# Spring 2020 Tacticaldefensemedia.com CASUALTY CA IR E

## RAPID RESPONSE TO **MITIGATE THE SPREAD**

## **COMMANDER'S** CORNER



**COL Michael B. Lalor** Commander **U.S. Army Medical Logistics Command** Ft. Detrick, MD



Mr. Jeffrey Pacuska **Integration PM R&T** Integration U.S. Army CCDC-Soldier Center Natick, MA



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COVID-19 Response Deployed TCCC Mitigating Hemorrhage Access to Clinical Trials Health Assessment Lite Ops (HALO) Asset Deployment

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## COMBAT & CASUALTY CARE



## **RAPID RESPONSE TO** A GROWING PANDEMIC

The U.S. Army Combat Capabilities **Development Command (CCDC)-Soldier** Center, Natick, MA, is responding to the need for personal protective equipment (PPE) to combat the expanding COVID-19 pandemic.

Interview with members of U.S. Army CCDC-SC at SSC, Natick

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**COL Michael B. Lalor** Commander **U.S. Army Medical Logistics Command** Ft. Detrick, MD



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Major advancements in U.S. military medicine, in particular changes to pre-hospital battlefield medicine, have resulted in unprecedented survival rates for casualties in current conflicts. By Matthew Hackett



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**Streamlining Mobile Med Learning** Despite modern advancements, "potentially survivable" deaths due to hemorrhage are still far too common on the battlefield. An electronic med data management system by Allogy, LLC is poised to help critical info. result in positive outcomes. By Adam Wagner



#### Adapting Foreign Disaster Medicine to Future Wartime

The lessons learned during the Hurricane Dorian relief effort in a non-threat environment, can be adapted to the Indo-Pacific area of operations for potential wartime operations.

By HMC Wayne N. Papalski



Assessing Health, Promoting Mission Optempo Developed by the Army's Medical Communications for Combat Casualty Care (MC4) Product Management Office, the Health Assessment Lite Operations (HALO) software acquisition program provides IT capabilities for deployed medical forces. By Paul Clark

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#### Facing the Signature Wounds of War

Walter Reed Army Institute of Research (WRAIR), Bethesda, MD, is tasked with understanding future conflict to forecast likely medical threats and develop medical countermeasures to mitigate them. By COL Devdre Teyhen



#### Advancing Health Through Enhanced Access

The U.S. Department of Veterans Affairs, in collaboration with the National Association of Veterans' Research and Education Foundations (NAVREF), is promoting positive outcomes through greater access to clinical trials. **By Rick Starrs** 

Cover: Lt. Col. Carl Skinner, Chief of Emergency Medicine, reviews proper procedures with his doctors Peter Stull, MD (center), and Lt. Col. Aaron Cronin, MD, as they simulate emergency care for a COVID-19-positive patient at Madigan Army Medical Center, Joint Base Lewis-McChord, Tacoma, WA. (Photo by John Wayne Liston, MAMC)



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## **INSIGHTS**

As the globe continues to address the COVID-19 viral pandemic, a key supporter of efforts to stem the spread here at home has been the U.S. Defense Department. As need has inevitably grown for the availability of personal protective equipment (PPE) in hospital and clinic-based settings, so has the reality that peak casualty rates have yet to be seen. In the Spring 2020 issue of *Combat & Casualty Care*, we visit this and related areas of tactical combat casualty care (TCCC) as the nation brings DoD's expertise to bear in what may be a protracted fight.

Facing what could be the greatest health crisis in modern global history, the U.S. Army's Combat Capabilities Development Center- Soldier Center (CCDC-SC), at Soldier Systems Center, Natick, MA, has boots on the ground addressing critical shortages of PPE and the need for mobile triaging capabilities. A number of key personnel including Mr. Jeffrey Pacuska, Integration Program Manager on the Research and Technology Integration Team at the CCDC-SC, spoke with C&CC regarding efforts to provide prototyped nasopharyngeal swabs with various additive manufacturing materials to be evaluated as a solution to producing an alternative version of the swabs for COVID-19 testing. On the inoculation hunt, Army researchers at Fort Detrick, MD are fast at work growing batches of COVID-19 to help test treatment options and eventually find a vaccine.

Amidst this ongoing battle with an invisible enemy, the day-to-day duties of COL Michael Lalor, Commander, U.S. Army Medical Logistics Command (AMLC), and others at Ft. Detrick, MD, must go on. Projecting and sustaining medical materiel capabilities and data in order to build and enable readiness for the Army and Joint Services is at the forefront of AMLC's collective conscience. From the logistics of managing medical materiel to the deployment of medical capability on the battlefield, advances in next-generation pre-hospital combat medicine are resulting in unprecedented survival rates where there were previously high numbers of fatalities. Army CCDC's employment of enhanced Joint TCCC training tools are enabling medics to bring greater skillset to mobile casualty treatment where evacuation to facility is not immediately available. From treatment to communications, the latest in Health Assessment Lite Operations (HALO) software capability managed by the Medical Communications for Combat Casualty Care (MC4) Product Management Office, Ft. Detrick, is poised to bring more efficiency to the management and flow of critical patient data from point-of-injury and beyond.

With recent advances in the understanding of brain injury, an often-overlooked result of combat duty, the Walter Reed Army Institute of Research (WRAIR), Silver Spring, MD, is on the front lines of helping facilitate the transition of capabilities development into fieldready applications. We round out the Spring issue with a look at efforts by the National Association of Veteran's Research and Foundations (NAVREF) and the Dept. of Veterans Affairs in ensuring veterans greater access to clinical trials for earlier approval of lifechanging medical treatments.

As always, your comments are welcome. Thanks for the readership and stay safe!

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# ANSWERING THE NATION'S CALL ACCELERATING CRITICAL EQUIPMENT READINESS RAPID RESPONSE TO A GROWING PANDEMIC



Interior of one of the Rapid Response Shelters set up as a demonstration of "proof-of-concept" during the Rapid Response Shelter deployment exercise conducted this week at Walter Reed National Military Medical Center. This is not in response to any increase in patients or diagnoses; it is a preemptive measure to assess the ability to rapidly expand our facility in the event of a patient surge. (photo by Harvey A. Duze, WRNMMC)

Members of the U.S. Army Combat Capabilities Development Command's Soldier Center (CCDC-Soldier Center), at Soldier Systems Center, Natick, MA, spoke recently with Combat & Casualty Care regarding efforts to provide federal-level response to growing need for the resupply of hospitals with critical test and personal protective equipment (PPE) in the face of an expanding health crisis across the nation. CCDC is a subordinate headquarters at Aberdeen Proving Grounds, MD, under the recently-formed Army Futures Command in Austin, TX.

C&CC: What are some of the most pressing equipment needs that hospitals are experiencing at present?



**Mr. Gary Proulx:** As the COVID-19 crisis has continued to impact more people and more regions, a critical shortage of test kits at hospitals has developed. A key shortfall has been in the nasopharyngeal swabs used to take samples from patients' nasal passages. Hospitals have run out and are often unable to test patients. On 20 March 2020, members of the CCDC Soldier Center's Engineering Innovation Center (EIC) were contacted by

Lt. Col. Kit Parker at Harvard University and invited to participate in a discussion with representatives of Harvard University, Beth Israel Deaconess Medical Center (BIDMC) in Boston, and industry to discuss developing an alternative design for the nasopharyngeal swab. The companies producing the original design were unable to ramp up production and a new design was needed that would not infringe on their intellectual property. Dr. Kit Parker, assigned as reservist to the U.S. Military Academy at West Point's department of chemistry life sciences and working at Harvard University for his civilian job, is aware of CCDC Soldier Center's capabilities, especially in Additive Manufacturing (3D Printing).



**Mr. Matthew Hurley:** Based on the discussions, CCDC-Soldier Center EIC staff designed and prototyped nasopharyngeal swabs with various additive manufacturing materials to be evaluated as a solution to producing an alternative version of the swabs. The EIC needed to produce prototypes that used materials that could survive both the heat of autoclaving necessary for sanitization and the reagents used for testing. Prototypes were

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### ANSWERING THE NATION'S CALL ACCELERATING CRITICAL EQUIPMENT READINESS

rapidly produced (24 hours) and delivered to Harvard University and BIDMC for evaluation of the ability to apply nylon fiber and sterilize as well as suitability for use by medical staff. The CCDC-Soldier Center EIC staff is also performing specialized testing of these prototypes to compare their mechanical performance to the COTS solution in order to address patient safety concerns. CCDC Soldier Center has also been in daily contact with other representatives of the US Army Additive Manufacturing Community of Practice (AM CoP), in an effort to coordinate the many critical needs presented by the COVID-19 crisis and the unique solutions this community has to offer. Cooperation has continued with Harvard University, BIDMC, industry, and the AM CoP to address the critical needs of the medical community.

#### C&CC: In terms of first responder needs to enable ongoing safe testing at levels necessary to address patient presentation, what are the current challenges?



**Mr. Mathew Correa:** Members of the CCDC-Soldier Center workforce in the Office of the Chief Systems Engineer as well as the Design, Engineering, Prototyping & Test Branch have been actively engaged in finding a solution to the nationwide shortfall of N95 facemask respirators. Through our relationships across the Army modernization enterprise our role as Soldier system integrators, we have been building collaborations with our partners to help navigate the pre-testing,

testing, and certification of new/alternative filter materials, alternative (3D printed) facemask designs, and qualification of new producers of N95 Respirator masks. While the identification of respirator suppliers and materials has largely been addressed through the Office of the Secretary of Defense Manufacturing Institutes (Advanced Functional Fabrics of America https://www.manufacturingusa.com/ institutes/affoa, Advanced Robotics Manufacturing https://www. manufacturingusa.com/institutes/arm) and other industry partners.



**Mr. Jeff Pacuska:** CCDC-Soldier Center has had the lead in aligning the material producers with material certifiers via interagency engagements with the National Institute for Occupational Safety and Health https://www.cdc.gov/niosh/index.htm , U.S. Army Public Health Command, and CCDC-Chemical and Biological Center. In addition the Army Additive Manufacturing Community of Practice as represented by CCDC-Armaments Center and CCDC-Soldier

Center has led DOD efforts on establishing the feasibility of on-site 3D printable and reusable face forms which could accept certified filtration media. Other opportunities have also presented themselves for current suppliers of Defense products to convert their operations for the purposes of manufacturing needed PPE. In particular, the Parachute Industry of America (PIA), working through CCDC-Soldier Center's Aerial Delivery Directorate has actively reached out to identify areas in which they could have impact. CCDC-Soldier Center is engaging and creating partnerships to best align with Army Futures Command and state priorities.

