Innovations in Technology to Extend the Golden Hour:
An Interagency Workshop to Propel Innovative Solutions for Military and Civilian Trauma and Emergency Care

Introduction

Trauma care focuses on the critical time immediately after an injury or acute shock, in an event that may affect one person or many. Termed "the golden hour," the exact window of time depends on many variables, including the patient's underlying health, the nature of the traumatic occurrence, the scale of casualties, and the equipment and expertise at hand.

Bioengineered solutions hold promise for improved diagnostic treatment of acute injuries and shock to increase survival and recovery rates. Technologies have been introduced in the past few years; many pioneered in battle in Afghanistan and Iraq. Others face technical, financial, or logistical obstacles before their potential to save lives is realized.

A workshop held March 21–22, 2019, linked nascent bioimaging and bioengineered solutions with the needs of the Department of Defense and Department of Health and Human Services, and broadly of trauma care in a range of settings. The National Institute of Biomedical Imaging and Bioengineering (NIBIB), Uniformed Services University of the Health Sciences (USUHS), and Food and Drug Administration (FDA) cosponsored the workshop.

Several common themes emerged from presentations and breakout sessions:

- Trauma research, product development, and training will benefit from strengthened military-civilian collaboration, with joint ownership of trauma care;
- Future situations will diverge from current realities and require new solutions, such as prolonged periods of field care in austere environments, mass civilian casualties, or radiation exposure;
- Filling the gap in data collection and analytics will improve decision-making;
- Healthcare providers markedly prefer technologies that are simple and easy-to-use versus over-engineered solutions;
- Artificial intelligence has a role in providing diagnostics and treatment, particularly in non-hospital situations, but implementation questions remain.

Joint Ownership of Trauma Care

Bruce Tromberg, PhD, NIBIB director, launched the workshop by reinforcing the importance of civilian and military collaboration. He shared a vision for accelerating basic science and technology to develop new clinical diagnostics and therapeutics. He called for "moving the equilibrium to the right," that is, investing in basic S&T and removing barriers to accelerate translation, validation, and commercialization of new technologies.

Arthur Kellerman, MD, MPH, dean of the USUHS School of Medicine, stressed the significance of a joint NIH-DoD-FDA trauma care event held on the NIH campus. Historically, wartime

lessons have advanced medicine and surgery, from the Civil War onward. Yet while combat casualty rates in Afghanistan and Iraq were the lowest in the history of the country, 1,000 people still died from preventable injuries, and as many as 20,000 to 30,000 civilians die each year from preventable trauma.[1] "Coming together today is an opportunity to scale impact, coordinate efforts, and rapidly move forward," he said. "This meeting can be a watershed moment in the advancement of trauma and emergency care. The stakes are too high and the opportunities too great to rest."

Current Status and Future Needs: Civilian and Military

Covering the civilian perspective, Thomas Scalea, MD, physician-in-chief of the Adams Cowley Shock Trauma Center, University of Maryland, characterized trauma as a time-sensitive disease. (Dr. Adams Cowley was the pioneer in trauma medicine credited with coining the term "golden hour.") Despite advances, mortality rates have remained static. It is time to rethink trauma systems, evaluation, and therapy, pushing in-hospital therapy to the field (or the community setting) and training a range of practitioners in new technologies.

Col. Michael Davis, MD, director of the Combat Casualty Research Program, drew from several DoD documents[2] that project future military operations to include a lack of air superiority/on-demand evacuation, contested communications, and other factors that will change emergency care. They point to the need for new technologies and systems, including a potential 72-hour window before hospitalization.

DoD and NIH fund trauma research differently. At DoD, according to Col. Todd Rasmussen, MD, USUHS, medical research is a requirements-driven acquisition activity. At NIH, the Office of Emergency Care Research has a coordinating function, explained its director, Jeremy Brown, MD. A very rough estimate puts total NIH support at $1 billion, but this amount does not reflect the burden of disease that unintentional injury represents to the population. Emergency or trauma research can be investigator-initiated (unlike at DoD), but has no "home" institute.

In describing the FDA regulatory process for medical devices, Michael Hoffman, MS, deputy director of the Neurological and Physical Medicine Devices section, urged researchers to collaborate with regulators early in the process to shorten the timeline to an FDA decision. A pre-submission process can provide feedback prior to the testing and regulatory pathway.

