CONTINUUM OF CARE IMPROVES OUTCOMES

MG Brian C. Lein
Commanding General
Ft. Detrick, MD
Army Medical Research and Materiel Command
Deputy for Medical Systems
ASA/AL&T

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Commanding General
Ft. Detrick, MD
U.S. Army Medical Research
And Materiel Command
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Improving Survival and Recovery
C&CC spoke recently with COL Todd Rasmussen, M.D., Director, National Capital Area DoD Combat Casualty Care Research Program, headquartered at Ft. Detrick, MD.
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Cover: U.S. Army 1st Lt. Antqualeena Johnson, center, and Spc. Theodore Bailey, left, both with Charlie Company, 94th Brigade Support Battalion, Task Force-Dagger, Brigade Special Troops Battalion, 4th Brigade Combat Team, 10th Mountain Division, assist a soldier with simulated wounds during a Mass Casualty (MASCAL) exercise on Forward Operating Base Fenty, Nangarhar province, Afghanistan, Oct. 19, 2013. A MASCAL is an exercise where soldiers demonstrate their medical knowledge in a controlled environment and are evaluated on their performance. (U.S. Army photo by Spc. Vang Seng Thao/Released)
With the warmth of summer and the unpredictable nature of storms that accompany a rise in mercury, so go the hand-in-hand evolution of the heat of combat and care for resultant casualties. As past conventional battlefields continue to morph into undefined zones of asymmetric danger, the techniques employed to facilitate modern wound care need be as efficient as they are effective.

In the summer 2015 MHSRS issue of Combat & Casualty Care, we face the topic of continuum of care head-on, from initial point-of-injury assessment to new tool-driven techniques application to long-term effects monitoring for maximizing outcomes. From a uniquely Ft. Detrick perspective, readers are offered a spotlight cover interview with MG Brian Lein, tri-hatted Commanding General, Ft. Detrick, U.S. Army Medical Research and Materiel Command (USAMRMC), and Deputy for Medical Systems, Army Acquisition, Logistics and Technology (AL&T), who offers insights into many innovative programs the Army medical community is working, and in many cases, currently implementing. Also out of Ft. Detrick, an inside look into DoD’s Combat Casualty Care Research Program from National Capital Area Director COL Todd Rasmussen, as he details some current focus areas addressing lessons learned in recent years of U.S. combat operations.

As all combat medics know, the hour of utmost importance is that which is golden, or in other words, the first one post-injury. With this in mind, the continuum that is full combat casualty care goes well beyond the point of injury through transport, facility, and long-term treatment. Efforts at the U.S. Army Institute of Surgical Research (USAISR) to field a new Joint Trauma System (JTS) poised to ‘revolutionize vascular injury management’ in combination with advances in rapid medical evacuation are moving full speed ahead. With battlefield trauma survival rates increasing in recent years thanks in no small part to enhanced training and equipment, a key factor to be considered here is the increasing success that ‘prolonged field care’ is having in situations where casualty transport is either delayed or not possible.

From a surgical point of view, or in this case non-surgical, the evolution of non-invasive techniques to resolve conditions previously only possible by open incision has and continues to happen. At the U.S. Naval Medical Center San Diego (NMCSD), doctors are replacing damaged or faulty aortic valves in patients’ hearts without surgical chest entry using a procedure called a Transcatheter Aortic Valve Replacement (TAVR). Through a small incision in the upper leg, surgeons have enough access to fully repair this critical part of heart structure without having to qualify patients as healthy enough for cardiac surgery, as is the case with open-heart procedures. Of equal importance, advances in blood monitoring technology are helping to boost long-term care throughout the healing process.

As always, feel free to contact us with comments or suggestions. Thanks for your readership!

Sincerely,

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Lives are saved and lost daily at this school. Fortunately, it’s a few good mannequins who do the surviving and dying, all in the name of building better medical evacuation service members at the U.S. Army School of Aviation Medicine Joint Enroute Care Course (JECC) and Army Medical Department Aviation Crewmember Course (A2C2). The courses take doctors, physician assistants, nurses and medics out of the hospitals and ready them to perform MedEvac missions to save the lives of wounded service members around the world, said Sgt. 1st Class Aaron Burrows, NCO in charge of the USASAM JECC and AMEDD A2C2.

“Many of our students are nurses and docs who never get to see pre-hospital care at all,” Burrows said. “They’re already medically trained – we’re just getting them used to doing it this way. It’s a big learning curve because they’re used to having up to 10 people around one patient – ‘Hey, you do this, you do this, you do this,’ and being able to divide up those tasks, versus in the back of an aircraft with point of injury care – it’s just them. They get that bird’s eye view of how to perform an actual patient assessment in the pre-hospital setting; how to do that advanced medical care that is that rapid treatment that’s going to stabilize (the patient) enough to enable them to survive until they get to that surgical intervention,” he added.

Fourteen Days of Intense Training

With JECC being a two-week course, the information comes at students at a rapid pace, and the realism the school provides raises the intensity, according to 1st Lt. Christopher Hunt, a physician assistant from the 115th Combat Hospital at Fort Polk, Louisiana. “I thought it was the best course in the Army I’ve been to so far,” the lieutenant said during the final day of the course. “Honestly, there’s a lot of information packed into two weeks and it’s solid – not a lot of fluff in it at all.”

One source of that realism comes from the mannequins that give off real vital signs and show reactions to their wounds, such as coughing, and also respond to treatment the students provide. Instructors operate the mannequins from computers outside the mock fuselages in the school’s training facility.

“This training is probably best you’re going to get other than treating real patients,” Burrows said. “Creating the curriculum is a continuous cycle, we make adjustments and changes each iteration – we continue to progress, try to get more advanced, more realistic as far as treatment and scenarios. All of our scenarios are designed based off of actual patients that we have seen downrange. All scenarios you see are extremely realistic and they are exactly the scenarios that were seen downrange.”
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But realism also comes in the form of a dedicated cadre who inserts its years of experience, saving Soldiers' lives on real-world battlefields for over a decade, Burrows said, adding the training is leaps and bounds ahead of the training he received seven years ago.

“Honestly, the standard with this instructor group, compared to the standard from when I went to flight medic school compared to now is top tier – just because our command and everybody that is here, all we think about is, ‘how do we make the training better, how do we make it more realistic?’” he said. “With us, this instructor corps, we’ve all had multiple deployments, and we know what works and what doesn’t work, and we’re able to come here and use our experiences.”

Multi-Environment Preparation
Above and beyond the MedEvac portion of the class, students also get water survival and survival training, and Hunt said the water survival portion proved his biggest challenge during the course.

“Somebody purposely putting you under water and flipping you upside down, and you have to hold your breath for so long and then get out and [try] not to panic was the biggest thing,” he said. “I’m from California, I’ve swam in the ocean, but I’ve never been flipped upside down and told to get out of a seatbelt and then get out of the water. I tried to prepare for it, but it’s hard to fully get it into your head what it will be like.”

The JECC teaches Army, Navy and Air Force flight medics, along with the occasional members of the Coast Guard, and also international medics. Each class is usually between 20-30 students, but the minimum is 10 and the maximum is 35, according to Burrows. The cadre varies between nine or 10 instructors. And that cadre is confident that the graduates of the school have the skillsets they will need to go out and save lives, said Sgt. 1st Class Timothy White, flight medic, instructor and operations NCOIC for the school.

“We train them the best we can – make it as realistic as possible, give them real-world scenarios and actual standards, show them what is actually out there and then train them to meet that mission requirement,” he said. “Anyone who graduates from any of our courses, when they leave here, they have the tools to conduct the mission based on what they learned here. They’re ready to go once they’re done training.”

And that’s the mission: building better MedEvac operators – ready to go save the lives of their comrades in arms, and leave the dying part to the mannequins.
In recent military conflicts, outcomes from battlefield trauma showed a decreasing case fatality rate. This encouraging trend stems from improved protective gear and enhanced battlefield care capabilities in spite of overall increased injury severity.

Battlefield priorities for the next decade of military medicine will be focused on a new role of battlefield medicine under the concept of “Prolonged Field Care”. This paradigm encompasses providing medical care in an austere environment and in place of injury during scenarios where evacuation of a casualty is either not possible or is significantly delayed.

What new tools are under development today that could conform to the new realities of combat medical care?

Remote Triage and Decision Support
A significant enhancement of the medic’s capability to diagnose injury severity can be achieved from retrieving additional information from existing vital signs. Vital signs such as heart rate and the electrocardiogram (ECG) provide useful information from the casualty and can be used to help medics and providers to better assess the health of the compensatory mechanisms and reserves.
of the injured. In light of this, the concept of remote triage means that a medic could assess the status of casualties from telemetrically acquired vital signs such as the ECG. Research from the U.S. Army Institute of Surgical Research (USAISR) completed on civilian trauma patients and combat casualties suggests that retrieval of non-invasively derived HRC and HRV-based vital signs can enhance the diagnostic capabilities of medics. However, translation of previous research in this area is dependent on reliable, wearable ECG monitoring and wireless capabilities for transmission of the vital signs. One example of this capability in the civilian domain is the Aesculon critical care monitor (Osypka Medical, Berlin, Germany/San Diego, USA) which carries a real-time capability of retrieving ECG from body surface electrode data and is also capable of calculation of additional information about the health of the cardiovascular system in the injured.