#### RESPONDENTS

*Mr. Jeffrey Pacuska*, Integration R&T PM, U.S. Army Combat Capabilities Development Command – Soldier Center

*Mr. Gary Proulx*, Mechanical Engineer, U.S. Army Combat Capabilities Development Command – Soldier Center

*Mr. Matthew Hurley*, Mechanical Engineer, U.S. Army Combat Capabilities Development Command – Soldier Center

*Mr. Mathew Correa*, Enterprise Integrator, U.S. Army Combat Capabilities Development Command – Soldier Center





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## CASE STUDY: DEPLOYED MEDICINE

After identifying the lack of a centralized source for trusted standards and training, the Defense Health Agency partnered with Allogy to create an easy-to-use, easy-to-access platform designed to distribute official DoD policy and up-to-date combat medicine best-practices. The result is Deployed Medicine, a mobile- and web-based outlet that provides standards-based training and content to improve readiness and performance of deployed military medical personnel.





#### DHA relies on Allogy's custom app development for Deployed Medicine.

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# NEXT-GEN COMBAT MEDICINE EXPANDING BATTLEFIELD CAPABILITY PUSHING PRE-FACILITY SURVIVAL

Major advancements in U.S. military medicine, in particular changes to pre-hospital battlefield medicine, have resulted in unprecedented survival rates for casualties in current conflicts.

By Matthew Hackett, PhD, Science and Technology Manager, U.S. Army Combat Capabilities Development Command - Soldier Center



U.S. Navy Reserve members of the 4th Medical Battalion, carry a simulated casualty to be evaulated by the Shock Trauma Platoon (STP) at the Forward Resuscitative Surgical Suite (FRSS) during a combat support training exercise at Fort McCoy, WI. The training was a part of a U.S. Army Reserve-hosted Combat Support Training Exercise involving Multinational and U.S. Forces. (U.S. Army Reserve photo by Staff Sgt. Robert Waters)

The standard of care employed for the treatment and stabilization of battlefield casualties is tactical combat casualty care (TCCC). TCCC is focused on evidence-based medicine, including evidence showing that military units fully trained in TCCC have documented the lowest incidence of preventable deaths. However, TCCC training across the Services is faced with a number of challenges.

To begin, instruction of TCCC lacks standardization across the Services. The Services leverage TCCC guidelines during the creation of training doctrine, but differing implementation strategies and Servicespecific needs cause variation between the Services. Furthermore, even within a Service, instruction varies from installation to installation, based on prior knowledge from the instructor or the use of passeddown training materials. Compounding this issue, when students or instructors search for definitive TCCC content, it has historically been found in a wide variety of locations, including the NAEMT website, Health.mil, or even contractor websites. This scattering of content has led to the proliferation of outdated TCCC content, creating a challenge for the Committee on Tactical Combat Casualty Care (CoTCCC) to ensure everyone has ready access to the latest TCCC guidance.

#### **EMBRACING A TRAINING EVOLUTION**

In addition to the aforementioned issues, the next generation of learners necessitate a shift in training paradigms. A 2015 Defense Health Agency (DHA) survey of 1,356 combat medical personnel explored current TCCC learning behaviors. The survey found 34% reviewed TCCC training content less than twice per year, and 17% said they never search for information outside the 1-2 year refresher training cycle. Over half of those surveyed were not engaged in continuous learning. The vast majority, 87%, felt adding mobile learning would enhance their TCCC learning experience, and 82% chose a free mobile app as their preferred learning platform. Understanding how to effectively deliver TCCC education to a NextGen medical workforce has the potential for driving major breakthroughs in clinical performance on the battlefield. NextGen learners have been shown to prefer personalized, flexible and self-directed learning experiences using

### NEXT-GEN COMBAT MEDICINE EXPANDING BATTLEFIELD CAPABILITY

their personal mobile devices. In order to tap into these additional learning opportunities for the NextGen audience, future TCCC education and training systems will need to incorporate a broader range of pedagogical approaches and embrace digital platforms as a channel for learning engagement.

To address these challenges, the Defense Health Agency (DHA), the Joint Trauma System (JTS), and the Army Futures Command are designing new methods for delivering TCCC education and training to NextGen medical forces. Specifically, the Learning Strategy, Tactics and Technology (LSTT) research program was created by the DHA as a strategic science & technology (S&T) initiative to conduct research and rapid prototyping to accelerate the development and fielding of trauma training capabilities. The research program includes two



At Ft. Benning's Medical Simulation Training Center, medics practice treating "junctional" wounds, those at points where limbs connect to the human torso. The medics participated in a close review of a new curriculum that will be used to teach servicemembers a type of battlefield first aid called Tier 2 Tactical Combat Casualty Care. (U.S. Army Reserve photo by Staff Sgt. Robert Waters)

principle efforts: (1) development of Joint, role-based TCCC curriculum and (2) research and development of a mobile application to support TCCC training.

The Joint TCCC curriculum being developed will directly address Department of Defense Instruction 1322.24, which mandates all Service-members receive TCCC training commensurate with their role. To address this need, TCCC subject matter experts across the DoD have teamed up with the University of Miami, combining the operational knowledge of Military providers with rigorous academic instructional design. The new curriculum will be delivered in four tiers: Tier 1 All Service Members; Tier 2 Combat Lifesaver; Tier 3 Combat Medic / Corpsman; and Tier 4 Combat Paramedic / Provider. The new curriculum is advancing TCCC educational practice using modern learning science concepts, such as micro-learning and spaced repetition. The curriculum combines a variety of student resources, such as skills cards and how-to style videos, with supporting instructor materials, such as skills assessment checklists and course guides, to provide a complete training package. Importantly, the new curriculum is being design in a modular fashion. The modular approach provides the Services with the flexibility to implement the training in multiple formats, while still ensuring the core TCCC training objectives are met. At the date of this publication, Tiers 1 and 2 have been completed, with Tiers 3 and 4 in development and being released in the coming months.

Complementing the new curriculum, the government has partnered with Allogy Inc. to develop the Deployed Medicine platform, which will support TCCC instruction and accommodate the learning preferences of NextGen audiences. At present, Deployed Medicine serves as the definitive source for on-demand TCCC training content, hosting YouTube-style video, audio podcasts, study guides, and other didactic content. Since all the content on Deployed Medicine is approved by the Joint Trauma System, users can be assured the TCCC content is the most current and comprehensive available. To improve accessibility, Deployed Medicine is available as an iOS app, Android app, and website, allowing access on mobile devices or via standard web browsers. Deployed Medicine meets the objective of delivering dynamic learning content using current, highly accessible technology, and helps to promote a self-directed and continuous study of medical best practices. In addition to serving as the repository for TCCC training materials, the Deployed Medicine platform is currently undergoing further development to add an assessment capability, allowing learners to evaluate their TCCC performance and understanding. This includes the capability to deliver content in sequenced courses, enabling distance learning in a guided fashion.

#### MARRYING CAPABILITY AND MOBILITY

In addition to learners, the Deployed Medicine platform puts new capability into the hands of TCCC instructors. Instructors will have the ability to push content to students before classes, thereby shifting costly class time away from 'death by PowerPoint' and towards interactive, hands-on skills stations. Analytics from the assessment suite will provide instructors with a snapshot of the strengths and weaknesses a class or single learner has related to TCCC. Using this information, an instructor can tailor the training to focus on the identified weaknesses, thereby personalizing the educational process and ultimately improving learning performance.

The combination of the Joint TCCC curriculum with a mobile technology platform holds the promise of advancing TCCC education in a meaningful way. The new Curriculum will reduce TCCC training variance, providing a medical force that is more uniformly trained to treat battlefield casualties. The addition of the Deployed Medicine technology platform meets the demands of NextGen learners and allows for novel instructional design approaches to training TCCC. The modern battlefield is constantly shifting, and through research efforts at the DHA and beyond, the Military Medical force is continuously adapting educational practices to always be ready.

# INDUSTRY PARTNER STREAMLINING MOBILE MED LEARNING

Despite modern medical and technological advancements, studies show that nearly "a quarter of the 4,596 combat deaths in Iraq and Afghanistan between 2001 and 2011 were 'potentially survivable." Of those, 80 to 90 percent were due to uncontrolled blood loss resulting in death before ever reaching a medical treatment facility.

By Adam Wagner, Chief Content Officer, Allogy



Though combat survivability is at an all-time high, these numbers illustrate the absolute importance of proper resources and training. Unfortunately, one of the biggest problems with TCCC training is the amount of incorrect or out-of-date information available online (e.g. videos on YouTube displaying incorrect tourniquet protocol). With Deployed Medicine, JTS now has an outlet for publishing standards-based training and content, delivering that content in real time, and tracking how and where that content gets used. It also makes it easy to keep that content up to date as best-practices evolve.

#### WHAT IS DEPLOYED MEDICINE?

After identifying the lack of a centralized source for trusted standards and training, the Defense Health Agency partnered with Allogy to create an easy-to-use, easy-to-access platform designed to distribute official DoD policy and up-to-date combat medicine best-practices. The result is Deployed Medicine, a mobile- and web-based outlet that provides standards-based training and content to improve readiness and performance of deployed military medical personnel.

Deployed Medicine utilizes the proven pedagogical advantages of mobile learning, emphasizing knowledge retention and skills acquisition while delivering the right information to the right audiences at the point of need. Service members can access training and content at any time and any place-even without internet access, which can be lifesaving in the field-learning and reinforcing skills at their own pace or accessing vital information as necessary.

#### **CHANGING TRAINING CONTENT DISTRIBUTION**

Mobile learning has rapidly changed the landscape of continued education and training. According to the Pew Research Center, 94 percent of adults in the U.S. between the ages of 18-49 own a

smartphone. This sort of mobile access allows learners to engage with training content from anywhere and at any time, which has proven to not only improve motivation and engagement but also boost knowledge retention and successful skills acquisition.

