Integrated DoD Biomedical Research and Development Strategy

# Medical Innovation for the Future Force







Prepared by the Armed Services Biomedical Research, Evaluation and Management (ASBREM) Community of Interest (Col)

December 2017

# **Executive Summary**

The Armed Services Biomedical Research Evaluation and Management (ASBREM) Community of Interest (Col) represents 20 participating departments and agencies across the Department of Defense (DoD) that perform or sponsor biomedical research and development (R&D) in support of current and emerging needs of United States (U.S.) military forces. ASBREM Col members' R&D efforts range from basic research efforts that provide the foundation for future product development, through advanced development efforts that set the stage for fielding and upgrading the full-rate production of materiel capabilities and the integration of evidence-based research into clinical practice. The ASBREM is one of 17 Cols within Reliance 21, the overarching framework of the DoD's Science and Technology (S&T) joint planning and coordination process. The goal of Reliance 21 is to ensure that the DoD S&T community provides solutions and advice to the Department's senior-level decision makers, warfighters, Congress, and other stakeholders in the most effective and efficient manner possible.

The ASBREM Col is structured to ensure flexible and adaptive responses to a wide range of challenges. This structure includes the Senior Leadership Advisory Group (SLAG); the Science and Technology Advisory Group (STAG); the Advanced Development Advisory Group (ADAG), which is unique to the ASBREM Col; the Secretariat; and, at the heart of the organization, the seven Joint Technology Coordinating Groups (JTCGs). The JTCGs include representatives of the members of the ASBREM Col and other interagency and Military Health System (MHS) representatives, and they engage and include other departments, agencies, and stakeholders in their ac tivities. The JTCGs address capability gaps through seven research areas:

- 1. Biomedical Informatics/Health Informatics Systems and Technology (BI/HIST, JTCG-1)
- 2. Military Infectious Diseases (MID, JTCG-2)

- 3. Military Operational Medicine (MOM, JTCG-5)
- 4. Combat Casualty Care (CCC, JTCG-6)
- 5. Medical Radiological Defense (MRD, JTCG-7)
- 6. Clinical and Rehabilitative Medicine (CRM, JTCG-8)
- 7. Medical Chemical and Biological Defense (MCBD, JTCG-9)

The health services challenges on which this strategy focuses include supporting forces that are *dispersed over great distances* and that *rapidly aggregate and disaggregate*, providing health services to forces that are increasingly being integrated at lower echelons than is currently the case, and integrating with non-DoD mission partners. These challenges must be addressed in a strategic environment that is becoming more fiscally constrained, while still meeting the high expectations for positive medical outcomes, even in contested environments.

In response to these future operating environments, the ASBREM Col's vision is to promote the coordination and synergy of the DoD biomedical R&D efforts to provide medical products and information that are required to protect and sustain the health of Soldiers, Sailors, Airmen, and Marines of the U.S. Armed Forces so that they can accomplish the National Security Objectives and execute the mission of the DoD. The

<sup>1</sup> Joint Concept for Health Services (JCHS), 31 August 2015, p. 5.

goals to reach this vision are to ensure that our warfighters and health service teams are better prepared, better protected, and better cared for as they execute their missions. Collectively, the ASBREM community realizes this vision and goals through its members by delivering quality medical materiel and knowledge products by conducting innovative R&D that is aligned to validated capability gaps.

Military biomedical R&D is a vital national security interest that ensures the readiness of our service personnel in current and future conflicts. The products and capabilities developed by ASBREM Col members, academia, and industry support the full military medical life cycle, from pre-deployment through deployment, field operations, combat care, evacuation, medical treatment facility (MTF) care, recovery, and rehabilitation. This strategy provides a common framework to ensure that ASBREM members continue to discover, develop, and deliver the medical capabilities required today and in the future. It provides the basis for ASBREM members to optimize infrastructure and coordination and information exchange among the Services and other DoD agencies, as well as the federal government, and the civilian sector. Additionally, this strategy enables ASBREM members to partner with academia and industry to infuse investments and innovation into DoD medical operations and capabilities. This strategy ensures that the DoD's biomedical investments continue to be responsive to medical readiness and the warfighting needs today and well into the future.



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#### Foreword to the ASBREM Research and Development (R&D) Strategy

Modern technologies allow rapid travel and instant, continuous communication to connect our world as never before. These advances have led to opportunities for better worldwide engagement, understanding, and tolerance. Conversely, these same technologies also illuminate differences that can divide us as global relations remain complex, and are often fragile.

We cannot always predict the next time, location, or circumstance requiring the presence and power of the U.S. military forces, but we can count on the enduring need of our warfighters to be provided with the best available medical capabilities to ensure their readiness, protection, and treatment when conflict occurs.

Military combat is a joint Service activity, and ensuring the best quality medical care of the Warfighter must also be a cross-component, collaborative effort. In order to be responsive to current needs and ready for the next fight, the U.S. Department of Defense (DoD) invests significant resources into the research and development (R&D) of medical materiel products (e.g., equipment, tools, and devices) and knowledge products (e.g., treatment guidelines and protocols) for the warfighter.

Two notable recent accomplishments of military medicine were the rapidly-developed Zika virus vaccine that moved from the lab into human clinical studies within nine months, and the development of Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA), a technique which stems truncal hemorrhaging, the leading cause of preventable battlefield deaths.

The Department coordinates its medical R&D investments through a joint, cooperative body called the Armed Services Biomedical Research Evaluation and Management (ASBREM) Community of Interest (Col). The ASBREM Col is made up of military leaders, user groups, and medical research experts from every major DoD Component conducting or benefitting from military medical R&D.