**Telemetry Answering Critical Need**
In the future, remote triage based on distant assessment of ECG and telemetry of derived vital signs may be put in hands of medics with intent of enhancement of their diagnostic capabilities. This approach constitutes decision support to medics with the aim to enhance their diagnostic capabilities in a resource constrained environment and scenarios of prolonged field care.

In addition to telemetry and remote decision support, three innovative therapeutic capabilities are emerging as solutions for the battlefield of the future.

With respect to hemorrhage, the past few decades have manifested an increase in the severity of battlefield injuries. A number of these massive injuries are located above the groin or in the torso region, thus making them non-compressible by traditional means of hemorrhage control, such as tourniquets. Traditionally the torso injuries were either non-survivable or required a rescue thoracotomy—or emergency opening of the chest by a surgeon and direct compression of the aorta by application of a hemostatic clamp. Due to its invasiveness, thoracotomy carries significant risks and, although successful in a small percentage of cases, has been the only therapeutic option for casualties massively bleeding from areas of the body where application of the tourniquet is not possible. Intense research efforts are ongoing with respect to adoption of endovascular balloons to stopping bleeding during non-compressible hemorrhage. The new approach is termed “Resuscitative Endovascular Balloon Occlusion of the Aorta”, or REBOA. In REBOA, a balloon catheter is inserted into the femoral artery; advanced into the aorta where, upon inflation of the balloon, it occludes the aorta stopping blood flow below the occlusion site. This approach has been validated in animal studies and was applied very successfully to a case series of human trauma patients with trauma and internal hemorrhage. Recently, a new design of the REBOA catheter was developed by Pryor Medical Inc., Arvada, CO. This catheter is expected to be commercially available in the first quarter of 2016.

**Joint Trauma Know-how**
The REBOA concept is the subject of a new clinical practice guideline published by the Department of Defense Joint Trauma System. Due to its reduced size and invasiveness the new ER-REBOA™ catheter can be placed as an arterial monitoring line in patients suspected of hemodynamic instability. Should the patient’s condition deteriorate showing signs of hypotension, the balloon can be inflated, buying time (30-60 minutes) for the providers to assess the source of the instability and repair it before life-threatening bleed out. Utilization of REBOA devices is envisioned at Roles II and higher.

Another promising concept to be used on the battlefield of the future is mobile modular extracorporeal life support. This features a panel of different devices capable of sustaining life and treating the organ-specific consequences of massive trauma. Extracorporeal life support (ECLS) is an approach used in severely injured critically ill that cannot rely on their own physiologic mechanisms to maintain breathing and circulation of blood. Importantly, as it pertains both to support of ventilation and cardiovascular function in critically ill patients, specific ECLS systems called extracorporeal membrane oxygenator (ECMO) devices ensure gas exchange (lung function) and maintain whole body circulation. ECMO involves placement of a plastic catheter to remove blood from a major vein; passing it through a gas exchanger/membrane where CO2 is removed and O2 is added; and reinfusion of the oxygen-rich blood back into the patient via the same or another major vein. This modality of ECMO exists to support respiration and, with adequate blood flow through the ECMO device, can be used as an adjunct or alternative to mechanical ventilation. Avoidance of mechanical ventilation prevents further worsening of lung injury keeping the patient alert, and conscious-mobile vs. bed-ridden. ECMO has been successfully used to resuscitate a trauma patient with severe lung damage as early as 1972. The current success rates with modern ECMO are 60-80%; considering the severity of injury patterns in military setting, ECMO is a highly promising therapy for early intervention in the most severely injured with a capability to initiate respiratory support in the austere environment due to the self-contained nature of the ECMO devices.

**Second Chance Transference**
ECMO has also been introduced as a means to emergently resuscitate patients with myocardial infarction and out of hospital cardiac arrest. This technique described as emergency cardiopulmonary resuscitation (ECPR) involves drainage of blood from a major vein and reinfusion to the femoral artery with advancement of the catheter high into the aortic arch. There is accumulating data from multiple studies around the World that shows promise in utilization of ECMO as an
emergency resuscitation. This encouraging work is directly applicable to the most severe combat casualties but needs to be translated via preclinical research utilizing combat-relevant trauma models. In these studies the complementary roles of REBOA and of ECMO must be studied as applicable to severe trauma models with massive blood loss.

**Stem Cells for Acute Traumatic Injury**

The most novel field of therapeutic interventions in critical care involves stem cell therapeutics. Stem cells are cells that are at early stages of their differentiation and capable of giving rise to several different types of cells from blood cells, to muscle and bone, for example. Preliminary data in rodents suggests that stem cells derived from bone marrow, subcutaneous fat as well as upper and lower airways hold significant potential to jump start regeneration in a multitude of organs after trauma. There are about 100 clinical trials investigating the therapeutic potential of various forms of stem cells in humans. However, application of stem cells for treatment of acute traumatic injury is new. There are several ongoing experiments at the U.S. Army Institute of Surgical Research which address early utilization of various forms of stem cells in combat relevant research studies. This data is crucial for a profound understanding of the role of stem cell therapies in the combat setting.

**Looking Ahead**

Emerging treatments for massive trauma and bleeding are promising with respect to rapid control of bleeding when difficult to compress areas of the body are affected. REBOA provides a means to achieve control of bleeding in a less invasive manner than thoracotomy. Short of that, it also enables monitoring of blood pressure through the hollow channel in the catheter in potentially unstable patients. ECLS and, specifically, ECMO permits an alternative means to mechanical ventilation and a possibility to rapidly resuscitate casualties in clinical death with a possibility of extended circulatory support and hypothermia. Technologies like REBOA and ECMO provide advanced therapeutic capabilities for the most severely injured, with the possibility of continuing support during evacuation. It is highly likely that utilization of all new concepts with particular role for noninvasive monitoring will be needed in order to achieve the next level of improvements in outcome in combat medicine. Noninvasive monitoring, diagnostics, and decision support to providers on how to most effectively utilize early interventions such as REBOA and ECLS individually, and in combination with early targeted regenerative therapies will likely have a major impact on improving outcomes in future combat scenarios.

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MG Brian Lein grew up in New York and attended the United States Military Academy. He graduated in 1984 as a Distinguished Military Cadet with a Bachelor of Science, and was commissioned a Second Lieutenant in the Medical Service Corps. He then attended Temple University School of Medicine in Philadelphia. He graduated in 1988 as an Alpha Omega Alpha Scholar with an MD degree. He completed his Internship in General Surgery at Madigan Army Medical Center in 1989. He completed his Residency in General Surgery at Abington Memorial Hospital in 1993. He is board certified in general surgery. MG Lein's military education includes graduation from the AMEDD Officer Basic and Advanced Courses, the U.S. Army Command and General Staff College, the U.S. Army War College and the U.S. Army Airborne School. Following commissioning in the Regular Army, MG Lein served as a General Surgeon in 2d General Hospital/Landstuhl Army Regional Medical Center. During this assignment he was assigned to the 67th Forward Surgical Team (Airborne) and deployed to Bosnia-Herzegovina in support of Operation Joint Endeavor. His next assignment was as Chief of General Surgery, William Beaumont Army Medical Center. There he was PROFIS to the 31st Combat Support Hospital (Caretaker) as the Chief of Surgery. During this time he was also assigned to Joint Special Operations Command as a general surgeon. His next assignment was as the Division Surgeon, 4th Infantry Division (Mechanized). He served on the Army Surgeon General Panel for Objective Force Redesign for Medical Force Structure. In 2003, he graduated from the U.S. Army War College. He then served as Commander, Evans Army Community Hospital, Fort Carson, Colorado. His next assignment was Command Surgeon, Coalition Forces Land Component Command/U.S. Army Central/Third Army. He then served as Commander, Landstuhl Regional Medical Center. He also served as Command Surgeon, U.S. Army Forces. During this assignment, MG Lein deployed in support of Operation Enduring Freedom as Command Surgeon, ISAF Joint Command, from February to May 2012. His most recent assignment was as the Deputy Surgeon General and Deputy Commanding General, Operations, U.S. Army Medical Command. 

Interview conducted by C&CC Editor Kevin Hunter

MG Brian C. Lein
Commanding General, Ft. Detrick, MD
U.S. Army Medical Research and Materiel Command
Deputy for Medical Systems ASA/ AL&T

C&CC: Please speak to your roles as Commanding General of USAMRMC and Fort Detrick, as well as Deputy for Medical Systems to the Assistant Secretary of the Army for Acquisition, Logistics, and Technology.