But mobile learning isn't just about viewing training content on a mobile device. That's why Allogy built Deployed Medicine on their Capillary platform. With Capillary, Allogy has created something unique– combining both the capabilities of a content-management system (CMS) and a learning-management system (LMS) with an architecture that is specifically designed for mobile training and pedagogy. This new approach to knowledge management provides standards-bearers the necessary tools to distribute standards-based content and deliver reliably high-quality training on both web and mobile in the form of either structured formal-learning programs or as on-demand resources for just-in-time learning.

With Capillary's mobile capabilities and organizational benefits, learners can educate themselves on new procedures as necessary, refresh their memories on important skills, and access vital information at the point of need—even offline. This sort of mobility of information helps learners be better trained, better equipped, and more confident in their abilities.

#### **PUTTING CAPABILITY TO WORK**

Allogy's Capillary platform provides software and support that let organizations create branded outlets for trusted, standards-based content and training resources for global audiences.

Access to a robust CMS makes creating and organizing important information and training content easy, while the publishing wizard ensures that even non-technical professionals can create beautiful content, taking the guesswork out of instructional design. A powerful LMS offers the ability to deliver structured formal-learning programs and fulfill certification requirements.

Capillary's analytics enable the creation of customizable dimensions of user data to better understand the who, where, and why of contentuse. You can monitor force readiness with course-level, instructor-level, and global-usage metrics; fulfill certification requirements and track learner's progress with courses and assessments; better understand your audience to optimize content and training with custom user data fields; send push notifications for emergency alerts or reminders to engage with important content.

It's impossible to eliminate the danger associated with combat, but it's vital that emergency efforts be met with the training, preparation, and information needed to do everything possible to prevent unnecessary casualties. Often, this marks the difference between "potentially survivable" and "survivable." And the best way to be prepared: having unfettered access to necessary resources and proper training from a trusted source.

### COMMANDER'S CORNER

## PROJECTING AND SUSTAINING MATERIEL PREPAREDNESS

Colonel Michael B. Lalor was commissioned into the United States Army through the ROTC program at the University of Scranton, Scranton, PA, in May 1995. Entering military service from his hometown of Goshen, NY, COL Lalor has served throughout the U.S. Army in a variety of troop leadership and staff assignments.

COL Lalor joins the Army Medical Logistics Command after serving as the Military Assistant to the Assistant Secretary of Sustainment, Office of the Secretary of Defense, Washington, D.C., from July 2018 – August 2019. COL Lalor joined OSD after serving as the Commander, 1st Armored Division Sustainment Brigade, Fort Bliss, Texas, from June 2016 – June 2018.

During his career, COL Lalor has commanded formations at the company, battalion and brigade level in Afghanistan: Company Commander, Headquarters and A Company, 210th Forward Support Battalion, 2nd BCT, 10th Mountain Division (LI), Fort Drum, NY, and Operation Enduring Freedom (2003); Battalion Commander, 710th Brigade Support Battalion, 3rd BCT, 10th Mountain Division (LI), Fort Drum, NY, and Task Force Spartan, Operation Enduring Freedom (2013-2014); Brigade Commander, 1st Armored Division Resolute Support Sustainment Brigade, Operational Freedom's Sentinel and Operation Resolute Support (2017).

COL Lalor has also deployed as an M1A1 Tank Platoon Leader with 1st Battalion, 37th Armor, 1st BCT, 1st Armored Division, Friedberg, Germany and Operation Joint Endeavor, Bosnia and Herzegovina (1996); Division Logistics Planner, 10th Mountain Division (LI), Multi-National Division Center and South, Operation Iraqi Freedom (2008-2009).

Other notable assignments include: Executive Officer to the Assistant Deputy Chief of Staff, G-4, Headquarters, Department of the Army, Washington, D.C. (2010-2012); Brigade Commander, 3rd BCT / TF Spartan, 10th Mountain Division (2014-2015), leading the brigade through its inactivation.

C&CC spoke recently with COL Mike Lalor, Commander of U.S. Army Medical Logistics Command, Ft. Detrick, regarding current areas of focus and challenge in ensuring the right medical materiel capability is where and when the Army and Joint DoD partnering forces need it.

## C&CC: What is the Army Medical Logistics Command and why was it formed?

**COL Lalor:** The U.S. Army Medical Logistics Command (AMLC) is a new major subordinate command activated June 1, 2019 under the U.S. Army Materiel Command (AMC). AMLC is integrated within the Army's primary logistics and sustainment command, AMC, which creates



#### COL Michael B. Lalor Commander U.S. Army Medical Logistics Command Ft. Detrick, MD

efficiencies for the Army and allows us to capitalize on the expertise already inherent within the enterprise.

The AMLC's mission is to project and sustain medical materiel capabilities and data in order to build and enable readiness for the Army and Joint Forces across the full spectrum of operations.

The creation of the AMLC was part of several larger Army medical reform efforts designed to ensure medical readiness, support wartime requirements, and enhance the quality of care for soldiers and their families. Readiness is the top priority with this transition. We must ensure medical forces have the specialized equipment and materiel they need to continue the best care for Soldiers, on and off the battlefield.

#### C&CC: What are the AMLC's core competencies?

**COL Lalor:** The AMLC's direct reporting units include the U.S. Army Medical Materiel Agency (USAMMA); the U.S. Army Medical Materiel Center-Europe (USAMMC-E); and the U.S. Army Medical Materiel Center-Korea (USAMMC-K).

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### **COMMANDER'S CORNER**



A Soldier assigned to the 563rd Medical Logistics Company conducts medical supply warehouse operations at the U.S. Army Medical Materiel Center - Korea. (Photo Credit: Lt. Col. Marc R. Welde, USAMMC-K)

#### Our core competencies fall into four main areas:

#### **Strategic Power Projection**

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- Manage and sustain medical Army Prepositioned Stocks (APS) and other medical materiel readiness programs.
- Coordinate medical Foreign Military Sales (FMS) in collaboration with the U.S. Department of State to strengthen our Allied Partners and ensure inoperability.

#### **Industrial Base Readiness**

- Provide depot-level repair, calibration, and recapitalization of medical equipment and medical special purpose test, measurement and diagnostic equipment (TMDE-SP).
- Deploy medical maintenance experts to operational environments to provide forward repair and maintenance support.

#### **Supply Availability**

- Distribute vaccines and provide Cold Chain Management training.
- Support medical materiel quality control and hazard recall messaging.
- Provide theater-level medical logistics support to Army and joint medical forces.

#### Logistics Information

- Manage and update the medical materiel catalog.
- Provide technical business support and record system training.

C&CC: Medical technology is advancing at a rapid pace, which would seem to create some challenges for organizations, such as AMLC, in keeping pace with sustainment and modernization. How is AMLC managing the incredible pace of change?

**COL Lalor:** We are committed to maintaining a partnership with the U.S. Army Medical Research and Development Command (MRDC) product managers who develop new medical technologies and modify existing commercially available products. Our goal is integrate medical logistics and sustainment considerations into medical materiel development and acquisition life cycle processes. The goal is always to provide units with the right tools to save lives on the battlefield -- but that doesn't mean

### COMMANDER'S CORNER

the right tool is the same one used in a fixed hospital. Field conditions are very different and present unique logistical challenges, including environmental considerations (e.g., extreme heat/cold, sand and debris) and transportation burden (i.e., How large or heavy is the product? Can it be transported without breaking if put in a container and strapped inside a ship or airplane? Does it require refrigeration or power?). Another consideration is medical maintenance capability and cost (i.e., How often must the device be calibrated? What is the overall cost of sustaining it?). The Army's goal is to provide the right tools in the right places at the right time -- without adding extra logistical burden to the operational force.

## C&CC: From a joint perspective, in what ways does AMLC coordinate across the Services and with other government and non-government partners?

**COL Lalor:** Medical logistics enables an entire system of medical readiness, from the deployability of service members in garrison to the delivery of medical care in an operational environment. The Army rarely deploys alone, so coordination among all military services and interoperability with allied partners is essential. The AMLC coordinates directly with external commands and agencies for professional and technical matters and mission support.

#### Our government partners include:

- Defense Logistics Agency (DLA), for management of strategic medical materiel acquisition, distribution, and readiness programs
- Defense Health Agency (DHA), in its execution of Defense Medical Logistics programs and shared services, such as materiel standardization and data management
- Defense Medical Logistics Enterprise (DMLEnt), for collaborative forums and initiatives to promote materiel standardization and joint interoperability
- Army Service Component Commands (ASCC) and Combatant Commands (CCMD), for development and execution of MEDLOG portion of health service support plans

In fact, in terms of military medical logistics, working collaboratively is greatly facilitated by the fact that we all share the same building (the Defense Medical Logistics Center) on Fort Detrick, where the Army, Navy, Air Force and Defense medical logistics partners work side-by-side every day.

## C&CC: As AMLC develops, what are some of your priorities for the command? What challenges do you face and how are you working to overcome them?

**COL Lalor:** My number one priority is readiness and streamlining end-to-end Class VIII medical materiel distribution. There is a need for speed and agility to ensure deploying troops get the right medical supplies and equipment when and where it's needed.

I am also focused on modernizing and operationalizing medical APS. We must make sure we have the most modern and maintained medical materiel capabilities, so we can provide options to combatant commanders and force-providing units.

Another priority is streamlining our medical catalogue and lowering the burden of materiel for our commanders and maintainers, while preserving, maintaining and updating our medical capabilities for clinicians. This requires striking a careful balance. We only have so much storage space and transportation resources. Medical must work closely with all of the classes of supply, so that medical moves in sync with the other commodities and does not disrupt it.

We have really begun to see ourselves more clearly through several recent exercises. We are also looking very carefully a unitlevel demands to determine the foundation of what is required to meet basic medical needs at a moment's notice, supporting everything from aid stations to field hospitals to APS.