As the Principal Deputy, performing the duties of the Assistant Secretary of Defense for Research and Engineering, I oversee the research activities of the DoD laboratories and agencies. We must promote coordination, cooperation, and technology exchange across the Department, ensuring that we are effective in our mission, are fiscally responsible, and maintain the public's trust. The ASBREM CoI is an instrument for achieving this goal for the medical domain, and I am excited to endorse this Integrated DoD Biomedical R&D Strategy. This strategy represents the Military Health System's research enterprise and communicates our collective approach to meeting the needs of our warfighters through coordinated and innovative scientific research and application.

lary J. Miller

Performing the Duties of the Assistant Secretary of Defense for Research and Engineering

# Table of Contents

Executive Summary
Foreword
Development (R&D) Strategy
Tomorrow's Biomedical Challenges
The Future Operating Environment
The Future Research and Development Environment
Health Services Opportunity
The ASBREM Col
ASBREM Organization
Vision and Guiding Principles
Goals
Goal 1: Better Prepared
Goal 2: Better Protected
Goal 3: Better Cared For
Research Collaborations Will Be Key to Future Capabilities Development
Conclusion: Achieving Readiness in the Future Operating Environment
Appendix A: ASBREM Col Membership
Appendix B: ASBREM Joint Technology Coordinating Groups
JTCG – 1: Biomedical Informatics & Health Information Systems and Technology $\ldots$ .28
JTCG – 2: Military Infectious Disease
JTCG – 5: Military Operational Medicine
JTCG – 6: Combat Casualty Care
JTCG – 7: Medical Radiological Defense
JTCG – 8: Clinical and Rehabilitative Medicine
JTCG – 9: Medical Chemical and Biological Defense
Appendix C: Joint Concept for Health Services Implementation
Appendix D: Abbreviations and Acronyms

# Tomorrow's Biomedical Challenges

The DoD expects that the joint operating environment will grow more complex as adversaries become more transregional, multi-domain, and multi-functional. The Department also anticipates rapid advances across many different R&D disciplines that underlie the biomedical sciences. Against this backdrop, it is critical that the military's medical capabilities are agile, integrated, and innovative to prepare, protect, and care for our warfighters against any current and future threats.

# The Future Operating Environment

Now and in the foreseeable future, the operating environment will be characterized by increasing complexity and rapid change. A few of the major factors that drive this change are listed below:

- Globalization
- Technology diffusion
- Demographic shifts<sup>2</sup>

Against this backdrop, the Joint Force must be able to rapidly adapt to new threats while maintaining a comparative advantage over existing threats. Success will increasingly depend on how well the military can support and enable our network of allies and partners. The 2015 National Military Strategy (NMS) calls for greater agility, innovation, and integration. It reinforces the need for the United States (U.S.) military to remain globally engaged to shape the security environment and to preserve our network of alliances.

The Joint Operating Environment 2035 posits a wide range of threats and persistent conflict over the next 20 years. The Department of Defense (DoD) expects that the joint operating environment will grow more complex as adversaries become more transregional, multi-domain, and multi-functional. The Capstone Concept for Joint Operations: Joint Force 2020 describes the Chairman's vision for future joint operations. It proposes the idea of globally integrated operations (GIO) premised on the ability to take elements of a globally postured force, quickly combine the elements, execute the mission, and disaggregate in preparation for the next task.<sup>3</sup>

The Services have also envisioned the future operating environment and have identified core challenges against which they must prepare today. Each of the Service line strategies reflects the same overarching vision of a complex future environment that is dispersed with rapidly evolving threats. This battlespace poses logistics and communications challenges that could deter a rapid and forceful response where and when needed, leading to significant readiness challenges, as shown in Figure 1.

<sup>3</sup> Included in the Foreword of *Joint Concept for Health Services* (JCHS), 31 August 2015.

<sup>2</sup> National Military Strategy (NMS), 2015, p. 1.

#### Future Battlespace

Increased time/distance
Distributed operations
Degraded/denied communications
Logistics challenges

Challenged air superiority

Figure 1. Challenges of the Future Battlespace

# The Future Research and Development Environment

Against this complex and dynamic future operating environment, the DoD can also anticipate rapid advances across the many different research and development (R&D) disciplines that underlie the Biomedical sciences. Some examples of these advances are listed below.

 An enhanced understanding of cell function and structure as well as new molecular biology concepts and tools will continue to create fundamental opportunities to understand injury and disease. Mechanistic understanding will lead to improved medical responses, including personalized diagnostics, pharmaceuticals, and medical care.

- 2. The evolution of information and data science and technology will create new abilities to access, store, analyze, and present medically critical information in ways usable by all levels of personnel. Medical informatics can be structured and accessed in a way to simplify medical records management and to be capable of free-form data extraction for optimal patient/casualty care and medical research.
- 3. Improvements in artificial intelligence will continue and will create wide-ranging force multiplication opportunities. Expected applications range from automating the management of big data sets resident in electronic health records to enabling the delivery of adaptive training tailored to an individual's unique learning preferences to facilitating autonomous operations patient-evacuation and transport platforms. The need to provide decision support tools as a force multiplier for point-of-injury (POI) medical care is critical to evolving and applying this technology advancement.
- 4. Advances in unmanned systems will provide opportunities to improve

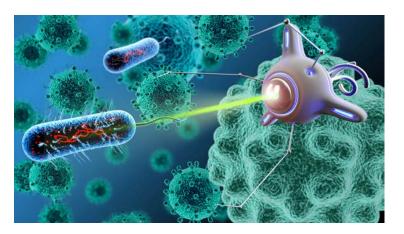


#### Lab Testing

An enhanced understanding of cell function and structure as well as new molecular biology concepts and tools will continue to create fundamental opportunities to understand injury and disease. (U.S. Air Force photo/ Senior Airman Josie Walck) medical support, particularly in remote or operational environments. Unmanned systems will offer the capacity to deliver additional medical supplies that cannot be carried by a medic or to restock medical supplies that are used up in a crisis situation. Unmanned systems that are large enough to carry one or a few individuals and are capable of remote operation, either through teleoperations or through advanced autonomy, will play an important role in rescue and transport operations.

- 5. Developments in nanotechnology will enable diagnostic systems that are miniaturized and hardened for field use and are usable with limited training and expertise, and will create new approaches for assessing warfighter readiness in real time. For example, a blood chemistry and hematology system the size of a current cell phone, with very small volume and weight supplies, would be critical where standard-hospital or clinic medical care is not possible.
- Innovations in additive manufacturing will create unique opportunities to synthesize medical device parts, as well as biologicals and pharmaceuticals, at the point of need by using common raw materials. The net result will be significant efficiencies in the massive logistics tail needed to sustain today's formularies.

These types of R&D advances will provide the foundation upon which to meet the capability gaps of the future and enable our warfighters to survive and thrive in the future battlespace.



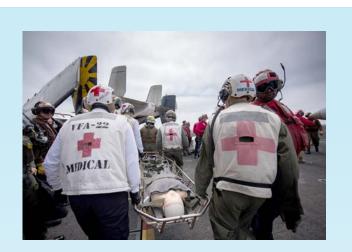


# Health Services Opportunity

The future operating environment and the Joint Forces' response to it pose several issues for the provision of healthcare. The Joint Concept for Health Services (JCHS)<sup>4</sup> document framed the military problem as follows: "How can the Joint Force provide comprehensive health services to deployed forces in an operating environment characterized by highly distributed operations and minimal, if any, pre-established health service infrastructure?"