MG Lein: As the Commanding General of the U.S. Army Medical Research and Materiel Command (USAMRMC) and Fort Detrick, I serve as an advocate for the important work that is being done to advance military medicine, by our more than 7,100 military, civilian and contractor personnel. As the Deputy for Medical Systems to the Assistant Secretary of the Army for Acquisition, Logistics, and Technology, I am responsible for assisting the Army acquisition executives with medical issues, health hazards, and the human implications of nonmedical systems acquisitions. Being dual-hatted in these positions, not only strengthens the Army acquisition executive team, but also strengthens the research - acquisition–logistics enterprise, provides for robust life-cycle management and ultimately helps us to transition the best capabilities to the Warfighter in a timely and cost-effective manner.

C&CC: USAMRMC is headquartered in Frederick, Maryland, but also is a worldwide organization. What is its mission focus?

MG Lein: Ensuring our armed forces remain in optimal health and are equipped to protect themselves from disease and injury,
From research, development and fielding to on-going testing, evaluation and sustainment to fill capability gaps and meet operational requirements, the USAMRMC is involved in each step of the process as the full-lifecycle medical materiel developer.

particularly on the battlefield, is the job of the U.S. Army Medical Research and Materiel Command. We work proactively to support the warfighter and because the U.S. military may be called upon in a moment’s notice to serve anywhere in the world, it is our duty to develop the tools necessary to sustain and protect our Soldiers, no matter where they are deployed or what they may face.

Six medical research laboratory commands execute the science and technology program to investigate medical solutions for the battlefield with a focus on various areas of biomedical research, including military infectious diseases, combat casualty care, military operational medicine, medical chemical and biological defense, and clinical and rehabilitative medicine. The Command manages a large extramural research program with numerous contracts, grants, and cooperative research and development agreements to provide additional science and technology capabilities from leading academic, private industry, and other government organizations.

Six additional subcommands focus on medical materiel advanced development, strategic and operational medical logistics, and medical research and development contracting, to complete the full life cycle of medical materiel acquisition.

C&CC: USAMRMC is the Army’s only life-cycle management command. What does that mean?

MG Lein: At the U.S. Army Medical Research and Materiel Command (USAMRMC), the science and technology, acquisition, resource management and logistics communities must all work together with the interests of the Soldier in mind. From research, development and fielding to on-going testing, evaluation and sustainment to fill capability gaps and meet operational requirements, the USAMRMC is involved in each step of the process as the full-lifecycle medical materiel developer.

In order to support this process, the USAMRMC developed and implemented Decision Gate, an overarching process designed to integrate best industry business practices, methodologies and governance with the DoD acquisition process for military medical product development. This process is designed to help move products and devices through the product lifecycle with defined decision gates enabling us to work towards a common goal.

Once products have made it to the Soldier, products may require updates or small changes based on design, usage, or environment. USAMRMC manages a program to modify fielded products so that they can continue to meet the needs of our fighting forces.

Other key aspects of the lifecycle are the procurement and sustainment of materiel in the operational force and the medical health facilities. The medical logistics commands provide theater level materiel management, storage, and distribution to ensure unit readiness across the globe. In addition, USAMRMC has several programs from centralized materiel to depot level medical maintenance that further enhance unit readiness.

C&CC: Can you tell us why partnerships are so important to the success of the USAMRMC mission?

MG Lein: The success of our mission relies heavily on the execution of extramural research, contracts and partnerships with academia, private industry and other government organizations. This collaboration enhances our capabilities and supports economic development, while providing opportunities for individuals who possess the critical skills and expertise to create innovative military-relevant medical solutions. We rely on the collaboration with our partners to help us look at these issues in a new light.

The strategies and tactics in which we fight and win wars are constantly changing. What was a threat yesterday may not be one tomorrow. In order to remain ahead of the curve, we have to accept the fact that we cannot do everything. Our partners in business and academia are the only way that we are able to accomplish our goals.

C&CC: What are some examples of recent USAMRMC medical innovations?

MG Lein: The Adenovirus poses a major health threat in training environments. The Adenovirus vaccine has been protecting military trainees from infections by Adenovirus serotypes 4 and 7 since October 2011, when the military services resumed its use after a 12-year gap. Data shows the vaccine is 99 percent effective at preventing disease associated with Adenovirus type 4. Since it was reintroduced, the vaccine has prevented 50,000 cases of Febrile Respiratory Illness (fever plus respiratory symptoms), saving roughly 150,000 training days that would have been lost to illness. Clinical trials for the vaccine were conducted jointly by the Army’s Walter Reed Army Institute of Research and the Navy.
Japanese encephalitis, which is caused by a mosquito-transmitted virus, is found mainly in Asia. No treatment is currently available for Japanese encephalitis and only the Japanese encephalitis vaccine effectively prevents the disease. As Japanese encephalitis is a serious and growing public health threat in Asia, military personnel now have an efficacious and safe vaccine to protect themselves during deployments. The Walter Reed Army Institute of Research (WRAIR) developed the technology which, through a cooperative research and development agreement, was transferred to a commercial company who used their own resources to achieve licensure of the Japanese encephalitis vaccine that will be used by the DoD. WRAIR also participated in the conduct of the pivotal clinical trials. U.S. Army Medical Materiel Development Activity functioned as the liaison between the Military Vaccines Agency, and the Defense Supply Center Philadelphia. USAMRMC continues to study and monitor this vaccine for safety and efficacy.

Malaria is an entirely preventable and treatable disease which kills over 650,000 people each year. Programs like those of the U.S. Military bring together researchers from public-private industry to conduct pivotal research on this topic. USAMRMC’s WRAIR and Smith Kline Beecham (now GlaxoSmithKline - GSK) entered into a collaborative research and development agreement from 1992 to 2010 that was instrumental in evaluating the RTS,S malaria vaccine in early clinical studies. Because of WRAIR’s unique capabilities to conduct malaria clinical trials evaluating safety, immunogenicity, and efficacy by exposing volunteers to malaria-infected mosquitoes, WRAIR continued to partner with GSK and contributed greatly in evaluating additional formulations of RTS,S and dosage schedules. The pivotal phase 3 clinical trial in African children, which included over 1500 children enrolled at WRAIR’s overseas site in Kenya, demonstrated 56% efficacy against clinical malaria bringing development of the first malaria vaccine closer. Under a new cooperative research and development agreement, WRAIR’s partnership with GSK continues to explore improvements to RTS,S to increase protection for the warfighter.

Cutaneous leishmaniasis is not generally life threatening, but it is painful, disruptive and potentially life altering with no FDA-approved treatment. It affects U.S. service members and travelers to subtropical regions of the world where it is widespread. Cutaneous leishmaniasis is a parasitic disease transmitted through the bite of an infected sand fly. In the Phase III Cutaneous Leishmaniasis trial study results for the combination cream with the antibiotics promomycin + gentamicin showed a cure rate of 81 percent in patients who participated in the trial. Patients saw shrinking of the lesions, regrowth of normal skin and the absence of relapse. A cream
containing paromomycin alone had a similar cure rate of 82 percent. Only 58 percent of patients receiving placebo saw the lesions cured. Less than five percent of all study groups reporting adverse events which were primarily minor reactions at the applications site. The financial support and scientific expertise for topical paromomycin’s development was provided by scientific researchers, product managers and regulatory scientists at the U.S. Army Medical Research and Materiel Command and its labs the U.S. Army Medical Materiel Development Activity and the WRAIR.

Several non-invasive neurodiagnostic technologies exist that can detect the symptoms of TBI, even if they are not easily recognizable. Examples include the tracking of eye movements, measuring balance, quantitative electroencephalogram analysis, voice analysis, and reaction time testing. We are exploring those noninvasive technologies which, when used in conjunction with clinical data and diagnostic aids such as the Glasgow Coma Scale and neuroimaging, could help to refine TBI diagnosis, return-to-duty determinations, or the decision to refer the injured Warfighter to a higher level of care. USAMRMC is partnering with several industry leaders on this effort via collaborative research agreements and cooperative research and development agreements.

A significant number of combat wounds occur in regions of the torso where compression cannot be applied, such as the pelvis or shoulder. Bleeding from these types of wounds is called non-compressible hemorrhage. XSTAT-30™, is designed to control bleeding associated with non-tourniquet and non-compressible injuries, such as those found in the groin or armpit regions of the body. The XSTAT-30™ consists of mini sponges contained in a compact delivery device that fits in the medic’s aid bag. This technology involves injecting small, rapidly-expanding cellulose sponges coated with chitosan into a wound cavity using a syringe-like applicator. Within 30 seconds of contact with blood, the sponges expand to fill the wound cavity. This creates a temporary barrier to blood flow, and provides pressure to stop bleeding. The sponges have been shown to stop the flow of blood within four minutes of delivery and maintained it for up to four hours. The device is being developed by the Combat Casualty Care Research Program of USAMRMC in coordination with RevMedx, Inc.