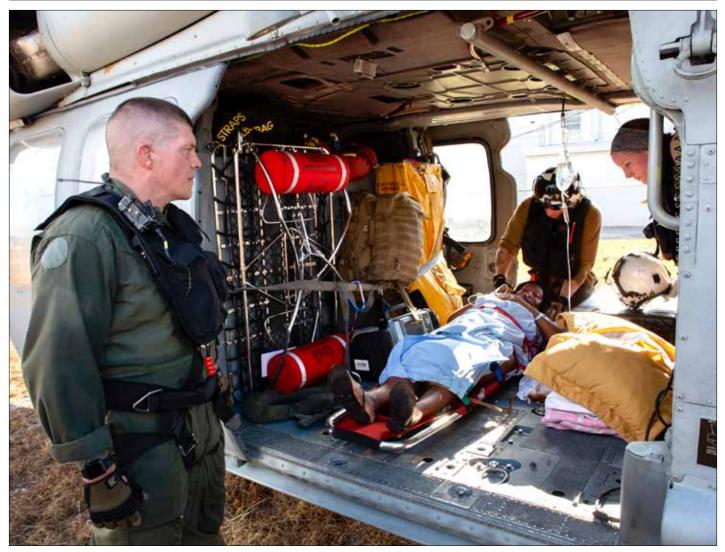
We are completely about challenging the status quo of how things have always been done because we know that we must evolve. Medical logistics is modernizing so that we are prepared -- now -- to support the future fight.



## ENROUTE CASUALTY CARE FILLING THE POINT-OF-INJURY TO FACILITY GAP ADAPTING FOREIGN DISASTER MEDICINE TO FUTURE WARTIME

Lessons learned during the Hurricane Dorian relief effort in a non-threat environment can be adapted to the Indo-Pacific area of operations for potential wartime operations. Given the recent hurricane relief effort, it could be argued that medical crews are not ready to operate remotely in a hostile environment from an island base with limited communications, fuel, command and control, and information on casualties.

By HMC Wayne N. Papalski, CAPT Ben Walrath MD, AWSCM Shane Gibbs, MSG Mike Remley, SGT Ricky Deitzel, HM1 Ryan Honnoll, and LCDR Paul Roszko, ER Phys, WRNMMC



A Search and Rescue Medical Technician stabilizes a patient being transported for hypertensive crisis during Hurricane Dorian relief operations. (Walter Reed Nat. Mil. Med. Center)

In early September 2019, the category five Hurricane Dorian stalled over the northern Bahamas for two days, marking a spot in history as the most destructive storm to wreak havoc on the island chain. The U.S. Navy was tasked to provide humanitarian relief effort via Helicopter Sea Combat (HSC) and Helicopter Mine Countermeasure (HM) Squadrons comprised from the Helicopter Sea Combat Wing Atlantic (HSCWL). The response from the HSCWL support to the Bahamas resulted in:

- Eight SAR/TACEVAC mission with 108 survivors treated/ recovered and transported
- 417 passenger transports

- 29,000 pounds of food and water delivered
- 203,850 pounds of cargo

Although the Foreign Disaster Relief (FDR) response was extremely successful, this was the first time in U.S. naval history that a mission was completed in an outside the continental U.S. (OCONUS) relief effort that started and ended each day from a continental U.S. (CONUS) base. That dynamic environment caused critical medical, logistical, communication, and human factor concerns that can be adapted to the future peer-to-peer wartime environment. While traditionally commands rise to challenges and turn "water into wine", these already problematic caps on the ability to just show up to the fight ready put our fighting forces at risk.

#### EARLY OPERATIONS

HSCWL began flying missions within nine hours of their arrival to Homestead by transiting the 197 miles to Nassau, Bahamas. That transit time took approximately an hour and twenty minutes each way depending on weather and winds. Initial reports to crews flying were that the only fuel source was Nassau International Airport, at the Odyssey Fixed-Base Operator (FBO). This FBO is also where the United States Agency for International Development (USAID) and Virginia Task Force 1 (VA-TF1) teams were being based out of to support all initial relief.

The first crews landing at Nassau were met with no immediate command and control tasking for the HSCWL assets to support. There were multiple USAID and VA-TF1 assets that had been sitting on the FBO for days needing flights to the Marsh Harbor and Freeport areas in the Bahamas. Their initial missions were to be the first set of US government surveyors to assess the damage in those areas. During the confusion of getting mission tasking together on these first days of flying, the FBO was overwhelmed with all forms of rotary and fixed wing traffic. The average wait time for a fuel truck that day was over an hour, causing crews to hand walk the fuel truck attendant to their aircraft to be fueled up.

Fueling during the entire first three days of operations became the main focal point of planning all missions to properly operate in the vast island chain environment. Distance and limited fuel was one of the major threats posed to crews during the entire relief effort. All operations had to plan for fuel in Nassau due to the there being no fuel in any of the islands' normally functioning FBO's. This caused operations to be extremely conservative due to majority of the transit being of great distance and overwater.

Following initial tasking and mission planning for fuel came attempts to leave Nassau. Nassau was the only controlled airspace in the Bahamas the first few days after the storm hit, with all relief effort landing and taking off from there. There was limited ramp space on the FBO, crowds of aircraft waiting to taxi, extremely long wait times to receive identification codes to take off, and the threat of transiting traffic once immediately airborne. There were all forms of aircraft support from the Department of Defense, Homeland Security, other government agencies, Foreign government agencies, non-profit, for profit, and good Samaritan fixed and rotary wing support. The term "aerial Cajun Navy" was coined as lesson learned from the string of help in the form of boats from Hurricane Harvey.

Once finally off deck from Nassau, missions revolved around working with USAID and VA-TF1 to assess the heavily damaged areas. Within minutes of flying the first missions in the objective areas, crews found themselves: landing to assess crowds waving the helicopter down; inserting USAID into certain areas to assess tasking they received prior; or evacuating patients being turned over to HSC crews. Prior to the first tactical evacuation (TACEVAC) mission, all patients were to be transported to Nassau to the FBO, to be triaged at a makeshift collection point. This was relayed to crews by Liaison Officers (LNO) in Nassau. A lot of this was to control undocumented populous coming from the islands. However, communications became a critical issue early on in trying to execute any and all TACEVAC missions.

There was little service to communicate in the transits to and from Nassau. Once in the majority of the objective areas, communications were limited to anywhere that may have had an undamaged cell tower or if communications with a designated relay aircraft worked. The majority of the communications came from using a commercial off the shelf (COTS) unclassified applications, such as "What's App". All command mission tasking and updates were made via "What's App" and logged by a Squadron Duty Officer (SDO) back at the deployed unit center (DUC). The majority tasking for TACEVAC missions was impromptu, causing deviations in fuel planning to take place in order to determine if the crew had the fuel to successfully take the mission.

#### SAR/TACEVAC MISSION

The tasking for search and rescue (SAR) and TACEVAC missions came by chance for crews. With the extremely limited communications, crews were often conducting other designated missions and found themselves getting mid-mission tasking to rescue or pick up a patient/survivor. This came either via "What's App", tasking by parties on the ground in the objective area, landing at certain survey sites, or social media. The Coast Guard was screening and fielding all media aspects to render aid, however, there were few instances of aid workers on the ground showing coordinates to crews of where people were stuck after they saw it online. This accounted for recovery of 30+ stranded survivors who had been left with no food or water on remote outer islands, days after the storm hit.

Medical supplies and logistics for critically sick patients became another serious issue. Due to the little to no communication on the tasking of patient type, crews often arrived on scene with no incoming report on the patient. There were two missions where HSC commands had to turn the TACEVAC mission down because they did not have the proper gear to safely care for the patient. While a casualty evacuation (CASEVAC) asset can accept the risk, search and rescue medical technicians (SMTs) attached to HSC commands shall deliver advanced life support (ALS) care as per the OPNAVINST 3130.6e. There have been well-documented issues related to supply problems for SMTs Level B kits, resulting in an inability to meet the ALS mission set dictated by doctrine. Both of the turned-down missions were for sick medical patients that required sedation, ventilator management, and a capable ALS-level provider to care for them during the lily-padding of Island Transport back to Nassau. Both missions were turned down at the patient bedside or in the presence of the patient's provider. Accepting either patient would have knowingly put them in harm's way, given the lack of proper gear and medications to care for them during a long transit with limited fuel. Further complicating matters was the fact that both critical patients were left in a resource-limited environment with few medical supplies and no alternative evacuation asset immediately available to complete the mission. Crews learned the next day while dropping off aid supplies that one of the patients unfortunately succumbed to their illness.

Additional mission concerns were the possibility of unknown patient transport requests. Routine cargo transport missions turned into USAID or VA-TF1 members rushing the HSC crews with a sick patient to be urgently transported back to Nassau. A similar pop-up tasking came from VA-TF1 leadership in certain sites, reporting that there were severely dehydrated survivors on certain islands and crews would break tasking if fuel was available to perform the rescue. While normally an easy undertaking, the island hopping, limited fuel, and requirement to bring all patients back to a single staging area overwhelmed by aircraft posed risk to rotary wing crews.

Medical providers in any disaster relief scenario anticipate

### ENROUTE CASUALTY CARE FILLING THE POINT-OF-INJURY TO FACILITY GAP

treating large numbers of casualties with poly-trauma or medical patients requiring critical care medicine. While those patients did pop up on a few missions, the majority of the patients treated by the crews were suffering from chronic conditions with no treatment available. There were a number of rescues for patients out of food and water resulting in severe dehydration. The bulk of all critical patients transported were sick due to the sudden inability of local healthcare resources to manage chronic illnesses. The lack of infrastructure and extremely limited health care required crews to manage exacerbations of chronic obstructive pulmonary disease (COPD), asthma, heart failure, and diabetes, hypertensive emergencies, and complications of missed dialysis sessions.

#### **CLINICAL MEDICINE**

While in the middle of operations, a crew was tasked with going with a USAID survey team to a small island north of Freeport called Grand Cay Island. This was five days after the storm had passed. The USAID team asked to have a SMT from the aircraft remain on station with them due to the unknown amount of time the survey team needed to be on station. The SMT established contact with councilman via the USAID personnel to evaluate if there were any emergent medical needs. Grand Cay was a larger remote population with a small clinic on the island. Prior to the storm, the staff from the clinic departed to evacuate and had not returned.



While the clinic structure was left unharmed, there was a large amount of internal flooding due to leaks in the ceiling. With help from the local community, the SMT helped clean up a treatment area and assessed the condition of the clinic's supplies.

After aiding in the clinic clean up, there was a gathering of community members outside the clinic to be evaluated. Normally, the clinic was open for the community to get their regular medical needs. Due to the storm though, some chronic medical conditions had been left unmanaged. The SMT evaluated over 35 patients that had been advised a "medical provider" was around the clinic. The primary medical skillset of SMTs is point of injury medical and trauma illness/ injury and the enroute care of emergent acute and chronic medical conditions. Out of 35 patients, six required actual clinical procedures ranging from multiple sutures, diabetic evaluations, tooth removal, and a high-risk pregnancy. The lack of medical infrastructure in the entire area of operations (AOR) crippled the ability to provide proper care for patients. Even if the patient was evacuated to Nassau, their operating capacity was overwhelmed within days of the storm hitting (Nassau, although being the capital of the Bahamas, was one of the smallest islands affected by the storm).

