

19 September 2022

MEMORANDUM FOR RECORD

SUBJECT: Fiscal Year 2022 (FY22) Military Burn Research Program (MBRP) Stakeholders Meeting

The following is a summary of the main topics discussed during the FY22 MBRP Stakeholders Meeting. Please note that all comments are not captured in this summary report. This summary also does not reflect the opinions or views of the MBRP, the CDMRP or the Department of Defense (DOD).

1. The MBRP held a stakeholders meeting on 13 May 2022. The stakeholders meeting provided an opportunity to engage scientific, clinical, and military burn experts, as well as lived-experience subject matter experts, in an open-dialogue forum to identify critical issues and underfunded areas of military burn research and care. Representatives from burn injury-related non-profit organizations, academia, government institutions, and the public contributed broad perspectives on potential barriers in research and patient outcomes, key knowledge or scientific gaps, and potential approaches for the treatment of burn injuries incurred while in the course of military Service. A list of stakeholder participants, invited speakers, and other attendees are included in [Appendix A](#).

2. Welcome and Overview of the Congressionally Directed Medical Research Programs (CDMRP) (Enclosure 1)

Ms. Sandy Snyder, Program Manager for the MBRP, welcomed the participants and emphasized the importance of stakeholders meetings for informing the strategies of new and established programs managed by the CDMRP. Ms. Kristin Jones Maia offered a moment of silence in honor of Service Members that have suffered burn injuries. Ms. Snyder described the purpose of the meeting as identifying knowledge gaps to inform future MBRP research funding and strategic directions. Mr. Scott Wheeler provided an overview of the meeting agenda and explained his role as the lead meeting facilitator. Last, Ms. Allison Poore provided administrative remarks before Ms. Snyder began her introductory comments.

Ms. Snyder gave a brief overview of the CDMRP's history, mission, and vision, noting the unique role of consumer advocates in each aspect of the program. She described the program cycle and the two-tier review process used by CDMRP, highlighting the differences between peer review and programmatic review.

3. Overview of the MBRP (Enclosure 1)

Ms. Snyder introduced the MBRP, which was established by an FY11 \$8 million (M) appropriation. She noted that that the FY22 appropriation for the program is \$10M. Ms. Snyder highlighted the program's intent, vision, mission, and funding portfolio. She acknowledged the

SUBJECT: FY22 MBRP Stakeholders Meeting

essential participation of burn survivor advocacy organizations and the work of consumer reviewers at both peer and programmatic review.

4. Topic Area Presentations

4A. Combat Casualty Care Research Program - Severe Burn Injury Portfolio Research and Development Overview (Dr. Bonnie J. Woffenden) (Enclosure 2)

Dr. Woffenden introduced herself as the Severe Burn Injury Portfolio Manager for the Combat Casualty Care Research Program (CCCRP)/Joint Program Committee 6 (JPC-6). She noted that delayed evacuation from combat as well as prolonged field care (PFC) at any level is expected in future conflict; this will have significant impact on the care and treatment of military burn injuries. She explained that the CCCRP funds both knowledge and materiel products and that their investments are guided by requirement documents. She noted that high-priority focus areas are novel burn wound covers, non-surgical debridement, and therapeutic covers that do not generate antibiotic resistance. Dr. Woffenden explained that the CCCRP works with numerous partners within the Department of Defense as well as other government and outside partnerships.

4B. Overview of the U.S. Army Institute of Surgical Research (Dr. Kai Leung and Dr. Leopoldo Cancio) (Enclosure 3)

Dr. Leung introduced himself as the Science Lead for the Combat Wound Repair Group for the U.S. Army Institute of Surgical Research (USAISR). He explained that USAISR supports the CCCRP and U.S. Army Medical Materiel Development Activity (USAMMDA's) development of products to treat and repair burn wounds. He provided information about multiple products currently in development and noted that the USAISR has received MBRP funding for therapeutic development.

Dr. Cancio introduced himself as the director of the Burn Center at the USAISR and noted his military expertise in the field of combat care and burn wound treatment. He reviewed the history of military burn injuries in prior conflicts as well as concerns about future conflicts, including lack of air superiority, which would lead to delays in care. He also noted that even one burn patient can overwhelm combat medical staff, which has implications for any mass casualty event involving burn injuries. He also emphasized the importance of the entire spectrum of burn care, including a focus on long-term outcomes.

5. Breakout Session Discussion Summaries

These are not the official programmatic gaps for the FY22 cycle. The stakeholder-defined gaps may be used by the MBRP Programmatic Panel to determine the program's strategy for funding opportunities. Please refer to future funding opportunities for any final gaps and Focus Areas associated with a specific application receipt cycle.

5A. Emergency/Point of Injury (POI)/Field Care (Subgroup 1)

SUBJECT: FY22 MBRP Stakeholders Meeting

The subgroup discussed their top concerns within emergency/POI/and field care (including PFC). The high-priority gaps include:

- Atypical Burns, including any burn not caused by high heat thermal
 - This could include chemicals, white phosphorus, electrical, nuclear, radiation, cold/frostbite, directed energy, hyperbaric, laser, or any type of new weaponry.
 - Therapeutics for frostbite or therapeutics to address multiple types of burns at once; combat medical personnel have limited space to carry or store medical supplies so treatments need to be more universal.
 - Establishment of a far-forward standard of care for these types of burns.
 - Establishment of accurate preclinical models for these types of injuries.
 - Noted the impact of inhalation injuries and the need for PFC/POI treatments.
- Burn Wound Conversion, which sparked debate over whether a human burn wound converts or progresses after the injury, or if initial wound assessment does not fully capture the extent of the injury
 - Stakeholders had differing opinions on whether burn wound conversion has been proven in humans.
 - Those who contend burn wound conversion occurs in humans noted the lack of therapeutics to stop progression of burns at POI.
 - Those who questioned whether burn wound conversion occurs in humans noted that preclinical animal models of burn wound conversion may not accurately represent the human burn wound.
- Improved/Novel Dressings, particularly those that could be applied in austere, resource-limited environments or under delayed evacuation
 - Included bioactive dressings that are easy to use.
 - Dressings with multiple benefits and/or active ingredients to address infection, inflammation, pain control, barrier function.
 - Dressings that are elastic and adjust to changing size of injury to minimize dressing reapplication.
- Infection Control, which stakeholders agreed was a serious concern due to minimal options for field care and as a frequent contributor to fatality
 - Strategies for prevention and therapy are needed.
 - Lack of characterization of the pathogens to support development of treatments.
 - Handheld diagnostics to determine pathogen presence, other fieldable diagnostics that could be used in austere, resource-limited environments.
 - Nontraditional antibiotic interventions that would avoid development of resistance.
 - Broad spectrum infection control approaches that address multiple disease-causing organisms.

SUBJECT: FY22 MBRP Stakeholders Meeting

- Need to learn more about biofilms and their interaction with the host.
- Alternate treatment approaches for local versus systemic infections combined with polytrauma.
- Strategies for the treatment and/or prevention of sepsis.
- Inflammation control, which the stakeholders considered critical during PFC, as unregulated systemic inflammation over multiple days contributes to mortality
 - Addressing hypermetabolic inflammation response in PFC scenarios through treatments or prevention.
 - Establishment of standards of care for inflammation control in PFC.
 - Mitigation of immune suppression and/or preventing infection during the inflammatory phase of burn injury.
 - Preliminary studies using biologics to alter inflammation.
 - Topical approaches that reduce inflammation and also increase wound closure and decrease scar formation.
- Other considerations:
 - Burns with concurrent polytrauma (i.e., traumatic brain injury [TBI], radiation exposure) will complicate every aspect of burn care and need more research; some also noted that these types of injuries can quickly overwhelm medical staff even with only a small number of patients.
 - Inhalation injuries remain a challenging problem in burn care and need strategies for PFC/POI management.
 - Resuscitation in PFC/POI scenario remains a challenge due to large amounts of fluid needed and other challenges; the group suggested the use of a powder versus fluid that could be more easily carried.
 - Long-term scarring could possibly be improved by intervention at this early stage.
 - Preparation for mass burn casualty events will require establishment of evidence-based standards of care for triage, stabilization, addressing polytrauma, resuscitation, and evacuation strategies.
 - Measuring efficacy of any treatment in an accurate, measurable, and quantitative way, especially when non-military populations are used (i.e., unhoused populations to study frostbite injuries)
 - Non-surgical debridement remains an important challenge in PFC/POI care in need of products and/or strategies to address situations where a burn surgeon is not available.

5B. Acute/Intensive Care Unit (ICU) Hospital Care (Subgroup 2)

The subgroup discussed their top concerns within acute/ ICU hospital care. The high-priority gaps include:

SUBJECT: FY22 MBRP Stakeholders Meeting

- Burns and Polytrauma, including burns not caused by heat/thermal
 - A need for multi-center studies to address military-relevant burns with polytrauma
 - Establishment of care guidelines including triage of multiple injuries within one casualty (i.e., burn and TBI, burn and inhalation injury, burn and radiation exposure).
- Infection Control, which could possibly be combined with inflammation control. Stakeholders also noted that many of these studies are difficult to conduct with civilian populations.
 - Need for diagnostic markers that could be an early indicator for infection.
 - Biomarkers for sepsis that could be quickly tested.
 - Studies needed for additional understanding of the balance between immune function and inflammation.
 - Need for an understanding of what currently used silver-based products are doing to the wound microbiome.
 - How early skin grafting impacts the wound microbiome.
 - Fungal infections can happen later in the course of the injury but are difficult to address.
- Inhalation Injuries were designated as a top gap for this group; however, some stakeholders felt that significant investment has been made in this topic without significant advancement. Some stakeholders felt that additional investment would not change outcomes and others felt that additional investment in this topic was needed.
 - Need for a uniform definition of inhalation injury and subsequent diagnostic criteria.
 - Strategies for diagnosis and treatment of various types of inhalation injuries (i.e., those associated with thermal burns versus those associated with chemical burns).
 - Accurate early diagnosis is critical and current strategies are lacking; secondary to this would be new treatment modalities that could intervene early.
 - Studies on what is in the patient's airway in the first 6 hours post-injury could be helpful in determining chemical exposure and toxin absorption.
- Burn Wound Closure
 - Importance of maintaining joint elasticity, especially in the hands, while addressing burn wound closure.
 - Establishing different strategies for burn wound closure within PFC hospitalization, which may require delayed grafting.
 - Functional skin grafts that have true skin barrier function, not just the physical appearance of skin.
 - Any cells used for closure need to perform barrier functions; the best strategy may be multiple layers and multiple types of cells.
 - Need for evidence-based clinical endpoints for patients on burn wound closure evaluation.

SUBJECT: FY22 MBRP Stakeholders Meeting

- Study of the skin microbiome that may be aiding in closure or causing delay.
- The whole body impact on burn wound closure (systemic inflammation, gut health).
- Inclusion of all elements of skin such as pigment, sweat glands, and hair follicles.
- Resuscitation, which stakeholders noted is currently performed with guidelines that are 50 years old and require large amounts of fluid for one patient
 - Prevention strategies that could be implemented to reduce need for resuscitation.
 - Need for low volume resuscitation.
 - Understanding the pathology of edema and ways to resuscitate that improve organ function.
 - Understanding the time and role of immunotherapies.
 - Establishing the role of prevention and prior determination of genetic response (i.e., Hunter Reflex).
 - Strategies for post-fluid resuscitation management.
 - New blood and blood products needed for resuscitation treatment options.
- Other considerations:
 - Strategies for burns other than those caused by heat/thermal when they reach hospital/ICU care.
 - Improved guidelines for polar medicine: treatments for frostbite and conducting care for burn injuries in cold climates.
 - Combat or field hospitals/ICUs lack the resources of a burn center and need fast, minimal resource strategies for all of these problems.
 - Inflammation control and how that relates to infection control, including sepsis within a hospital setting.
 - New, emerging weapons may cause burn injuries that will require new treatment and prevention strategies (i.e., microwave, lasers, directed energy).
 - Polytrauma is a significant concern, including whole body radiation exposure.
 - Determination of presence of burn wound conversion in humans.
 - Strategies for early interventions for psychological health in an acute care/ICU setting.
 - Strategies for pain management that are non-narcotic; stakeholders acknowledged that unmitigated pain and current narcotic medicines are associated with post-traumatic stress disorder (PTSD) and substance use disorder (SUD).
 - Stakeholders noted a large blind spot within research on mass burn casualty events, including the need for automation, faster and more automated resuscitation, best standard of care within limited resource and limited medical personnel environments.

5C. Subacute Burn Care/Rehabilitation (Subgroup 3)

The subgroup discussed their top concerns regarding subacute burn care and rehabilitation. The high-priority gaps include:

- Tissue regeneration and repair
 - Portable devices that can preserve skin elements.
 - Strategies for reduction in skin grafting by applying cells to the wound (possibly, cells from the patient to avoid rejection).
 - Devices and products that can be used in the field by non-medical personnel.
 - Muscle also needs to be regenerated.
- Novel and/or improved strategies of dressing
 - Need dressings that address inflammation and infection.
 - Big data approaches could be useful in evaluating new dressings along with a central data repository.
 - Real-time data-driven wound monitoring is needed.
 - Decrease the need for dressing changes; survivors note dressing changes as one of the most painful procedures.
- Burn wound closure and injury progression/conversion
 - Hypovolemia and Hypothermia are both still major issues.
 - Occurrence of secondary necrosis after a burn (burn wound progression or conversion) needs to be addressed with preventative therapeutics.
 - Establishing the optimal cell source for burn wound closure cell therapies.
 - Wound coverings that preserve dermal elements.
 - Alternatives to surgical debridement are needed.
 - Translation of preclinical research findings to humans is not always accurate.
- Infection and Inflammation Control
 - Early field-based measures to prevent infection are needed.
 - Topical treatments for infection and inflammation need to be evaluated for systemic effects.
 - Topical applications need to be usable by non-medical personnel and applied early.
 - Treatments that address many types of bacterial infections are needed.
- Rehabilitation/Clinical Care (emphasizing mobility and exercise); the stakeholders renamed this gap to reflect a more comprehensive view of this stage of care.
 - Strategies are needed for prevention of limited mobility.
 - Prevention of tissue fibrosis and inappropriate bone growth are needed.

SUBJECT: FY22 MBRP Stakeholders Meeting

- Dressings need to allow for early mobility in rehabilitation.
- Mobility, exercise, and range of motion need to be emphasized early in rehabilitation to prevent contractures, especially with hands.
- Other considerations:
 - Transitions to different phases of care need additional attention and are often challenging for the patient mentally and physically.
 - Psychological health and pain were both initially selected as a top gap in this group, but were outside the top five upon a vote in the second breakout session.
 - Pain in burn patients is multi-faceted and can be from nerve pain, blood vessels, contractures; strategies for pain management should address the various causes.
 - Concerns over lack of data with burns not caused by heat thermal.
 - Best practices need to be established for treatment of polytrauma, especially when that delays treatment of the burn.
 - Need for a large-scale database of patient characteristics for all of those who enter a burn center.

5D. Long-Term Challenges (Subgroup 4)

The subgroup discussed their top concerns regarding long-term challenges in burn care. The high priority gaps include:

- Behavioral Health, Functional Recovery, and Holistic Well-being, a more comprehensive category replacing the original Psychological Health
 - Strategies for improved motivation and adherence to long-term treatment regimens.
 - Transitions were identified as a significant challenge in the continuum of care; burn survivors indicated that leaving a burn center was the time they were most at risk for Behavioral Health concerns and they felt vastly underprepared for return to their homes and lives.
 - Strategies for cognitive recovery.
 - Inclusion of psychological well-being in rehabilitation, not just the focus on physical recovery.
 - A need for social skills training, help navigating social situations, and help with body image concerns so that survivors do not feel they have to isolate.
 - Survivors discharged to rural environments may not be able to easily access care at a U.S. Department of Veterans Affairs (VA) Medical Center and there are significant barriers to treatment.
 - Care delivery strategies so that survivors can be treated in their homes versus traveling are needed.
 - Facial injuries can be challenging at this stage.