The Public Health Agency of Canada developed the rVSV-ZEBOV Ebola Virus Disease vaccine and licensed the candidate to NewLink Genetics Corporation who, in turn, sublicensed to Merck Sharp & Dohme Corporation. The vaccine’s intent for both pre- and post-exposure prophylaxis would allow both those exposed and those not yet exposed to Ebola to avoid developing Ebola virus disease. When the Ebola epidemic occurred, it became clear to the U.S. government and the global community that they needed to quickly advance the development of a vaccine. In response to this need, the Defense Threat Reduction Agency requested support from the WRAIR.
to prepare and execute a human clinical trial and develop a lab test to support the assessment of the rVSV-ZEBOV vaccine’s safety. The WRAIR lab enterprise, which is both domestic and international, may look like a number of individual programs, but really we are a collection of science and science support professionals with expertise in infectious diseases. We have a number of platforms, capabilities and competencies that are generally applicable to whatever the DOD determines to be a threat. Furthermore with our adaptable platforms and capabilities, the military can direct and redirect its resources as the needs and requirements arise.

Systems Biology is an information science that uses holistic approaches to understand and control biological complexity. It uses collaborative and cross-disciplinary approaches to integrate many multi-scale types of biological information. As an example, we use data from genes, proteins, metabolites and physiology. This enables development of predictive and actionable models of biology or disease. This can give us a sense of “exposure science.”

The impacts of Systems Biology are being seen in:

- Personalized medicine
- TBI biomarkers
- Individual impact/risk of chemical, physical and biological stressors
- Predisposition to health risks or performance benefits

Our team at USAMRMC applies an integrated approach to environmental, physiological, and psychological threats using a brand new state-of-the-art rodent vivarium and instrumentation laboratory at Fort Detrick, Maryland.

C&CC: We know your work is based on requirements for the warfighter; however many times these products can translate to the public sector. Do you have examples where that is the case?

MG Lein: In addition to protecting our sons and daughters on the battlefield, our research programs continue to provide promise for advancement in global health as well. What was born out of necessity for the battlefield often develops into a vital component in saving lives daily, no matter where in the world or for whom, to ensure that severely wounded patients are treated quickly and effectively.

The work that we do is about saving lives; the results are critical to protecting our nation.

The list of accomplishments achieved by our Command is vast.

To highlight just a few of our successes to illustrate the impact our research has on global health:

- The HemCon bandage is an advanced hemostatic dressing. The HemCon, 4 x 4, bandage was the first hemostatic dressing supplied to all Soldiers in theater in Operation Iraqi Freedom/Operation Enduring Freedom. The active ingredient, chitosan, forms a strong seal over bleeding wounds. The HemCon bandage is used to save lives in civilian emergencies as well by first responders and emergency departments for controlling severe bleeding caused by traumatic injuries.
- Guidelines for Pre-hospital Trauma Life Support were developed to provide recommended training and practice guidelines to enable medics to effectively treat the types of severe injuries encountered during combat. This product transitioned into civilian use to provide guidelines for fire, rescue, police and other public safety personnel providing trauma care in hostile situations such as riots or terrorist attacks.
- The innovative Hydraswitch system is a patented device that enables personal hydration systems to deliver not only clean water, but also nutrients on demand. This product has been used by endurance athletes, hikers, mountain bikers, adventure racers, first responders and occupational laborers who experience high water replacement requirements.
- In Sentinel Lymph Node Biopsies, lymph node removal is limited only to the first few nodes that receive lymph drainage from the breast. A multicenter clinical trial was conducted using the sentinel lymph node biopsy to determine the spread of disease. Physicians are now routinely using sentinel lymph node biopsy to determine the extent cancer spread in individuals who have been diagnosed with breast cancer.
- Ova1, an in vitro diagnostic index assay test, is the only FDA-approved blood test to help determine whether an ovarian mass is malignant or benign prior to surgery. Physicians in the civilian world are using the blood test Ova1 prior to surgery to help determine is a woman is at risk for a malignant pelvic mass.

These are a few of the innovative products and technologies that have successfully transitioned into civilian medical practice, the impact of our work spans the globe.
**WITHIN THE GOLDEN HOUR**

From point of injury, advances in field care are boosting casualty outcomes.

By Steve Melito, C&CC Correspondent

How can medical providers and suppliers support the continuum of care?

Combat casualty care doesn’t begin in a helicopter or a hospital. It starts at the point-of-injury or wounding, continues through battlefield evacuation, and is delivered at emergency treatment, forward surgery, and full medical facilities. During the wars in Iraq and Afghanistan, the U.S. military strengthened its medical evacuation (MEDEVAC) capabilities to ensure that the wounded reach advanced-level treatment facilities within “the golden hour”, the first 60 minutes after injury. Additional MEDEVAC choppers and even field hospitals were deployed, but in-hospital care alone does not account for survival rates that were, in some cases, as high as 98% for casualties arriving at a combat hospital.

According to Lt. Col. Robert L. Mabry, Ph.D., Director of Trauma Care Delivery of the Joint Trauma System (JTS) at the U.S. Army Institute of Surgical Research (USAISR), multiple factors account for successes such as “the revolution in vascular injury management” during recent military operations. In a 2012 article for the Journal of Trauma and Acute Care Surgery, Mabry and other medical experts explain what supports the “the golden hour” standard. “This paradigm has been sustained,” Mabry and several peers write, “because of a combination of life-preserving tactical combat casualty care, strategic positioning of forward surgical capability, and the use of rapid medical evacuation within a Joint Trauma System.”

**JTS and the Continuum of Care**

A USAISR program of record since 2010, JTS seeks to improve trauma care delivery and patient outcomes across the full continuum of military medical care. In an interview with C&CC, JTS Deputy Director Mary Ann Spott explained how “JTS defines this continuum as all phases of care beginning with point-of-wounding through discharge from the VA/rehab.” Evidence-based medicine and continuous performance improvement (PI) support robust medical capabilities and integrate feedback from Role 1 (triage), Role 2 (emergency treatment), and Role 3 (medical treatment facility) providers.

“JTS conducts PI on all care along the continuum,” Spott notes, and “invites participation” by offering regular, continuing medical education to medics and Role 1 personnel. From its headquarters in San Antonio, Texas, this arm of USAISR also fosters engagement between Role 1, Role 2, and Role 3 providers through “a weekly combat casualty care conference call and a twice-monthly combat medic and prehospital conference call”. Direct communication between JTS and field units occurs on a regular basis, and individual providers can always ask questions and request assistance as needed. In addition, medical providers rely upon Clinical Practice Guidelines (CPGs) that JTS develops and maintains.

“CPGs are evidence-based practices that are recommended for use by all health care providers to which the guideline applies,” Spott explains. “These guidelines do not replace clinical judgements,” she adds, “but rather offer the best practices as supported by evidence-based literature and subject matter experts.” Although CPGs do not recommend specific brands or types of medical devices or products, JTS “identifies the devices that are scientifically known to be effective” For medical providers, technologies from Tactical Medical Solutions, North American Rescue, Nonin Medical, and Roemer Industries can help to address the full continuum of combat casualty care.

**Tactical Medical Solutions**

Tactical Medical Solutions Inc. (Greer, SC) supplies medical gear such as the TacMed Adaptive First Aid Kit (AFAK), a versatile pouch-like product designed by former U.S. Army Special Forces Medics in response to requests from active-duty Special Operations personnel. As John Carlson, the company’s Sales & Training Manager explains, combat medics want...
“a solution that fits them”. Soldiers don’t just want the ability to customize the contents of a first-aid kit; they also want to wear the kit in a way that’s secure, accessible with both hands, and designed for use with or without body armor.

Different combat medics have different equipment preferences, Carlson notes, and some units have their own standard operating procedures about how first-aid kits are worn. That’s why the AFAK is built with “flexible but solid mounting configurations”, including a pouch-style design and tourniquet strap that supports either horizontal or vertical mounting. This first-aid kit mounts on a combat medic’s “padded war belt”, and can be worn in the small of the back thanks to a lanyard with Velcro. Because “there are no snaps to come undone,” Carlson adds, the kit’s contents won’t accidentally spill onto the ground. When the AFAK is opened, separate elastic loops help secure items such as a decompression needle.

Although the first-aid kit’s contents are what Carlson calls “completely customizable,” standard items are designed to provide “the level of care that individuals on an A team could provide to themselves or their soldiers. This includes a SOFTT-W tourniquet with strap system, QuickClot Combat Gauze, Fox chest seal, and Oleaes 4” modular bandage. Typically, combat medics also use the AFAK to carry trauma sheers, nitrile gloves, and a nasal airway with lube. This first-aid kit from Tactical Medical Solutions Inc. is designed for use at the point-of-wounding, but Carlson sees potential, future uses aboard ambulances or helicopters. “It’s extremely versatile,” he explains.
North American Rescue

North American Rescue (NAR) of Greer, SC also makes military products such as casualty response kits, but is especially well-known what for what Robert Miller, Chief Technology Officer, calls “an important innovation in combat casualty care”. Litters have been used to transport the wounded for over 2,000 years, but NAR’s Talon II Model 90C Collapsible Handle Litter is as old as the 1996 Atlanta Olympics. Designed specifically as a decontamination-capable product, the Talon II Model 90C meets another important need of the military marketplace. Because this litter is capable of transporting a patient from the point-of-wounding to Role 1, 2, and 3 facilities, there’s “no break in continuity of the standard of care across the board,” Miller explains.