It is critical that the military's medical capabilities continue to prepare, protect,

<sup>4</sup> JCHS, 31 August 2015, citation for quote on military problem.



Sailors transport a mannequin during a medical evacuation drill on the flight deck of the aircraft carrier USS Theodore Roosevelt (CVN 71). ASBREM must be able to meet the challenges of the future battlespace head-on and succeed. (U.S. Navy photo by Mass Communication Specialist 3rd Class Anthony J. Rivera/Released)



Central Command Area of Responsibility (Aug. 16, 2017) U.S. Sailors and Marines with Special Purpose Marine Air-Ground Task Force. Future medical forces and the technologies that enable them must be immediately responsive to a range of contingencies. (U.S. Marine photo by Lance Cpl. Ariana Acosta/Released) and care for our warfighters against any current and future threats. Armed Services Biomedical Research Evaluation and Management (ASBREM) must be able to meet the challenges of the future battlespace head-on and succeed. The projected health services challenges include supporting forces that are *dispersed over* great distances and that must be able to rapidly aggregate and disaggregate, providing health services to forces that are increasingly being integrated at lower echelons than is currently the case, as well as integrating with non–DoD mission partners. To meet these challenges, the DoD medical R&D coordination community, called the ASBREM Community of Interest (Col), must facilitate the development of biomedical solutions that are agile, integrated, and innovative.

Agile: Future medical forces and the technologies that enable them must be immediately responsive to a range of contingencies anytime and anywhere. According to the 2015 NMS, "the ability to quickly aggregate and disaggregate forces anywhere in the world is the essence of global agility. [The Joint Force] is striving to increase agility by improving campaign planning, sustaining a resilient global posture, and implementing dynamic force management processes that adjust presence in anticipation of events, to better seize opportunities, deter adversaries, and assure allies and partners."<sup>5</sup> Accordingly, medical service teams and capabilities must be tailorable and scalable, regionally aligned, and globally responsive to enable a force that is fast, lightweight, and lethal.

5 NMS, 2015, p. 15.

**Integrated:** The JCHS states that its key concept of Globally Integrated Health Services (GIHS) is a critical enabler of GIO that hinges on interoperable service capabilities guided by common standards and procedures and the ability to tailor support to meet a wide variety of operational and strategic requirements.

"The integration of combat units at lower echelons in support of GIO will require better integrated delivery of health services than previously required. Accordingly, the future medical force must be able to support Service-unique missions while also operating with an optimal degree of inter-Service integration. This integration will require interoperability in capability development areas such as medical equipment and logistics; clinical databases, patient administration, and management systems; techniques and procedures; and, to some degree, medical research and technology development. Interoperability goals should be applied judiciously so Service-specific capabilities may persist to support unique operational environments or characteristics."6

Innovative: The 2015 NMS7 predicts that globalization and the proliferation of technology and information will challenge the ability of U.S. forces to maintain current capability advantages over state and non-state adversaries during operations. These adversaries may well obtain equivalency or even superiority in the various operating domains, thereby increasing the threat to the health of the force, increasing operational risk, and potentially limiting Joint Force freedom of action. The DoD biomedical R&D community must encourage the pursuit of novel ideas and approaches to meet complex Service requirements and must be willing to embrace some calculated risks to achieve the breakthroughs needed to sustain the highest levels of medical capability.

<sup>6</sup> JCHS, 31 August 2015, p. 3 (include quotation marks if/where appropriate).

<sup>7</sup> NMS, 2015, p.1.

# The ASBREM CoI

The ASBREM Col is part of the Reliance 21 framework, an Office of the Secretary of Defense-led effort for joint planning and coordination. The ASBREM Organization is structured to ensure flexible and adaptive responses to a wide range of challenges. This construct promotes the coordination and synergy of DoD biomedical R&D efforts to provide medical products and information that are required to protect and sustain the health of Soldiers, Sailors, Airmen, and Marines of the U.S. Armed Forces.

The DoD established the ASBREM Committee in 1981, responding to a Congressional consolidation mandate. The original membership consisted of Medical Materiel Flag Officers (2-stars) from each Service and the Chairs of seven Joint Technology Coordinating Groups (JTCGs) that each focused on an element of the biomedical research portfolio. ASBREM provided a durable forum to facilitate DoD biomedical R&D strategy through communication and the assessment and resolution of competing demands for funding priorities. ASBREM processes informed organizational policy and provided the opportunity for process improvement.

In 2013, ASBREM reorganized into a Col within the Reliance 21 framework, an Office of the Secretary of Defense (OSD)–led effort for joint planning and coordination with the goal of reducing unnecessary duplications of work. Reliance 21 is led by the DoD S&T Executive Committee (ExCom), whose role is to prioritize resources and provide strategic oversight and guidance to the combined S&T work– force, laboratories, and facilities of the DoD. S&T ExCom ensures that the Department's S&T priorities correspond with broader Defense needs and strategic guidance. As a Col, ASBREM expanded its membership to include representatives from all DoD medical Research, Development, Test, and Evaluation (RDT&E) components, including those outside of S&T and in the capability development area, (sometimes referred to as advanced development). ASBREM is unique in its coordination of a medical materiel acquisition process that is relative to the integrated life-cycle management of medical products from concept to disposal. The life-cycle management can be viewed from user need and laboratory investigations-through clinical trials, Food and Drug Administration (FDA) approval, and manufacturing processes-to the delivery of the product to the warfighter and/or warfighter medic/ corpsman. The advanced development teams specifically work to transition S&T discoveries and products through clinical trials, FDA approval, and manufacturing, to the materiel delivery community.

In accordance with the ASBREM charter, the Defense Health Agency (DHA) Director of Research and Development became the ASBREM Col Chair in 2014. ASBREM's primary focus remains advancing communication, coordination, and collaboration across the entire DoD medical research enterprise.

# ASBREM Organization

The ASBREM Col is structured to ensure flexible and adaptive responses to a wide range of challenges. This structure includes the ASBREM Chair and three advisory groups supported by the Secretariat, as well as the JTCGs that oversee seven medical research areas, as shown in Figure 2. Appendix A provides more detail on ASBREM Col members.