SUBJECT: FY22 MBRP Stakeholders Meeting

- A strong need for a sense of community and family once discharged from a burn center; burn survivors indicated they felt a sense of loss when they left a burn care community such as USAISR.
- Concerns over loss of identity if they cannot return to duty.
- Need for early management of delirium.
- Functional Skin and Scar Prevention/Treatment
 - Prevention of severe scarring could drastically improve quality of life concerns.
 - Focus on early care of skin and scarring but minimal investment in long-term skin concerns.
 - Need for innovative medical devices to remold scarred tissues.
 - Scarring mechanisms of facial skin are a significant challenge and need to be evaluated separately from information about trunk and extremity skin.
 - Functional skin that includes hair follicles and sweat glands and that can regulate temperatures would improve long-term outcomes for survivors.
 - Considerations for cellular therapies include their reliance on the viable tissues left behind post-injury and that some stem cell treatments do not engraft and therefore will have a temporary effect.
- Pain/Neuropathic Pain/Itch, a category the stakeholders suggest renaming to encompass the multi-faceted pain that survivors experience
 - Alternatives to opioid medications are critical because of addiction as well as functional impairment from opioids.
 - Non-pharmacological interventions need to be tested and evaluated (i.e., laser therapy).
 - Itching can be so severe that patients cannot differentiate it from acute pain.
 - Novel treatments in this area are a critical need.
- Clinical Care, Rehabilitation
 - Motivation and support throughout rehabilitation is necessary.
 - Pharmacology, environment analysis, and diet/nutrition should all be part of a comprehensive rehabilitation process.
 - Survivors spend the most amount of time in the rehabilitation and/or long-term outcomes stage but there is little emphasis on it.
 - Transitions of care, especially when leaving a burn center, are a huge challenge for survivors. Survivors note feeling cared for at burn centers and then extremely isolated, alone, and abandoned once they return home.
 - Lack of trained burn care providers in the survivor's home area represents a significant need for every type of provider (internal medicine, pain management, mental health).
 - Veterans have significant barriers to care, and burn care provider stakeholders indicated that many patients in this category are not heard from at all post-discharge.

SUBJECT: FY22 MBRP Stakeholders Meeting

- Burns and Polytrauma
 - Lack of evidence-based information on long-term sequelae from these injuries (i.e., amputations and TBI along with a burn injury).
 - Burns are evaluated in clinical study as a separate event, which creates a huge knowledge gap.
 - Stakeholders felt that central nervous system impacts of burn injuries with polytrauma, including pain agitation, hypoxemia, delirium, and long-term cognitive function are not well studied.
 - Need for useful ways to quantify the severity of injury.
- Other considerations:
 - Lack of information about aging burn survivor populations.
 - Lack of medical staff outside of burn centers with expertise in this area creates fragmented, ineffective long-term care where the survivor lives.
 - Scarring and pain are the primary challenges noted by burn survivors.
 - Transplants without help for psychosocial impacts leads to poor outcomes.
 - Fixing a scar does not change other factors like neuropathy, inhalation injuries, and painful contractures that delay return to Service or regular life activities.
 - Nutrition is an area of need for patients to maintain weight, muscle, and bone health, all of which affect quality of life.
 - Long-term impacts need to be considered in studies of any intervention at an earlier continuum stage; as an example, stakeholders indicated that many burn wound closure studies only used 30-day wound closure as the clinical endpoint.
 - Chronic reopening of wounds is an issue.
 - Contractures remain a significant challenge related to pain and functional mobility; stakeholders expressed the need for reversing contractures via cell turnover or reprogramming fibroblasts.

6. Adjournment

Ms. Snyder described how gaps identified during the stakeholder meeting will be used to inform MBRP investment strategy discussions and strategic planning discussions and will be shared with internal and external collaborators. She also noted that outcomes of the meeting would be posted on the CDMRP webpage for public dissemination. Ms. Snyder thanked the participants for their time and careful consideration of the gaps to be addressed by the MBRP.

SUBJECT: FY22 MBRP Stakeholders Meeting

Appendix A: Meeting Attendees

The following individuals were present for the video conference:

Invited Speakers

Dr. Leopoldo Cancio	USAISR
Dr. Kai Leung	USAISR
Dr. Bonnie Woffenden	CCCRP/JPC-6

Invited Stakeholders

Dr. Ronald Acierno	University of Texas Health Sciences
Ms. Amy Acton	Phoenix Society for Burn Survivors
Dr. Aftab Ahmad	University of Alabama at Birmingham
Dr. Bhagwat Alapure	Louisiana State University Health Sciences Center New Orleans
Dr. Praveen Arany	University of Buffalo
Dr. Evangelos Badiavas	University of Miami, Aegle Therapeutics Corp.
Dr. Austin Baird	University of Washington
Dr. Sigrid Blome-Eberwein	Lehigh Valley Health Network
Dr. Lorena Braid	Aurora Biosolutions, Inc.
Mr. Thomas Brett	University of Virginia
Dr. Eric Brown	Synmedix, Inc.
Dr. David Burmeister	Uniformed Services University of the Health Sciences (USU)
Dr. Leopoldo Cancio	USAISR
Dr. Jill Cancio	USAISR
Dr. Sylvain Cardin	Naval Medical Research Unit (NAMRU), San Antonio
Dr. Anders Carlsson	USAISR/The Metis Foundation
Dr. Jeffrey Carter	Louisiana State University, Health Sciences Center
Dr. Lourdes Castanon	University of Arizona
Dr. Curtis Cetrulo	Massachusetts General Hospital/Harvard Medical School
Dr. Donna Chang	Hope Biosciences
Dr. Chris Chao	National Institute of General Medical Sciences (NIGMS)
Ms. Elizabeth Chipriano	The Joint Program Committee-2/Military Infectious Diseases Research Program (JPC-2/MIDRP)
Dr. Mashkoor A. Choudhry	Loyola University Chicago
Dr. Richard A. Clark	Neomatrix Therapeutics, Inc.
Dr. Keith Cook	Carnegie Mellon University
Dr. David Herndon	Joseph M. Still Research Foundation
Dr. Ross Donaldson	Critical Innovations, LLC
Dr. Melanie Doyle-Eisele	Lovelace Biomedical
Dr. John Elfar	Pennsylvania State University
Dr. Alan Epstein	CCCRP/JPC-6
Dr. Fateme Fayyazbakhsh	Missouri University of Science and Technology
Dr. Michael Feldman	Virginia Commonwealth University

SUBJECT: FY22 MBRP Stakeholders Meeting

Dr. Celeste Finnerty	University of Texas, Medical Branch
Dr. Alberto Forcella Jr.	MBET Health, LLC
Dr. Sheldon Garrison	Rogers Behavioral Health
Dr. Luis Garza	Johns Hopkins School of Medicine
Dr. Aarti Gautam	Walter Reed Army Institute of Research (WRAIR)
Dr. Colleen Gibney	U.S. Army Medical Research and Development Command/Small Business Innovation Research (SBIR) Office
Dr. Nicole Gibran	University of Washington
Dr. Angela Gibson	University of Wisconsin, School of Medicine and Public Health
Dr. Jacob Glaser	NAMRU, San Antonio
Dr. Kerriann R. Greenhalgh	Kericure Medical
Dr. Bronwyn Griffin	Griffith University
Dr. Jianjun Guan	Washington University in St. Louis
Dr. Geoffrey Gurtner	Stanford University
Dr. Jin-Oh Hahn	University of Maryland
Dr. Saher Hamed	Remedor Biomed, Ltd.
Dr. David Harrington	Brown Surgical Associates
Dr. Mark Hemmila	University of Michigan
Dr. Rhonda Holgate	Houston Methodist Hospital
Dr. James H. Holmes IV	Atrium Health Wake Forest Baptist Burn Center/The ABA Burn Research Network
Dr. Seok Jong Hong	Northwestern University
Dr. Suresh G. Joshi	Drexel University
Dr. Karen Kowalske	University of Texas Southwestern, Parkland
Dr. John Kubasiak	Loyola University Medical Center
Dr. Alexandra Lacey	Regions Hospital Burn Unit
Dr. James A. Lederer	Brigham and Women's Hospital, Harvard Medical School
Dr. Kai Leung	USAISR
Dr. Jakkarin Limwongyut	University of California, Santa Barbara/National University of Singapore
Ms. Kristin Jones Maia	U.S. Army Medical Materiel Development Activity (USAMMDA)
Dr. Luis Martinez	NAMRU, San Antonio
Dr. Sanjeev K. Mathur	NAMRU, Dayton
Dr. Bryan McCranor	United States Army Medical Research Institute of Chemical Defense (USAMRICD)
Dr. Mehdi Mirsaeidi	University of Florida
Dr. Lauren Moffatt	MedStar Washington Hospital Center
Dr. Nyssa Morgan	Georgia Institute of Technology
Dr. Rachel M. Nygaard	Hennepin Healthcare
Ms. Lori Palfalvi	American Burn Association
Dr. Tina L. Palmieri	University of California, Davis
Dr. Ingrid Parry	University of California, Davis

SUBJECT: FY22 MBRP Stakeholders Meeting

Dr. Shaurya Prakash	The Ohio State University
Dr. Jagadeesha Prasad	Pennsylvania State University
Dr. Anthony Pusateri	USAISR
Dr. Laurence Rahme	Massachusetts General Hospital, Harvard Medical School
Dr. Joseph F. Rappold	Maine Medical Center
Dr. Vivek Raut	Organogenesis Holdings, Inc.
Ms. Andrea Renner	SBIR Office
Dr. Julee Rendon	Johns Hopkins University
Dr. Paul Robben	WRAIR
Dr. Evan Ross	USAISR
Dr. Chad J. Roy	Tulane University School of Medicine
Dr. V. Sujith Sajja	WRAIR
Dr. Miyuki Sakuma	Massachusetts General Hospital
Dr. Alisa Savetamal	Bridgeport Hospital
Dr. Carl Schulman	University of Miami
Dr. Chandan K. Sen	Indiana University School of Medicine
Dr. Linda Sousse	University of Texas Health Science Center
Dr. Wesley Thayer	Vanderbilt University Medical Centre
COL Stuart Tyner	JPC-2/MIDRP
Dr. Evelina Vågesjö	Ilya Pharma
Dr. Haitao Wang	Mayo Clinic
Mr. James West	SAIC, PEO Aviation Fixed Wings
Dr. Kenneth Wilson	University of Chicago
Dr. Bonnie Woffenden	JPC-6/CCCRP
Dr. Steven Wolf	University of Texas Medical Branch
Dr. James K. Wright	University of Alabama at Birmingham
Dr. Peter Yen	Burn and Reconstructive Centers of America
Dr. Yuanyuan Zhang	Wake Forest Institute for Regenerative Medicine

Government Observers

Ms. Sandy Snyder	Program Manager, MBRP, CDMRP
Dr. Gayle Vaday	Civilian Deputy Director, CDMRP
Dr. Rebecca Fisher	Deputy Director for Program Management, CDMRP
Dr. Kristy Lidie	Deputy Director for Program Management, CDMRP
Dr. Melissa Tursiella	Program Manager, CDMRP
Dr. Ray Santullo	Program Manager, CDMRP
Dr. Robin Walker	Science Officer, Goldbelt

Leidos Support Contractors

Ms. Bethany Orlando	Task Order Manager
Ms. Allison Poore	Scientific Manager, MBRP
Ms. Mariah Baldwin	Biomedical Life Scientist
Ms. Alexandria Bakke	Biomedical Life Scientist
Ms. Caitlyn Barnes	Biomedical Life Scientist
Ms. Sydney Bentz	Biomedical Life Scientist

SUBJECT: FY22 MBRP Stakeholders Meeting

Ms. Angela Braunschweiger	Biomedical Life Scientist
Ms. Cynthia Chiang	Database Administrator
Ms. Maggie Defreytas	Biomedical Life Scientist
Ms. Veronica Doxey	Biomedical Life Scientist
Dr. Cindy Estremera Gauthier	Facilitator, Strategy Arts
Ms. Christina George	Biomedical Life Scientist
Ms. Elizabeth Guman	Facilitator, Strategy Arts
Mr. William Huggins	Facilitator, Strategy Arts
Dr. Janet Hsu	Biomedical Life Scientist
Ms. Adeola Olufunmilade	Biomedical Life Scientist
Ms. Caroline Rocourt	Biomedical Life Scientist
Mr. Scott Wheeler	Facilitator, Strategy Arts

SUBJECT: FY22 MBRP Stakeholders Meeting

Enclosure 1
Overview of the CDMRP and MBRP

Welcome

Welcome to the FY22 Military Burn Research Program (MBRP) Stakeholders Meeting!

The meeting will begin promptly at 9am ET

During the meeting:

- Please update your name in Zoom using your full name
- ***Please mute your audio unless you are speaking.*** Please state your name before speaking.
- Please stay connected through breaks and lunch to avoid any technical issues.
- Please use the chat pod within Zoom if you are having any technical issues and Leidos staff will assist you.

Congressionally Directed Medical Research Programs

Military Burn Research Program (MBRP) 2022 Stakeholders Meeting Briefing

CUTTING EDGE RESEARCH

Sandy Snyder, MSN, RN, CCRN-K
Program Manager



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CDMRP 
Department of Defense

27 September 2021

Moment of Silence

Moment of Silence
Ms. Kristin Jones Maia

Meeting Overview and Objectives

Mr. Scott Wheeler (Strategy Arts)

Stakeholder Meeting Agenda

8:45 – 9:00 a.m.	Log in and Registration	All Participants
9:00 – 9:15 a.m.	Welcome and Introductions	Ms. Sandy Snyder
9:15 – 9:20 a.m.	Moment of Silence	Ms. Kristin Jones Maia
9:20 – 9:25 a.m.	Meeting Overview and Objectives	Mr. Scott Wheeler
9:25 – 9:30 a.m.	Leidos Administrative Remarks	Ms. Allison Poore
9:30 – 10:00 a.m.	Overview of the CDMRP and MBRP	Ms. Sandy Snyder
10:00 – 10:10 a.m.	Overview of the Combat Casualty Care Research Program	Dr. Therese West or MAJ Elaine Por
10:10 – 10:20 a.m.	Overview of the U.S. Army Institute of Surgical Research	Dr. Kai Leung and Dr. Leopoldo Cancio
10:20 – 10:30 a.m.	Breakout Session Guidelines and Outcomes	Mr. Scott Wheeler
10:30 – 10:45 a.m.	<i>Break</i>	All Participants

Stakeholder Meeting Agenda

Breakout Session 1: Gaps Identification (1.75 hours)

10:45 a.m. – 12:30 p.m.

Breakout Session 1.1:
Emergency/Point of Injury/Field Care Subgroup 1

Breakout Session 1.2:
Acute/ICU Hospital Care Subgroup 2

Breakout Session 1.3:
Subacute Burn Care/Rehabilitation Subgroup 3

Breakout Session 1.4:
Long-Term Challenges Subgroup 4

12:30 – 1:30 p.m.

Lunch All Participants

Main Session Discussion of Identified Gaps (1.25 hours)

1:30 – 2:45 p.m.

Discussion All Participants

2:45 – 3:00 p.m.

Break All Participants

Breakout Session 2: Gaps Prioritization (1.5 hours)

3:00 – 4:30 p.m.