#### LESSONS LEARNED FROM THE TYRANNY OF TIME AND DISTANCE

While there was no direct threat during Hurricane Dorian, not having a naval vessel near the AOR made remote operations, communications, and control aspects even more difficult. Relief crews were constantly left in periods of no communications, which in a threat environment could directly impact mission effectiveness and safety. Fuel considerations in this environment are equally as important. The single source for fuel in these operations is an exploitable weakness during wartime. Disrupting this would hinder operations considerably. Additionally, other Services have inflight refueling as an option for their rotary wing assets. The Navy currently does not have this refueling option for the MH-60 model helicopters. Having that capability would be a mission enhancement that can increase force support and lethality in wartime operations.

In the wake of a potential mass casualty or combat operations in the amphibious/maritime environment, the inability to get on scene quickly continues to stretch medicine beyond the "Golden Hour" response. The added factor of remote operations, fueling, and communications concerns creates chaos as crews try to gain tactical understanding of what type of mission tasker they could be responding to. Delayed response to a mass casualty or combat operation mimics the scenes from the recent Hurricane Relief where the majority of patients were over 48 hours from the onset of their injury/illness. Not all patients were poly-trauma and many medical illnesses were worsened by deteriorating environmental conditions, leading to dehydration, sepsis, malnourishment, heat injuries, etc...

The most important part of the initial response is being mission ready. Currently, the well documented problem within the HSC community is the force health protection and TACEVAC response not being mission ready. Crippled with no funding, commands are failing to meet the doctrine of being advanced life support capable. Not having medical supplies such as appropriate monitors, point of injury consumables, ventilators, and required medications to treat casualties will continue to put lives at risk, now and for the next fight! •

## DEPLOYED MED COMMS LINKING CAPABILITY WITH FORCE NEED ASSESSING HEALTH, PROMOTING MISSION OPTEMPO

By Paul Clark, Strategic Communications Chief, MC4 PMO



Medical providers register the very first patient encounters using HALO at the Role 2 hospital at Kabul, Afghanistan last November. So far this year, through the end of January, over 1,000 patient encounters have been registered at the hospital using HALO. (MC4 PMO)

Developed by the Medical Communications for Combat Casualty Care (MC4) Product Management Office, Ft. Detrick, MD, the Health Assessment Lite Operations (HALO) software acquisition program was tasked with primary responsibility for providing Army operational health IT capabilities for deployed medical forces. The current version of HALO is designed primarily for documenting out-patient treatment at Role 1 battalion aid stations and at Role 2 military treatment facilities (MTFs).

Due to the success of the HALO deployment, Army leaders will begin rolling out HALO to medical forces worldwide during the remainder of 2020 and the first quarter of 2021.

#### **RIGOROUS FIELD EVOLUTION**

HALO was initially piloted to Army medical units in Romania and Bulgaria in September 2018. On November 15, 2019, it went live and deployed to the Role 2 MTF in Kabul, Afghanistan. This was an important deployment, as it not only enabled MC4 engineers to evaluate HALO's effectiveness at a Role 2 MTF near the battlefront, but it also allowed the MC4 team time to assess additional features needed for future HALO enhancements. U.S. and Allied medical providers, after receiving less than two hours of training, were able to document patient encounters using HALO. In the first two days of use, three times as many electronic patient encounters were documented than in the two weeks leading up to the HALO "go live" date using the legacy software, Armed Forces Health Longitudinal Technology Application – Theater (AHLTA-T).

"The launch of HALO exceeded expectations and 'validated' the software as an application that can be deployed quickly to fulfill the critical mission of electronically capturing patient health data in operational settings," noted Mr. Tracy Ellis, Product Director for MC4. "This real-world deployment provided the MC4 team the opportunity to receive feedback from providers regarding ease of use and adequacy of training, and to identify requirements to incorporate into the next version of HALO."

Through the end of January 2020, more than 1,000 patient

#### www.tacticaldefensemedia.com

encounters have been documented electronically using HALO by both U.S. and North Atlantic Treaty Organization (NATO) providers, according to MC4 engineers. Many of these encounters would have been documented previously on paper.

In a post-deployment survey, MC4 staff at Hospital Kabul International Airport (HKIA) asked clinicians about their level of satisfaction with HALO. Feedback received from the HKIA medical staff indicates a high degree of interest with HALO over AHLTA-T. "The beauty of HALO is its simplicity. It is easy to use and overall it's a vast improvement over AHLTA-T," described Maj. Paul Schunk, emergency care physician. When asked if she would rather go back to using the legacy AHLTA-T after using the HALO application, Capt. Lesley Tarongoy, an emergency room nurse, gave an emphatic "No." The same answer was given by all survey respondents when asked the same question.

Sgt. Kenneth Roberts, an Army medic with 2nd battalion, 3rd Security Force Assistance Brigade, described HALO as "selfcorrecting... and a system that's easily broken down," in describing the features and user interface. When asked what he thought overall, Roberts remarked, "very satisfied." •

## **INTERVIEW WITH THE PD**

So we could learn more about the next steps for HALO as an Army Operational Health Information Technology (OHIT) solution, I sat down with MC4 Product Director (PD) Tracy Ellis.

First, before we get into HALO as a software solution, can you tell me about electronic health records [EHRs] and why they are important to operational medical forces?

Mr. Ellis: It's all about taking care of Soldiers, Sailors, Airmen, Marines, and other deployed personnel.

Documenting health care for deployed service members is a critical part in continuity of care, patient safety, and ensuring that proper medical care is provided when they leave the service. Electronic documentation has many advantages over paper records. When there is network connectivity, EHRs can be transmitted in seconds and are then viewable by medical personnel with network access. Electronic records aren't easily lost when compared to paper records. Information in the electronic record can be data mined to support medical research and to provide leadership with near real-time information for use in decision making. We want to achieve the same high guality health record - whether deployed or at home station. Finally, a comprehensive, lifelong EHR provides medical information to ensure that the service member gets the right care at the right time - both while they are in the service and when their care transitions to the VA or civilian sector upon their separation from service.

#### What operational challenges does this present?

**Mr. Ellis:** Electronic documentation in a deployed environment presents a number of challenges. The number one issue is that network communications are not always available or can become degraded – the term used by the military is "disconnected, intermittent, or low bandwidth" (DIL). That is why there's a requirement that deployed operational health IT systems have the ability to continue to document health care in a DIL environment. While the legacy AHLTA-T software provides this capability, it depends on a server to store the patient encounter. If the connection between the provider's computer (a.k.a. client) and the server is lost, it requires reconfiguring the provider's computer



Tracy Ellis

as a client-server to operate in this environment. This is normally handled by deployed personnel with systems administration expertise- who may or may not even be co-located with you. HALO was designed specifically to allow electronic documentation to continue and then forward the patient encounters once communications are restored, with no additional steps required.

If HALO is designed for situations with low bandwidth, or when network communications go out, can you explain more about how that works; perhaps provide

a scenario?

**Mr. Ellis:** Much like your internet and cable in your home, the time it takes to install your cable connection, like for issues such as weather, technical issues, user error, and low bandwidth, can all affect your service. Take all of these factors, then add in potential for disruption of the communications network by our adversary, and you can see examples that could create a DIL environment that could last from a few minutes to a few days or longer.

## You recently began HALO deployment in Afghanistan. How did that go?

**Mr. Ellis:** Our HALO deployment in Afghanistan was actually the second time HALO's been used in the field. In September 2018, we deployed HALO to several Army units deployed in Eastern Europe. After several months of use by units in Bulgaria and Romania, we took lessons learned from that deployment and used the agile fielding approach to software development to make changes to HALO prior to deploying an updated version to Afghanistan in November 2019.

The November deployment to Afghanistan exceeded our expectations. Forty-one hospital staff members (20 U.S., 21 NATO) received two hours of HALO training prior to "go live." Most were able to document patient care electronically using HALO without further assistance from the HALO training team. Prior to deploying HALO, NATO providers and many U.S. providers rarely used the legacy AHLTA-T software, as it was too hard to learn during their 90-120 day deployments.

## Do you see HALO used with other application advancements, say telehealth?

**Mr. Ellis:** Yes. If virtual health is involved, that information is still documented in HALO and becomes part of the patient's record. So it is compatible with telemedicine advances.

## Can providers communicate with each other through the application? Can you explain a bit about its capabilities?

**Mr. Ellis:** HALO allows a patient encounter to be open and accessible to other providers who may have a requirement to also provide documentation or co-sign. An example might be the physician who is documenting notes while a medic is continuing to monitor and document vital signs. HALO provides an alert any time more than one individual is documenting in the open patient encounter. The current health care software does not allow more than one individual to access the open encounter.

#### So how does HALO save the Army money?

**Mr. Ellis:** Because HALO is simple and easy to use, the savings are realized by reducing the number of hours spent on training. Since HALO is so easy to support, it will allow IT personnel to spend more of their time supporting other applications. The small size of the HALO application compared to the legacy application has the potential to reduce hardware costs.

#### As an Army acquisition program, what are you doing to support the Army's leadership priorities and support multi-domain operations? In other words, how does MC4 remain relevant?

Mr. Ellis: The deployment and further development of HALO supports the Army's priorities - readiness, modernization and reform. Advances in operational health information systems, such as HALO, provide real-time data in support of medical mission command. This helps maintain Readiness through the ability to rapidly shift resources in support of the fight. HALO is fit-for-purpose, lightweight, and agile enough to rapidly modify as required. While the focus of this interview is on HALO and electronic health care documentation, the MC4 program deploys operational health IT solutions that support all 10 health care functions, including logistics, preventive medicine, and medical mission command. In each of these areas, lightweight, scalable, cost effective solutions that incorporate commercial-off-theshelf hardware and software solutions are being developed to deliver capability in support of multi-domain operations ranging from early entry operations through large-scale combat operations. And the rapid, incremental delivery of capability are consistent with Modernization and Reform efforts by leveraging power of operational health information systems to help maintain the Army's competitive edge.