## Advisory Groups

The members of the Senior Leadership Advisory Group (SLAG), the Science and Technology Advisory Group (STAG), and the Advanced Development Advisory Group (ADAG) are General Officer/Flag Officer/Senior Executive Service-level representatives, or those with comparable responsibilities. The SLAG's role is to provide senior-leader organizational and programmatic coordination and strategic guidance to the STAG and ADAG on improving the DoD components' responsiveness to medical readiness and warfighter needs. The STAG advises the ASBREM Col Chair and SLAG on the status of the biomedical S&T portfolios;

reviews the portfolios for compliance, quality, and progress; and recommends ways to enhance coordination across the Col. The ADAG advises the ASBREM Col Chair and SLAG on the status of, and recommendations to enhance the coordination of, development and acquisition activities between DoD components. Medical advanced development addresses FDA approval and manufacturing development to ensure the delivery of solutions suitable for hospital or field use. The STAG and the ADAG work closely together, and both groups make recommendations to facilitate and improve transitions from S&T activities to advanced development that lead to fielding or implementation.

# The Secretariat

The Secretariat is composed of experienced (Level O-4/O-5/O-6) military personnel or civilian equivalents designated by SLAG members to be their representative and to assist in conducting all of the functions and activities of the ASBREM Col.

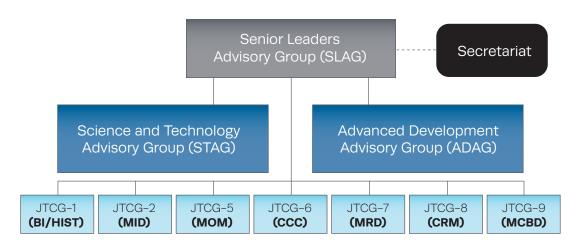


Figure 2. ASBREM Col Organization

# Joint Technology Coordinating Groups

The operational units of the ASBREM are the JTCGs. The JTCGs are comprised of representatives of the members of the ASBREM Col and other interagency and Military Health System (MHS) representatives. The JTCGs maintain visibility of the complex medical R&D programs across all ASBREM Col organizations, attempting to ensure strategic and balanced investments and conducting reviews, programmatic studies, and analyses to facilitate coordination, collaboration, and communication among the DoD components and OSD. The JTCGs are organized into core medical portfolios, based on the types and focus of the research that they oversee. Listed below are brief descriptions of the seven JTCGs that collectively address the health capabilities required for optimal medical readiness and response. More details on the JTCGs are presented in Appendix B.

#### JTCG – 1: Biomedical Informatics & Health Info Systems and Technology (BI/HIST)

The BI/HIST JTCG is focused on enhancing coordination and collaboration across all stake holders in military medical modeling and simulation training and health information technologies/informatics research and transferring research solutions and knowledge to meet the DoD's goals. Major categories of medical simulation and training research include Combat Casualty Training, Medical Readiness Training, Health Focused Education, and Tools for Medical Education. Health informatics categories of research include Theater/Operation Medicine, Health Services and Population Health, Health Operations Resourcing, and Enterprise Infrastructure Management.

#### JTCG – 2: Military Infectious Disease (MID)

The MID JTCG is focused on enhancing coordination and collaboration across all stakeholder communities in infectious-diseases research leading to the fielding of effective, improved means of protection and treatment to maintain maximal global operational capability with minimal morbidity and mortality. Major categories of research focus on protecting the warfighter against naturally occurring, known, predictable, endemic disease threats.

#### JTCG – 5: Military Operational Medicine (MOM)

The MOM JTCG is focused on enhancing coordination and collaboration across all stakeholders involved in developing effective medical countermeasures against operational stressors and preventing physical and psychological injuries during training and operations to maximize the health, performance, and fitness of Service members (SMs). Major categories of research include Psychological Health and Resilience, Injury Prevention and Reduction, Environmental Health and Protection, and Physiological Health and Performance.

#### JTCG – 6: Combat Casualty Care (CCC)

The CCC JTCG is focused on enhancing coordination and collaboration of all stakeholder communities seeking to optimize survival and recovery in SMs injured in combat across the spectrum of care from the point of injury (POI) through en route care and facilities. Major categories of research include Traumatic Brain Injury (TBI); Hemorrhage Control; Resuscitation and Blood Products; as well as portfolios addressing care delivered in specific field medical environments, such as En Route Care and Forward Surgical and Critical Care. Medical photonics is a significant enabler, crosscutting the other portfolios.

#### JTCG – 7: Medical Radiological Defense (MRD)

The MRD JTCG is focused on enhancing coordination and collaboration of all stakeholder communities involved in discovering and developing materiel and knowledge that reduce medical capability gaps relevant to radiation health effects, enhance military readiness in a radiation environment, and enhance medical capabilities against radiation exposure. Major categories of research focus on the development of medical countermeasures to prevent or treat the effects of Acute Radiation Syndrome (ARS).

#### JTCG – 8: Clinical and Rehabilitative Medicine (CRM)

The CRM JTCG is focused on enhancing coordination and collaboration of all stakeholder communities developing knowledge and materiel products to reconstruct, rehabilitate, and provide



definitive care for injured SMs. The goal is to return the SM to duty and restore their quality of life. Major categories of research include Neuro–musculoskeletal Injury (prosthetics, assistive devices, and rehabilitation and reintegration strategies), Pain (battlefield, acute, and chronic), Regenerative Medicine, and Sensory Systems (vision, hearing, and balance).

#### JTCG – 9: Medical Chemical Biological Defense (MCBD)

The MCBD JTCG is focused on enhancing the coordination and collaboration across all stakeholder communities for research, development, test, and evaluation of prophylaxis, therapeutics, and diagnostics against chemical and biological threats of security concern and against novel and emerging infectious–disease threats. Major categories of research focus on protecting the warfighter against these threats to maintain maximal global oper– ational capability with minimal morbidity and mortality.

# Vision and Guiding Principles

# ASBREM Vision

The ASBREM Col will promote the coordination and synergy of the DoD biomedical R&D efforts to provide medical products and information that are required to protect and sustain the health of Soldiers, Sailors, Airmen, and Marines of the U.S. Armed Forces so that they can accomplish the National Security Objectives and execute the mission of the DoD.

The National Security Environment of today and the future requires DoD forces to be ready to rapidly execute missions in austere environments where medical threats pose a significant risk. The ASBREM Col serves as a single point for coordinating the biomedical R&D portfolio to deliver solutions against these risks. This strategy will be reviewed periodically to ensure that it supports the ASBREM Col's role.

## **Guiding Principles**

To achieve its vision, ASBREM executes its mission under the following guiding principles:

- Driving innovation in DoD biomedical research. R&D is essential to maintaining medical readiness and improving responsiveness to warfighter needs. By driving the R&D of products to meet the highest priority needs posited by Combatant Commands, the Joint Force will be well positioned to tackle the toughest biomedical challenges of the future.
- Maintaining strong biomedical R&D connections to other government agencies, industry, and academia.
   Research discoveries and innovation can



arise anywhere and anytime. ASBREM stakeholders and subject matter experts interact with the larger federal, private, industry, and academic biomedical communities to ensure that they are aware of the advances made by others and to better inform research objectives, priorities, and investments. Collaborations with academia and industry are leveraged to provide faster, more effective, and more cost-effective military medical solutions for the warfighter.