Up-and-Coming Technologies

Eight short presentations covered (1) new biomaterials for wound management; (2) portable bone-imaging technology; (3) a mobile system to initiate extracorporeal life support (ECLS) early and at the point of injury; (4) new systems to triage after radiation exposure; (5) personal

[1] National Academies of Science, Engineering, and Medicine. (2016). A National Trauma Care System: Integrating Military and Civil Systems to Achieve Zero Preventable Deaths after Injury. Washington, DC: National Academies Press.
[2] E.g., U.S. Army, (2018). The U.S. Army in Multi-Domain Operations 2028, TRADOC Pamphlet 525-3-1.

devices for real-time infectious disease monitoring; (6) new methods to stop truncal hemorrhaging; (7) injectable biosensors for long-term continuous monitoring of body chemistries; and (8) wearable devices to monitor hemoglobin, lactate, and other functions.

Despite the differences in technologies, presenters faced common challenges. Most seek a range of military and civilian applications to expand the market for their innovations, including, in several cases, pediatric cases. Federal funding can spur research and development, yet they still face long-time horizons in bringing products to market. As one presenter commented, the marketing of the product has turned out to be harder than the technology development.

Delving Deeper

Workshop attendees participated in five breakout sessions on different technologies. Common messages across the sessions included the following:

- Technological solutions must be developed that medical staff with little previous training and without large support infrastructure can use;
- Innovation should encompass support devices that can be deployed outside the hospital setting, including well beyond a literal hour of time before reaching a hospital;
- Public education and training are needed to increase translation of new technologies from the lab to the field;
- A high priority across technologies and settings is how to collect, access, and use data effectively.

Extracorporeal Organ Support Technologies

Participants identified renal support and lung support as highest-priority technology needs, but they warned against over-engineering. Prevention of dislodgment of support devices requires better tools, systems, and training for medics, with transport methods taken into consideration. The group urged closer collaboration between DoD and FDA so that devices move through the approval process more rapidly. A company cannot rely on the U.S. Army (or any one entity) as its only customer to remain commercially viable. Part of the innovation should be support devices that are simple and portable to deploy outside the hospital setting.

Radiation Exposure/Burn and Wound Healing

Major challenges include outdated regulatory guidance, especially when an innovation spans sectors (e.g., devices and drugs/biologics). Better diagnostics and treatment based on the type of wound or burn are needed; imaging could greatly assist. One challenge in preventing the translation of radiation technologies from the lab to the clinic is fear. Fear makes the public and providers resistant to prepare for, train, and rationally discuss how to deal with post-radiation. Current education and marketing models are hard to understand, especially for laypeople. Needed improvements and/or wished-for new technologies include a better substitute for burn treatment in a non-surgical setting, skin substitutes or dressings to use until a patient is transported to a hospital setting, and better pain management.

Hemostatic Medical Devices

Improved training, technology development, and capture and use of data are critical issues. Physicians are rarely at the site of injury; medics, first responders, or even laypeople show up first. Possibilities include devices that provide their own instructions (i.e., as with a defibrillator, no specialized training needed), as well as biosensors and wearable devices for remote triage. These could play a role in situations of prolonged field care and in austere environments, where infection, organ failure, and other complications may be triggered. The lack of data on trauma in general hampers decision-making. Focused empiricism and real-world evidence, in the absence of randomized control trial data, may be the most practical option.

Portable Imaging Technologies

The discussion about gaps in imaging to extend the golden hour focused on ultrasound and other technologies in extremely resource-limited settings. Devices must not only be portable, they must be easy to use, multipurpose, and the results easy to interpret by medics and others with limited training in imaging. A closed loop is needed, although it would require dynamic imaging to prevent the system from making bad decisions. Contrasting agents that are easy to transport and administer are another potential advance. Researchers are "hungry" for data for artificial intelligence (AI), and participants asked about ways to de-identify and make accessible data in the DoD's Joint Trauma Registry. Echoing the dual benefits of investing in imaging research, "anything that helps the warfighter will help the person in a car accident," a military participant said, while a civilian participant reinforced that "as a funder of new technology, I want to see it applied to the military in a new way."

Wearable Biosensors

The 21st Century Cures Act envisions wearable/implantable sensors, but translation has proven challenging. Collecting good data for AI is a hurdle. For research, participants noted the need to develop clean datasets and to make the datasets available or aggregating them (rather than "reinvent the wheel"). For field use, the group called for one sensor to encompass multiple uses, rather than a number of different devices. They acknowledged the data overload that exists in emergency room environments and how to streamline. Sensors need to be integrated into real life. A sensor may be worthless in some battlefield scenarios. Similarly, implantable sensors are useful in an emergency, but how can a healthy person be convinced to use one?

Next Steps

The workshop was a milestone in collaboration and interaction between NIH and DoD on critical issues related to trauma care. Civilian and military researchers, health care providers, and others agreed on the need to continue to work together, learn from each other, and find new solutions to prevent casualties, reduce trauma, and improve health.