Breakout Session 2.1:
Emergency/Point of Injury/Field Care Subgroup 1

Breakout Session 2.2:
Acute/ICU Hospital Care Subgroup 2

Breakout Session 2.3:
Subacute Burn Care/Rehabilitation Subgroup 3

Breakout Session 2.4:
Long-Term Challenges Subgroup 4

4:30 – 4:45 p.m.

Out Brief and Next Steps Ms. Sandy Snyder

4:45 p.m.

Adjourn All Participants

Guidelines for Discussion

- ◆ Everyone participate; no one dominate
- ◆ Listen to understand; all ideas are valid
- ◆ Share your unique perspective
- ◆ Disagree without being disagreeable; Use “I” statements
- ◆ Critique ideas, not people
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Tips for Teleconferences/Virtual Meetings

- ◆ Participate 100%
- ◆ Introduce yourself prior to speaking
- ◆ Use mute when not speaking
- ◆ Utilize chat for technical support

Leidos Administrative Remarks

Ms. Allison Poore

- ◆ **Attendees of today's meeting are not precluded from applying to the MBRP's FY22 Funding Opportunities**
- ◆ **During the meeting:**
 - **Please update your name in Zoom using your full name**
 - ***Please mute your audio unless you are speaking. Please state your name before speaking.***
 - **Please stay connected through breaks and lunch to avoid any technical issues.**
 - **Please use the chat pod within Zoom if you are having any technical issues and Leidos staff will assist you.**

Overview of the CDMRP and MBRP

Ms. Sandy Snyder, Program Manager

Outline

- ◆ Meeting Objectives
- ◆ Overview of the CDMRP
- ◆ MBRP History, Funding, and Portfolio
- ◆ Other organizations with Burn-related Portfolios
- ◆ Review Stakeholders Book and Data Collection Instrument (DCI)
- ◆ Breakout group discussions
- ◆ Outcomes
- ◆ Next Steps

Stakeholders Meeting

◆ Purpose and Intent

- **A stakeholder is a person or group who has an interest – vested or otherwise – in an enterprise and whose support is required in order for an enterprise to be successful**
<http://searchcio.techtarget.com/definition/stakeholder>
- **Experts from different subject areas are brought together to pinpoint the knowledge gaps, discuss the landscape of burn research, identify the outcomes and needs for the military and civilian burn care community, and recommend a way forward**
- **Account for various voices and opinions to refine a research program focused on improving care and options for patients who sustain traumatic burn injuries**



Objectives

◆ State of the Science/Patient Care

- ◆ Understand the needs of the burn care community
- ◆ Reflect on the common ground between military and civilian burn care needs (mass casualty scenarios, disasters, remote access, etc.)
- ◆ Discuss current funding landscape
- ◆ Identify knowledge gaps
 - ❖ Key challenges and themes
 - ❖ Military and civilian considerations
 - ❖ Current research capabilities
 - ❖ Needs of the patient and clinical care teams
- ◆ Account for stage of science
 - ❖ Gaps along the research continuum

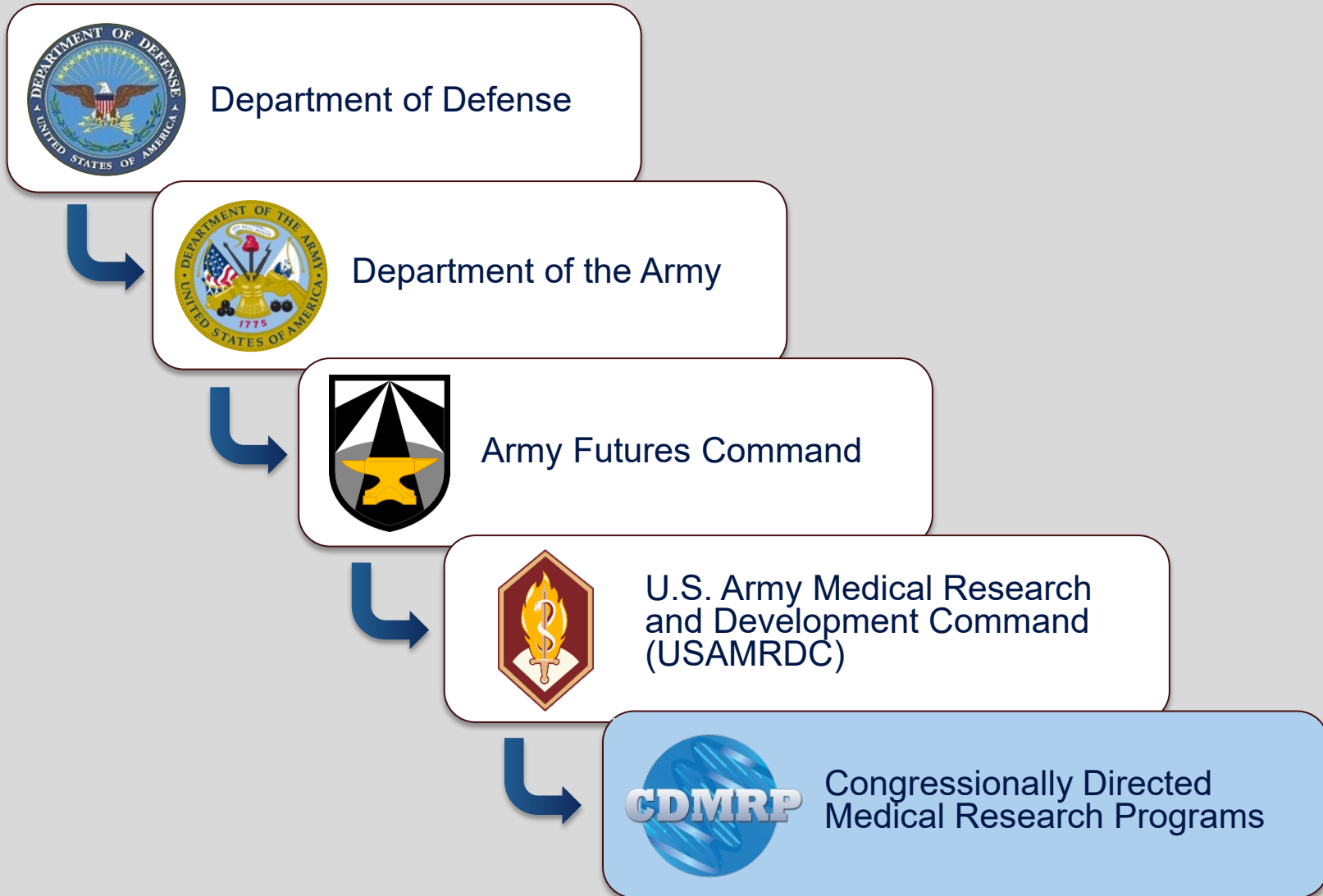
◆ Outcome

- ◆ Inform future MBRP research funding investment discussions
- ◆ Incorporated into MBRP Strategic Plan



Overview of the CDMRP

WHO is the CDMRP?



About CDMRP

DIRECTOR
COL Sarah Goldman

◆ CONGRESSIONAL PROGRAMS

- ❖ Manages extramural research programs directed by Congress
- ❖ Started in 1992 with a focus on breast cancer research; currently includes over 30 research programs
- ❖ Congress specifies the focus area; the CDMRP determines research strategy and competitively selects the best projects
- ❖ Unique public/private partnership encompasses the military, scientists, disease survivors, consumers, and policy makers
- ❖ Funds high-impact, innovative medical research to find cures, reduce the incidence of disease and injury, improve survival, and enhance the quality of life for those affected

◆ DOD PROGRAMS

- ❖ Provides support to Program Area Directorates (PADs)/Joint Program Committees (JPCs) for managing extramural and intramural research portfolios to advance their missions



CDMRP Vision and Mission

Vision

**Transform healthcare for
Service Members and the
American public
through innovative and
impactful research**

FUNDING GROUNDBREAKING, HIGH-IMPACT RESEARCH

Mission

**Responsibly manage collaborative
research that discovers, develops,
and delivers health care solutions
for Service Members, Veterans and
the American public**

CDMRP FY22 Appropriations

Research Program	FY22 \$M
Alcohol and Substance Abuse Disorders	\$4.0
Amyotrophic Lateral Sclerosis	\$40.0
Autism	\$15.0
Bone Marrow Failure	\$7.5
Breast Cancer	\$150.0
Chronic Pain Management	\$15.0
Combat Readiness Medical	\$10.0
Duchenne Muscular Dystrophy	\$10.0
Epilepsy	\$12.0
Hearing Restoration	\$10.0
Joint Warfighter Medical	\$40.0
Kidney Cancer	\$50.0
Lung Cancer	\$20.0
Lupus	\$10.0
Melanoma	\$40.0
Military Burn	\$10.0
Multiple Sclerosis	\$20.0
Neurofibromatosis	\$20.0

Research Program	FY22 \$M
Orthotics and Prosthetics Outcomes	\$20.0
Ovarian Cancer	\$45.0
Pancreatic Cancer	\$15.0
Parkinson's	\$16.0
Peer Reviewed Alzheimer's	\$15.0
Peer Reviewed Cancer (20 Topics)	\$130.0
Peer Reviewed Medical (50 Topics)	\$370.0
Peer Reviewed Orthopaedic	\$30.0
Prostate Cancer	\$110.0
Rare Cancers	\$17.5
Reconstructive Transplant	\$12.0
Spinal Cord Injury	\$40.0
Tick-Borne Disease	\$7.0
Toxic Exposures	\$30.0
Traumatic Brain Injury and Psychological Health	\$175.0
Tuberous Sclerosis Complex	\$8.0
Vision	\$20.0

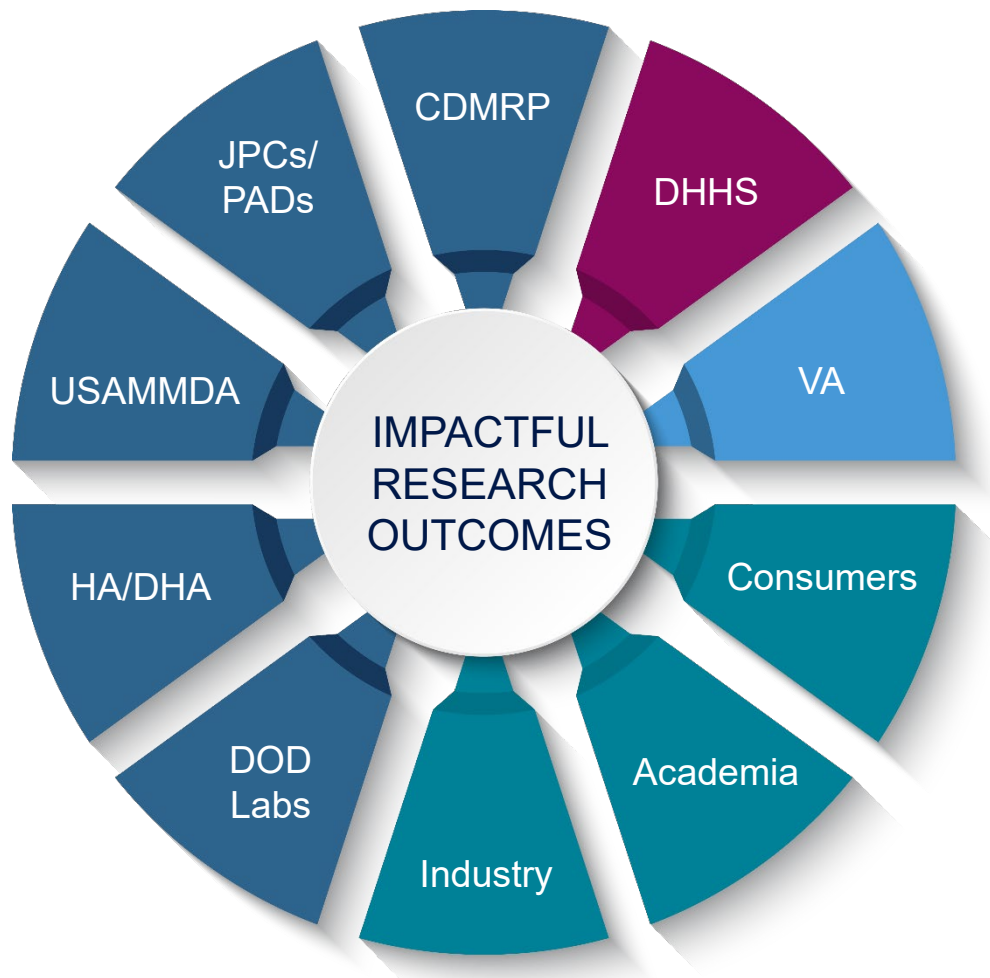
TOTAL = \$1.544B

CDMRP Hallmarks



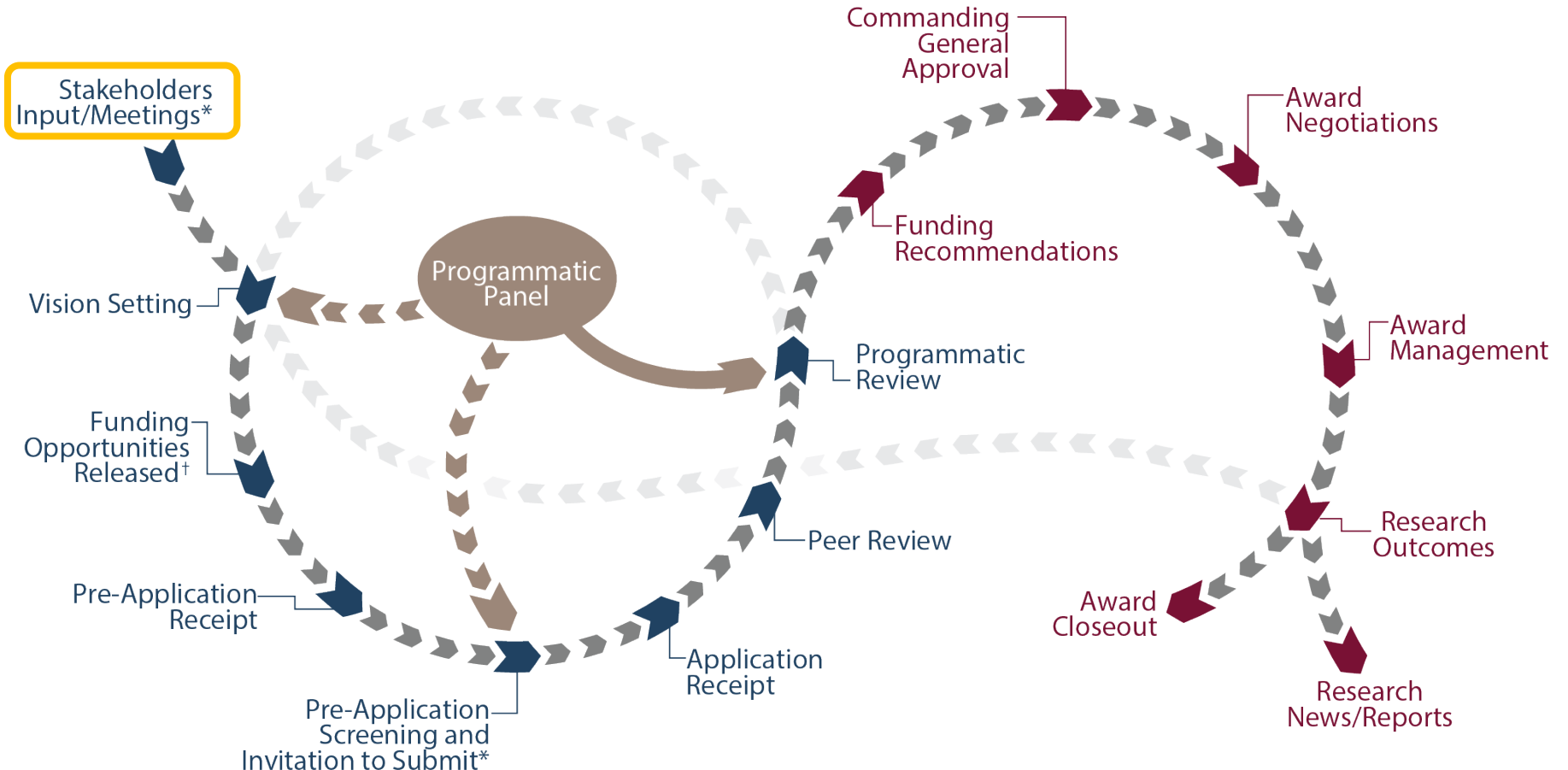
- ◆ Congress adds targeted research funds to the DOD budget
- ◆ Funds high-impact innovative research
- ◆ Avoids duplication with other funding agencies and targets unfunded/unmet gaps
- ◆ Follows the National Academy of Medicine-recommended model for application review
- ◆ Consumers participate throughout the process and are the “True North” and foundation of the programs
- ◆ Annually adapts each program’s vision and investment strategy allowing rapid response to changing needs
- ◆ Funding flexibility
 - ❖ Funds obligated up-front; limited out-year budget commitments
 - ❖ No continuation funding
 - ❖ No “pay line” – funding recommendations are based on portfolio composition, adherence to mechanism intent, relative impact, and technical merit
- ◆ Transparency and accountability to stakeholders
- ◆ Low management costs maximize research dollars