- Coordinating and integrating portfolios across the DoD. Unique missions mean that Service and agency specific needs will always exist. ASBREM seeks to be a force multiplier by fostering the communication, integration, and synchronization of efforts across the DoD biomedical research community, and by including other Cols, as appropriate, in the development of novel medical capabilities for the Joint Force.
- Improving resource management and efficiency. Promote timely and effective cross-Service and cross-agency R&D collaborations with the intent of increasing productivity, accelerating the delivery of capabilities to end users, and streamlining efforts to reduce unnecessary duplications.



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# Goals

The ASBREM Community of Interest strives to ensure that the Joint Force is Better Prepared, Better Protected, and Better Cared For throughout the operational life cycle. Collaboration on research activities will be critical to developing materiel and knowledge products that the Services require for mission success in the future operating environment.

Achieving the ASBREM vision in the current and future strategic environment requires enduring goals that are relevant to the full spectrum of challenges facing the MHS. These goals are advanced via integrated and synchronized biomedical research activities that draw upon the broad scope of expertise throughout the DoD biomedical research community. Collaboration across the ASBREM Col on these research activities will be critical to developing materiel (e.g., devices, biologics, preventive and therapeutic medicines and vaccines) and knowledge (e.g., information, protocols, and methods) products that the Services require for mission success in the future operating environment.

Whether the future fight takes our forces to the four corners of the earth or beyond, the ASBREM Col strives to ensure that the Joint Force is (1) Better Prepared, (2) Better Protected, and (3) Better Cared For throughout the operational life cycle. These goals, which are summarized in the subsections below, are collectively supported by the JTCGs whose strategic drivers and research focus areas are detailed in Appendix B.

# Goal 1: Better Prepared

Warfighters are equipped with capabilities and knowledge to optimize their health and achieve peak performance in all mission domains. This includes providing new approaches to delivering training to ensure that warfighters and medical service providers develop the knowledge, skills, and abilities appropriate to their mission sets; creating new technologies to ensure the retention of these skills and abilities in a network constrained environment to relay critical medical information; anticipating and mitigating exposure to biological and chemical threats; developing strategies and interventions to build cognitive and psychological resilience; creating technologies to monitor real-time data regarding warfighter physiology; and developing technologies for sustaining operational performance in environmental extremes.

# Goal 2: Better Protected

Warfighters are equipped with a layered protection of materiel and knowledge to minimize or eliminate exposure to, and the consequences of, biomedical risks, including infectious diseases, preventable injuries, radiation and chemical exposures and other environmental/workplace hazards. This includes creating new tools to identify and monitor biomedical threats in the environment; developing tools to monitor an individual warfighter's physiological status and exposure to environmental or occupational threats; accelerating promising, innovative prophylaxis and therapeutics solutions to combat emerging infectious diseases; and developing new approaches to protect against sensory-system injuries.





# Goal 3: Better Cared For

Warfighters are provided with multi-layered health services that minimize morbidity and mortality and maximize recovery across the treatment continuum-from the POI, during en route care, to definitive care and rehabilitation. This includes developing capabilities to support prolonged field-care and critical-care capabilities, including products for portable diagnostics, resuscitation, hemorrhage control, endovascular stabilization, pain control, organ support, blood replacement, and burn treatment; enhancing patient movement and management during en route care; developing novel therapeutics/delivery technologies against wound infection pathogens and biofilm processes; restoring and rehabilitating injured warfighters (e.g., prosthetics and assistive devices, skin substitutes); providing treatment protocols for physiological and psychological injuries, such as burns, loss of limbs, or post-traumatic stress disorder (PTSD); and improving regenerative medical techniques.

In summary, Table 1 provides a snapshot demonstrating the alignment of the ASBREM goals with the JTCGs and with currently envisioned materiel and knowl– edge products.

It is clear from this mapping that achieving the ASBREM strategic goals requires the contributions of multiple JTCGs to achieve a holistic approach of layered protection. The challenges posed by the projected future combat environment will shift the emphasis even more strongly toward collaborative and coordinated programs by the entire biomedical R&D community.

Table 1. JTCG Alignment with Strategic Goals

Goals	JTCG	Equipment/Materiel Products	Information/Knowledge Products
Better Prepared	1 – BI/HIST 2 – MID 5 – MOM 7 – MRD 9 – MCBD	<ul> <li>Preventive medicines and vaccines against parasitic, bacterial, fungal, and viral infectious diseases</li> <li>Nutritional supplements</li> <li>Immune system stimulants</li> <li>Realistic simulations of combat injuries and treatments</li> <li>Augmentation devices</li> <li>Validated models to inform treatment of injury and disease</li> </ul>	<ul> <li>Health guidance based on feedback from wearables</li> <li>Occupational hazard mitigation guidance</li> <li>Medical threat assessment</li> <li>Exposure mitigation methods</li> <li>Protocols to accelerate the review and approval of new countermeasures</li> <li>Realistic simulations of large-scale health emergencies</li> <li>Joint medical force planning</li> <li>Medical education modules, medical information access, and information tools to focus and enhance medical understanding at all levels</li> </ul>
Better Protected	1 – BI/HIST 2 – MID 5 – MOM 7 – MRD 9 – MCBD	<ul> <li>Biomedical threat detection sensors</li> <li>Exposure monitoring devices</li> <li>Medical countermeasures</li> <li>Protective gear/devices</li> <li>Wearable sensors</li> <li>Rapid pathogen sequencing tools</li> <li>Restorative sleep technologies, pharmaceuticals or nutraceuticals</li> <li>Rapid response toolkits for countermeasure development</li> <li>Preventive therapy for chemical, biological and radiation threat mitigation</li> </ul>	<ul> <li>Global health surveillance system</li> <li>Exposure models</li> <li>Disease spread models</li> <li>Analysis of health stressors and impacts</li> <li>Medical situational awareness tools</li> <li>TBI prevention and monitoring</li> </ul>
Better Cared For	1 – BI/HIST 5 – MOM 6 – CCC 7 – MRD 8 – CRM 9 – MCBD	<ul> <li>Prolonged field-care and critical-care capabilities (e.g., unit-level ALS [amyotrophic lateral sclerosis])</li> <li>Resuscitation products</li> <li>Portable diagnostic tools</li> <li>Battlefield pain control</li> <li>Endovascular stabilizing capabilities</li> <li>Blood products</li> <li>Hemorrhage control</li> <li>Concussion dosimetry</li> <li>Organ support</li> <li>Virtual medicine (at distance)</li> <li>Novel pharmaceuticals for Psychological Health Disorders</li> <li>Biomarkers for Psychological Health Disorders</li> <li>Deployable medical treatment packages (capability at the point of need)</li> <li>En route intensive care</li> <li>Medical robotics</li> <li>Burn treatment products</li> <li>Pain control (e.g., MTF, post-MTF)</li> <li>Alternative medicine</li> <li>Prosthetics and assistive devices</li> <li>Skin substitutes</li> <li>Vascular repair</li> </ul>	<ul> <li>Self-care guidance</li> <li>Decision aids for unit-level, en route, and MTF care</li> <li>Integrated/interoperable electronic health records</li> <li>Telemedicine protocols</li> <li>Virtual medicine information systems</li> <li>Predictive models (e.g., patient deterioration)</li> <li>Burn treatment protocols</li> <li>TBI diagnosis and treatment methods</li> <li>Bioinformatics and analytics</li> <li>Psychotherapy treatments (including PTSD)</li> <li>PTSD diagnostic and treatment protocols</li> <li>Regenerative medical techniques</li> </ul>

