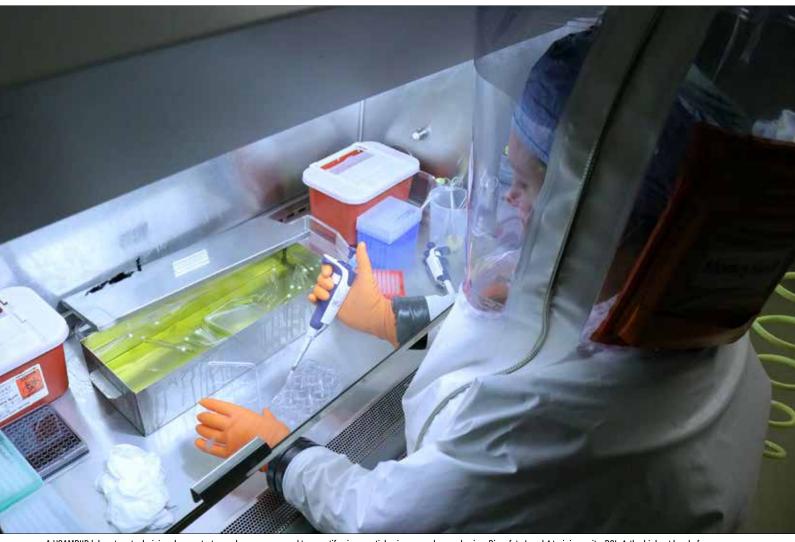
base perimeter. Hospital staffers dressed as enemy role-players ambushed the TCCC students, requiring them to establish perimeter security measures, conduct follow-on casualty assessments and move to a Casualty Collection Point (CCP) where they were assessed on their newly acquired life-saving skills.

"From a medical provider standpoint, equipping other soldiers with prehospital lifesaving skills that can be readily used prior to medical personnel arriving on-scene provides a force multiplier aspect into any deployment setting," said Levesque. "The training provided to our NATO partners is designed to empower them, increase situational awareness and ensure survivability while out on missions," said HKIA Role 2 Hospital Commander Captain Anne Alvarado, 224th ASMC, Maryland Army National Guard. "TCCC training provides all of that, along with peace of mind through confidence, knowing you can save a life."

#### PITTING MODERN GENETICS AGAINST VIRAL DISEASE

The U.S. Army Medical Research Institute of Infectious Diseases, Fort Detrick, MD, is developing novel vaccines to treat rodent-borne infections in humans.

By Dr. Connie S, Schmaliohn, Senior Research Scientist for Medical Defenses Against Infectious Disease Threats, USAMRIID



A USAMRIID laboratory technician demonstrates a plaque assay used to quantify virus particles in research samples in a Biosafety Level 4 training suite. BSL-4, the highest level of biocontainment, is required to safely study the world's most hazardous viruses, including Ebola. (Photo by John W. Braun, USAMRIID)

Without a doubt, the most significant technological addition to today's military infectious disease prevention toolbox is the ability to rapidly identify pathogens through gene sequencing, and then use that information to produce key portions of the microbe to generate vaccines, diagnostic tests and therapeutics. For example, a DNA vaccine can be synthesized in a few weeks by cloning the important genes of a virus into a bacterial plasmid. This vaccine is safe for all populations, can't be transmitted person to person and has no chance for reversion to virulence.

Diagnostic tests that detect a pathogen or that measure a person's immune response to an organism can both be derived from laboratory manipulations of the pathogen's genes. This trend has extended to routine diagnosis in hospital laboratories, in which it is possible to take a throat swab and perform polymerase chain



reaction to identify the microbe within a matter of minutes. Genomics research and the development of next-generation sequencing instruments will continue to revolutionize our awareness of potential infectious disease threats. They will also facilitate the discovery of novel pathogens while clarifying the human immune response to threats.

#### Viral Threat Uncovered

Hantaviruses have now been identified in more than 50 species of rodents, shrews, moles and bats throughout the world. All hantaviruses known to be pathogenic to humans are carried by

persistently infected rodents and are transmitted in aerosols of rodent excreta. Specific hantaviruses are carried by unique rodent hosts. These viruses don't impact the health of the rodents, which

have carried them for thousands of years; only humans are known to become ill when infected with hantaviruses. Servicemembers who come in contact with rodents during field or training exercises are at risk of infection in many diverse geographic regions. During wartime, a breakdown of infrastructure exacerbates the problem.

Western medicine first became aware of the disease (then known as Korean hemorrhagic fever) during the Korean War, when thousands of U.S. and U.N. troops became ill, with some progressing to kidney failure and shock. It wasn't until the late 1970s that a U.S. Armyfunded effort led to the discovery of the virus causing this disease in Korea. The virus was named Hantaan virus after a river in Korea. Our laboratory was the first to characterize this and similar viruses, resulting in the establishment of the Hantavirus genus of viruses.