Major Partners and Collaborations



- ◆ Strategic input and planning
 - ❖ 58 from DHHS (NIH, CDC, FDA, BARDA, etc.) and 29 from VA on programmatic and other panels across CDMRP
 - ❖ Coordinated funding
- ◆ Research performers
 - ❖ Both extramural and intramural
 - ❖ Consumer inclusion
- ◆ Research and technology transitions
 - ❖ Next phase of research or development – commercial or federal
- ◆ Implementation and dissemination

CDMRP Program Cycle



*As needed

†Pending Congressional appropriation

MBRP History, Funding, and Portfolio

FY22 MBRP Vision and Mission

Vision Statement

Deliver the best burn trauma care to improve health and performance outcomes in support of the Warfighter

Mission Statement

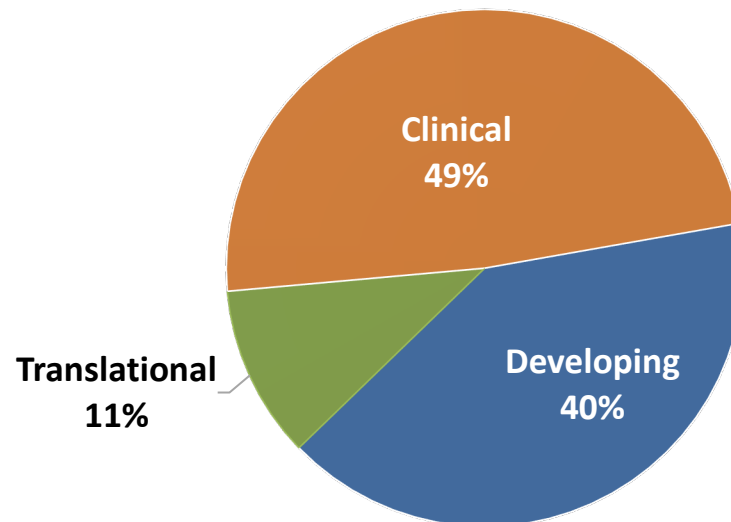
Identify and address gaps in burn trauma care through military focused research

The Role of the MBRP

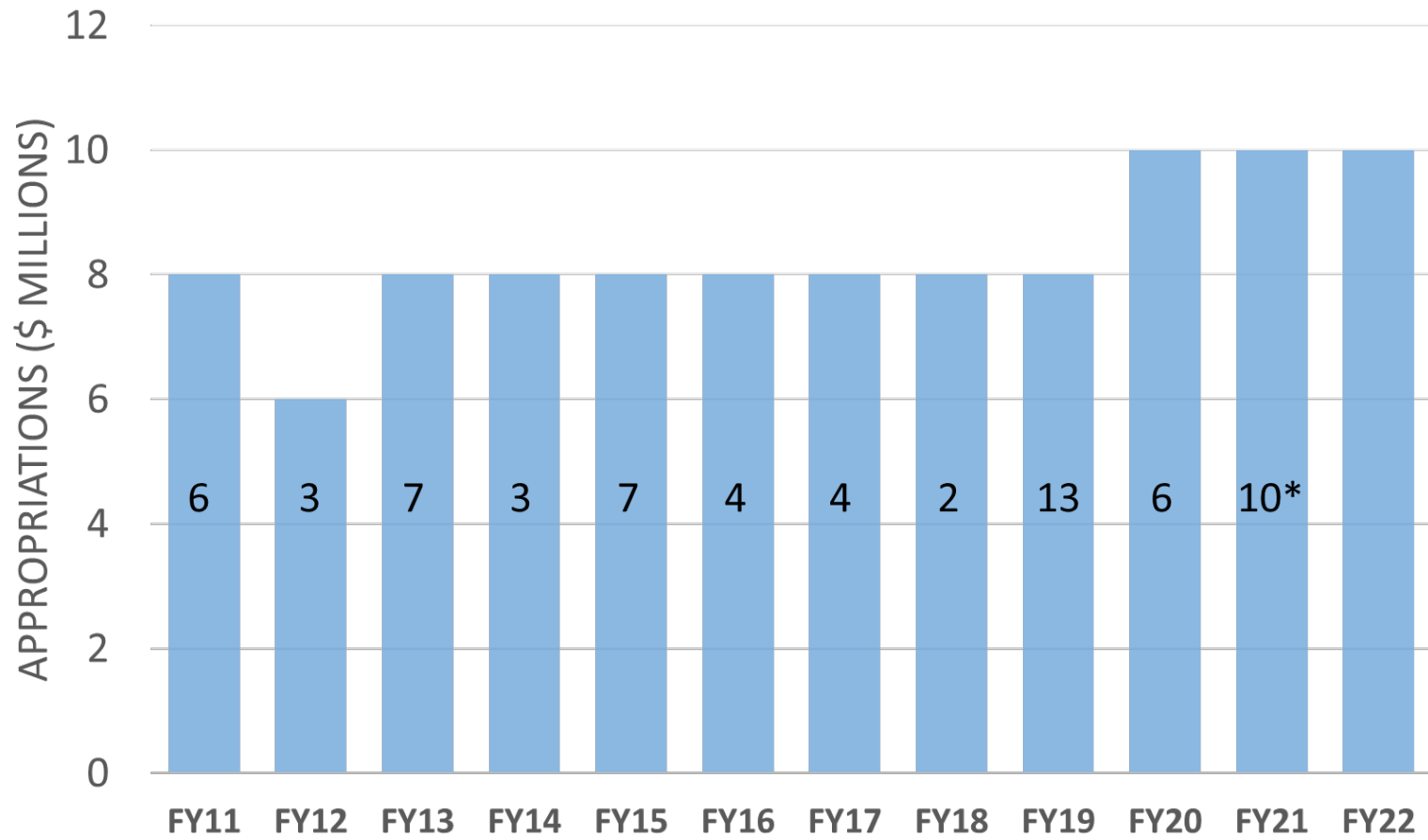
- ◆ High risk/high gain projects
- ◆ Develop the field for collaborative burn trauma research
- ◆ Fund translational research to move the field forward
- ◆ Fund clinical trials to move interventions into the clinic
- ◆ Provide the clinical evidence to impact clinical care



FY11-FY20

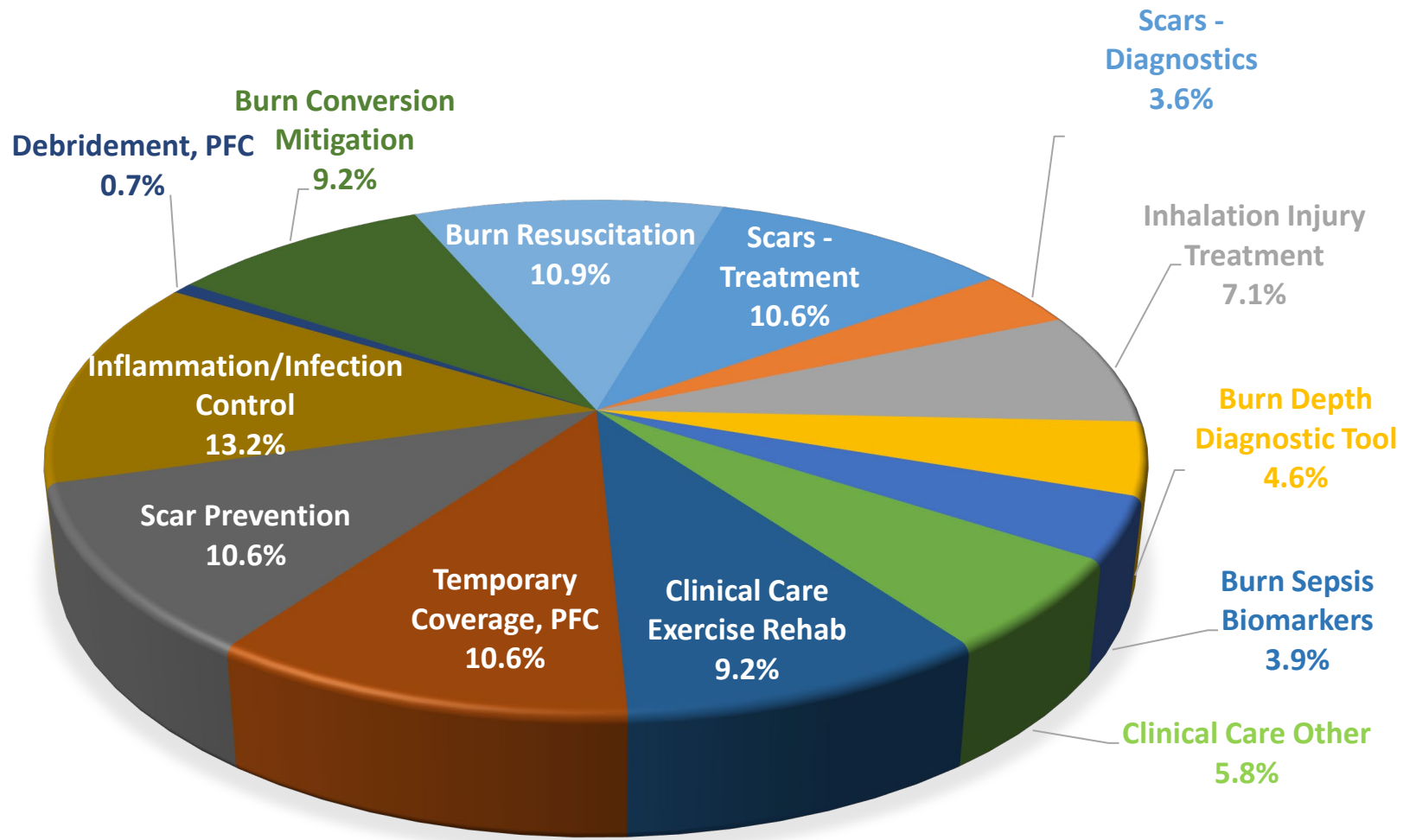


MBRP Funding History



- Total Congressional appropriations (FY11-FY22): \$100M
- Total Awards made (through FY20): 55
- *FY21 Awards under negotiation: 10

MBRP FY11-FY20* Portfolio, by topic



*FY21 awards are currently under negotiation.

Consumer and Advocate Involvement

- ◆ **American Burn Association (ABA)** - dedicate their efforts and resources to promoting and supporting burn-related research, education, care, rehabilitation, and prevention.
- ◆ **Phoenix Society for Burn Survivors** - serves burn survivors, loved ones, burn care professionals, researchers, and anyone else committed to empowering the burn community and building a safer world.
- ◆ **Consumer reviewers for MBRP** - burn survivors, caretakers, clinicians, rehabilitation professionals participate at both stages of application evaluation: peer and programmatic review. Consumer reviewers are full voting members of all panels and an essential part of the CDMRP process.

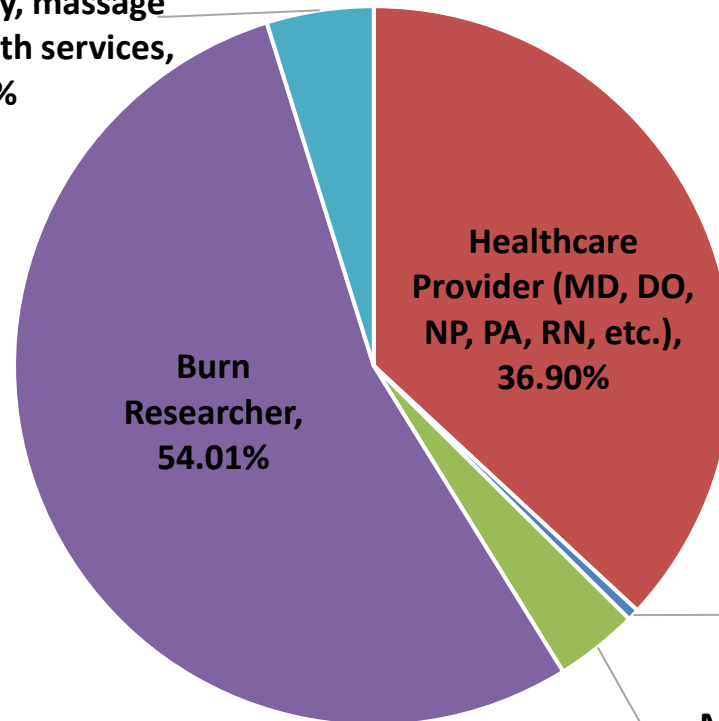
Review Stakeholders Book and Data Collection Instrument (DCI) results

MBRP Data Collection Instrument (DCI)

- ◆ MBRP posed 5 questions to Stakeholders via Survey Monkey about capability gaps and challenges along the burn care continuum
- ◆ Results were analyzed and summarized by MBRP staff and ended with a list of potential capability gaps
- ◆ Potential gaps generated from the DCI data *do not* represent an exhaustive list or the opinions of all Stakeholders, but serve as a starting point for today's live discussion

DCI Results – In Brief

**Ancillary Healthcare Provider
(e.g. physical therapy,
occupational therapy, massage
therapy, mental health services,
etc.), 4.81%**

