

Military Burn Research Program

Strategic Plan

INTRODUCTION

The Congressionally Directed Medical Research Programs (CDMRP) represents a unique partnership among the U.S. Congress, the military, and the public to fund innovative and impactful medical research in targeted program areas. In 2015, a special committee within the National Academies of Sciences, Engineering, and Medicine evaluated the CDMRP's two-tier review process and its coordination of research priorities with the U.S. Department of Health and Human Services and the U.S. Department of Veterans Affairs. As part of their final report, the committee recommended that each CDMRP program "... develop a strategic plan that identifies and evaluates research foci, benchmarks for success, and investment opportunities for 3 to 5 years into the future," and that these strategic plans "should specify the mission of the program, coordination activities with other organizations, research priorities, how those priorities will be addressed by future award mechanisms, how research outcomes will be tracked, and how outcomes will inform future research initiatives."

In response to these recommendations, the CDMRP's Military Burn Research Program (MBRP) Strategic Plan identifies the high-impact research goals of greatest importance to its stakeholders. This plan provides a framework to address those goals with the flexibility to adapt to changes in the military burn research environment. This plan provides a transparent view of the program's goals and priorities to stakeholders and the general public.

BURN RESEARCH AND FUNDING ENVIRONMENT

The American Burn Association estimated that 30,000 burn victims in the United States required hospitalization at 4,500 tertiary care hospitals around the country.² The top three causes of burn injuries in civilians are fire/flame, contact with hot liquids (scald), and contact with hot objects (contact burn). Burns sustained in military operational settings are often more complex than burns sustained in civilian settings. The majority of combat-associated burns result from explosive device detonation, leading to a greater Injury Severity Score, an increase in inhalation injuries and a larger, full-thickness burn size. In addition to burns, Service Members may also concurrently suffer from penetrating trauma, hemorrhage, amputations, smoke inhalation, and head injuries. This traumatic assault adds additional burden to the body's innate immune response and increases the likelihood of infections and organ damage. Active-duty service members are twice as likely as the civilian population to suffer a burn injury. During Operation Iraqi Freedom and Operation Enduring Freedom, approximately 5% to 20% of combat-related casualties included severe burns, and 10% of all combat-related injuries to the head and neck region were the result of burns.3

Treatment of combat-associated burn injuries brings a complexity not typically seen in the civilian sector. This is due to the immediate and prioritized treatment of concomitant life-threatening injuries such as hemorrhage or airway emergencies. Only after successful delivery of life-sustaining interventions can medical attention turn to burn injuries. As a result, comprehensive treatment of burn injuries on the battlefield is often delayed, leading to a higher risk of complications and a larger, deeper burn wound. Beyond the immediate and early acute care necessary to effectively treat burn-injured service members, comprehensive care must also be provided to support them throughout their physical and psychological recovery to maximize eventual return to duty. As the

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military prepares for a future battlefield that requires immediate and potentially prolonged medical care in resource-limited settings, the MBRP will continue to support research to develop and validate new technologies, techniques, interventions, and treatment paradigms that accommodate this military need.

VISION: Advancing combat burn trauma care for the Warfighter

MISSION: Identify and close gaps in combat burn trauma care through military-focused research

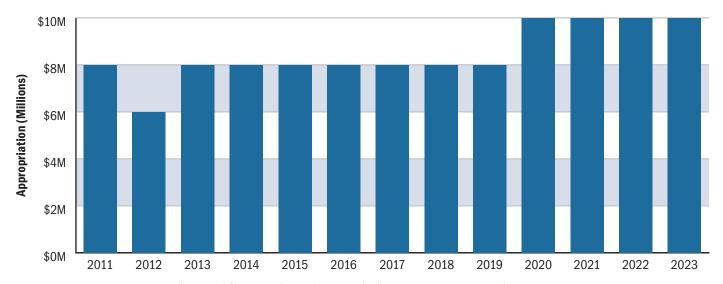


Figure 1. Congressional Appropriation to the MBRP by Fiscal Year

Congress initiated the MBRP in 2011 to address combat-related and trauma-induced burn injuries, as well as to improve health and performance outcomes for Service Members and the general public. Since fiscal year 2011 (FY11), Congress has appropriated \$110 million (M) to the program.

While the MBRP is currently the only federally funded research program dedicated entirely to burn injury, research funding for burn and burn-related topics comes from a variety of sources outside of the MBRP. Many of these research projects are funded by other government and non-government organizations. The MBRP takes into account the entire research funding landscape and works with these partners to ensure research efforts are complementary without being duplicative. This continuous assessment of the research landscape allows the program to effectively respond to changes for maximum value and impact of MBRP-funded research. The following organizations make significant contributions to burn research:

- The Defense Health Agency and the individual military services maintain a vested interest in research and development for combat-relevant burn injuries through the U.S. Army Medical Research and Development Command Combat Casualty Care Research Program, the U.S. Army Medical Materiel Development Activity, and the U.S. Small Business Administration's Small Business Innovation Research program.
- The HHS contributes to burn research funding through the NIH, the Administration for Strategic Preparedness and Response, and the Biomedical Advanced Research and Development Authority.
- The VA Office of Research and Development.
- The American Burn Association offers grant and fellowship opportunities to its members to advance the educational and research needs of burn care professionals.