# Conclusion: Achieving Readiness in the Future Operating Environment

The JCHS document describes GIHS as a concept for the future of joint medical operations in increasingly challenging battlefield environments. The JCHS Transition *Plan* provides the joint medical enterprise with a guide for developing a comprehensive set of medical capabilities required to implement GIHS. The JCHS recognizes the critical role for the DoD biomedical R&D community in developing the knowledge and products that will provide the needed future capabilities. Accordingly, it calls for action across the entire MHS to establish common joint efforts, whenever possible, while preserving Service-unique capabilities where necessary. Appendix C includes a crosswalk of ASBREM JTCGs arrayed against selected JCHS Concept Required Capabilities.

Achieving readiness in the future operating environment, as detailed in the JCHS document and other strategy documents, will require agile, integrated, and innovative military health solutions to the evolving operational challenges. The development



Research Collaborations Will Be Key to Future Capabilities Development

# *Meeting a Future Challenge*: Increased Distance from Point of Injury to Definitive Care

The anticipated distance between the battlefield and definitive care sites in potential future operational environments, as well as the development of advanced en route care procedures and medical devices, will be critical to the survival of injured warfighters. Developing this capability requires increased R&D in multiple technology areas, from information systems and management (JTCG-1) and the cybersecurity implications (Cyber Col), to critical care and patient movement (JTCG-6, Autonomy Col) and physiological and environmental monitoring (JTCG-5, Sensors/ Human Systems Col).

of these solutions will cut across multiple technology areas and will necessitate increased coordination and collaboration across the JTCGs and other Reliance-21 Col partners. Through implementation of this Integrated DoD Biomedical R&D



Strategy, ASBREM will accelerate the R&D of solutions that address JCHS guidance<sup>8</sup> to improve health services for future Joint Force operations. These solutions will address key military requirements for improvements across the full spectrum of military health services, from pre-deployment through deployment, field operations, evacuation, treatment, recovery, and rehabilitation, and will include injury and disease prevention, human performance optimization, and force protection.

Just as the ASBREM Col acknowledges that the environment will continue to evolve, this strategy will also need to evolve to reflect the changes to the operational and technological environment. In the short term, ASBREM expects that communicating this strategy to the broader Biomedical R&D community will pave the way for innovative technological advancements and collaborative partnerships across the Federal Government as well as with our academic and industry partners. In turn, ASBREM anticipates that these partnerships will provide deeper clarity into how best to continually ensure that our warfighters and health service teams are better prepared, better protected, and better cared for.

<sup>8</sup> Appendix C includes an analysis of Armed Services Biomedical Research Evaluation and Management Joint Technology Coordinating Groups arrayed against selected JCHS Concept Required Capabilities.

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# Appendix A: ASBREM CoI Membership

Table 2 lists the joint organizations, along with their website addresses, that are Armed Services Biomedical Research Evaluation and Management (ASBREM) Community of Interest (Col) members.

Table 2	2. ASBREM	Col Meml	bership

Joint Organizatio	n
Joint Chiefs of Staff	http://www.jcs.mil/
<ul> <li>Joint Staff Surgeon</li> </ul>	
Joint Program Executive Office for Chemical and Biological	https://www.jpeocbd.osd.mil/
Defense	
Joint Requirements Office for Chemical, Biological, Radiological	https://jsportal.sp.pentagon.mil/sites/J8/
and Nuclear defense	DDFP/JRO/default.aspx (CAC-enabled)
Offices of the Assistant Secret	tary of Defense
Office of the Assistant Secretary of Defense for Research and	http://www.acq.osd.mil/chieftechnologist/
Engineering	
Office of the Assistant Secretary of Defense for Health Affairs	https://health.mil/About-MHS/ASDHA
<ul> <li>Office of Health Research Policy Oversight</li> </ul>	
<ul> <li>Defense Health Agency Component Acquisition Executive Directorate</li> </ul>	
<ul> <li>Defense Health Agency Research and Development Directorate</li> </ul>	
<ul> <li>Uniformed Services University of the Health Sciences Office of Vice President for Research</li> </ul>	
Office of the Assistant Secretary of Defense for Nuclear,	http://www.acq.osd.mil/ncbdp/
Chemical and Biological Defense Programs	
<ul> <li>Defense Threat Reduction Agency</li> </ul>	
<ul> <li>Joint Science and Technology Office for Chemical and Biological Defense</li> </ul>	
Services	
Army	https://www.army.mil/asaalt
<ul> <li>Office of the Assistant Secretary of the Army for Acquisition, Logistics and Technology</li> </ul>	http://mrmc.amedd.army.mil/
<ul> <li>The United States Army Medical Research and Materiel Command</li> </ul>	
Navy and Marines	https://www.onr.navy.mil/
The Office of Naval Research	http://www.med.navy.mil/Pages/Default.aspx
The Navy Bureau of Medicine and Surgery	http://www.hqmc.marines.mil/Agencies/
<ul> <li>The Medical Officer to the Marine Corps</li> </ul>	Health-Services/Medical-Officer-USMC/
Air Force	http://www.airforcemedicine.af.mil/
<ul> <li>Office of the Air Force Surgeon General</li> </ul>	
The 59th Medical Wing	
The 711th Human Performance Wing	
Additional Organizat	tions
United States Special Operations Command	http://www.socom.mil/
Defense Advanced Research Projects Agency	http://www.darpa.mil/about-us/offices
Defense Logistics Agency	http://www.dla.mil/

# Appendix B: ASBREM Joint Technology Coordinating Groups

The Armed Services Biomedical Research Evaluation and Management (ASBREM) Joint Technology Coordinating Groups (JTCGs) are comprised of representatives of the members of the ASBREM Community of Interest (CoI) and other interagency and Military Health System (MHS) representatives. JTCGs engage and include other departments, agencies, and stakeholders in their activities. JTCG participation includes representatives of all Department of Defense (DoD) organizations and agencies conducting health and medical research in each of the following respective major sub-areas (see the subsections below) of the biomedical research and development (R&D) portfolios described within the ASBREM Col.