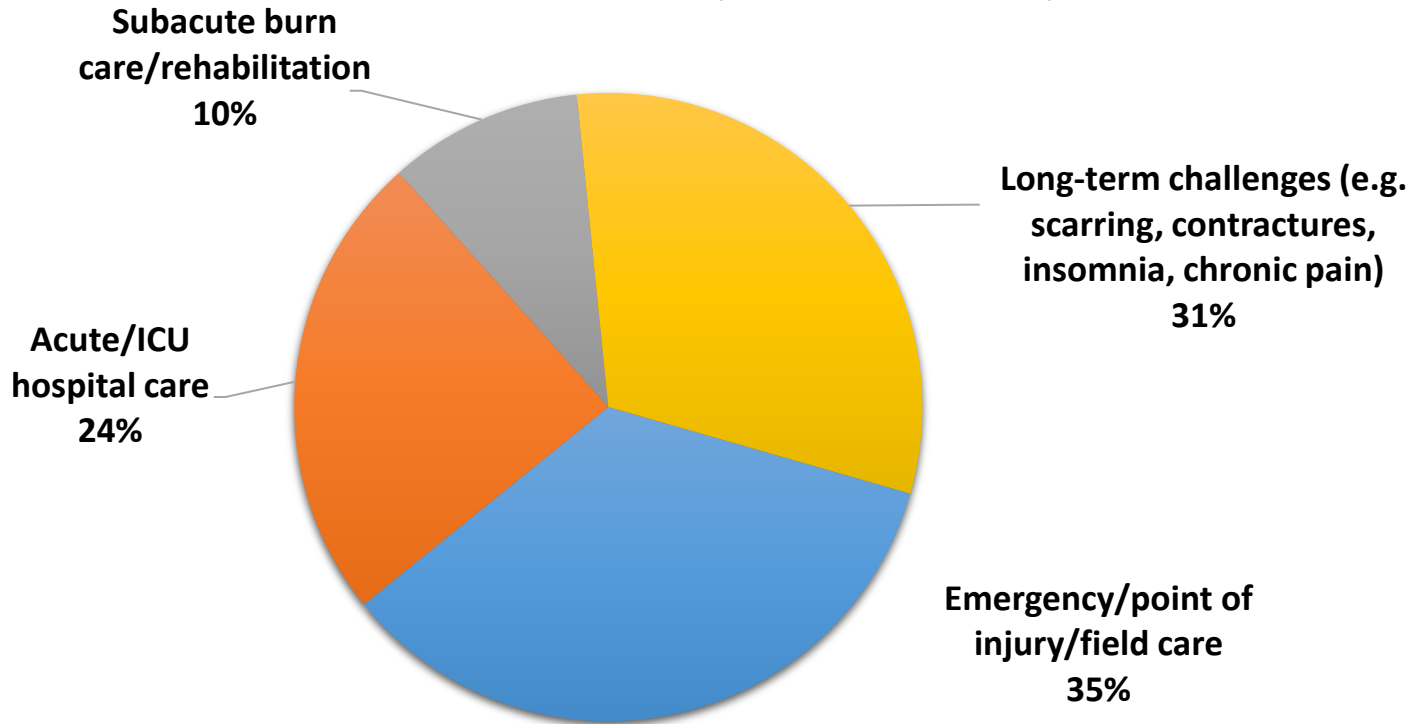


**Burn survivor/or
family member of
burn
survivor/advocate,
0.53%**

Military Expert, 3.74%

DCI Results – In Brief

Question 1: Which of the following areas along the burn care continuum need more research investment and, if funded, could make a significant impact on military/combat-relevant burn injuries and clinical outcomes? (Please choose one):



DCI Results – In Brief

Question 2. What are the top three knowledge or capability gaps, outcomes, or product needs within the burn care continuum category you selected for Question 1?

Inflammation Control

Scar Prevention/Treatment

Infection Control Burn Wound Conversion

Tissue Regeneration/Repair

Burns and Polytrauma **PFC/POI Care**

Resuscitation

Improved/Novel Treatments

Clinical Care, Other

The top 10 capability gaps, outcomes, or product needs identified by respondents to the MBRP DCI. Text size is directly proportional to number of mentions, with PFC/POI care receiving the most at 56 responses. Each response could be counted in no more than two categories.

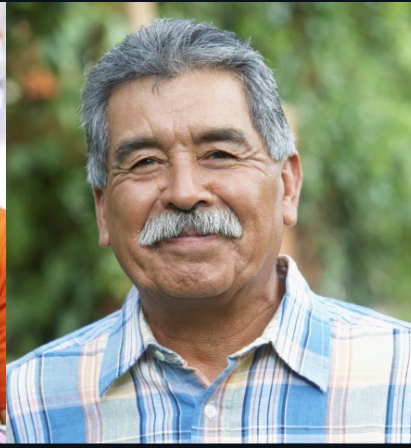
DCI Results – In Brief

Question 3. What do you perceive to be the biggest challenge in caring for burn patients?

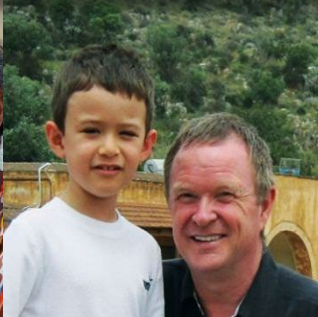


The biggest challenges in caring for burn patients, as identified by respondents to the MBRP DCI. All challenges with more than 5 responses were included in this word cloud analysis. Text size is directly proportional to the number of responses related to this category. Responses were counted in no more than two categories.

For your Service and Participation

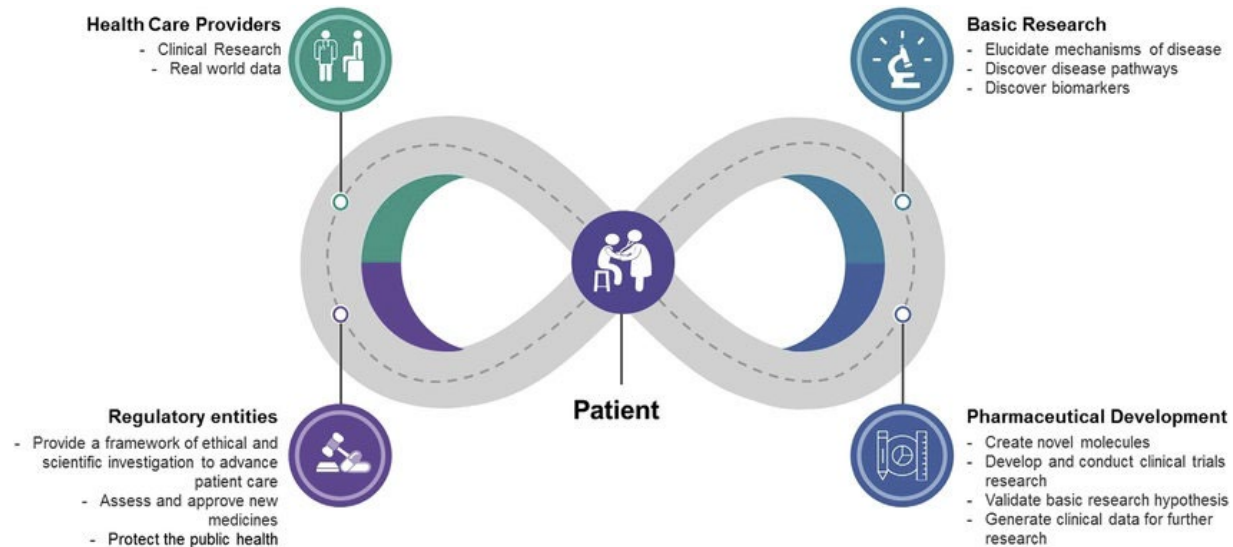


Thank you



◆ FINAL THOUGHTS

- ❖ MBRP has historically focused on the early care of burn injured casualties
- ❖ All phases of care are interconnected
- ❖ All subgroup topics are relevant to the care of burn injured casualties
- ❖ Think about how treatments/interventions during early phase of care can impact outcomes later (EX: early antifibrotic therapy may reduce severe scarring)



Breakout Groups – Guidelines for Discussion

Mr. Scott Wheeler

Guidelines for Discussion

- ◆ Everyone participate; no one dominate
- ◆ Listen to understand; all ideas are valid
- ◆ Share your unique perspective
- ◆ Disagree without being disagreeable; Use “I” statements
- ◆ Critique ideas, not people
- ◆ Respect each other’s thinking and value their contributions
- ◆ Treat everything you hear as an opportunity to learn and grow
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Breakout Sessions by Topic Area

Breakout Session Discussion Facilitator	Topic Area
Breakout Session 1 Mr. Scott Wheeler	Emergency/Point of Injury (POI)/ Field Care
Breakout Session 2 Ms. Elizabeth Guman	Acute/ICU Hospital Care
Breakout Session 3 Mr. Bill Huggins	Subacute Burn Care/Rehabilitation
Breakout Session 4 Dr. Cynthia Estremera Gauthier	Long-term challenges

Meeting Outcomes

Next Steps

- ◆ **Prioritized Top 5 Gaps from each breakout group will directly inform the FY23 MBRP Vision Setting and investment strategy discussions**
- ◆ **Secondary/Tertiary Gaps will be incorporated into MBRP strategic planning discussions**
- ◆ **All gaps will be referenced for inclusion in future MBRP Vision Setting discussions (if appropriated)**
- ◆ **All gaps will be provided to our funding partners for cross-agency data sharing**
- ◆ **Files and outcomes of the Stakeholder meeting will be made public on the CDMRP website**

MBRP Further Information

Website

<http://cdmrp.army.mil/mbrp>

Twitter

[@CDMRP](https://twitter.com/CDMRP)

(twitter.com/CDMRP)

YouTube

youtube.com/user/CDMRP

◆ **Program Summary Sheet**

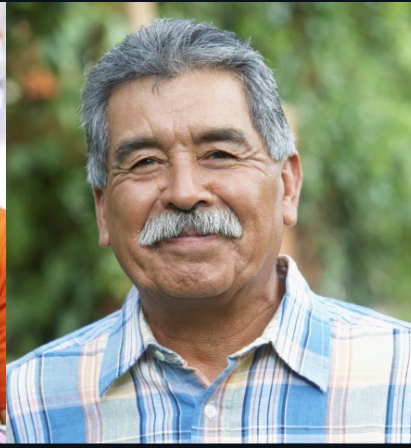
◆ **FY22 Funding Opportunity Announcements**

◆ **Strategic Plan, Research News & Highlights**

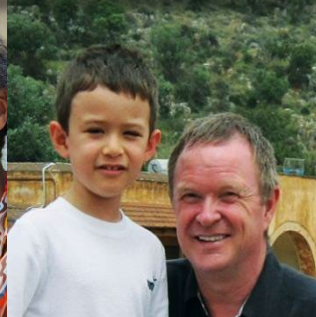
◆ **Press Releases**



For your Service and Participation



Thank you



SUBJECT: FY22 MBRP Stakeholders Meeting

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Enclosure 2
Overview of the CCCRP

The views, opinions, and/or findings contained in this presentation are those of the author(s) and should not be construed as an official Department of the Army position, policy, or decision.



Department of Defense Severe Burn Injury Portfolio Research and Development Overview

Bonnie J. Woffenden, Ph.D.

Severe Burn Injury Portfolio Manager, Combat Casualty Care Research Program

13 May 2022





Overview



- Background – The Problem
- Portfolio Scope and Purpose
- End State
- Requirements, Capability Gaps
- Product Development Pipeline
- Synergy and Leverage
- Summary

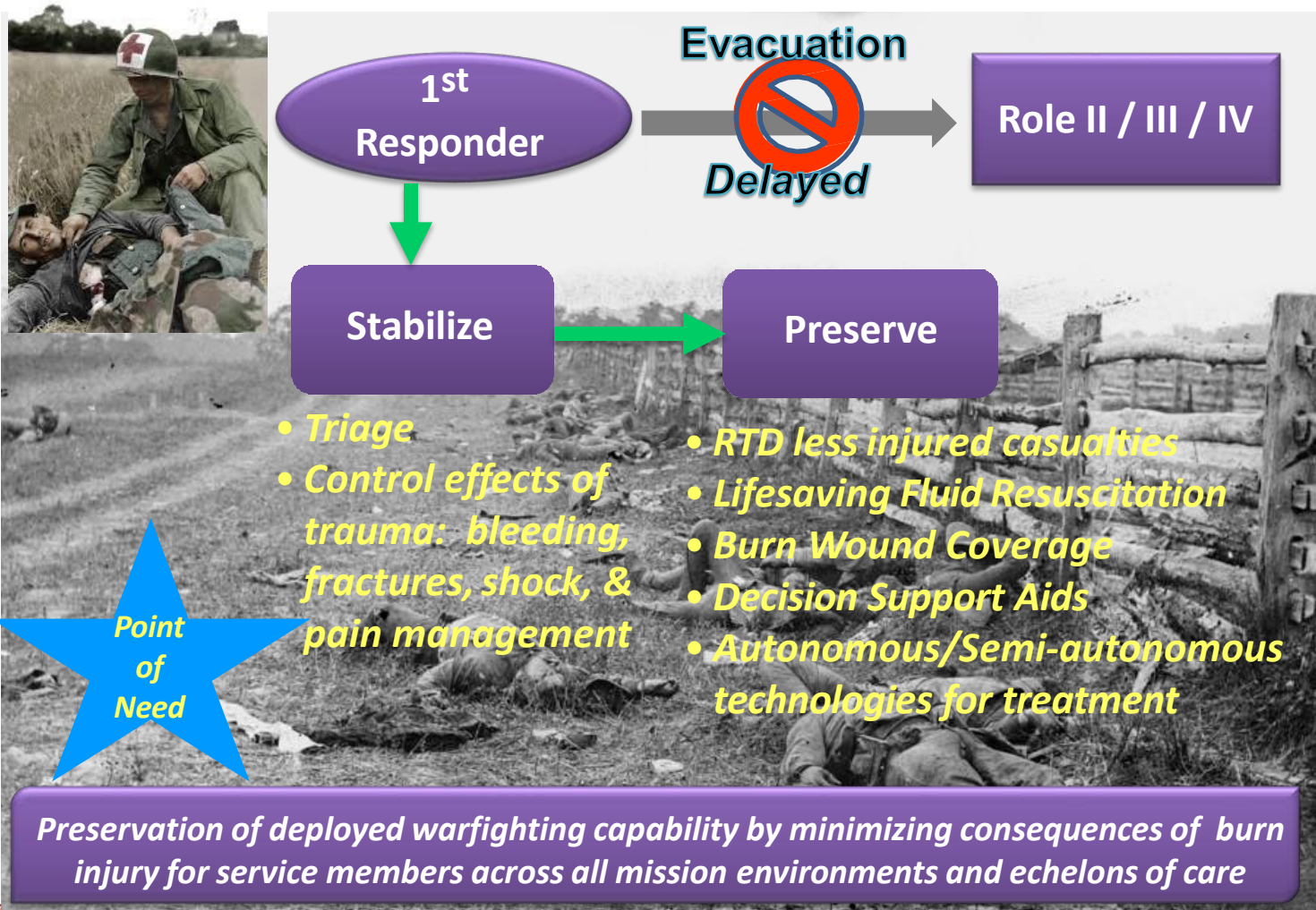


Burn Injury Management



The Problem in Multi Domain Operations (MDOs) and Large Scale Combat Operations (LSCOs)

- ❖ To provide Standard of Care, burn casualties must be evacuated from theater to the San Antonio Military Medical Center Burn Center.
- ❖ Easy to use tools to effectively treat burn injuries for optimal functional recovery and improve Return to Duty without evacuation are unavailable.





Severe Burn Injury Portfolio

Scope and Purpose



Scope:

- Research and development to deliver militarily relevant, safe and effective, burn injury management solutions for deployment in all operational environments, at the point of need, across the continuum of care

Purpose:

- Maintain the fighting force by accelerating return to duty, decreasing the burden of survivorship, and reducing morbidity following potentially debilitating burn injury
- Identify, develop, and transition methods, therapeutics, and technologies to provide advanced treatment solutions for burn injuries at the point of need to support operational requirements, save lives, and optimize functional recovery and quality of life outcomes for burn casualties



Severe Burn Injury Portfolio

Target End State



- Safe and effective, easy to use, logistically supportable toolsets to manage and treat severe burn injuries will be deployed across the continuum of care.
- Next generation life-saving, patient-stabilizing, and healing-promoting solutions for burn care will be available at the point of need, in all operational environments, to enhance medical provider and provider-extender capability and capacity.
- Evidence-based knowledge products will support development of new and/or revised clinical practice guidelines
- Novel, advanced capabilities for effective burn treatment will support the operational demands of battlefield clearing and other unit challenges in Multi Domain Operations (MDOs)/ Large Scale Combat Operations (LSCOs) by providing non-surgical interventions far forward.
- Accelerated functional recovery from burn injury will reduce the requirement for casualty evacuation from theater and increase return to duty (RTD) rates to sustain the fighting force.
- Casualties sustaining potentially debilitating burn injury will realize optimized healing outcomes.