Isn't the DoD already moving out with modernizing its EHRs? Why not just use that solution in the deployed environment rather than develop an application like HALO? **Mr. Ellis:** MHS Genesis is military medicine's modernized, enterprise-level EHR that has also been adopted by the VA. But it is not ready to field to operational forces. Until it is ready, being satisfied with the legacy operational health care applications is not the answer, especially when there are opportunities to get enhancements and additional capabilities in the interim to our deployed Soldiers. We see HALO as a cost-effective improvement over the legacy electronic health record (EHR) that can serve as a bridging solution until the Military Health System's MHS GENESIS program is ready to deploy to operational forces. We see HALO as a cost-effective improvement over the legacy EHR that can serve as a bridging solution until MHS GENESIS is ready to deploy to operational forces. That is still projected to be 3-5 years from now.

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#### **TELE-SURGICAL ROBOTICS GOES GLOBAL**

XSurgical, a surgical robotics technology company, Cambridge in MA, will soon bring to market a tele-surgical robot, guided by surgeons from remote locations, to battlefields and other critical environments (such as areas affected by disasters, third world countries and other mobile settings). The in-development product marries elements of technologies that bear CE certification – indicating its conformity with health, safety and environmental protection standards sold within the European Economic area – with a native design for field operations.

Currently patients in war zones are triaged and transported to treatment centers for surgery, thereby receiving minimal care during the first most critical hours following injury. Present-day robotic surgical solutions, due to size, weight, fixed installation and sterile environment requirements, cannot be applied at a war or other disaster site.

The XSurgical remote methodology comprises onsite containers with surgical robots and actual emergency rooms, guided remotely by off-site surgeons – a superior alternative to transporting a critically wounded patient miles to a treatment center, leveraging the best Al and haptic technologies to provide minimally invasive and open surgery procedures.



The first iteration of XSurgical's robot called the Alpha. A third iteration, the Gamma, is in development. (XSurgical)

More info: xsurgicalrobotics.com

#### MODULAR & HIGH-FIDELITY COVID-19 AIRWAY CONTAMINANT KIT

7-SIGMA Simulation Systems, maker of modular airway skills training technology, has introduced its 7S3 Modular COVID-19 Victim Airway Skills Trainers which enable realistic simulated intubation. The Modular Airway Skills Trainers ingrain and fortify the skills in proper intubation by providing the most comprehensive simulation of an actual patient in a cost-effective package:

•Airway mimics that of a victim with COVID-19 airway contamination-Saliva spray with contaminated COVID-19 simulant -Nano particles aerosolized to be airborne up to 6 feet via exhalation-cough simulation to expel excess mucous contaminant-UV (blacklight) assessment of cross contamination-Excellent training realization of contamination after doffing

- Anatomically correct epiglottis, tongue, vocal cords, & tracheal rings
- · Realistic biomechanics of the jaw, neck, tongue, & epiglottis
- Supports positioning, oral and nasal intubation, and all supraglottic devices.
- Modular components to use with the 7S3 Airway Skills Trainers
- Saliva and Mucous simulate contaminated airway with UV assessment by black-light

Of note: Like an actual COVID-19 patient, the 7S3 COVID19 airway is more difficult to intubate. Kit comes with 7S3 COVID-19 Airway Contaminant Saliva, in-line aerosolizer, and UV flashlight. BVM and external air supply is not provided. Recommend 40 LPM wall air flow for optimum presentation.

More info: 7-sigma.com

#### **RACING TOWARDS A CURE**

Army researchers at U.S. Army Fort Detrick, MD are fast at work growing batches of COVID-19 to help test treatment options and eventually find a coronavirus vaccine. "They take some of the virus and put it onto cells," Dr. Kathleen Gibson, a core laboratory services division chief at the U.S. Army's Medical Research Institute of Infectious Diseases [USAMRIID], explained through a triple-glass window as Army researchers wearing protective gear worked with the deadly virus. "They look for the virus that will actually kill portions of the cells and they'll count those killed portions."

These Army scientists have been working double shifts growing large amounts of the COVID-19 virus at this sprawling lab complex. "We have more capacity to run more studies at the same time," Col. E. Darrin Cox, USAMRIID commander, explained. "We can be running things in parallel rather than having to do things sequentially, and that's helped speed up the process of the science."

"We have a large capacity to be able to test a very large number of products. Most other places don't have that infrastructure to be able to develop or test as many products at a time," according to Dr. John Dye, USAMRIID viral immunology chief. "There are at least eight different companies that are developing vaccines that all can be assessed looking for safety in humans. Having multiple shots on goal is our best chance of being able to basically battle this virus."

Army researchers have shot compounds such as chloroquine into vials of COVID-19 to see how it's reacted. "We can test about 300 drugs or compounds in each plate," Dr. Sheli Radoshitzky said. "We add the compounds using this robotic system and then we transfer the plates into bio-containment where we add the virus."

More info: army.mil/news

#### **ROBOTS JOIN THE VIRAL FIGHT**

For the first time in the U.S., autonomous vehicles are being used to transport medical supplies and COVID-19 tests at Mayo Clinic, Jacksonville, FL.

At a time when healthcare resources and personnel are stretched thin, the Jacksonville Transportation Authority (JTA) has partnered with Beep and NAVYA to use autonomous vehicles to facilitate the safe transport of COVID-19 tests collected at a drive-thru testing location at Mayo Clinic.

"This deployment is a historic moment for the Jacksonville Transportation Authority," said JTA Chief Executive Officer Nathaniel P. Ford Sr. "Along with our partners Beep, NAVYA and Mayo Clinic, we are leveraging our learnings from three years of testing autonomous vehicles through our Ultimate Urban Circulator program. Our innovative team saw this as an opportunity to use technology to respond to this crisis in Northeast Florida and increase the safety of COVID-19 testing."

On Monday, March 30, 2020, up to four autonomous vehicles began operating along an initial route, in full autonomous mode without attendants or other people onboard, to transport COVID-19 tests from a drive-thru testing site to a processing laboratory on Mayo Clinic campus. The COVID-19 test samples are placed in secure containers prior to Mayo Clinic healthcare professionals loading the samples onto the shuttle.

"During a time of rapid change and uncertainty, the ability to think innovatively alongside the Jacksonville Transportation Authority, NAVYA,

and Beep during the pandemic has strengthened all of our teams through community collaboration," said Kent Thielen, M.D., CEO, Mayo Clinic. "Using artificial intelligence enables us to protect staff from exposure to this contagious virus by using cutting edge autonomous vehicle technology, and frees up staff time that can be dedicated to direct treatment and care for patients. We are grateful to JTA, Beep, and NAVYA for their partnership in these challenging times."

The JTA, Beep, NAVYA and Bestmile teams partnered to create, test and deploy the routes for the autonomous vehicles at Mayo Clinic in Florida to address the fluid developments of the COVID-19 pandemic. The routes are isolated from pedestrians, traffic and staff. Beep, Mayo Clinic and the JTA will closely monitor the service from a mobile command center to maintain safe operation. Beep, an autonomous shuttle fleet service provider, transported the shuttles through Eagle Express Inc. from Lake Nona, Florida, an innovation hub 150 miles away where the company is headquartered in Orlando, FL. An additional shuttle is being utilized from the JTA's Ultimate Urban Circulator (U2C) program. The JTA has actively tested AV technology since 2017 to prepare for a conversion and expansion of its Skyway automated people mover in downtown Jacksonville into a network powered by autonomous vehicles.

More info: go-beep.com

#### **MRI FOR MOBILE TRIAGE**

Mobile triage and mobile medical care equipment is not only a vital part of any tactical or deployed conflict but has recently become a vital part of protections taken to treat our homeland population in times of pandemics and other major conflicts. Magnetic resonance imaging (MRI) building installations incorporate expensive electromagnetic interference (EMI) shielding enclosures called Faraday cages that protect operators and ensure accuracy of image detail. Mobile units need to have a more flexible, easily installed, lighter weight shielding system expanding MRI capability to be more widely used in mobile medical applications. Current cages are susceptible to radiation leaking, especially at higher frequencies where the MRI units are more interference susceptible. Mitigating these leaks with traditional materials is difficult. A new approach, using a narrow band shield, fault tolerant design centered around the operating frequency of the MRI, would improve MRI performance - vital to the needs of a mobile unit.

MRI develops images by measuring signals occurring at a specific frequency, the Larmor frequency, which is a known function of the MRI equipment's applied magnetic field. EMI at the Larmor frequency is especially problematic. Infinite Technologies RCS, Inc. (RCS), Integument Technologies, Inc. (ITI), and Johns Hopkins University Applied Physics Lab (JHU-APL) have created a low cost, flexible solution using metamaterials that act similar to a band-stop filter. Combining metamaterials and Faraday cage shielding enclosure materials complement each other to customizes and mitigate the most detrimental EMI at the Larmor frequency for MRI instruments. The resulting system will provide highly effective, lightweight, fault tolerant, and easily fieldable electromagnetic isolation improving the signal-to-noise ratio of fielded systems.

Metamaterials are formed from repeating structures of known and common materials, but represent a state-of-the-art advancement in

materials design and fabrication. By their nature, metamaterials are best suited for narrow-band applications. Our system of combining metamaterials with a light weight Faraday cage constitutes an excellent solution to noise absorption. In MRI applications these metamaterials' ability to effectively absorb frequencies in a narrow bandwidth prove very beneficial. The general concept involves the addition of layered metamaterials/Faraday cage on the walls of a room or space where imaging is to occur. This addition of an absorptive layer combined with a Faraday cage backing will prevent both unwanted signals from entering the room and provide a significant reduction to the ambient EM noise by absorption.

The advantages for improved mobile MRI usage include:

- Reduced MRI scan times required to produce the same image quality.
- Higher image quality improving patient care and reducing the need to purchase more expensive machines.
- Reduced environmental interference with open MRI equipment, which cannot be fully encased in a Faraday cage, allowing claustrophobic patients to receive high-guality open MRI scans.
- Enabling the use of other medical equipment in the MRI room, such as life support equipment, without interference.
- Improved ease of protective structure transport without concern for shielding degradation through the introduction of this fault tolerant approach.

The flexibility of this lightweight, highly effective system is ideally suited for temporary mobile operations.