Provided below are the end-state vision, strategic drivers, and research focus areas under which research activities that lead to materiel and knowledge products are developed.

# JTCG – 1: Biomedical Informatics & Health Information Systems and Technology

Biomedical Informatics and Health Information Systems and Technology (BI/HIST) research is focused on emerging military medical simulation and health information technologies/informatics research across all stakeholder communities and transferring research solutions and knowledge to meet the DoD's goals. The BI/HIST program currently addresses two capability areas: Medical Simulation and Health Information Technologies and Informatics (HITI). A third area, Medical Capabilities to Support Dispersed Operations, will be added in the future.

## End-state Vision

Advance HITI has the following end-state vision

- Increase patient safety and the quality of care
- Address MHS current and future HITI needs in theater and garrison
- Meet military medical capability gaps and requirements based on stakeholder-driven priorities
- Research, test, and prove the maturity, usability, benefit, and performance of HITI components and subsystems prior to integrating them into live environments in order to reduce risk to Major Automated Information Systems and the MHS enterprise

Medical Simulation has the following end-state vision:

- Enable combat casualty care by enhancing the MHS capabilities through the application of simulation to contemporary and future medical battlespaces
- Increase medical readiness to optimize medical outcomes for the warfighter by strengthening provider skills and healthcare delivery within and across the Continuum of Care
- Improve medical education training tools through a reduction and replacement of live tissue training; the delivery of personalized and predictive simulation systems; and promoting an integrated Medical Simulation Enterprise across the DoD

Medical Capabilities to Support Dispersed Operations has the following end-state vision

- Utilize autonomous systems to enable unmanned delivery modes of medical capability
- Enable prolonged care by exploiting emerging communications and information technologies
- Utilize robotics on the battlefield to support medical tasks

#### Strategic Drivers

Medical Capabilities Supporting Disbursed Operations (MCSDO):

- CNA FY16 Capability Gaps
- Theater Medical Information Requirements/Information CDD
- TRADOC PAM 525-66
- Future Operating Capability 09–06 Health Services Support
- The US Army Robotic and Autonomous Systems Strategy, US Army Medical Department Center and School/Health Readiness Center of Excellence SPAR Product Review FY17/18
- CBA IS-CDD TMIR, October 2016

Medical Simulation (MedSim):

- 2015 Air Force Medical Component (AFMS) Capabilities Based Assessment (CBA) Report 17, September 2015
- AFI 10-601 Operational Capability Requirements Development, 6 November 2013
- Air Force Medical Modeling and Simulation Training (AFMMAST) Learning Management System (LMS) Capabilities Development Document (CDD), 3 May 2012
- CJCSI 3170.01I, Joint Capabilities Integration and Development System, 23 January 2015
- Combat Trauma Lessons Learned from Military Operations of 2001–2013, 9 March 2015
- Department of Defense (DOD) Instruction 5000.02, Operation of the Defense Acquisition System, 7 January 15
- Force Health Protection (FHP) Concept of Operations (CONOPS), 17 November 2011
- Health Readiness Concept of Operations (CONOPS), January 2010
- Joint Concept for Health Components (JCHS) CONOPS, 31 August 2015
- Joint Force Health Protection (JFHP) Initial Capabilities Document (ICD), 24 February 2010
- Joint Theater Patient Evacuation (JTPE) DOTmLPF-P Change Recommendation (DCR), 15 May 2015
- Joint Training Functional Concept (JTFC), Version 1.0, 14 August 2007
- Medical, Modeling, and Simulation (MM&S) Requirements Management DOTmLPF-P Change Recommendation (DCR) DRAFT, 30 November 2015
- Theater Combat Casualty Care Initial Capabilities Document (ICD), October 2007

Health IT and Informatics (HIT/I):

- DHA Health Information Technology Directorate Strategic Plan, 2016 2019
- Federal Health IT Strategic Plan, 2015 2020, The Office of the National Coordinator for Health Information Technology (ONC), DHHS http://healthit.gov

- The Federal Big Data Research and Development Strategic Plan
- The Networking and Information Technology Research and Development Program May 2016
- Joint Chiefs of Staff (JCS) Joint Concept for Health Services, August 2015
- Theater Medical Information Requirements (TMIR) Information System (IS) CDD
- National Defense Authorization Act (NDAA) 2016 Section 217 Mandates Science and Technology Activities to Support Major Automated Information Systems (MAIS) Acquisitions [JOMIS]. Tab 1 FY17 NDAA Conferenced Bill Title VII, 29 November 2016
- Department of Defense Instruction (DODI) Number 8330.01, 21 May 2014
- Interoperability of Information Technology (IT), Including National Security Systems (NSS) Initial Capabilities Document for Department of Defense (DoD) Combat Casualty Care Medical Research and Development, 14 November 2014
- Joint Force Health Protection ICD, 24 February 2010
- Concept of Operations (CONOPS) for the DoD Trauma Enterprise (DTE), 26 October 2016
- The Department of Defense (DoD) Trauma Enterprise (DTE) Capabilities Based Assessment (CBA) Requirements Report

Theater Operational Medicine Reach (TOMI REACH):

- Information System Capability Development Document (IS-CDD) for Theater Medical Information Requirements (TMIR)
- Defense Trauma Enterprise (DTE) CONOPS, 3 October 2016
- Theater Operational Medicine Agility (TOMI Agility) Strategic Driver: IS-CDD TMIR, 3 October 2016
- Medical Resourcing for Theater/Operational Medicine Strategic Driver: IS-CDD TMIR, 3 October 2016

#### **Research Focus Areas**

The research focus areas of HITI are as follows:

- Theater/Operational Medicine Research for Medical Capability in Dispersed Operations
- Theater/Operational Medicine Agility/Medical Intelligence from Data
- Theater/Operational Medicine Medical Resourcing to Support Theater Information Technology Performance MedSim
- Joint Evacuation and Transport Simulation
- Point of Injury Training System
- Warfighter Preparation, Resilience, Enhancement, and Protection

The research focus areas of Medical Capabilities to Support Dispersed Operations are as follows:

- Medical Autonomous and Unmanned Platforms
- Virtual Health
- Medical Robotics

# JTCG – 2: Military Infectious Disease

The Military Infection Disease (MID) research program focuses on work leading to the fielding of effective, improved means of protection and treatment to maintain maximal global operational capability with minimal morbidity and mortality. The program employs a requirements-driven process to protect the warfighter against naturally occurring, known, predictable, endemic disease threats.