The first discovery of pathogenic hantaviruses in the U.S. was in 1993, and USAMRIID again played a key role in the discovery. I was hosting a visit by a former U.S. Army lieutenant colonel, Tom Ksiazek, who had recently moved from USAMRIID to the Centers for Disease Control and Prevention (CDC) as head of their Diagnostic Section. He received a call from CDC about an unexplained severe respiratory distress outbreak in New Mexico and instructed his staff to perform several serological tests, including a test he and his colleagues at USAMRIID had developed for hantaviruses.

Neither of us suspected hantaviruses as the cause of this outbreak, as the hantaviruses we work with (from Asia, Europe and Scandinavia) do not normally cause respiratory distress. A bit later, he got the news that the only positive result was with the hantavirus assay. After several repeated assays and intense rodent trapping investigations by CDC and USAMRIID, the pathogen was confirmed to be a hantavirus, but not one that any of us had seen before. This is an excellent example of an emerging infectious disease, caused by a virus that has existed in the environment for a long time, that was recognized only when the right circumstances brought it into contact with humans.

Due to the importance of hantaviral diseases as well as their global distribution, USAMRIID has worked for many years to develop an effective vaccine. We and our partners at Walter Reed Army Institute of Research have recently conducted both Phase 1 and Phase 2 clinical studies of a DNA vaccine with excellent response rates in volunteers. We are working toward having this vaccine ready for emergency use in Korea if the need arises.

#### **Defining Optimal Prevention**

Vaccines are the best way to prevent infectious diseases. The "pendulum" of funding agencies swings either toward vaccines or toward therapeutics, but a true balance is needed. Of course, it is desirable to have an approach for treating or curing a disease, but it is better if our Servicemembers do not acquire the disease in the first place. The sticking point, as with many other issues, is funding. Although vaccines can be developed in a very short period of time, regulatory requirements for licensing a vaccine can take many years and a lot of money. Once an effective vaccine is developed, however, the savings in terms of lost duty days, not to mention lives, are well worth it. It is very frustrating to me to have come to a point where we have an effective vaccine for hantaviruses, but money for further development is not available without investment by a commercial partner. A consistent eye on the goal, coupled with stable long-term funding, would go a long way toward improving our ability to prevent infectious diseases.



USAMRIID investigators work with commercial partners to develop and/or adapt technologies to deliver DNA vaccines. Here, a scientist has loaded an early version of PharmaJet's intradermal jet injection device with a DNA vaccine for hantaviruses. Research shows that delivery technologies like jet injection or electroporation can increase vaccine immunogenicity, likely by increasing the amount of DNA delivered into cells. (USAMRIID)

For example, in the recent Ebola epidemic, treatment of patients with antibody therapy proved useful, but it wasn't feasible for preventing the disease. Furthermore, even if sufficient stocks of the antibodies had been available to treat everyone, those antibodies had limited effectiveness late in the disease course. The ring vaccination strategy, where susceptible individuals in a prescribed area around the outbreak are immunized, is likely a good strategy for many infectious diseases. However, it was difficult to determine how effective it was against Ebola virus, since the epidemic was coming to a close by the time the vaccination effort began. It is also important to understand the disease and locale you are dealing with; what might be possible in the U.S. is much more difficult in Africa.

#### Sustaining Critical Funding

Finally, I would like to say that the career I have had working on infectious diseases at USAMRIID could not have been more rewarding. I have constantly felt like my research is important, that I work with some of the best scientists in the world, and that I have had opportunities that I would not have had elsewhere. It is my sincere hope that the military continues to recognize the value of medical research conducted in their laboratories and finds a way to make funding of this work a priority so that the next generation of military medical researchers feel as I do. Adequate funding for military medical research laboratories would be a small price to pay for ensuring the best infectious disease preventive care possible for our Servicemembers. •

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## **BRAIN CELL CARE AFTER TBI**

A medical research company has shown an early signal of brain cell protection in traumatic brain injury (TBI) patients with its repurposed drug and is now progressing the preventive treatment program into advanced clinical trials.

By Steve Campbell, Campbell & Company Strategies Inc.



Traumatic brain injury, or TBI, is characterized by the demise of energy-producing mitochondria inside brain cells, and subsequent metabolic energy crises, during the acute-care treatment phase that may greatly increase the patient's brain cell damage and loss and, sadly, eventual disability. Post-traumatic stress disorder, or PTSD, is a TBI follow-on condition, and may also be a metabolic disorder. Research is now demonstrating that protecting mitochondrial energy production inside stressed brain cells during the first few days post-injury could be a critical strategy in minimizing long-term brain damage and disability.

#### **Repurposing an Established Drug**

In recent years, cyclosporine (CsA), an established and well-studied immunosuppressant used to prevent tissue rejection in organ transplant recipients, has been found to have promising neuroprotective capabilities in moderate to severe TBI. By protecting neuronal mitochondrial energy production, the pharmaceutical has the ability to appreciably reduce eventual long-term damage.