More info: jhuapl.edu

## VIRAL RAPID RESPONSE PROMOTING RE-SUPPLY FLUIDITY BRINGING ASSET SUPPORT TO THE FIGHT

During the COVID-19 pandemic, the Defense Logistics Agency has been reaching out aggressively to 'take the pulse' of industry and offer support as defense companies respond to Coronavirus disruptions. Along with this effort, DLA continues to execute its national security mission to support the military with repair parts, fuel, food and more. By Chris Erbe, Defense Logistics Agency



A forklift driver of the 404th Army Field Support Brigade works during a cargo off-load on Joint Base McGuire-Dix-Lakehurst, N.J. The supplies will be used to help individuals in New York and the surrounding areas affected by the COVID-19 pandemic. (Photo by Staff Sgt. Jake Carter)

In a March 20 memo, Under Secretary of Defense for Acquisition and Sustainment Ellen Lord told the defense industrial base, "Consistent with the President's guidelines: 'If you work in a critical infrastructure industry, as defined by the Department of Homeland Security, you have a special responsibility to maintain your normal work schedule."

During this unprecedented crisis, a 'normal work schedule' can be a tall order for some companies. As the main provider of military supplies, has a vested interest in not only the state of its current and future contracts, but on the overall health of the 12,000 companies it works with. Nearly 9,000 of those suppliers are small businesses with varying capacities to stay financially viable during disruptions brought on by the pandemic.

"The COVID-19 pandemic won't change the fact that our suppliers are the lifeblood of the DoD industrial base," said Director Army Lt. Gen. Darrell K. Williams. "We're staying on top of what this coronavirus is doing to our industry partners and we'll do everything we can to support them as they support us."

#### **STAYING IN TOUCH**

Communication is key, and Defense Logistics Agency (DLA) has taken a proactive approach in passing on information and assessing the health of partner companies during the crisis. In mid-March, Williams took part in a conference call with representatives from seven industry associations representing more than 4,000 companies, informing them of changes and accommodations DLA had made in response to the virus, as well as listening to their concerns. Organizations represented on the call included the Aerospace Industries Association, National Defense

### VIRAL RAPID RESPONSE PROMOTING RE-SUPPLY FLUIDITY



At the request of U.S. Army Europe and Installation Management Command Europe, in support of COVID-19, DLA Distribution Europe's Theater Consolidation and Shipping Point is shipping 19,200 bottles of hand sanitizer and 19,200 American Red Cross comfort kits for use by soldiers, civilian and family members assigned to U.S. Army Europe. (DLA photo)



DLA Distribution Norfolk, Virginia's workers supported the load-out mission of the USNS Comfort before it set sail for New York City in support of non-COVID-19 patients to help make space at area hospitals for COVID-19 patients. (DLA photo by Navy Capt. Thomas Neville)

Industrial Association, National Defense Transportation Association, Professional Services Council, National Council of Textile Organizations, American Apparel & Footwear Association and SourceAmerica.

"The DLA director also made about 17 personal one-on-one calls to key defense industry executives," said DLA Ombudsman Timothy Stark. "That was in addition to nearly 400 direct calls made by leaders of DLA's major subordinate commands who oversee purchases for specific supply chains."

To further assist communication with industry, DLA has optimized analytic and data collection tools to assess impacts to the supply chain, including a new Post-Award Request System reason code that allows industry to highlight any contracts where problems may exist due to coronavirus impacts.

"If you have a contract with us and you have some issue you need to talk to a contracting officer about, PARS is a way for you to submit that information into an automated system so that our contracting officers can take action on it," Stark said.

DLA also created a Request for Information website that allows suppliers to inform the agency of potential impacts to their workforce and their contracts. They are using some of the already over 3,400 RFI responses to help assess the current health of the supplier base.

#### TAPPING PROVEN CONNECTIVITY

DLA laid the groundwork for close communication with its suppliers well before the coronavirus. In recent years, the agency established the DLA Ombudsman Office to facilitate industry outreach and issued an Industry Engagement Plan to emphasize stronger partnerships. The agency also holds yearly Demand Forecasting Summits and Industry Days to help industry plan for future demand. Supplier surveys and semiannual Industry Association Luncheons further those efforts and provide venues for feedback and discussions of current issues.

"DLA has worked hard to strengthen the partnership between the agency and our industry base," Williams said. "In this moment of crisis, we are seeing the benefits of that work as we make a determined effort to hear our suppliers and help coordinate the industrial base response to this crisis."  $\hfill\blacksquare$ 



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# COMBAT ENVIRONMENT MITIGATING THREATS THROUGH INNOVATION FACING THE SIGNATURE WOUNDS OF WAR

For the Walter Reed Army Institute of Research (WRAIR), Silver Spring, MD, it is the duty of Army medical practitioners and researchers to understand future conflict, forecast the medical threats that Soldiers will face, and develop medical countermeasures to meet them. By COL Deydre Teyhen, Commander, Walter Reed Army Institute of Research



WRAIR is working to develop solutions that can be used easily in a "point of injury" scenario in a field environment (photo by Master Sgt. Michel Sauret, 200th Military Police Command)

Historically, the most consequential threats to deployed Servicemembers are disease and non-battle injury—a trend that continued through combat operations in Iraq and Afghanistan where behavioral health and disease were leading causes of evacuation.

Since 1893, the Walter Reed Army Institute of Research (WRAIR) has been a leader in solving the most significant threats to Soldier readiness and lethality, including in combat casualty care. WRAIR has expeditionary laboratories on four continents that work in concert to afford Soldiers the best protection and support possible

before, during, and after deployment. Our mission is to discover, design and develop solutions for military relevant infectious disease and brain health threats through innovative research protecting and optimizing warfighter lethality. Put simply, WRAIR exists to advance the science that protects our most prized weapon system on the battlefield—the U.S. Soldier.



COL Deydre Teyhen

#### PROMOTING EARLY BRAIN INJURY DIAGNOSIS

Former Secretary of Defense and retired Marine General James Mattis once said, "the most important six inches on the battlefield is between your ears," a reference to the critical role that your brain plays in decision making, learning, critical thinking and other critical battlefield skills. Indeed, as authorities and permissions normally reserved to higher leadership echelons are pushed downward through the chain of command to the battlefield, these cognitive

abilities gain renewed importance in the multi-domain operations (MDO) environment.

According to the Defense and Veterans Brain Injury Center (DVBIC), approximately 83 percent of traumatic brain injury (TBI) cases are the result of concussion or mild TBI. Symptoms for mild TBI or concussion include confusion, diminished attention span, impaired

## COMBAT ENVIRONMENT MITIGATING THREATS THROUGH INNOVATION

decision making and anxiety-factors that can be debilitating to MDO. More severe symptoms can be intracerebral hemorrhage, skull fracture or epilepsy. In combat or austere environments in which transportation to definitive care may be prolonged, innovative technology to more accurately objectify the patient's TBI status is a critical capability gap; determining whether or not a Soldier needs a CT scan to exclude intracranial hemorrhage or other ominous findings is a key necessity for combat casualty care.

Over the past decade, WRAIR and its partners worked to identify blood-based biomarkers for brain injury. The initial approach focused on GFAP (glial fibrillary acetic protein) a marker for neuroinflammation, and UCHL1 (ubiquitin carboxy-terminal hydrolase-L1) a marker for neuronal cell death—two biomarkers that were approved in 2018 to aid concussion diagnosis. WRAIR also established the Laboratory Assay for Traumatic Brain Injury Integrated Product Team in 2009 to establish a biomarker-guided strategic capability for the Military Health System to diagnose and triage brain-injured casualties on the battlefield.

WRAIR is continuing work to identify additional biomarkers to not only detect concussion, but also to detect bleeding deep in the brain and distinguish between TBI severity levels. The ultimate goal of a "lab-on-a-chip" that quickly and accurately integrates and automates tests on a small device easily utilized on the field. To date, there are no FDA-approved drug therapies to treat TBI. Working with partners from academia and industry to fill this gap, WRAIR helped establish the DoD-sponsored Operation Brain Trauma Therapy (OBTT) Consortium to screen the most promising TBI drugs across multiple pre-clinical TBI models to accelerate clinical translatability while reducing risk. OBTT was the first to incorporate blood-based biomarkers into its preclinical studies, showing correlations in over 1200 subjects between TBI biomarkers and different types and severities of brain injury. This evidence provided further validation to support the recent FDA approval of TBI blood-based biomarkers for diagnosing concussion.

Even more importantly, OBTT has shown that TBI biomarkers correlate with improved outcomes and reduced brain injury, indicating these biomarkers may be useful in validating the therapeutic efficacy of TBI drugs undergoing clinical testing. The OBTT provides an outstanding example of how leveraging partnerships can accelerate the velocity of relevance to identify a drug that will help Soldiers exposed to TBI in training or on the battlefield.

#### MITIGATING THE HEMORRHAGE CASCADE

Most recently, WRAIR has leaned into developing innovative drug delivery solutions that can be readily employed at the point of injury, to mitigate morbidity and mortality in a prolonged field care environment, following TBI. These solutions include intranasal, intratympanic, and transdermal drug delivery (for concussion), a nanoparticle-mediated precision drug delivery systems, and a hydrogel based drug delivery platform designed to seal the wounded environment and to facilitate the controlled, continuous release of potent hemostatic agents to stop the bleed, antimicrobials to prevent infection and anti-inflammatory drugs to mitigate brain swelling and brain herniation.

The vast majority of TBIs occur in conjunction with extremity trauma, increasing the complexity of brain injuries that require tailored medical solutions. The primary focus of current work to address this concern is to experimentally replicate these complex brain injuries to assess various medical solutions to polytraumatic injuries, including testing pre-hospital resuscitation strategies and prophylactic administration of heparinoids for mitigating deep vein thrombosis in trauma patients, both of which target the standards of care and clinical practice guidelines for trauma patients.

#### **STAYING AHEAD OF INFECTION**

Without air superiority or quick access to surgical care, wound infections are only poised to worsen as a threat during multidomain operations. The threat of bacterial wound infections has already proven to be a major problem in Iraq and Afghanistan, where approximately half of casualties had bacteria in their wounds upon arrival to a hospital and approximately a third went on to develop infections. In the future of MDO, combat casualties will have to remain in unsterilized, field environments for longer periods of time. As current antibiotics continue to lose efficacy due to antimicrobial resistance, new, fieldable chemoprophylaxis and treatments are needed to extend the golden hour.