Although some litters are cumbersome, the Talon II Model 90C can be carried in a backpack or a satchel. Moreover, it’s ideal for battlefield use. “This is a functional device that assault elements can carry in,” says Miller, who served as a Special Operations Combat Medic for 20 years. From the point-of-wounding, medics can carry and then load the litter into a ground vehicle. Pressing a button retracts the litter’s handles, which are equipped with a collapsible spring-based system. As Miller told C&CC, this feature was especially important during the Iraq War, when retrofitting ambulances with additional armor meant that the poles on some litters could prevent a vehicle’s doors from closing.

NAR’s Talon II Model 90C Collapsible Handle Litter has an Airworthiness Certificate, which allows its use with rotary aircraft such as the UH-60 Black Hawk, the Army’s front-line utility helicopter for aeromedical evacuations. “This litter can be flown or driven on any platform,” Miller notes, and can also be used with litter carriers. In the future, NAR’s Chief Technology Officer anticipates the use of unmanned systems and even robots during medical evacuations. In the meantime, he says, “we are always working on a better way” to support the military’s mission.

Nonin Medical

Nonin Medical Inc. (Plymouth, MN) is also committed to strengthening a continuum of medical care that begins at the point-of-wounding and continues through evacuation and clinical treatment. The company’s Onyx II 9550 fingertip oximeter “goes with the patient until they get to a place with a multi-parameter device”, says Mark Goldberg, product marketing manager, about this portable instrument for measuring the proportion of oxygenated hemoglobin in the blood. The Onyx II 9550 “can also be used between soldiers,” he adds, an important feature when medics must care for multiple casualties.

As Goldberg explains, the fingertip oximeter’s simplicity is one of its most important features. “Medics are in a chaotic situation,” he says, and movement and sensory stimuli can complicate tasks that require basic manual dexterity. Using the Onyx II 9550 is “just simple,” however, and the device has “virtually no operator instructions”. In fact, the acronym SYFII – “stick your finger in it” – largely explains how to use this fingertip-mounted device, which features green, red, and yellow colored lights that indicate profusion. The on/off switch uses a magnet instead of an infrared light, which can be detected by hostile forces equipped with night vision.

Importantly, the Onyx II 9550 is both rugged and airworthy. “You can’t quite drive a car over it,” Goldberg says, but the fingertip oximeter is approved for use aboard U.S. military aircraft at 40,000 ft. Earning an Air Force Aeromedical Certificate meant subjecting the oximeter to a battery of tests, including procedures for electrical safety, electromagnetic interference (EMI), altitude, rapid decompression, and explosive atmospheres. Designed to meet the demands of ground and air forces, Nonin’s Onyx II 9550 is suitable for a range demanding environments and is not limited to clinical care settings.

Roemer Industries

Refrigerators for blood products aren’t limited to full-treatment medical facilities either. Roemer Industries (Poway, CA) designs and manufactures portable refrigeration units for storing whole blood, red blood cells, plasma, and vaccines. According to Sia Mean, the company’s lead engineer, Roemer Industries’ first refrigerators were used on fishing trips where “people wanted to keep beer cold”. With its proximity to San Diego’s large military community, however, suggestions arrived about potential military applications. Today, Navy SEALS have acquired refrigerators for undisclosed uses.

According to Mean, additional applications include immunization programs, morphine storage, and the pre-positioning of vaccines and other medical supplies for global operations. “These refrigerators perform just like stationary units,” he explains, and are available in a variety of capacities. “Blood banks tell us that the 8L unit is ideal for one person,” but Mean notes that the smallest unit can hold 3L, weighs just 25 pounds, and “could be carried in a backpack”. Specifications
such as storage capacity and weight are important, but so are features such as “global power” requirements and the absence of moving parts beyond the compressor.

“The big difference between your home refrigerator and our portable models,” Mean explains, “is that our outer casing is the condenser.” Unlike home or hospital refrigerators, too, the Roemer Industries’ units can use solar power, DC power from a car battery, or AC over a range of voltages. Although these refrigerators are not yet used on military helicopters, R&D efforts are underway in conjunction with the University of New Mexico, the New Mexico Blood Bank, and the U.S. Air Force. Results are expected before the end of 2015, and could strengthen the profile of portable refrigerators that are already notable because they meet ABB/Red Cross standards for temperature range in stationary units.

Making the Most of the Golden Hour
In “Challenges to Improving Combat Casualty Survivability on the Battlefield,” an article in the Q1 2015 edition of Joint Force Quarterly (JFQ) 76, Lt. Col. Mabry writes that “once a wounded servicemember reaches the combat hospital, his or her care will be the best in the world”. Combat casualty care is a continuum, however, and Mabry also notes that “the pre-hospital phase of care . . . represents the next frontier for making significant improvements in battlefield trauma care.” Through evidence-based medicine, continuous PI, and treatments that stay with and support the wounded, military medical professionals are making the most of the golden hour.

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Forecasting Spread of Infectious Diseases

The chikungunya virus (CHIKV) is quickly spreading through the Western Hemisphere; as of May 15, 2015, the Pan-American Health Organization (PAHO) had tallied close to 1.4 million suspected cases and more than 33,000 confirmed cases since the virus’ first appearance in the Americas in December 2013. Spread by mosquitoes, chikungunya is rarely fatal but can cause debilitating joint and muscle pain, fever, nausea, fatigue and rash, and poses a growing public health and national security risk.

To accelerate the development of new infectious disease forecasting methods, DARPA launched its CHIKV Challenge competition last year. Thirty-eight teams from around the world vied to develop the most accurate predictions of CHIKV cases for all Western Hemisphere countries and territories between September 2014 and March 2015. On May 12, DARPA unveiled winners of the competition during a scientific review event held at the Agency’s offices in Arlington, VA.

The event, which included representation from the Centers for Disease Control and Prevention (CDC), the U.S. Department of Health and Human Services (HHS), the Department of Defense (DoD), and the White House Office of Science and Technology Policy (OSTP), highlighted results, lessons learned and potential next steps to improve state-of-the-art infectious disease forecasting.

“Predicting the speed, severity and direction of infectious disease outbreaks is incredibly challenging, in part because it’s difficult to determine the relative contributions of multiple factors—such as weather and climate, population density and travel patterns—under various conditions,” said Col. Matt Hepburn, DARPA program manager for the CHIKV Challenge.

Yet in just six months’ time, the participants made notable progress, Hepburn added. “The teams in the CHIKV Challenge identified gaps in current forecasting capabilities and created a set of tools that can immediately help improve forecasting and guide response decisions for the current chikungunya outbreak. We are on the cusp of enabling a revolutionary improvement in disease forecasting, in much the way that weather reports transitioned from surveillance to forecasting.”

Rapid Synthesizer

Synthetic molecules are the foundation for many products critical to the Department of Defense’s mission—from active pharmaceutical ingredients found in a medic’s kit to materials in modern batteries and fuel cells. Current processes for designing and producing new synthetic molecules, however, are very slow and can take years between the initial design of a molecular solution and when it’s available for use in large quantities.

DARPA’s Make-It program seeks to overcome this challenge by developing an automated synthesizer that could transform
simple raw materials into known or new molecules defined by
the user. The goal of Make-It is to develop a fully automated
chemical synthesizer that can produce, purify, characterize and
scale a wide range of small molecules. Accelerating the rate of
discovery and production of molecules could speed advances in a
number of areas important to national security.

“Synthesis is a bottleneck to the discovery and production
of new molecules,” said Tyler McQuade, program manager in
DARPA’s Defense Sciences Office. “Automated synthesizers exist
commercially for discrete systems such as natural biopolymers,
but the technology is not applicable across all molecules and
scale-up is difficult. The vision for Make-It is to create an
automated synthesizer that produces a wide variety of complex
small molecules at production scale in weeks instead of years.”

If successful, Make-It would widen access to synthetic
chemistry beyond chemists, enabling non-chemists from other
scientific disciplines to leverage the power of synthesis for
new applications. Another benefit would be to revolutionize
reproducibility. Currently, knowledge transfer is a challenge in
synthetic chemistry, because conditions and reaction set-ups vary
between lab locations worldwide. With a Make-It synthesizer,
chemical routes for new molecules could easily be replicated
by others as simply as by sending a text message. Additionally,
Make-It would make synthesis safer and greener by enabling
better control of process inputs such as starting materials and
solvents, as well as conditions such as temperature and pressure.