RESEARCH PORTFOLIO

To meet its mission, the MBRP has funded 69 research projects since 2011. These projects can be broadly categorized into 13 topic areas (Figure 2). The program continues to recognize a need for burn wound treatments for use in the immediate aftermath of the injury; therefore, the MBRP has invested approximately 41% of its appropriated funds to support projects related to *Burn Wound Treatment*. Understanding the high risk of complications among burn-injured Service Members, a large proportion of MBRP appropriations has supported research efforts related to *Inflammation/Infection Control* (13%). With delays in definitive care and advanced treatment, the program continues to invest in *Burn Conversion Mitigation* (10%). The program has also invested in projects covering additional critical areas including *Diagnostics* for assessing burn wound depth, *Burn Resuscitation* to mitigate the negative consequences of hypo/hypervolemia, *Clinical Practice Guidelines, Burn Scar Treatment, Inhalation Injury, Pain Control, Decision Support Tools, Exercise, Debridement, and Drugs/Biologics*.

MBRP-funded projects resulted in the advancement of novel therapies to treat burn wounds while impacting the current standard of care for treating Service Members, Veterans, and the general public. Several innovative therapies provide new avenues for treating scar size using lasers; reducing respiratory distress using repeated stem cell applications; demonstrating the benefit of Vitamin E in increasing pulmonary function in burn patients; and navigating the use of Omega-3 fish skin technology as temporary coverage for full-thickness burns. The MBRP is also impacting standards of care for burn patients by supporting the development of diagnostic tools such as burn wound depth assessment capabilities and infection/sepsis risk stratification. The program is committed to developing evidence-based clinical practice guidelines in several areas including, but not limited to, IV vitamin C to reduce the inflammation associated with burn injury and improve survival among burn patients; establishing the benefits of cool running water treatment in the immediate aftermath of a burn injury; and comparing the use of fresh frozen plasma versus albumin in burn resuscitation.

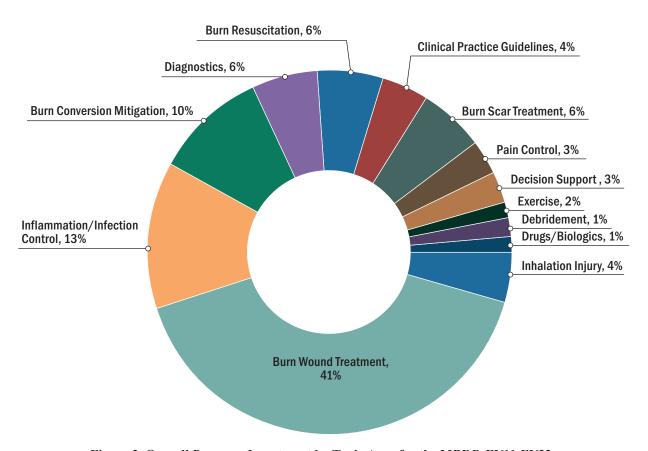


Figure 2. Overall Program Investment by Topic Area for the MBRP, FY11-FY22



STRATEGIC DIRECTION

The MBRP overarching strategic goal is to advance new burn care techniques to clinical practice and to address capability gaps for treating combat burn injuries from the point of injury to treatment at stateside Military Burn Centers and Military Treatment Facilities to improve survival, recovery, and rehabilitation for military burn patients. In order to keep abreast of the ever-changing research landscape and clinical environment, program staff solicit input from experts in burn care and burn research from the military services and academia. The MBRP Programmatic Panel, composed of representatives from military, other federal agencies, and clinical practice, regularly assess the current research environment related to the short- and long-term care of military burn patients, and also discuss emerging technological developments in the field. In addition to non-DOD research, the program routinely monitors research initiatives and outcomes of DOD-supported projects by Combat Casualty Care Research Program; the USAMRDC Armed Forces Institute of Regenerative Medicine; Biomedical Advanced Research and Development Authority; the Uniformed Services University of the Health Sciences' Infectious Disease Clinical Research Program; and many others. This strategic assessment of the research environment allows the MBRP to coordinate research funding and priorities across organizations, eliminate research duplication, and ensure that efforts are complementary in order to best address knowledge and capability gaps.

While researchers and clinicians continue to successfully develop burn care products and conduct burn-centric clinical research studies, many challenges remain. These areas of unmet need serve as a guiding beacon for the MBRP and help drive programmatic funding decisions. Key challenges in military medicine related to burn care focus on the early phases of care. While the long-term recovery of burn casualties is physically and emotionally trying for survivors, the program determined that projects focused on effective treatment strategies during the immediate and early phases of care will improve long-term outcomes.

