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Burn and Blast Medical Countermeasures Program: The Federal Perspective

The mission of ASPR's Biomedical Advanced Research and Development Authority (BARDA) is to develop medical countermeasures (MCM) that address the public health and medical consequences of chemical, biological, radiological, and nuclear (CBRN) accidents, incidents and attacks, pandemic influenza, and emerging infectious diseases. In this article, Dr. Narayan Iyer, BARDA's CBRN Burn and Blast Medical Countermeasures Program Director, shares more about BARDA's research and development into treatments for injuries sustained in a mass casualty burn incident (MCBI).

Dr. John Hick, ASPR TRACIE Senior Editor (JH)

How has the CBRN Countermeasures Program evolved over the years?

Dr. Narayan Iyer (NI)

Overall, ASPR leads the nation's medical and public health preparedness for, response to, and recovery from disasters and public health emergencies. To meet that goal, the federal government and ASPR in particular is tasked with bolstering preparedness, building resilience, and developing and providing promising medical countermeasures. This area is almost "solely led" by BARDA, whose reach has grown significantly over the years.

BARDA was formed in 2006 following several incidents and health threats in the early 2000's. As the years passed, our focus grew to include emerging infectious diseases and influenza in addition to CBRN. Within CBRN as the Director of the Burn and Blast program, I lead a dedicated team focused on burn and blast injuries and related radiation and nuclear countermeasures.

Related Resources

BARDA's First 15 Years

CBRN Burn and Blast Medical Countermeasures Program

National Preparedness: Countermeasures for Thermal Burns

Resource-related Information & Tracking Medical Communications Application (RITCA)

Related ASPR TRACIE Resources

Burn Mass Casualty Incidents: Triage, Assessment, and Treatment Considerations

Burns Topic Collection

Extreme Weather and Healthcare – Are you Ready for a Burn Disaster?

Healthcare Coalition Burn Surge Annex Template

Mass Burn Event Overview

Mass Distribution and Dispensing/ Administration of Medical Countermeasures Topic Collection

Step-by-Step Guide to Implementing the Coalition Burn Surge Annex TTX Template (PDF)

JH

How does BARDA foster research and development of products in a way that contributes to the Strategic National Stockpile and medical supply chain?

NI

Under the BARDA model, the federal government establishes unique private-public partnerships with industry to accelerate the research, development, regulatory approval, manufacturing, and stockpiling of vaccines, therapeutics and diagnostics to ensure that the Nation is prepared to effectively respond to a range of threats to national health security. BARDA provides our partners with multiyear funding, access to core development and manufacturing services, and a team of experts with sometimes decades of experience in all areas of drug development to both derisk and accelerate the development and availability of critically needed MCMs.

JH

How have the MCMs changed specific to mass casualty burn incidents?

NI

In 2012 The Government Accountability Office published National Preparedness: Countermeasures for Thermal Burns. This report highlighted the thermal burn MCMs included in the Strategic National Stockpile (SNS) and included steps the U.S. Department of Health and Human Services had taken to gauge the interest of the private sector in developing MCMs for thermal burns

Pertinent to MCBIs, a nuclear detonation causes three types of injuries: radiation, burns, and blast trauma. We were already working on radiation injuries. Burns and blasts had not been a major focus until about 2011. When we started to look at that, a few things became apparent including that no one in the government had true experience, technical expertise, or a national context surrounding how to develop countermeasures to support an MCBI. **Figure 1** illustrates the challenges and solutions we developed as a result of over 100 interviews, focus groups, and brainstorming sessions with the American Burn Association, surgeons, nurses, and others in the healthcare community.