Gastrointestinal Aid

For decades, American travelers to international destinations
have been plagued by acute gastrointestinal illnesses that can
arise from travel to other countries. The Center for Disease
Control (CDC) warns that depending on the destination,
between 30 to 70 percent of travelers can expect to experience
gastrointestinal distress from ingesting foreign or pathogenic
bacteria that can be present in poorly sanitized water or food.

But novel biotechnology under development at Harvard’s
Wyss Institute for Biologically Inspired Engineering could help
alleviate acute gastrointestinal illness for not only travelers
abroad but also those who suffer from chronic gastrointestinal
disorders, inflammation, or acute illnesses on home soil.

A new grant awarded by the Defense Advanced Research
Projects Agency (DARPA), for up to $4.7 million dollars over
the course of the work, will support the efforts of the project’s
co-principal investigators Wyss Core Faculty member Pamela
Silver, Ph.D., and Wyss Senior Staff Scientist Jeffrey Way, Ph.D.,
who will team up with Wyss Founding Director Donald Ingber,
M.D., Ph.D. The cross-disciplinary Wyss team aims to fight
gastrointestinal illness through tactics invisible to the naked
eye by developing an army of genetically engineered bacteria
designed to sense, report and combat harmful microbial
invaders.

Silver and Way will hijack nature’s own mechanisms to create
genetically engineered bacteria that are programmed to identify
and kill harmful pathogenic bacteria. Building off their previous
pioneering work, the synthetic bacteria will be engineered
to detect the chemical signature given off by gastrointestinal
inflammation. Then, once inflammation is detected, a series
of genetic circuits in the synthetic bacteria will be triggered
to attack invading bugs and restore healthy equilibrium in the
gastrointestinal tract.

Taken in probiotic pill form, the gut-on-a-chip is capable
of sustaining living human gut cells in direct contact with the
living microbiota within a microfluidic silicone chip for up to
several weeks in vitro. Using the gut-on-a-chip, the team will
mimic gastrointestinal inflammation with living human cells
to study the pathogens’ response to the collaborative consortia
of engineered microbes. In addition, to prevent unintended
environmental interactions, the gut-on-a-chip will be used to
model the species-specific chemical signals that will trigger the
consortia’s exclusive activation.

More info: darpa.mil
Masimo, a Pioneering Company in Noninvasive Patient Monitoring
By Mark Helbing

Masimo, inc. is a global provider of innovative patient monitoring technologies, including medical devices and a wide array of sensors. For over 20 years, Masimo has been focused on a singular mission--improving patient outcomes and reducing cost of care by bringing noninvasive patient monitoring to new sites and applications. The result is a portfolio of clinically proven products that lead the way in innovation, performance and patient safety throughout the continuum of care.

In 1995, Masimo debuted Masimo SET® Measure-through Motion and Low Perfusion™ pulse oximetry. Masimo SET® provides reliable SpO2 and pulse rate measurements even under the most challenging clinical conditions, including patient motion and low peripheral perfusion.¹

In 2005, Masimo introduced rainbow® Pulse CO-Oximetry™, a breakthrough noninvasive blood constituent monitoring platform that measures many blood constituents that previously could only be measured with invasive procedures. The rainbow SET® platform noninvasively and continuously monitors total hemoglobin (SpHb®), oxygen content (SpOC®), carboxyhemoglobin (SpCO®), methemoglobin (SpMet®), pleth variability index (PVI®), oxygen saturation (SpO2), pulse rate (PR), and perfusion index (PI).

Optimizing Technologies for Field and Operational Medicine
Masimo’s Rad-57® and Radical-7® devices have been customized by several U.S. Military field and operational medicine units to include a portion or all of the noninvasive rainbow® parameters. This customization allows the respective field unit the ability to noninvasively monitor total hemoglobin, carboxyhemoglobin, and/or methemoglobin blood constituents based on their specific clinical requirements. Further, Masimo manufactures the small, self-contained, mainstream EMMA™ Capnograph that is being utilized by several Special Operations units and the Marine Corps to manage down-range intubations and help guide patient resuscitation.

Masimo is committed to providing the U.S. Military with innovative, effective, and rugged noninvasive technology solutions to support the medic and forward clinician in combat casualty care. ■


More info: Masimo.com
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Military rescuers train with next-gen medical simulator

A combat search and rescue exercise, dubbed Angel Thunder 2015, at David-Monathan Air Force Base in Arizona revealed the latest medical simulators that will aid military medical aides in combat scenarios.

Three medical simulators were used as victims representing battlefield casualties. They were so advanced that rescuers could hear “breathing, heart beating, hear lung sounds, hear heart sounds; they can feel their pulses,” said Benjamin Stobbe, administrative director for The University of Toledo’s Interprofessional Immersive Simulation Center, who helped oversee training. “If they have a head injury, we can make their pupils unequal.”

The simulations allow us to do is create realistic injuries. One of the adults had a head injury from an IED blast and also a chest injury. The second adult was an amputation of the lower leg. The simulation is sophisticated enough to know that if they get the right pressure with the tourniquet, the bleeding stops.”

Kristen Barrera, a senior research psychologist at Wright-Patterson Air Force Base, Ohio declared, “Instead of a role player saying, ‘Oh, your arm is broken here, so you should react,’ the simulator actually does that,” she said.

The simulators also allowed rescuers to practice invasive procedures that couldn’t be done on living actors, such as inserting an IV or performing a needle decompression to treat breathing issues, said Barrera, who also oversaw training.

The University of Toledo has been working with Canadian company CAE, the University of Nebraska, Cubic Global Defense, and the Air Force’s 711th Human Performance Wing to develop the new medical training.

“(On previous drills) they would just use a regular mannequin,” he said. “They would have to listen to their instructor give them directions. They would have to look at their instructor and say ‘what’s their pulse?’”

Stobbe said the trainees “have to react to what they see and what the simulator’s doing instead of looking at their instructor for that information. It actually adds a little element of stress.”

Removing the instructors from the area also adds to the realism of an actual combat zone.

In future training, Barrera said, the setup will allow military bases to have their own simulators and hook up to a controller via Internet saving money and time in the long run.

Angel Thunder was operated from command centers at University of Toledo and the Air Force Medical Modeling and Simulation Training Center in Texas.

More info: utoledo.edu/centers/iiisc

Combatting the Cold

Hypothermia poses a major challenge for combat medics treating battlefield casualties; even mild hypothermia can potentially increase morbidity and mortality in combat evacuations. The Geratherm® Mini Rescue Blanket system combined with the compact DataTherm® temperature monitor, both products of RG Medical Diagnostics, Inc, provide an “in theatre validated method” to treat and reverse the effects of hypothermia from the site of the incident to a treatment facility.

Several years ago, a study was conducted by the Naval Medical Research Unit on Patient Active Warming Systems (PAWS). It was determined that Geratherm system performance was not affected by extremes in either temperature or elevation. The active warming blanket and temperature monitor are FDA Listed as Class II medical devices designed specifically for the treatment and prevention of hypothermia. The blanket’s embedded, dual temperature controller can be set to 98.6°F for the maintenance of regular body temperature, or 104°F for treatment of hypothermia. The blanket will continuously deliver radiant heat for 7 hours from a fully-charged 2590 Li-Ion battery regardless of ambient temperatures or high elevations, and a microprocessor which continuously monitors the blanket to ensure the temperature is within 2°F of the selected setting.

More info: rgmd.com

First-of-kind Early Pregnancy Blood Test

A simple new blood test, known as the i-STAT® Total β-hCG, can rapidly and accurately help detect the human chorionic gonadotropin (hCG) hormone that is usually used to determine whether a woman is pregnant. The test, which received U.S. FDA clearance, can detect if a woman is in the early stages of pregnancy by measuring very low levels of hCG in blood on Abbott’s i-STAT® System, a handheld, portable blood analyzer. By using two to three drops of blood, the test can provide high-quality results at a person’s bedside within 10 minutes.

Unlike urine testing, Abbott’s β-hCG test can measure hCG in whole blood or plasma. By providing results quickly, the test can streamline a doctor’s decision-making process, which can be vital in emergency situations. The i-STAT® Total β-hCG test not only provides qualitative results that determine whether hCG hormone is present in the blood, but also quantitative results that specify the amount of hCG present. This information may help identify how far along a woman is in pregnancy while potentially reducing false-negative results by being more sensitive. This is important as data have shown that urine pregnancy tests are susceptible to false-negative results.

More info: abbottpointofcare.com
Drones as Airdrop Emergency Medical Responders

Need an EpiPen? There’s a drone for that. Krossblade Aerospace Systems, an Arizona-based aviation startup, has created a prototype for SkyProwler drones, which can travel up to 60 miles per hour in order to deliver emergency medical equipment such as insulin and defibrillators.

At $50, the SkyProwler comes a fraction of the cost of the typical ambulance trip and takes only about seven minutes to arrive—nearly half of an average ambulance response time.