Building on data from its Multidrug-resistant organism Repository and Surveillance Network (MRSN), a resource that collects and characterizes bacterial isolates from laboratories and Military Health System sites around the world, WRAIR researchers are advancing several lines of effort to support the far-forward Soldier. Under the auspices of the Combatting Antibiotic Resistant Bacteria (CARB) presidential initiative, drug-developers are utilizing WRAIR's library of over 80,000 compounds and the Army's only x-ray diffractometer to advance new drug candidates. Furthermore, WRAIR is leading the way on developing bacteriophage therapeutics as an alternative solution to ineffective antibiotics. Bacteriophages are viruses that only infect specific bacteria and could be a novel way of addressing the spread of antibiotic-resistant infections.

Wound infections combined with TBI and other injuries can result in significantly more complicated injuries. WRAIR is hard at work to fully understand the relationship between multiple injuries, such as wound infections after blast-induced neurotrauma, in order to understand how treatment modalities and the body's physiological response influence treatments. These data are critical to informing both clinical practice guidelines and novel countermeasure development.

#### **MOVING FORWARD**

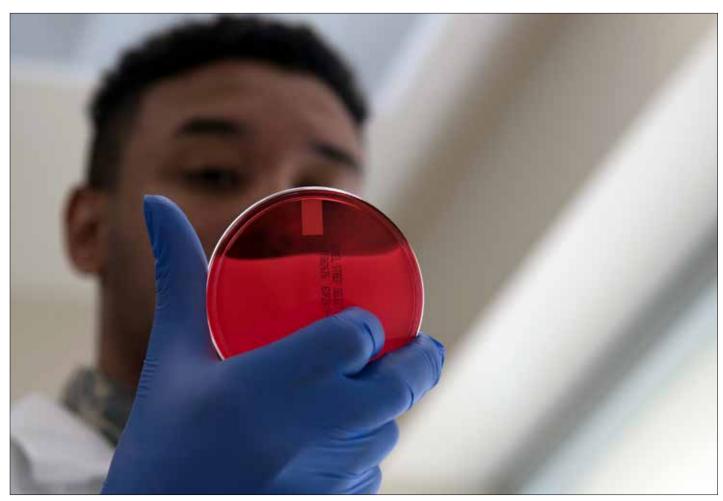
The American military is shifting its focus from counter-insurgency operations to near-peer competition. Just as the operational warfighter, logisticians, and others need to understand what that change means for them, so too will military medical researchers. WRAIR is evolving as well to meet the needs of the Army of 2028 and beyond to allow our Army to compete, penetrate, dis-integrate, exploit and re-compete any adversary, anytime and anywhere. These efforts to keep Soldiers ready and resilient, to prevent and overcome wound infection and address traumatic brain injury are just the beginning of our efforts to protect and enhance the nation's top weapons system before, during and after deployment.

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# PARTNERING FOR PROGRESS HEALTH ED, COMMS, AND ADVOCACY ADVANCING HEALTH THROUGH ENHANCED ACCESS

The National Association of Veterans' Research and Education Foundations (NAVREF), in collaboration with the U.S. Department of Veterans Affairs, is dedicated to providing veterans with greater access to clinical trials that promote positive outcomes and aid scientific progress toward potential cures.

By Rick Starrs, CEO, NAVREF



Airman 1st Class Chris Savinon, 20th Medical Support Squadron lab technician, holds a blood plate in the medical clinic at Shaw Air Force Base, SC. Purchased bacteria is grown on the plates then tested on machines to ensure they can identify the correct bacteria for quality control purposes. (U.S. Air Force photo by Senior Airman Kathryn R.C. Reaves)

The National Association of Veterans' Research & Education Foundations, or NAVREF, is the national member association for the 80 VA-affiliated nonprofit research and education corporations (NPCs) that administer externally-partnered research activities for U.S. Department of Veterans Affairs (VA) medical centers. The NPCs were authorized by Congress in 1988 to provide flexible funding mechanisms for the conduct of research and education activities at VA medical centers. NAVREF's mission is to advance the success of these NPCs in supporting veteran health through education, communication, and advocacy. One of the

ways we work to fulfill our mission is by bringing more research opportunities—from the National Institutes of Health (NIH), DoD, and especially industry sponsored clinical trials--to VA hospitals and the



veterans they serve. NAVREF bridges the gap between VA and the bio-medical industry—we help VA understand the needs of pharmaceutical and biomedical firms and we help those firms navigate VA while serving as a matchmaker connecting companies with appropriate VA investigators and study sites.

#### THE IMPORTANCE OF TRIALS TESTING

Clinical trials are research studies performed with people to evaluate a medical, surgical, or behavioral intervention. They are the primary way that researchers,

clinicians and regulators find out if a new treatment, like a new drug or diet or medical device (for example, a pacemaker) is safe and effective in people. Often a clinical trial is used to learn if a new

## PARTNERING FOR PROGRESS HEALTH ED, COMMS, AND ADVOCACY

treatment is more effective and/or has less harmful side effects than the standard treatment, if one is available. Some people join a clinical trial because the treatments they have tried for their health problem have not been as effective or had side effects that offset any benefits. Others participate because there is no treatment for their health problem. By being part of a clinical trial, participants may find out about new treatments before they are widely available.

Veterans are an underserved population for industry-sponsored clinical studies. We've learned from our industry partners that less than 2% of pharma-sponsored clinical trials conducted in the U.S. include VA hospitals. Unlike its intramural research program, VA never established a coordinated, standardized, enterprise-wide system for conducting externally-sponsored research. The variation, inefficiency, and unpredictability from site-to-site deterred study sponsors from engaging VA. Furthermore, clinical trials are rarely designed to consider a population of veterans who often have multiple co-morbidities or other conditions that would exclude them from participation. Recognizing these challenges, the VA's Chief Research and Development Officer (CRADO), Dr. Rachel Ramoni, designated "enhanced access to clinical trials" as one of her top 3 strategic priorities in late 2017 and partnered with NAVREF to kick-off the Access to Clinical Trials for Veterans (ACT for Veterans) initiative in April 2018.

#### **ENSURING STAKEHOLDER SUPPORT**

Many stakeholders are required to make this innovative initiative succeed. VA is the largest integrated health care system in the country and the drug development process is incredibly complex. At the heart of the initiative is the veteran to whom we are trying to deliver improved healthcare. Next are VA investigators and research administrators working at VA medical centers and their affiliated NPCs, hospital leaders at those medical centers, and leaders at VA Central Office including the VA's Office of Research & Development (ORD). Key players outside of VA include the pharmaceutical companies, contract research organizations, research sponsors, and patient advocacy groups. NAVREF works closely with all these players, in and out of government, in pursuit of improved access to clinical trials for veterans.

#### ADDRESSING CRITICAL HURDLES

The biggest challenges for this bold initiative involve changing the mind-set, getting buy-in from all stakeholders, and securing the required resources. VA built a very successful intramural research program that has earned Nobel Prizes, Lasker Awards, and ISO 9000 certifications. But research collaborations with industry partners have been infrequent and peripheral to the operation of the intramural program. Developing a centrally-resourced, standardized extramural research process is a new approach that will require a different way of thinking within VA about external partners. Directors and researchers must be willing to adopt centralized guidance and practices to improve system-wide efficiency. Pharmaceutical companies will need to reconsider their preconceptions about working with VA and be open to new opportunities. They may also want to consider how they interact with a truly national healthcare system. Together, VA and NAVREF need to find and secure the resources to establish the framework for long-term success.

Two years into the ACT for Veterans initiative, VA and NAVREF have made great strides in designing a streamlined process to initiate externally sponsored studies at VA medical centers. Most recently, VA in conjunction with NAVREF established a partnered studies program within ORD to serve as the single, national entry point and information clearinghouse for industry-sponsored studies—essentially a one-stop shop to facilitate study start-up. This program will not become fully functional until 2021, but it represents a paradigm shift in how VA supports extramural research. The CRADO also established a goal of "100 days faster" to start up clinical trials. In order to help meet this

supports extramural research. The CRADO also established a goal of "100 days faster" to start up clinical trials. In order to help meet this goal, VA has expanded its Central Institutional Review Board (IRB) capacity from one panel to two panels and initiated policy changes that allow for use of commercial IRBs in certain situations. Additionally, a Research Support Division within the Office of Information Technology was established in 2018 to reduce the time for review of information security requirements and improve consistency of review across VA sites. Furthermore, VA has been designing a standardized, efficient clinical trial process map that will lead to greater predictability and reliability, as requested by clinical trial sponsors.

Industry partnerships and collaboration has also been critical to the ACT initiative. We sought industry perspective to identify shortfalls and obstacles to working with VA and we continue to seek industry expertise to advise us on best practices and approaches to initiating externally sponsored clinical studies. We also seek industry resources to assist with developing the people, training, and infrastructure that will accelerate implementation of the initiative's goals. For instance, Cohen Veterans Bioscience has supported the ACT initiative since its inception and recently elevated its commitment to become NAVREF's exclusive "Champion Level" sponsor. We welcome contributions from any organization with an interest in improving the health of veterans.

#### **GOING FORWARD**

Over the next 12 months, we expect to see the fruits of our labor on this initiative. We anticipate that the changes in processes, policies, and structure will reduce start-up timelines, improve predictability, and help VA become industry's partner of choice for clinical trials. Ultimately, we'd like to see greater collaboration between VA research and the bio-medical community on veteran-focused needs. This will enable more opportunities for veterans and VA investigators to contribute to national efforts for improving the health of veterans and all Americans.

More info: actforveterans.org



*Editor's Note* Rick Starrs joined the National Association of Veterans' Research and Education Foundations (NAVREF) as Chief Executive Officer in January 2016 after concluding his U.S. Army career as

a Colonel. Prior to joining NAVREF, Rick enjoyed more than 25 years of leadership experience in the military health system ranging from leading troops in combat to working on Capitol Hill to overseeing the day-to-day operations of a multi-billion-dollar military medical research, acquisition, and logistics enterprise.

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SEP 21 - 23 **Global Security Exchange** Atlanta, GA GSX.org/TD

SEP 22 - 24 **Modern Day Marine** Quantico, VA Marinemilitaryexpos.com

OCT 12 - 14 **AUSA Annual Meeting** Washington, DC AUSA.org

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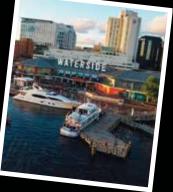
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