Severe Burn Injury Portfolio



DoD Requirements & Guidance Documents Define Capability Gaps and Bookend Authorized Research

- Initial Capabilities Document (ICD) for Combat Casualty Care (C3) Support for Future Operations (JAN2021)
- The Army Health System in Support of Multi-Domain Operations (27MAY2020)
- Training and Doctrine Command (TRADOC) Pamphlet 525-3-1-U.S. Army in Multi-Domain Operations 2028
- United States Army - Marine Corps White Paper, Multi Domain Battle: Combined Arms for the 21st Century (JAN2017)
- CBA, Prolonged Care in Support of Conventional Military Forces (APR2017)
- Joint DCR – CCC Medical Research and Development (MAR2015)
- ICD for DoD Combat Casualty Care (CCC) Medical Research and Development (MAY2014)
- ICD for CCC Devices and Products (DEC2014)
- Joint Force Health Protection Concept of Operations - Joint Casualty Management Capabilities, Appendix I: Joint Force Health Protection Capability Gaps Requiring Medical R&D (JUL2007)
- Initial Capability Document (ICD) for Theater Combat Casualty Care (OCT2007)
- Joint DCR - Provision of Forward Resuscitative Care in Support of Dispersed Operations (pending)

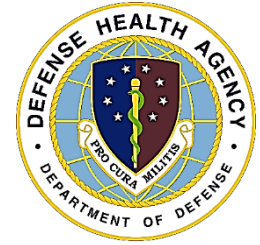


Severe Burn Injury Portfolio

Focus Areas Snapshot



- Understand burn injury physiology and current care capabilities and limitations for all mechanisms of burn (thermal, electrical, chemical, emerging weapons).
- Conduct preclinical and clinical R&D to translate innovative, safe and effective technologies and medical knowledge into clinical practice to optimize survival and recovery post burn injury.
 - ❑ Advanced strategies for fluid resuscitation of burn casualties
 - ❑ Advanced burn wound treatments
 - ❑ Innovative autonomous and semi-autonomous burn injury management solutions, and next generation decision support tools to enhance provider capability and capacity
 - ❑ Reduced medical complications of burn injury (e.g., infection, systemic inflammation, burn shock, multi-organ dysfunction, abdominal compartment syndrome, systemic hypermetabolism).
 - ❑ Novel treatments to improve outcomes following inhalation injury



Severe Burn Injury Product Development Pipeline

**Discovery/
Foundational
Knowledge
(6.1/6.2)
TRL 2-3**

- Development and characterization of animal model(s):
 - Emerging weapons induced burn injury
 - Burns of specialized tissues
 - Burns with trauma, other combined injury

**Late Discovery/
Technology
Development
(6.2/6.3)
TRL 3-4**

- Physiological responses to burn injury and fluid resuscitation
- Prognostic algorithms to monitor treatment effectiveness and guide care decisions
- Burn wound management
- Targeted Therapeutics
 - Precision medicine in fluid resuscitation
 - Treatments for burns caused by emerging weapons

**Product Development/
Transition
(6.3)
TRL 4-6**

Medical Materiel Devices & Therapeutics:

- Closed-loop and human-in-the-loop fluid resuscitation technologies
- Advanced, temporizing burn wound coverage
- Burn wound management

Knowledge Products To Support Clinical Practice

- Revision and validation of Clinical Practice Guidelines (CPGs)/Clinical Recommendations (CRs)/Best Practices
- Advanced fluid resuscitation of burn injuries

FDA
Clearance
or
Approval

Clinical
Knowledge
Implementation



Severe Burn Injury Research Intra-Agency Synergy



- ***Leverage expertise & funding across CCCRP portfolios (Army & DHP funding)***

Prolonged Care Portfolio:

- ✓ Prevent, diagnose, and treat infection and sepsis
- ✓ Prevent, diagnose, and treat multiple organ dysfunction
- ✓ Best practices to enable escharotomy at point of need
- ✓ Field deployable system to prevent hypothermia post-injury
- ✓ Field deployable tools to manage electrolyte and nutrition needs post-injury

Battlefield Resuscitation and Immediate Stabilization of Combat Casualties (BRISCC) /Prehospital Tactical Combat Casualty Care (TCCC) Portfolio:

- ✓ Fluid resuscitation in burn patients (plasma)

- ***Coordinate across other JPCs at seams between our research areas***

- ✓ Military Infectious Disease Research Program/JPC-2 - Wound Infection

- ***Harmonize planning w/ Product Development (PD) partners to facilitate technology transition***

- ✓ Burn Treatment Skin Repair IPT, Combat Wound Treatment & Management WG

- ***Leverage CSI and SBIR/STTR programs to complement JPC-6 managed equities***

- ✓ MBRP, CRRP, JWMPR CSIs
- ✓ CCCRP-prepared SBIR topics & others



Burn Injury Research Synergy Inter-Government and Externally



Inter-Government

- Visibility and input to/from other governmental partners
 - ✓ Joint Trauma System (JTS)
 - ✓ Uniformed Services University (USU)
 - ✓ Assistant Secretary for Preparedness and Response (ASPR)/Biomedical Advanced Research And Development Authority (BARDA)
 - ✓ Expanding inter-Service leverage

External Partnerships

- Food and Drug Administration
- Academia
- Industry



Burn Injury Summary



- The Burn Injury Portfolio is forward looking with investments targeting high priority, Joint burn care gaps across the continuum of care in future MDOs/LSCOs.
- Research to date has primarily focused on development of novel tools and knowledge products for improved fluid resuscitation of burn casualties (via IV & enteral hydration strategies) and advanced burn wound management strategies.
- Predicted research outcomes will provide urgently needed, novel capability and expanded capacity for prehospital burn care and improve burn injury management at higher echelons of care to optimize functional recovery outcomes for burn casualties.
- Portfolio successes have strong potential to enhance preparedness for burn mass casualty (MASCAL) incidents, as well as benefit civilian first responder capability.
- Increased future research investment to improve fundamental knowledge of emerging weapons threats and preclinical model development to study potential interventions for these as yet uncharacterized burn injury modalities is imperative to address evolving operational priorities.



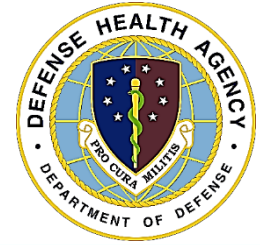
Thank You



Backup



Abbreviations



- AKI: Acute Kidney Injury
- AMEDD: Army Medical Department
- ARDS: Acute Respiratory Distress Syndrome
- ASPR: Assistant Secretary for Preparedness and Response
- BAA: Broad Agency Announcement
- BARDA: Biomedical Advanced Research and Development Authority
- BRISCC: Battlefield Resuscitation and Immediate Stabilization of Combat Casualties
- CBA: Capabilities Based Assessment
- CBRN: Chemical, Biological, Radiological, Nuclear
- CCC: Combat Casualty Care
- CDID: Capability Development and Integration Directorate
- CDMRP: Congressionally Directed Medical Research Program
- CPG: Clinical Practice Guideline
- CR: Clinical Recommendation
- CRRP: Combat Readiness Research Program
- CSI: Congressional Special Interest
- DCR: DOTmLPF-P Change Recommendation
- DHA: Defense Health Agency
- DHP: Defense Health Program
- DoD: Department of Defense
- DOTmLPF-P: Doctrine, Organization, Training, Materiel, Leadership and Education, Personnel, Facilities - Policy
- EMA: Execution Management Agency (CDMRP)
- FDA: Food and Drug Administration
- FY: Fiscal Year
- GAO: Government Accountability Office
- GDF: Guidance for the Development of the Force
- GLP: Good Laboratory Practices
- GMP: Good Manufacturing Practices
- HA: Health Affairs
- ICD: Initial Capabilities Document
- IPT: Integrated Product Team
- IV: Intravenous
- JPC: Joint Program Committee
- JTS: Joint Trauma System
- JWMP: Joint Warfighter Medical Research Program
- KTA: Knowledge Transition Agreement
- LSCO: Large Scale Combat Operation
- MBRP: Military Burn Research Program
- MDD: Materiel Development Decision
- MDO: Multi Domain Operations



Abbreviations



- MED CDID: Medical Capabilities Development Integration Directorate
- MPAI: Military Prototype Advancement Initiative
- MS A: Milestone A
- MS B: Milestone B
- MTEC: Military Technology Enterprise Consortium
- MOD: Multi-Organ Dysfunction
- MOF: Multi-Organ Failure
- OSD(HA): Office of the Secretary of Defense Health Affairs
- OTA: Other Transaction Authority
- PA: Program Announcement
- PD: Product Development
- PE: Program Element
- PC: Prolonged Care
- POI: Point of Injury
- PoP: Period of Performance
- PPBE: Planning, Programming, Budgeting, Execution
- PPV: Pulse Pressure Variation
- RDT&E: Research, Development, Testing, and Evaluation
- R&D: Research & Development
- RTD: Return to Duty
- S&T: Science and Technology
- SBIR: Small Business Innovation Research
- SOC: Standard of Care
- SOW: Statement of Work
- SPV: Systolic Pressure Variation
- STTR: Small Business Technology Transfer
- SVV: Stroke Volume Variation
- SWOT: Strengths, Weaknesses, Opportunities, Threats
- TA: Transition Agreement
- TBI: Traumatic Brain Injury
- TBSA: Total Body Surface Area
- TRADOC: Training and Doctrine Command
- TRL: Technology Readiness Level
- USAISR: United States Army Institute of Surgical Research
- USAMMDA: United States Army Medical Materiel Development Agency
- USU: Uniformed Services University



Burn Injury Relevant Clinical Practice Guidelines 2016-2021



1. Burn Care. (CPG ID:12) Joint Trauma System, 11 MAY 2016.
2. Burn Wound Management in Prolonged Field Care. (CPG ID:57) Joint Trauma System, 13 JAN 2017.
3. Infection Prevention in Combat-related Injuries (CPG ID:24) Joint Trauma System, 27 JAN 2021.
4. Sepsis Management in Prolonged Field Care. (CPG ID:83) Joint Trauma System, 28 OCT 2020.
5. Analgesia and Sedation Management during Prolonged Field Care. (CPG ID: 61) Joint Trauma System, 11 MAY 2017.
6. Invasive Fungal Infection in War Wounds. (CPG: 28) Joint Trauma System, 4 AUG 2016.
7. Chemical, Biological, Radiological and Nuclear (CBRN) Injury Part I: Initial Response to CBRN Agents. (CPG ID: 69) Joint Trauma System, 1 MAY 2018.
8. Chemical, Biological, Radiological and Nuclear (CBRN) Injury Response Part 2: Medical Management of Chemical Agent Exposure. (CPG ID:69) Joint Trauma System, 23 JAN 2019.
9. Airway Management of Traumatic Injuries. (CPG: 39) Joint Trauma System, 17 JUL 2017
10. Inhalation Injury and Toxic Industrial Chemical Exposure. (CPG ID: 25) Joint Trauma System, 25 JUL 2016
11. Frostbite and Immersion Foot Care. (CPG ID: 59) Joint Trauma System, 26 JAN 2017

SUBJECT: FY22 MBRP Stakeholders Meeting

Enclosure 3
Overview of the USAISR

The views, opinions, and/or findings contained in this presentation are those of the author(s) and should not be construed as an official Department of the Army position, policy, or decision.

Burns: Blueprint for the Future

Lee Cancio, MD, FACS, FCCM
Director, US Army Burn Center
US Army Institute of Surgical Research
Fort Sam Houston, TX

Presented to the Military Burn Research Program Stakeholders, 13 May 2022

Notes

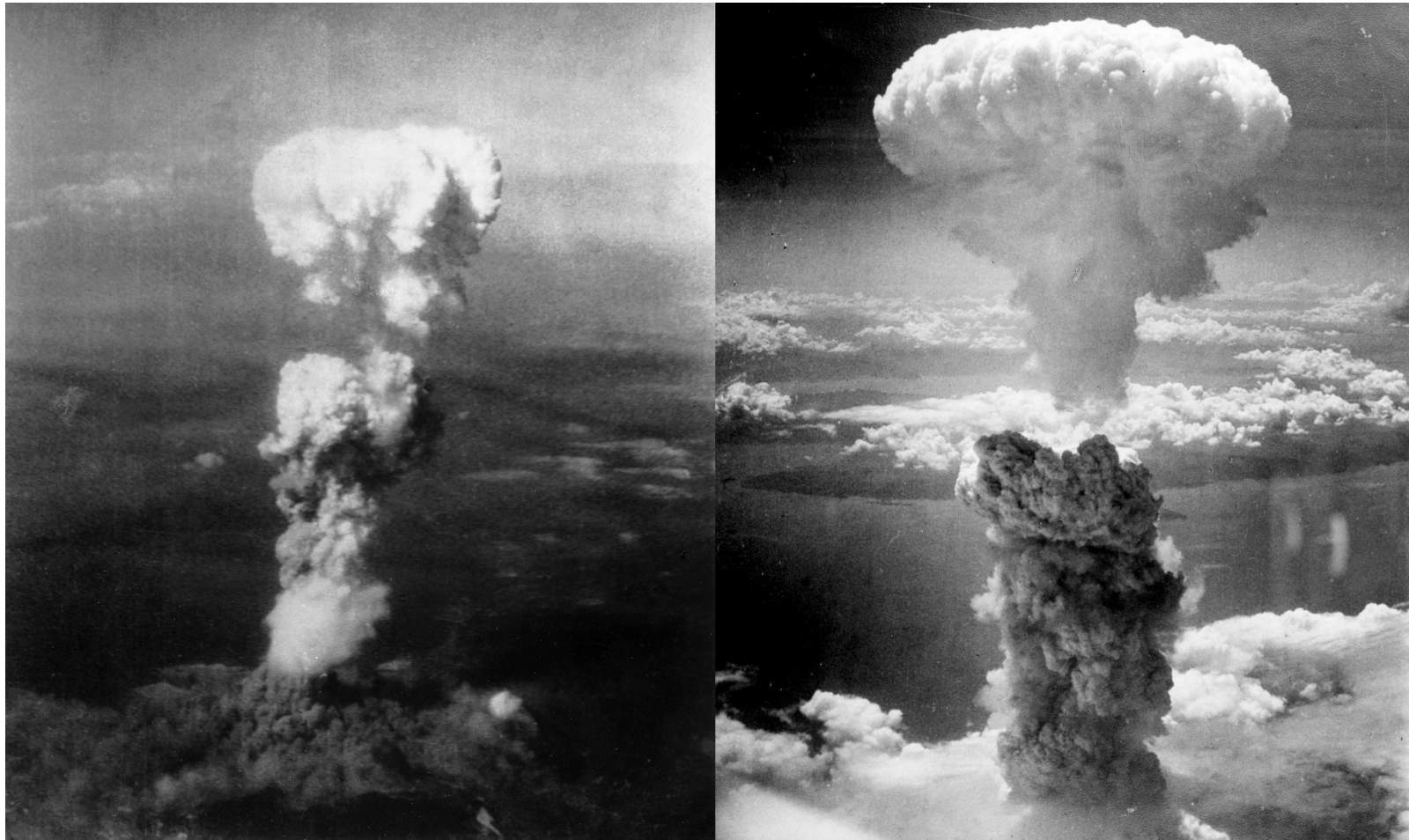
- The opinions or assertions contained herein are the private views of the author and are not to be construed as official or as reflecting the views of the Department of the Army or the Department of Defense.
- Author is an inventor of Burn Navigator (decision support system) (Arcos Medical, Inc.). Assigned rights to the Army. No royalties have been received.