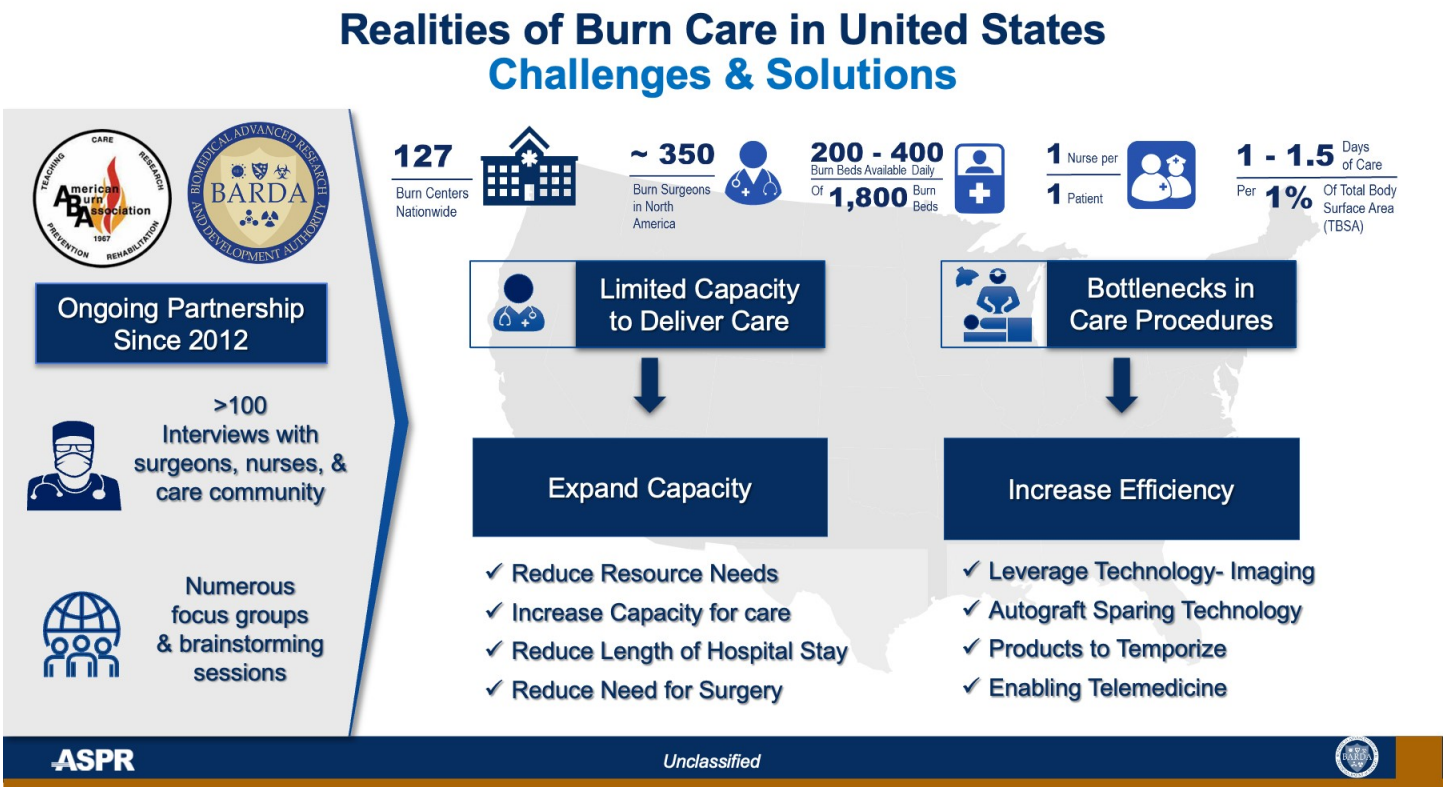

Figure 1. Realities of Burn Care in the United States

In 2012 there were 127 burn facilities and 350 burn surgeons in the U.S. Burn care is a labor intensive, highly specialized area of care with a ratio of one nurse per patient. Our meetings with the ABA and care providers highlighted our limited national capacity to deliver burn care and bottlenecks in the care continuum. In addition to relatively few burn centers and surgeons specializing in burn care, we discovered that there were limited number of new products that had been developed to address this very niche market. This was partially since only between 8,000-10,000 burn patients per year across the U.S. required such highly intense level of care and something we need to build preparedness for delivery of care in a mass casualty.

When you consider the fact that thousands of people in one region of the country might need burn injury care after a nuclear disaster, you quickly realize that resources are not in place to handle the overwhelming number of complex burn patients. We realized we needed to both expand capacity of care (for which we needed products as illustrated in Figure 1) and improve the efficiency of care (e.g., reduce length of stay and the need for surgery and enable telemedicine). We worked closely with ABA leadership to examine the different steps of caring for burn injuries that could be targets for improvement. What products, for example, minimize the need for autografting? Were there ways to avoid or aid surgical debridement (e.g., enzymatic debridement)? How can we improve overall clinical outcome? We went to the industry and asked who had the products that could help patients heal quickly or help us better determine the need for surgery.

JH

There are burn patients benefiting now every day from this development all over the US, but the numbers wouldn't otherwise drive commercial innovation otherwise.