A 1990s-era published case study of a German teenager hit by a car - a young man who, as it happened, was already using CsA

for immunosuppression following a liver transplant – illustrates the point powerfully. At the accident scene, the boy had an initial damage rating (GCS score) of three, and was later found to have multiple lesions in the brain associated with poor outcome. But, amazingly, he was discharged from the hospital five weeks later and went back to school after two months. MRIs conducted five months post-accident showed evidence of residual multiple cortical and subcortical hematomas in both hemispheres of his brain. His attending neurotrauma team suspected CsA may have been a factor in "...the good recovery after severe brain injury in this 14-year-old patient."

After receiving positive results in recent preclinical studies, NeuroVive Pharmaceutical, a mitochondrial medicine company that discovered cyclosporine's neuroprotective properties, is now leading NeuroSTAT, its non-allergenic (lipid emulsion-based) and Phase 2-ready formulation of cyclosporine, into advanced clinical trials.

#### **Brain Injury Reduction and Dosing**

NeuroVive's recent preclinical study (Journal of Neurotrauma, January 2019), performed on an advanced pig model at the University



The first few days after the initial brain injury are critical to reducing the amount of eventual brain damage and long-term disability. (NeuroVive Pharmaceutical)

of Pennsylvania, showed that its CsA delivered an exciting 35 percent reduction in brain injury volume as measured by MRI scans. Furthermore, these studies displayed positive changes in both brain energy metabolite levels and mitochondrial respiratory function, as well as decreased generation of reactive oxygen species (ROS), all key indicators of mitochondrial distress.

Another recent study, the Copenhagen Head Injury Ciclosporin (CHIC), was an open-label small-group Phase 2A study in treating severe human TBI with a goal of establishing the safety and pharmacokinetic profile of two dosing regimens of NeuroSTAT. The results showed that appropriate dose-dependent concentration levels can be measured in the blood and cerebrospinal fluid — confirming that NeuroSTAT reaches the CNS and, importantly, with no unexpected safety signals.

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NeuroSTAT\*, a non-allergenic, lipid emulsion-based formulation of cyclosporine, has received orphan drug designation in both the U.S. and Europe. (NeuroVive Pharmaceutical)

#### **Confirming Biomarkers**

NeuroSTAT's efficacy was also demonstrated in CHIC through an analysis of brain injury biomarker in patient cerebrospinal fluid samples. Each of the four biomarkers — GFAP, UCH-L1, NF-L and Tau — are considered by the global neurotrauma researcher community to be increasingly reliable indicators of different pathological aspects of TBI. Summary CHIC results showed a time-based change that correlated with administration of NeuroSTAT. These results signal the drug's promise to contain the debilitating TBI secondary injury phase that leads to mitochondrial destruction.

These emerging TBI biomarkers are critical advances for both the short-term diagnosis and treatment, and long-term care of concussion (mild) and moderate to severe TBI patients. They potentially provide regulatory bodies with evidence-based "endpoint" biomarker tools for evaluating and aiding the development of future pharmaceuticals such as NeuroSTAT. It's exciting to note that the FDA approved the first-ever

biomarker-based diagnostic test for concussion in the U.S. in February 2018. Its ability to measure levels of GFAP and UCH-L1 is an advance that could reduce the need for costly CT radiation scans in diagnosing concussion.

#### **Phase 2 Study Prep and Beyond**

NeuroVive is now gearing up for NeuroSTAT's next step: a Phase 2 proof-of-concept study to evaluate its efficacy and support a pivotal Phase 3 study. The company is working closely with neurotrauma trial-design experts in the U.S. and Europe, and with regulatory bodies such as the FDA, to ensure that the study's design and target endpoints — MRI and biomarkers, for instance — meet all current and emerging standards. If cyclosporine does indeed demonstrate an ability to reduce TBI brain damage and disability in an acute hospital setting, it would be

the first-ever pharmaceutical approved to treat TBI.

Repurposing cyclosporine beyond its decades-old organ transplant legacy to become a powerful treatment for TBI rests on a solid foundation of decades of research, funded by literally hundreds of millions of dollars globally, in conjunction with 20 years of weighty government and DoD investment aimed at generating viable treatments. Now, with the recent development of exciting TBI biomarkers, NeuroVive's readiness to proceed to a Phase 2 clinical study is well timed. Despite many TBI drug study failures in the past, the global TBI community of researchers, funders and clinicians will observe the development of NeuroSTAT with cautious optimism. •





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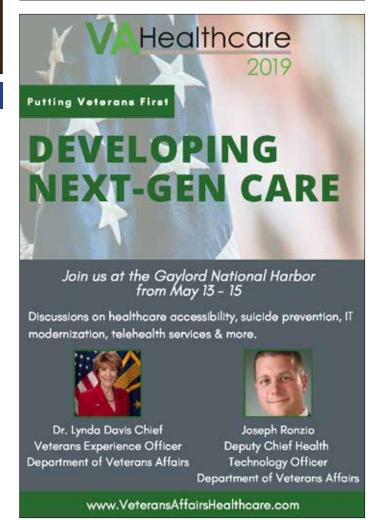
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