Military Relevance of Burns

- Significant burns complicate approx. 5-10% of combat casualties:

<u>Event</u>	<u>%</u>	<u>Number</u>
Hiroshima, '45	65-85	46K-60K
Vietnam, '65-'73	4.6	13K
6-Day War, '67	4.6	
Yom Kippur, '73	10.5	
Falklands, '82	18	140
Lebanon, '82	8.6	
Just Cause, '89	2.3	6
Desert Shield/Storm, '90-1	7.9	36
Iraq/Afghanistan, 2003-10	7-10%	

Nuclear War



War at Sea



HMS Sheffield, Falklands, 1982

Armor



Battle of 73 Easting, Desert Storm (Wikipedia)

Improvised Explosive Devices



Burn Patients in JTTR

- Total patients in JTTR, 86857
- Burn, 6369 (7.3%)
- Explosive (IED + other), 37062 (42.6%)
 - Burn and Explosive, 4248 (11.5%)
- IED, 27737 (31.9%)
 - Burn and IED, 3302 (11.9%)

As of 15 Nov 2019, courtesy of Brock A. Graham, JTS



AOAV.org.uk

Burn patients to ISR from current wars, 2003-13

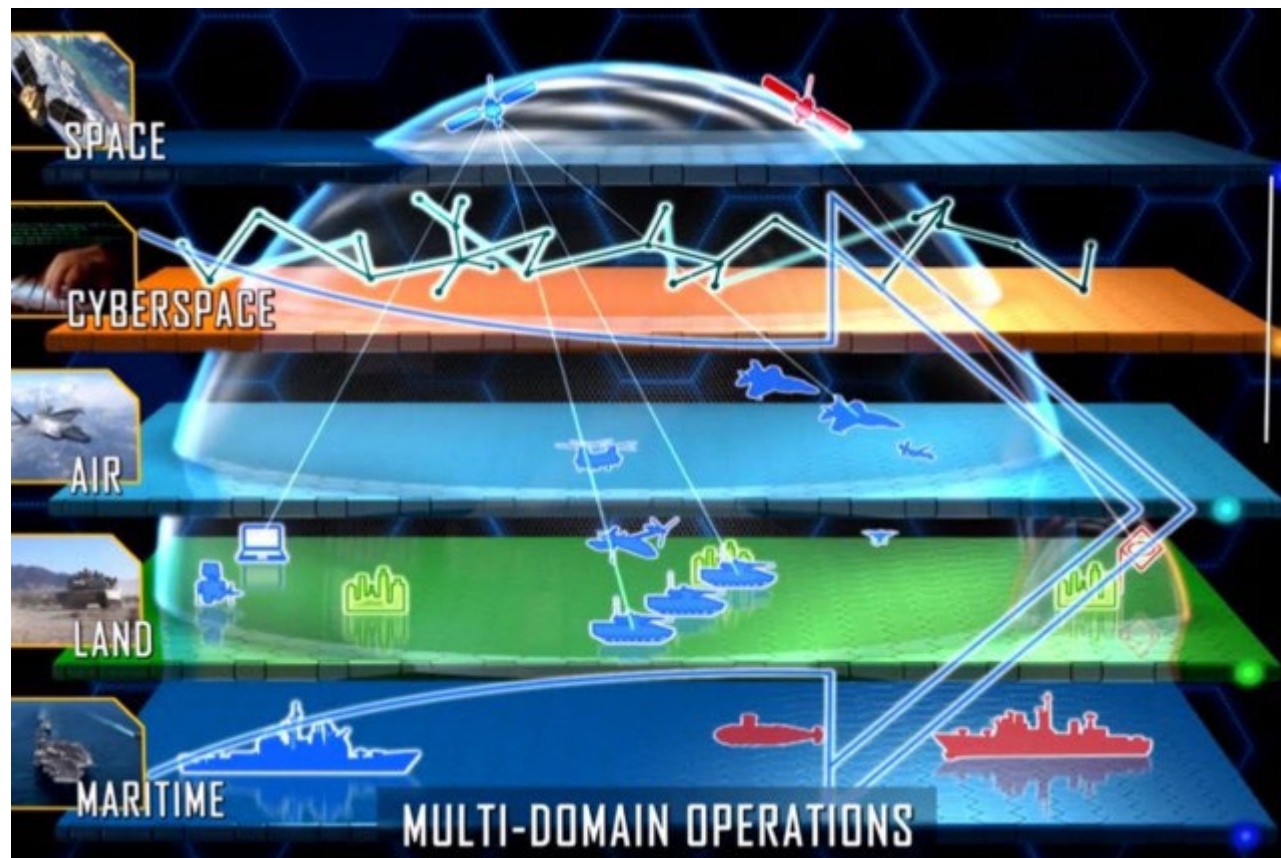
- **990 patients**
 - Afghanistan 218
 - Iraq 772
- **Service**
 - Army 722
 - USMC 208
- **Mechanism of injury:**
majority IED
- **Total burn size:** ~17%

As of Nov 2013, ISR registry data.



Future battlefield

- Peer or near-peer adversary
- Multi-domain operations
- Highly lethal battlefield
- More burns, inhalation injury
- Dense urban environment
- Loss of air superiority
- Delay in evacuation
- Delay in definitive surgical and intensive care
- **Prolonged field care**



https://www.army.mil/article/234845/futures_and_concepts_center_evaluates_new_force_structure

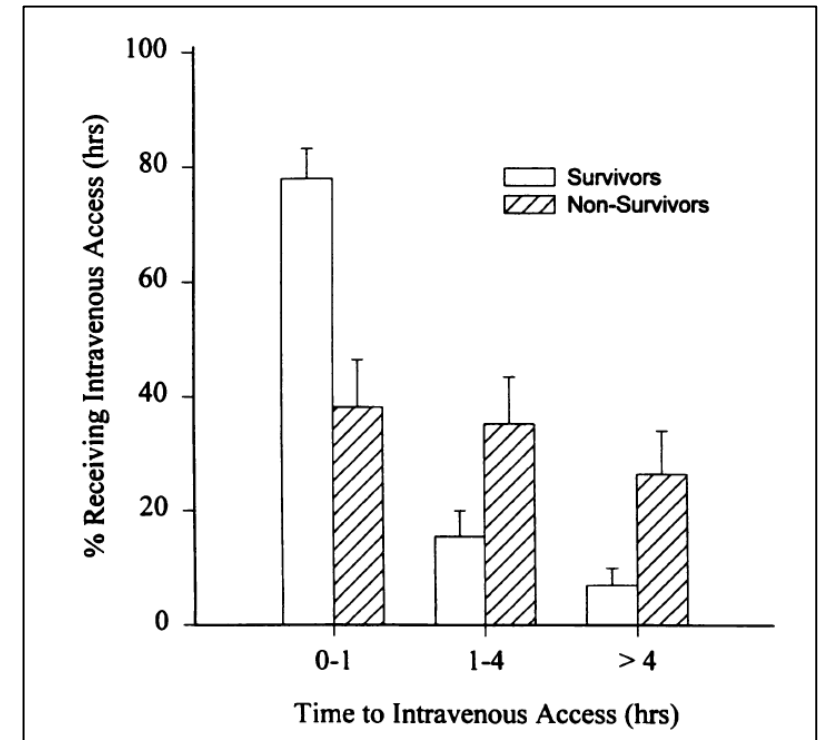
Mortality Determinants in Massive Pediatric Burns

An Analysis of 103 Children with $\geq 80\%$ TBSA Burns ($\geq 70\%$ Full-Thickness)

Ann Surg 1997

Steven E. Wolf, M.D., J. Keith Rose, M.D., Manubhai H. Desai, M.D.,
Joan P. Mileski, M.S., Robert E. Barrow, Ph.D., and David N. Herndon, M.D.

- Predictors of mortality (pre-hospital)
 - Lower age
 - Burn size
 - Inhalation injury
 - **Delayed IV access (mean 1.2 hours)**
 - Lower HCT (admission to Shriners)
 - Lower BD (same)
 - Higher serum osmolarity (same)



- 1982-1996
 - All pts fully excised w/in 48 hrs admission to Shriners
 - 70% arrived at Shriners w/in 48 hrs
 - Mortality rate 33%

CONTROL OF EXPERIMENTAL AND CLINICAL BURN WOUND SEPSIS BY TOPICAL APPLICATION OF SULFAMYLON COMPOUNDS

Robert B. Lindberg, J. A. Moncrief, A. D. Mason, Jr.

Ann NY Acad Sci 1968

PREVENTION OF LETHAL PSEUDOMONAS INFECTION IN BURNED SEEDED RATS BY TOPICAL SULFAMYLON*

No. Rats	Start of Treatment (hours post-seeding)	Deaths/ Total	Survival (days)	Mean Survival Time
25	<i>I</i>	0/25	—	—
25	24	0/25	—	—
25	48	3/25	12–16	15
20	72	8/20	10–16	12.2
20	96	20/20	8–12	10.2
56	—	49/50	8–11	9.6

* Infecting strain: 12-4-4 (59). 10% Sulfamylon in water-dispersible cream. Dose: 3 gm per animal, twice daily.



A Comparison of Conservative *Versus* Early Excision

Therapies in Severely Burned Patients

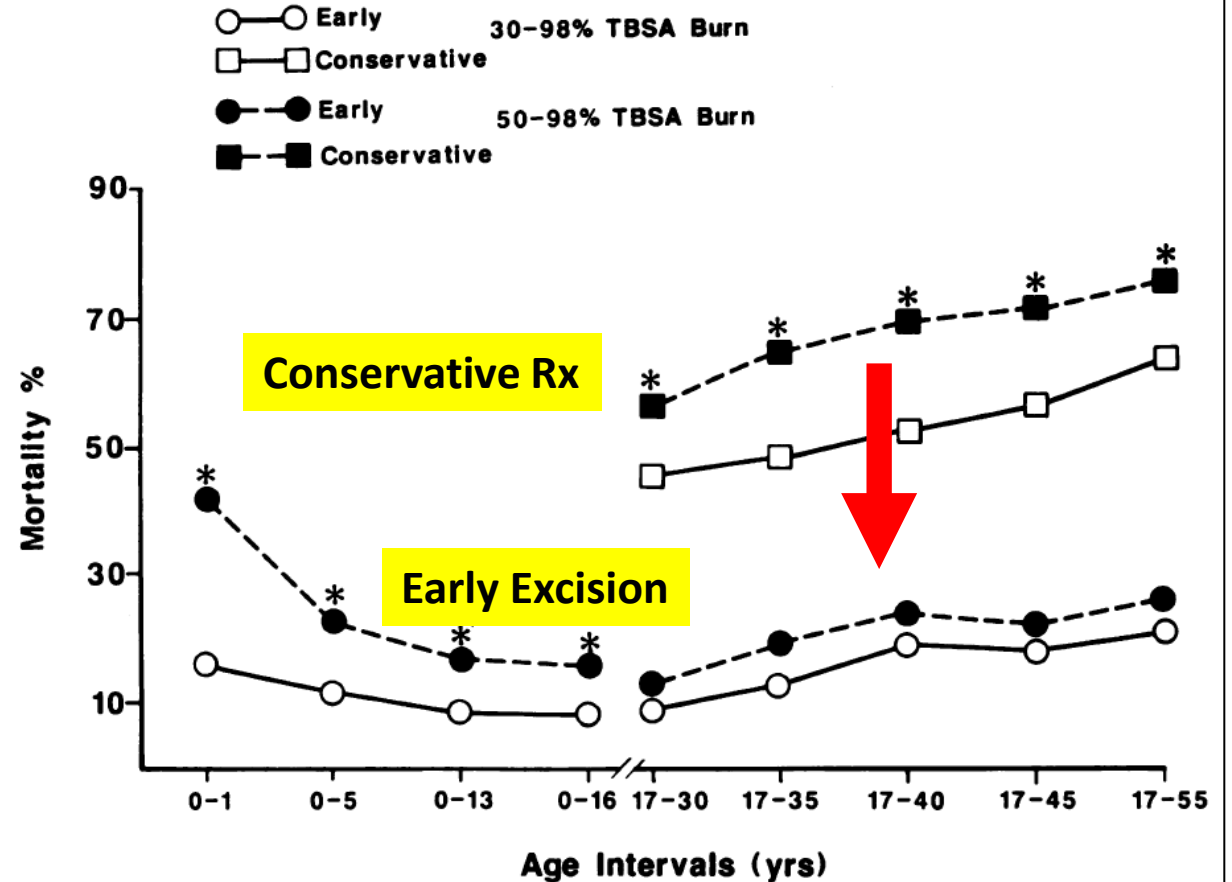
Ann Surg 1989

DAVID N. HERNDON, M.D., ROBERT E. BARROW, PH.D., RANDI L. RUTAN, B.S., MANU H. DESAI, M.D.

TABLE 2. Mortality for Conservative Versus Early Excision Therapy in Adults with 30%–98% TBSA Burns.
% Mortality With Number of Subjects in ().

Treatment	Age (Years)	Without Inhalation Injury	With Inhalation Injury
Conservative	17–30	45 (11)*	100 (5)
Early excision	17–30	9 (22)	90 (10)
Conservative	31–55	75 (16)	75 (8)
Early excision	31–55	57 (7)	60 (5)

* Significant difference between early and conservative, at $p < 0.025$.



Burns – “Golden Day” requirements

- Airway/mechanical ventilation
- IV access, monitoring
- Hypothermia prevention
- Burn shock resuscitation
 - Avoid over-resuscitation
 - Avoid under-resuscitation
 - Maintain organ perfusion
- Extremity perfusion
 - Escharotomy
- Prevent infection
 - Wound care
 - Topical antimicrobial
- Pain, sedation
- Ave. burn size is 20%
- Requires
 - One critical care nurse per pt.
 - One burn-experienced surgeon/intensivist
 - Fluids: 4 ml/kg/TBSA burned/24 hrs = 6.4 L
 - Ability to sedate/intubate/ventilate
 - Ability to monitor UO, vitals, blood gases, labs
 - Ability to keep pt. warm
 - Shelter
 - Basic surgical eqpt (cautery)
 - Gauze, antimicrobial dressings

A single patient w/ 40-80% burns during the Golden Day will overwhelm a medic, aid station, or FST

The Emperor's New Clothes



<https://europeanconservative.com/2019/01/the-great-disruptor/>

What can be done? – materiel solutions

- Improve resuscitation fluids
 - Plasma
 - Enteral resuscitation
- Improve resuscitation monitoring
- Enable medical escharotomy
- Enhance topical antimicrobials

Plasma

Plasma for burn shock resuscitation: is it time to go back to the future?