NI

That is true. Back in 2012, we realized that the last product that had been developed to treat burns was in 1996. In 2012, we invested and partnered with a company that was developing an autograft sparing technology to aid healing and BARDA was able to get it through FDA approval for use in 2018, almost 22 years later.

One of our missions is to illustrate the value proposition for each product. How much is this product benefiting burn patients? Will they experience shorter hospital stays, have less significant scars, and be able to return to work sooner? How much is it bending the cost curve? We partnered with a health economics company to develop and continually refine a health economics model to determine the answers to those very important questions which are at the key to product sustainability.

JH

Some of these products do not require significant expertise to apply. Is it fair to say that leveraging just-in-time education and telehealth for those products in an MCBI would be enough to help burn patients in the short term?

NI

It is fair to say that with a caveat. Even this process needs investment. While we were working on securing the U.S. Food and Drug Administration Biologics License Application for one product, it was critical to us to ensure that burn surgeons did not lose track of how to use the product. We secured an Expanded Access Protocol that allowed burn surgeons to continue to use the product and hone their skills. This benefited the physician and the patients while contributing to the refinement of the product and protocol over time. Providers could titrate down, decide what components of patient care could be handled by nurses, determine how to better manage patient pain, and adjust the level of sedation for each patient.

When you synergize investments, the process is streamlined even further. Combining tools and treatments (e.g., wound dressings and autograft sparing products) can allow physicians to get a better visualization of the burn wound to decide whether it needs skin grafting. They can determine the thickness of the wound and if simply covering it would be enough to help it heal. They can use an autograft sparing product to help decrease the size of the graft as well as the length of hospital stay for the patient. These combinations create better value for the patient and better value for burn care overall.

JH

The availability of silver impregnated dressings cannot be underestimated; you can leave those on longer than conventional dressings and they are very effective at reducing secondary infections. What are some of the other products stockpiled in the SNS that can help treat patients after an MCBI?

NI

We have a burn blast kit in the SNS that predates BARDA. It was developed after the 9/11 attack. At that time, it contained a cream (silver sulfadiazine) that was not the best option to deliver preliminary major burn care as we know now. The cream must be removed in order to examine the burn which was a very painful process. During Operations Iraqi Freedom and Enduring Freedom, the Department of Defense used silver-impregnated fabric dressings on burn patients with success. The burn dressing could stay in place on the burn wound for up to seven days. These dressings have other indications, including treating sulfur mustard and cutaneous radiation injuries (based on animal studies) and radiation dermatitis associated with cancer radiation therapy. We now carry silver-impregnated dressings in many forms (including rolls) in the SNS instead of silver sulfadiazine cream.

JH

What else is BARDA working on to treat potential burn and blast injuries?

NI

A nuclear incident will cause numerous traumatic injuries in addition to burns of the skin. We are focusing on other blast injuries, including blast trauma (e.g., traumatic brain injuries), lung injuries, penetrating injuries, fractures, and vascular repair. We modeled real-world data to determine what really happens in a blast trauma. We reviewed data from the Oklahoma City bombing, the Beirut explosion, 9/11, and the Boston Marathon bombing. We shared these results with leadership at the American College of Surgeons. We applied the same model of interviews and focus groups we used with the ABA during our burn product development. Based on these discussions, we decided to focus on traumatic brain injuries, thoracoabdominal injuries, hemorrhage control, musculoskeletal injuries, and burn and traumatic injury repair. **Figure 2** illustrates where that care needs to be delivered and by whom for approximately 80% of the types of injuries incurred from a nuclear mass casualty incident.