Krossblade’s latest version of the prototype uses automatic cargo drop doors to release the medicine or other supplies while the drone is in flight or in hover—a suggestion that came from the company’s customers.

Because the drone’s hover flight and cruise flight modes require rotors of different speeds and sizes, the SkyProwler’s unique switchblade transformation mechanism makes for a streamlined switch from one to the other. Krossblade’s CEO, Dan Lubrich, tells PSFK:

In order to optimize aerodynamics and cut down on wind resistance, it makes sense to fold the large slow rotors out of the way in cruise flight, when they are not needed. This makes SkyProwler much faster and more efficient than if the large hover rotors remained folded out.

Drones have already taken over various military services and with the new SkyProwler prototype, they could also become emergency medical responders.

With the potential to travel up to 40 minutes and 40 miles away from its controller, the SkyProwler may serve to provide isolated victims with medicine, food, or water until they can be transported somewhere with more resources.

Our hope is that regulations catch up with technology so that for simple but urgent emergencies we can achieve faster response time and lower cost. Also, many emergencies may not require delivery, but surveillance. A drone could very quickly be dispatched to the scene of a fire for example, giving firefighters an advanced look at the scene, while the firefighters are still driving to the scene.

More info: krossblade.com
C&CC: Please speak to some of your past experiences in the field.

COL Rasmussen: I attended medical school at Mayo Clinic in Rochester, Minnesota, as an Air Force Health Professions Scholar, pursuing general and vascular surgery. I completed my training a month before 9/11 and shortly thereafter began caring for the first wave of combat injured personnel returning from Afghanistan at Walter Reed Army Medical Center.

In 2004, I was assigned to Lackland Air Force Base, San Antonio, TX, and began deployments to both Operation Iraqi Freedom and Operation Enduring Freedom. During this time, I also participated in surgical training missions to Morocco, Pakistan, and Russia, and started a vascular injury and resuscitation research program. From 2010 to 2013, I had the privilege to serve as Deputy Commander, U.S. Army Institute of Surgical Research, San Antonio, and in the summer of 2013, I was assigned to direct the broader DoD Combat Casualty Care Research Program in the National Capital Area. I have a professorship at the Uniformed Service University of the Health Sciences in Bethesda, Maryland, and now see patients and perform surgical operations at the Veterans Administration Medical Center in Baltimore.

C&CC: What is your present assignment and responsibility set within the scope of U.S. Army Medical Research and Materiel Command guidelines?

COL Rasmussen: Currently, I serve as Director, Combat Casualty Care Research Program (CCCRP), a national research and development investment dedicated to delivering solutions for improving survival and recovery from combat-related injury. The program is a combination of both Army and Defense Health Program investment funds guided by the Commanding General, USAMRMC and the Director, Defense Health Agency Research, Development and Acquisitions Directorate.

CCCRP staff at Fort Detrick, MD are responsible for planning the programming, budgeting, and execution of the more than $100 million research dollars dedicated annually towards topics that span the spectrum of trauma care; including pre-hospital, en-route, and facility-based care. CCCRPs investments are organized into portfolios that include blood products, hemorrhage control and resuscitation, en-route care, forward surgical intensive care, and neurotrauma and military medical photonics. The research investment also includes scientific work at the U.S. Army Institute of Surgical Research, Joint Base Fort Sam Houston and Walter Reed Army Institute of Research.

My role also involves coordinating with strategic partners in both the federal and civil sectors. These partnerships include efforts with the Food and Drug Administration, the National Institutes of Health, and the White House National Security Council, as well as several civilian trauma centers and other private companies.

C&CC: From a combat trauma care perspective, what are the current research and technology efforts to save lives on the battlefield?

COL Rasmussen: CCCRPs efforts to apply lessons learned during recent decades of combat-related trauma experience. From the recent long wars in Afghanistan and Iraq while also looking to innovate for future and more complex operational scenarios. Learning from Afghanistan and Iraq, we know that most combat-related deaths occur before the casualty reaches the hospital. Therefore, the initial 60-minute period following injury – and during which lifesaving efforts are most important – can be described as the “Golden Hour.” The consistent use of this term has helped the military focus on establishing timely, lifesaving capabilities available for those severely injured in combat.

The most common causes of death in the “Golden Hour” are bleeding, the inability to establish an airway (i.e. intubation and breathing for the patient) and brain injury. As such, many of the CCCRPs research efforts focus on controlling bleeding – including bleeding originating from the extremities, the torso, and the junctional vessels located between the extremities and the torso. These research efforts include the study of new methods to externally compress bleeding vessels as well as novel efforts to stop bleeding from inside the blood vessel (i.e. endovascular methods). In addition
to controlling hemorrhage, trauma research is also focused on new and better ways to restore lost blood volume; including new ways to use fresh whole blood as well as innovative approaches to formulate, store, and deliver the different components of blood (i.e. platelets, plasma, and red blood cells). Research efforts are also underway to better enable those closest to the injured patient in establishing an airway and artificial breathing as needed. Moderate and severe traumatic brain injury is perhaps the most challenging scenario in the immediate hours following combat wounding, and one in which the research program is redoubling its efforts in order to provide better management tools to improve survival and recovery.

Importantly, the program also recognizes that combat casualty care in the initial “Golden Hour” in both current and future operational scenarios is likely to be vastly different than what it was during the wars in Afghanistan and Iraq. As such, the program is preparing for the next—and not the previous—war. Specifically, the program is working to develop hemorrhage control, resuscitation, airway management, and brain injury solutions that apply to future scenarios which may include delayed resuscitation, prolonged field care, and long-distance en-route care.

**C&CC: What are some of the greatest research advancements that have been made in recent times?**

**COL Rasmussen:** The most transformational advances in combat casualty care can be considered in two descriptive categories: knowledge solutions and materiel (i.e. technologies or devices) solutions.

**Examples of groundbreaking advances in the field of knowledge solutions include:**

- Defining the value of blood and blood components (plasma, platelets, and blood cells) in replacing lost blood volume. While this seems intuitive, major advances have been made in understanding how, when, and in which ratios to replace blood loss in severely-injured patients.

- Understanding the value of tactical combat casualty care in saving lives near the point of injury. This effort includes understanding the importance of tourniquet placement as well as the value of other life-saving maneuvers provided by fellow combatants (medics and non-medics) at the point of injury. Use of this specific knowledge product has been shown to reduce or eliminate preventable deaths on the battlefield.

- Understanding the life-saving value of enhanced en-route care capabilities in transporting severely injured troops. This includes understanding the value of augmented en-route care from the point of injury as well as that provided in longer, critical care air transport platforms. Knowledge gained from recent conflicts demonstrated that advanced en-route care from the point of injury provides a life-saving capability in a set of severely-injured personnel.

- Defining the value of certain medications in combat casualty care. This includes charting the effectiveness of an existing medication called tranexamic acid, which is used to reduce bleeding and inflammation during the acute phase of certain injuries. While used in previous capacities for several decades, the CCCRP demonstrated a newfound effectiveness of this drug following severe combat injury and hemorrhage.
Examples of groundbreaking advances in the field of materiel solutions include:

- The redesign and large scale production of a modern tourniquet. While the concept of a tourniquet is not new, the new devices stemming from research efforts during the war are the first to have been rigorously tested and designed to be self-applied and durable. It is estimated that tourniquets were responsible for saving over 2,000 lives during the wars in Afghanistan and Iraq.

- The evolution of extra-corporeal organ support technologies.

- The reappraisal and development of new trauma-specific endovascular devices to control hemorrhage and resuscitate the severely injured patient.

- The development of new blood products that are more easily stored, transported, and used at the point of injury; including dried forms of blood components (plasma, platelets, and fibrinogen).

- The development of new cardiovascular monitoring devices that improve the ability to monitor the injured patient. These devices also support decision making and allow medical staff to assess or predict the cardiovascular reserve of patients who have been severely injured.

C&CC: What are some of the biggest challenges right now in military trauma care?

COL Rasmussen: Reappraising the “Golden Hour” capability and delivering effective, lifesaving care in new and possibly more challenging operational scenarios is a challenge for military trauma care. Combat casualty care successes of the past wars may be difficult to sustain in future situations in which smaller numbers of dispersed troops are deployed and injured in remote locations. In such scenarios, the “Golden Hour” capability may not be afforded the familiar capabilities that exist in traditional levels or echelons of care. In this context, the research program is reappraising the “Golden Hour” to identify ways to provide life-saving and sustaining capability for situations in which resuscitation is delayed and both prolonged field care and long range en-route care are a reality.

Another weighty challenge exists in what is referred to as the “burden of survivorship” that accompanies low case fatality rates. Put another way, effective lifesaving maneuvers both at and following the point of wounding means that more severely injured patients are surviving to be cared for in the days and weeks following injury. The CCCRP is redoubling its efforts to reduce the “died of wounds” rate and improve quality survival for these severely-injured patients –including examining new ways to replace failing organ function, manage severe burns, and salvage mangled extremities. In past wars, these injuries would have been fatal. In this regard, the research program is working to reduce any “burden of survivorship,” and improve quality or functional survival of combat injured.