Transfusion 2019

Jennifer M. Gurney^{1,2}, Rosemary A Kozar,³ and Leopoldo C. Cancio¹



Transfusion of plasma at the MGH after the Coconut Grove Fire, 1942

- Standard for burn shock resuscitation ~ WWII
- Abandoned 1950s due to hepatitis risk
- Use on future battlefield
- Likely volume sparing effect in burns
- Endothelial glycocalyx protection?
- Multicenter RCT to start soon
- Effect on endothelial permeability, if present, is probably not huge

Enteral resuscitation

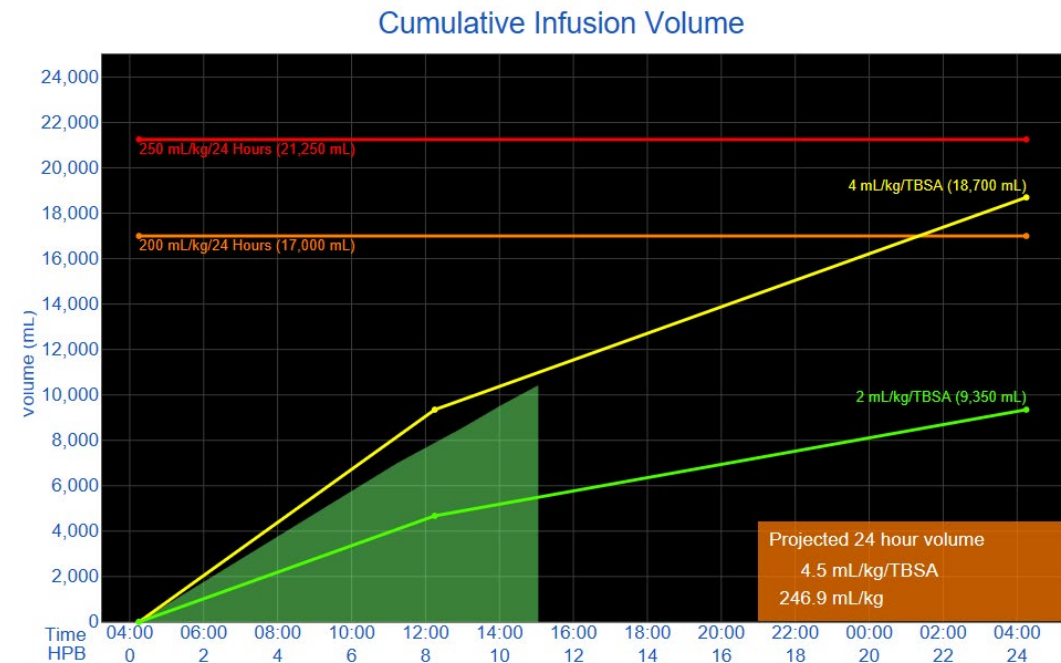
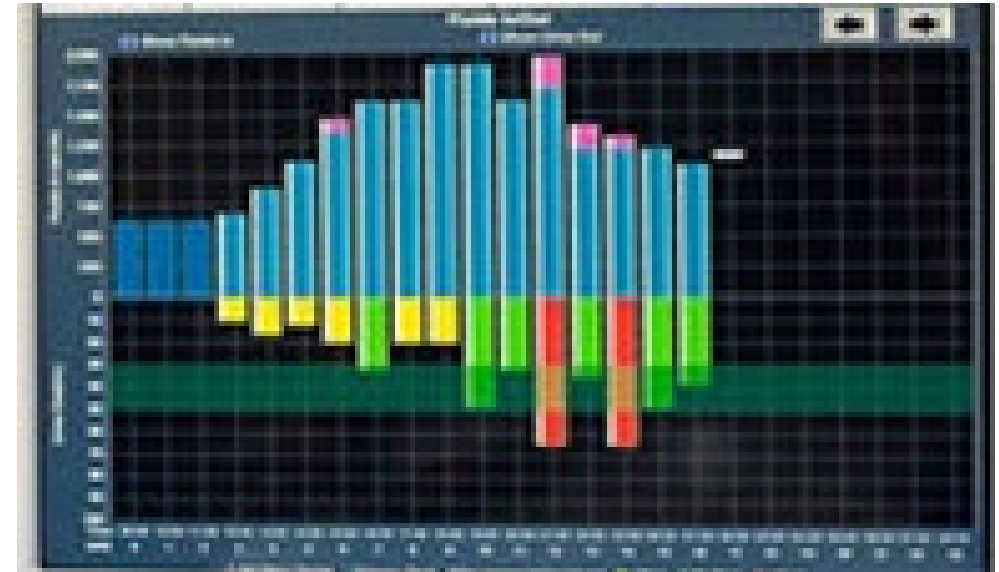
	Standard WHO ORS ⁽²⁾	New WHO reduced osmolarity ORS ^(25,26)
Glucose	111	75
Na	90	75
Chloride	80	65
K	20	20
Citate	10	10
Osmolarity	311	245

- **Oral, nasogastric, or rectal**
- World Health Organization (WHO) oral resuscitation solution
 - Cholera
 - Careful: revised formula is lower sodium
- Commercial, e.g. DripDrop
- Homemade
- Watch for vomiting
- Slower delivery—self regulating?
- Maintain GI function?
- Prospective obs. trial starting soon

Role of gut microbiome in critical illness/recovery?

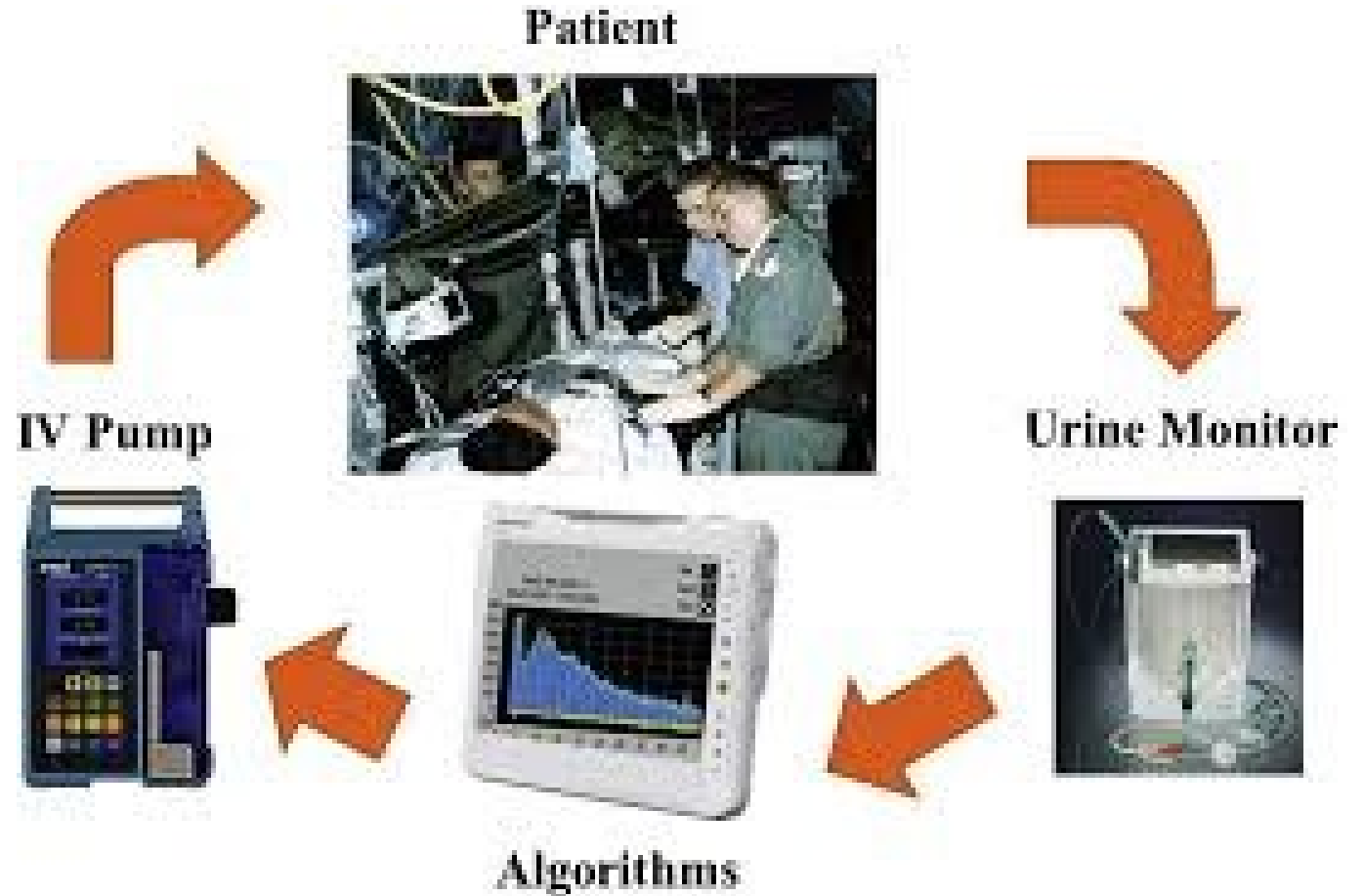
Resuscitation decision support

- Burn Navigator does:
 - Predict next hour's fluid needs based on last 3 hours of UO, TBSA, time postburn, and current fluid rate
 - Have business rules, encourage comms, provide situational awareness, predict ml/kg at 24 hours based on cumulative vol.
 - Decrease total fluid input



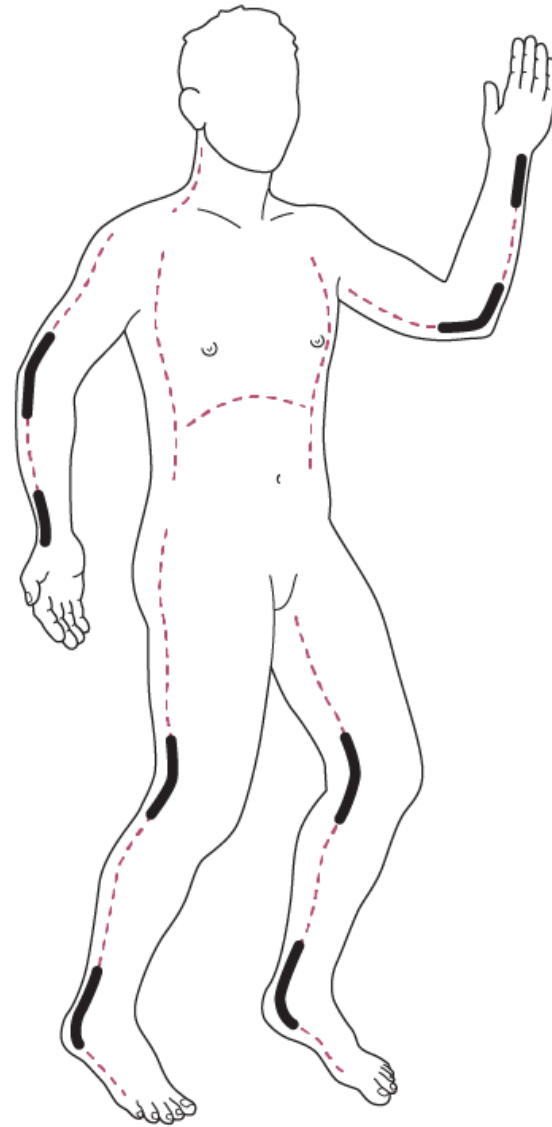
Resuscitation decision support, cont.

- Burn Navigator *does not*:
 - Use other vital sign data
 - Use other lab data
 - Connect to patient
 - Input data automatically
 - Make changes automatically
 - Perform closed-loop control
 - Replicate clinical decision making
- FDA challenges



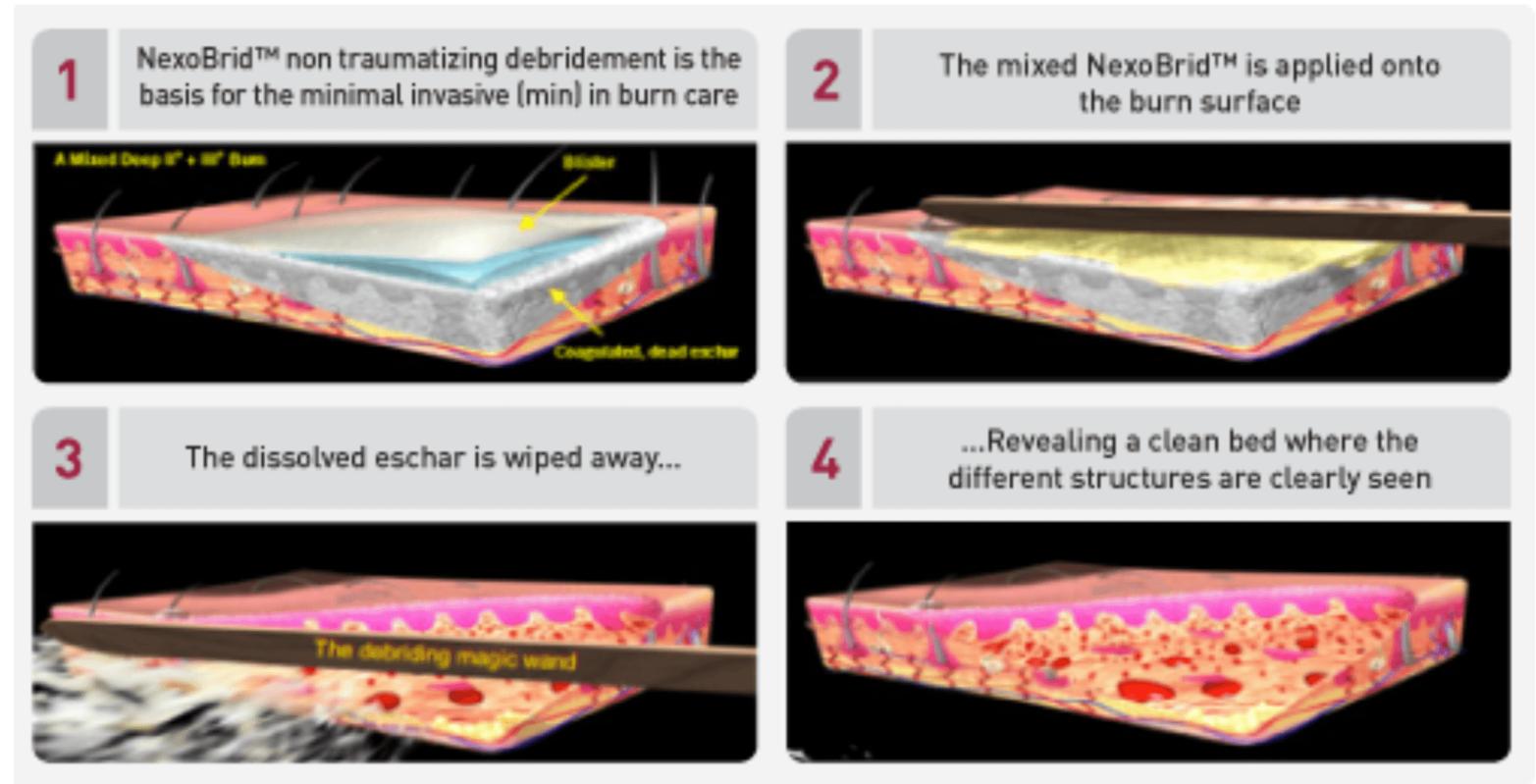
Escharotomy

- Eschar syndrome
- Circumferential full thickness burns
- Decreased blood flow or chest excursion
- Rx: surgical escharotomy



Enzymatic debridement/escharotomy

- Nexobrid
- Derived from pineapple
- Bromelain (proteolytic enzymes)
- Requires trained personnel (intended for burn center use)
- Painful, sedation needed
- Must be able to protect wound after use
- Pending FDA approval



Topical wound care

- Prevent invasive burn wound infection
- Debride wounds w/ CHG
- Apply topical antimicrobial
 - Creams (reapply daily)
 - Sulfamylon
 - Silver sulfadiazine
 - Silverlon/other silver dressing (reapply Q3D)
- Operate asap (3-4 days)



Delay in surgery?

- No FDA-approved ideal product
- Cerium nitrate
- Rare earth metal
- No antimicrobial effect
- Stabilizes eschar – protective effect
- Decreases inflammation – DAMPS
- Combine with antimicrobial
- Flammacerium (RCT proposal)
- Silver/cerium dressing? (MTEC RFI)



What about frostbite?



U.S. Army (Kentucky NG)

Burn Research: Key Issues in 2022

- **Spectrum of care**

- Point of injury thru rehabilitation and reintegration (return to duty/work)
- A physically and psychologically broken survivor is not a functional survivor

- **Human research**

- R&D that does not address clinical effectiveness is irrelevant

- **Multicenter and international research**

- No one center has enough patients with large burns
- Need for prolonged field care/austere research: less-developed countries

Thank you



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- <https://usaisr.amedd.army.mil/>