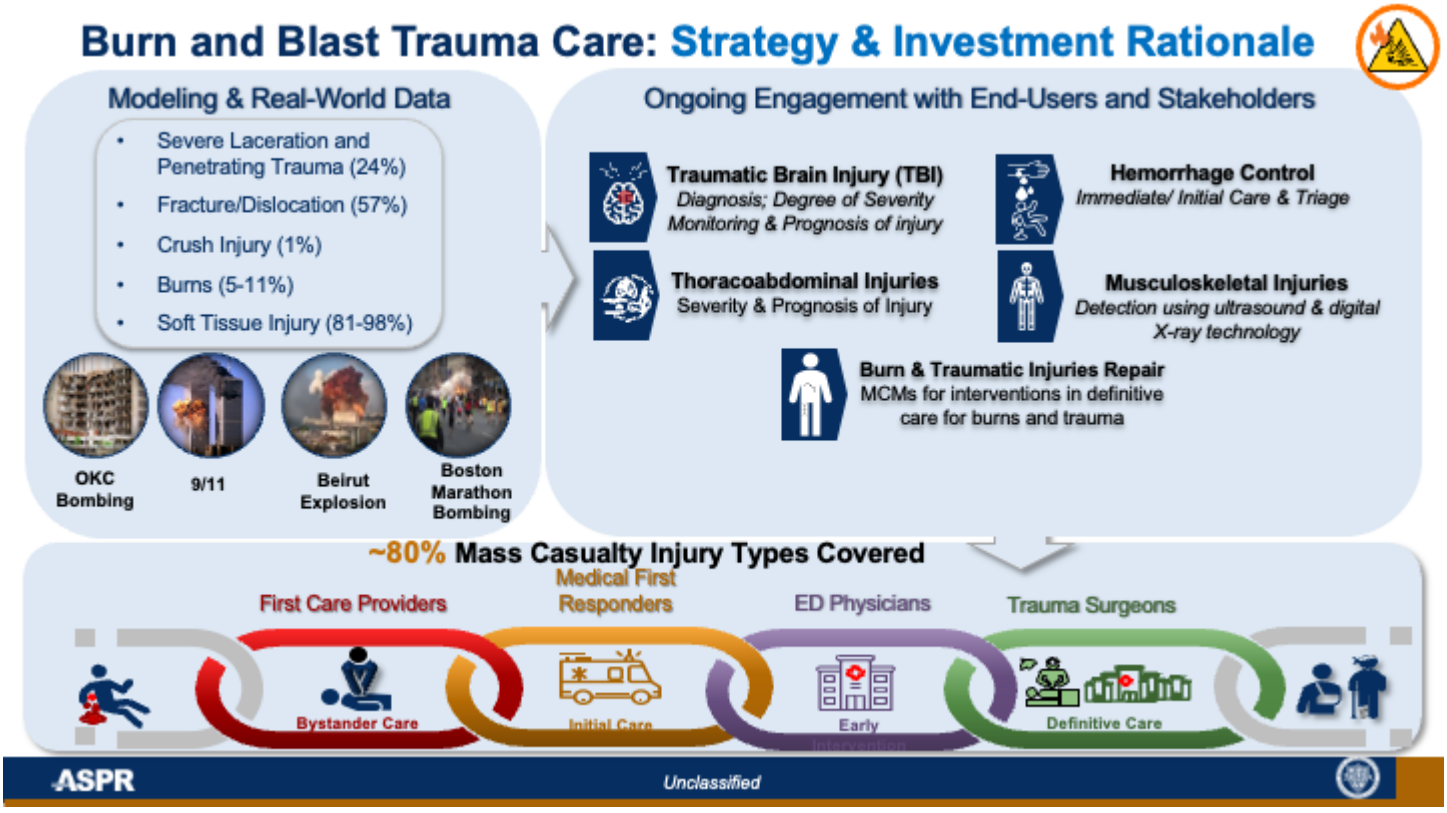

Figure 2. Burn and Blast Trauma Care: Strategy and Investment Rationale

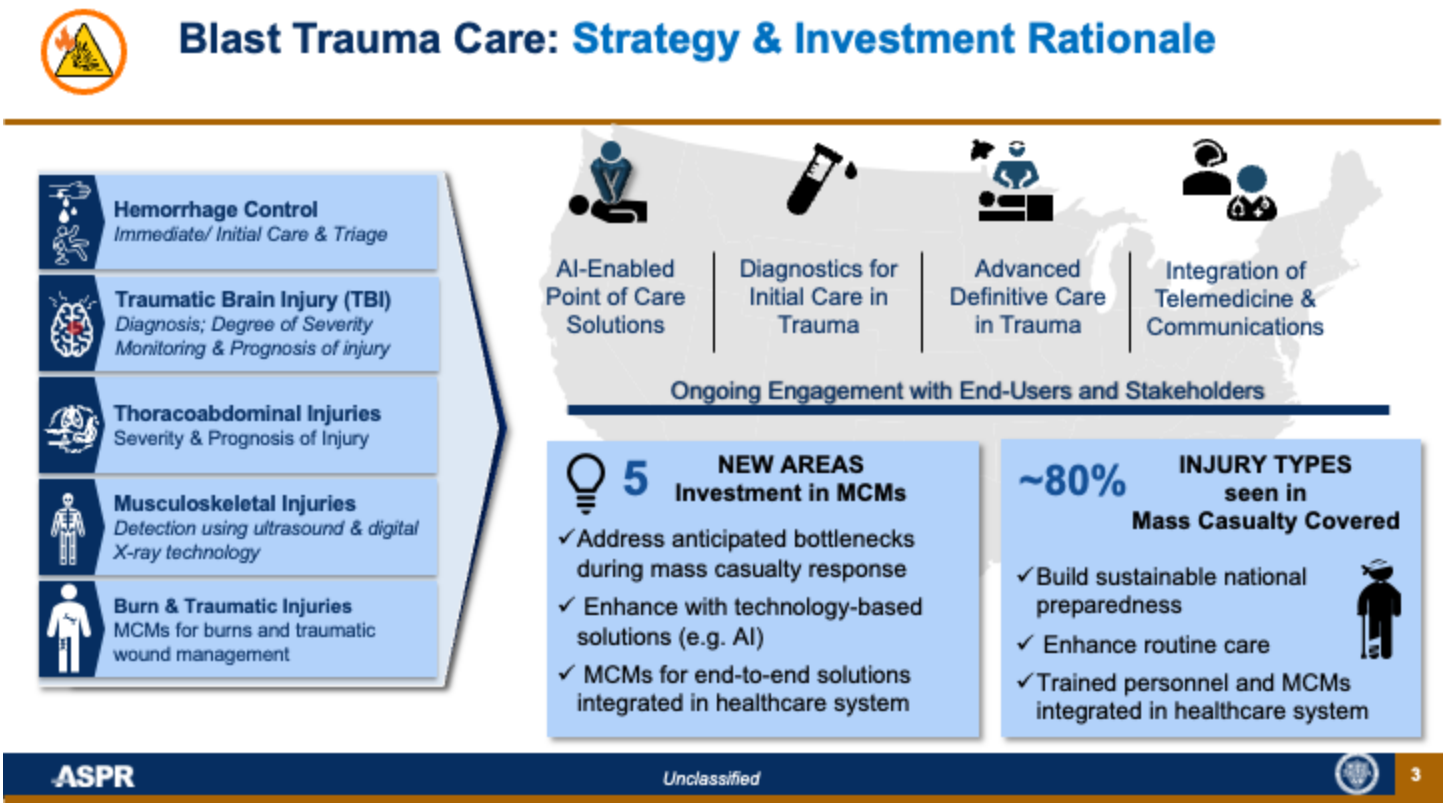

Figure 3. Blast Trauma Care: Strategy and Investment Rationale

Focusing on these five areas of engagement allows us to build a very sustainable national preparedness and help transform routine care.

In **Figure 3**, we list the products and MCM investment areas. We are developing biomarkers that allow healthcare providers to diagnose traumatic brain injury faster using a blood test. A point-of-care ultrasound (bolstered by artificial intelligence [AI]) technology available in the emergency department may allow providers to facilitate patient triage and aid in clinical decision-making.

JH

A patient who might suffer severe burns from a car fire is going to benefit from the work that BARDA has done bringing product to market. The ability to bring AI into ultrasound is breathtaking—even if the provider doesn't know exactly what they are looking at, AI can guide them to adjust the probe angle and help them interpret the results.

NI

Correct. These products can help accelerate the proficiency curve for less experienced clinicians and medical and surgical residents in training. It can also boost the development of regulatory language. The FDA does not have clinical guidance ready to go, so our partnership with them is cutting edge.

JH

What can we look for in the future from BARDA?

NI

We are trying to take this new government-owned knowledge and information and partner with the private developers to create freely available agnostic, AI-enabled software and communication technologies. This way we can further expand the impact of our current investments. We are also, for example, we are working with the Johns Hopkins University Applied Physics Laboratory to develop the Resource-related Information & Tracking Medical Communications Application

(RITCA). RITCA was designed to improve access to real-time information and improve communication on the front lines of care- both in routine care and especially valuable during a mass casualty incident.

As with our other products, RITCA was based on lessons learned from a burn mass casualty in 2015 caused by a color dust explosion at a concert in Taiwan which resulted in numerous simultaneous severe burn injuries. They did a phenomenal job communicating during that incident, considering the number of injuries (close to 500). Our goal is to provide a comprehensive solution which not only cover MCMs but all capabilities which make delivery of care possible.