Finally, the most vexing combat injury pattern –for which relatively less progress has been made in the recent wars– is moderate and severe traumatic brain injury (TBI), including penetrating brain injury. While progress has been achieved in diagnosing and managing the more frequent injury pattern of mild TBI, few such advances have come in the fields of moderate and severe TBI. The challenge for the CCCRP is to redouble efforts towards this seemingly insolvable injury pattern and push research to develop new ways to stabilize all forms of brain injury (mild, moderate, and severe) in the early and acute time frame after wounding (i.e. neuro-resuscitation). Stabilizing and providing effective support to an “at risk” brain in the hours and days after combat injury decreases the likelihood of progression, and increases the chance of meaningful survival and recovery. Regardless of its complexity or seemingly insolvable nature, severe –and even penetrating– brain injury will be a reality of combat operations. As such, it will be a priority for the research program to push the boundaries of possibility as they pertain to the management of this complex injury pattern.
Innovation in heart disease treatment at Naval Medical Center San Diego is enabling effective care by way of non-surgical repair.

By LCDR Joshua Kindelan, MC, USN and CDR Keshav Nayak, MC, USN

Cardiac medicine in the Navy has a long and successful history. At Naval Medical Center San Diego (NMCSD), we have employed an integrated collaborative model of patient care since 1987. Under this model, all patients needing surgery or complex non-surgical treatment are evaluated by a team consisting of cardiologists, heart surgeons, and radiologists to determine optimal treatment. A long part of the professional culture at NMCSD, this “heart team” model has only recently been advocated as the benchmark for all U.S. hospitals by the American Heart Association and other national organizations. Our capability for treating cardiac diseases is robust. The interventional cardiologists routinely perform complex coronary artery stenting, arrhythmia ablations, septal defect closures, and pacemaker implantation, while our cardiac surgeons perform comprehensive valvular surgery, coronary artery bypass grafting (CABG), and complex aortic reconstructions.

Medical and surgical treatment of heart disease is highly reliant on advanced technologies. The innovations that gave birth to this highly specialized field of medicine were the advent of the heart-lung machine, which allows operations on a non-beating heart, and coronary stents to open blockages in the arteries that supply blood to the heart through tiny punctures in an artery of the leg or arm. These technologies have been employed on a daily basis for decades to treat heart disease safely and effectively.

Non-invasive Valve Replacement
We are currently in a new era of innovation focusing on less invasive ways to treat complex diseases of the heart and aorta. The purpose of making heart procedures feasible through smaller incisions (or no incision at all) is to expand the number of patients who can benefit from treatment of their heart disease and to speed recovery. At NMCSD, we now have the ability to replace heart valves, cure some abnormal heart rhythms such as atrial fibrillation, and treat aortic aneurysms by minimally invasive methods. Particularly exciting is replacement of the aortic heart valve though a very small incision in the upper thigh. The procedure is called Transcatheter Aortic Valve Replacement (TAVR). This has allowed us to replace
certain heart valves in patients who would have been considered too sick for open heart surgery in the past. These are typically elderly patients who have a meaningful life expectancy were it not for their debilitating valvular disease. Other uses for TAVR are in patients who rely on a wheelchair or walker/cane. For such patients, healing the surgically-divided breastbone can be much more difficult than recovery of the heart following these surgeries due to the constant stress they put on their chest wall using those assist-devices.

**Historic First**

Launching a new and highly innovative program in a Department of Defense hospital is a big undertaking. Yet through the efforts of many dedicated individuals, and a very forward-looking and supportive leadership, such a program has become a reality at Naval Medical Center San Diego. On March 16th, 2015 the authors of this article and their 16-person team of physicians, nurses, and technologists implanted the first TAVR ever at a military treatment facility (MTF). The recipient of this valve replacement had a short stay in the hospital afterwards and went home to resume his normal activities within days of his procedure. Our program continues with great enthusiasm from patients, the TAVR implant team, and the NMCSD leadership. In addition, we have expanded our partnership with the San Diego Veteran's Administration Hospital to make possible TAVR implantation on their patients.

**TAVR Design and Implantation Technique**

The heart’s main job is to pump blood in one direction, first to the lungs to collect oxygen and discard carbon dioxide, and then to the rest of the body to deliver oxygen and collect carbon dioxide waste. At the most basic level, it accomplishes that feat by contracting the heart muscle which results in squeezing the blood in the ventricles of the heart. The blood is pushed towards a set of two valves, one prevents blood from going the wrong direction, while the other allows forward flow, snapping shut as soon as the exiting blood starts to flow backwards after its initial propulsion by ventricular contraction. Valves can become stretched out or develop holes causing leaking in the wrong direction, or can become calcified and narrowed preventing adequate blood and oxygen from reaching the body’s organs.

In a conventional valve replacement the patient is connected to a heart-lung machine which shunts the venous blood from the patient just before it returns to the heart, removes carbon dioxide and deposits oxygen, and then returns it to the aorta shortly after it exits the heart. In this way, the lungs and heart can be made motionless temporarily by cooling it to very low temperature and instilling large doses of the electrolyte potassium into the blood vessels to the heart. The diseased valve is cut out and a replacement valve is sewn into position. Following valve replacement, the heart is restarted by warming and allowing potassium to wash out of the heart’s circulation.

With TAVR, the replacement valve is tightly packaged in a thin plastic catheter and can be guided into position with the heart beating and the lungs inflating and deflating normally. Once positioned within the diseased valve, the replacement valve is released from its plastic covering sheath allowing it to expand. In the process the native, diseased valve is compressed against the wall of the aorta and in its place the TAVR valve remains. The two crucial elements of this deployment process are a rapidly-expandable outer casing of the valve, and durable, but highly compressible, valve leaflets. These elements ensure that a replacement valve, which has a diameter a bit larger than an inch, can be temporarily compressed down to a diameter of one-quarter of an inch for delivery to implant site.

The technology behind these TAVR valves represents the coupling of several brilliant engineering accomplishments that have produced a very elegant solution to a complex problem. The outer casing of the valve is made out of Nitinol, a nickel titanium alloy that has temperature-sensitive shape “memory.” At cooler temperatures Nitinol is compressible to fit into a delivery catheter. At body temperature the outer casing expands fully to an hourglass shape conforming to the anatomic shape at the site of implant at the aortic valve annulus. This metal is the same used in products such as certain eyeglasses that can be severely bent and distorted at room temperature and spring back to their original configuration when heated. The valve leaflets themselves are hand-sewn from three pieces of porcine pericardium, which itself has been carefully selected for precise thickness. The pericardium is put through a chemical process that ensures no living cells are present and confers resistance to calcification, a process that would otherwise lead to damage of the replacement valve.
The TAVR valves are a technologic triumph to be sure; however, they are likely to be only a part of (and not a replacement of) the current armamentarium for treating heart valve disease. The durability of these valves is currently unknown, but few experts believe that they will prove as long-lasting as conventional surgical valves. They are intended for patients who would benefit much more from ease of implantation and quick recovery than from prolonged valve durability.

**TAVR Application to Wounded Warriors**

A particular subset of patients for whom TAVR is ideally suited are those wounded warriors dependent on assist-devices, such as wheelchairs, or amputees who must use their upper-bodies for many physically demanding tasks when not employing limb prostheses. TAVR represents a means to replace aortic valves (the most frequently diseased heart valves) in these patients that allows them to resume full activity in a matter of days instead of weeks-to-months.

The use of TAVR in acutely injured troops is not currently performed. Combat-related cardiac and aortic injuries frequently carry a grave prognosis, so supporting those patients to a site where their injuries can be treated represents a significant challenge. If the evacuation challenge can be met, however, TAVR could play a role in initial treatment of aortic valve injury. While few multiple-system injured combat troops could tolerate open heart surgery in the early stages of their recovery, they almost certainly could tolerate TAVR implantation as a quick-fix of an aortic valve injury. In this scenario, the patient could be bridged through a complete recovery from injuries before returning to address the aortic valve when healthier and able to tolerate more definitive aortic valve procedures. For some, readdressing their aortic valve injury could mean simply providing long-term surveillance of their TAVR, while for others it could mean converting a TAVR to a surgical aortic valve replacement.

In conclusion, the treatment of cardiac disease at NMCSD has a long tradition of being a multispecialty effort offering comprehensive treatment of virtually all varieties of heart and aortic disease. We have long-embraced innovative procedures to augment the tried-and-true therapies we continue to offer. Much of the focus in innovation in recent years has been making approaches to treatment less invasive, and therefore better tolerated by a larger number of patients. This progressive philosophy recently culminated in our performing the first Transcatheter Aortic Valve Replacement ever performed in a U.S. Military Treatment Facility. TAVR offers a tremendous benefit to current patients not well-suited to conventional open heart surgery, and will likely have applications to both the delayed and acute treatment of wounded warriors.
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