Some of the challenges the program seeks to overcome include, but are not limited to, the inherent limitations in rendering burn care to a large number of burn casualties immediately after injury; limitations in the ability of combat medics to provide burn wound care in a forward operating environment; and lack of non-surgical debridement technologies. Other challenges include the lack of accurate burn wound depth assessment devices to aid in triage and evacuation decisions; the lack of animal models that mirror hypertrophic scarring in humans; and, finally, the lack of effective skin recovery technologies for use in a field hospital environment.

The MBRP continually strives to address these and other challenges to ensure that burn-injured military service members are given the best chance of survival, recovery, rehabilitation, and eventual reintegration into military or civilian life. While the program focuses on military-relevant burn injuries, the products and outcomes of MBRP-funded research projects also benefit first responders, burn patients, and health care providers across the civilian sector. Disastrous homeland events such as the Maui, Hawaii wildfires demonstrate the pressing need for burn triage and diagnostic devices to help in evacuation efforts, as well as effective burn care treatments for use in resource-limited environments. The MBRP will continue to prioritize research efforts toward knowledge and technology products that impact the care of burn patients in austere and resource-limited settings.

STRATEGIC GOALS AND PRIORITIES

MBRP Programmatic Panel members work collaboratively to identify unanswered research questions in the field of burn care in order to develop a multi-year strategic investment plan for the program that aligns with the vision, mission, and congressional intent of the program. This strategic plan provides a framework under which the short- and long-term investments will be decided upon and funded, contingent upon the availability of future appropriations. The Programmatic Panel will annually revisit the plan to review the state of the science, military priorities, and clinical needs; to ensure that the topic areas and capability gaps are still relevant; and to refine the plan as necessary.

The MBRP established four priorities to shape funding efforts over the next five years.

- Development of military-relevant interventions that improve survival from combat-associated burn and/or acute-burn
 lung injury. Proposed interventions should be usable on the battlefield for prolonged medical care in resource-limited
 environments. The program will focus on interventions aimed at flame and thermobaric burns; however, management of
 other types of burn injury such as frostbite, nuclear, are of interest to the program.
- Development of interventions that accelerate or optimize burn wound healing to minimize scarring and contractures in later phases of recovery. Preference will be given to solutions that are usable in a military theater of operation.
- Development or refinement of interventions or technologies that will enable non-burn specialists, such as field medics/ corpsmen/paramedics, to provide effective burn care closer to the point of injury, allowing for better survival and longterm outcomes.
- Development of interventions or advancement of standard-of-care practices addressing fluid resuscitation, inflammatory response, and complications of severe burn injuries including infection and sepsis of atypical burns and/or burns with concomitant polytrauma.

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Future priorities of the MBRP include research topics that expand upon the successes of burn-relevant research and interventions being developed by other research funding programs in and outside of the burn field. The MBRP will continue to monitor the state of burn care science to determine the program's role in the following areas: Assessing the epidemiology of burn injuries and associated treatment to better identify the gaps in knowledge and care for burn patients; driving clinically focused research to assess the safety and efficacy of existing burn treatments; and supporting high-impact clinical trials to advance the standard of burn care.

INVESTMENT STRATEGY

The MBRP plans to continue its commitment to funding exploratory research, clinical studies and trials, and expansions of prior/early-stage research investments via funding opportunity announcements offered by the program. The MBRP Programmatic Panel members emphasized a need for highly innovative, paradigm-shifting research for future investment consideration.

In the past five years, the MBRP has supported projects through the Clinical Translational Research Award, providing support for human research projects that provide high-impact changes to care of the burn-injured patient. In FY19 and FY21, the program offered the Idea Development Award, funding highly innovative early-stage research projects. In FY22 and FY23, the MBRP offered the Technology/Therapeutic Development Award, a product-focused award mechanism supporting translation of high-impact products into clinical trials.

The award mechanisms solicited by the MBRP will continue to reflect the phase of research (basic, translational, or clinical) based on the needs of the field and the funds appropriated to the program by Congress. This investment strategy will be re-evaluated and updated as necessary during the program's annual Vision Setting meeting.

MEASURING PROGRESS

MBRP-funded research projects have provided key research insights in advancing therapies and impacting standards of practice. The program will continue to measure its success in the short- and long-term based on its impact in the aforementioned topic areas. The number of research publications, patents, translated products (for both commercial and field use), follow-on funding resulting from MBRP-funded research, and impact on standard-of-care practices will also be captured and serve as metrics to assess progress made by the MBRP in addressing the needs of the burn care community.

Short-term outcomes (3-5 years): Progress will be measured by evaluating the amount of funding invested in each strategic goal, and by tracking contributions to the scientific and clinical communities including publications, patents, products, and clinical trials, which will vary based on the stage of the research project.

Long-term outcomes (6+ years): Progress will be measured by evaluating the proportion of funded investigators receiving additional awards to continue successful research, the production of commercialized products, changes in standard of care, decreased case fatality rates, and improved quality of life.

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