## End-state Vision

Develop effective control measures to combat the continuous threat of infectious diseases through the coordinated direction and execution of a military-focused infectious disease R&D program for the DoD. Successful control of the disease threat will be achieved through technology application and superiority based upon the following factors:

- Unified, innovative, basic, and applied R&D that is responsive to militarily-relevant operational requirements
- Promotion of the highest quality Science and Technology (S&T) through effectively resourced R&D facilities
- Coordination of R&D activities among government, academia, industry, and international health organizations
- Recruitment, utilization, and retention of the highest quality scientific personnel by offering them the opportunity to excel in their fields and the option to pursue an executive leadership path
- Integrated management organization focused on providing program direction and oversight

## Strategic Drivers

MIS receives guidance from the following sources

- Health System Support (HSS) CONOPS
  - HSS Capabilities: 4.1.10 Medical Research and Development
- Health Service Delivery (HSD) CONOPS
  - HSD Capability 15: Laboratory Diagnostic Services
  - HSD Capability 23: Disease Management
  - HSD Capability 27: Intensive Care
  - HSD Capability 28: Surgery (Inpatient)
  - HSD Capability 37: Amputee Care
  - HSD Capability 38: Burn Care

### **Research Focus Areas**

The research focus areas of MID are as follows:

- Malaria Vaccine
- Anti-parasitic Drugs
- Flavivirus Vaccine (Dengue)

- Bacterial Diarrhea Vaccine(s)
- Lethal Virus Medical Countermeasures
- Vector Control

# JTCG – 5: Military Operational Medicine

The Military Operational Medicine (MOM) program is focused on developing effective medical countermeasures against operational stressors and preventing physical and psychological injuries during training and operations to maximize the health, readiness, and performance of Service members (SMs) and their families.

#### End-state Vision

The end-state vision of MOM is to provide the Joint Force with the following resources/tools:

- Optimized health and operational effectiveness under extreme environmental conditions, such as altitude, heat, cold, and hazardous environmental chemicals, to reduce non-battle injuries
- Reduced the sensory (e.g., hearing, vision) and musculoskeletal injury rate and severity to decrease attrition, medical costs, and personal impact
- Improved biomedical countermeasures (e.g., fatigue, nutrition) to optimize/enhance cognitive and physical fitness and to maintain operational effectiveness
- Effective strategies and interventions that reduce the impact of mental disorders and concussions and that build psychological resilience among SMs and their families

#### Strategic Drivers

MOM receives guidance from several sources:

- The United States (U.S.) Army Vision Force 2025 White Paper, January 2014
- Capability Development Documents
  - For Air Soldier System, November 2007
  - For Core Soldier System, March 2005
  - For Ground Soldier System, April 2005
- Initial Capabilities Documents (ICDs)
  - For Joint Force Health Protection, February 2010
  - For Combat Casualty Care Medical R&D, May 2014
  - For Military Operational Medicine, February 2008
  - For U.S. Army Human Dimension, March 2012
  - For Military Operational Medicine, May 2017
- The National Research Action Plan, August 2013
- The U.S. Army Training and Doctrine Command's S&T Imperatives F2025B
- Air Force Strategic Master Plan, Air Force Future Operating Concept
- Air Force Medical Service (AFMS) Human Performance Concept of Operations

## **Research Focus Areas**

The research focus areas of MOM are as follows:

- Environmental Health and Protection
- Injury Prevention and Reduction
- Physiological Health and Performance
- Psychological Health and Resilience

# JTCG – 6: Combat Casualty Care

The Combat Casualty Care (CCC) program seeks to drive medical innovation through the development of knowledge and materiel solutions for the acute and early management of combat-related trauma, including point-of-injury, en route, and facility-based care. Medical photonics is a significant enabler, crosscutting the other portfolio.

## End-state Vision

Our vision is to optimize survival and recovery from combat–related injury in current and future operational scenarios. The CCC program seeks to leverage the nation's vast medical research program with dynamic in–house research and investments in key military–specific research areas.

## Strategic Drivers

CCC receives guidance from the following sources:

- Policies, such as the rebalance to the Asia Pacific region, Army Operating Concept (AOC) 2025B, and user communities
- Joint Capabilities Board (JCB) Initial Capabilities Document (ICD) on Combat Casualty Care Devices and Products (JROCM 026–15)
- Government Accountability Office (GAO) Report (#GAO-13-209), "Defense Health Actions Needed to Help Ensure Combat Casualty Care Research Achieves Goals," 2012
- AFMS Medical Readiness in an Anti-access/Area-denial (A2/AD) Environment ICD

### **Research Focus Areas**

The CCC program is adjusting to view its efforts through the lens of future care scenarios.

The research focus areas of CCC are as follows:

- Hemorrhage Control and Resuscitation
  - Ultra-low volume resuscitation fluids, including blood substitutes
  - Dried or lyophilized formulations of blood and blood components (e.g., plasma and fibrinogen
  - Compounds to modulate the adverse effects of inflammation and immune response
- Traumatic Brain Injury (TBI)
  - Clinical trials of drugs to improve recovery from TBI

- Acute interventions to preserve injured brain tissue and prevent secondary injury
- Identification of circulating biomarkers to improve diagnosis
- Burn and Wound Treatment
  - Cell therapy (i.e., stem cells) to reduce organ damage and to improve recovery
  - Single-organ and multi-organ extracorporeal organ support technologies
  - $\circ~$  Cell-based therapies to replace muscle and nerve loss and function
- En Route Care
  - Autonomous ventilators, which reduce oxygen requirements and personnel
  - Unmanned, automated medical evacuation capability
  - Intelligent tasking of advanced resuscitative and en route care capabilities
- Forward Surgical and Intensive Care
  - Prolonged field care enabled by advanced physiologic monitoring and telementoring
  - Decision support technology to empower medics to deliver life-saving interventions
  - Endovascular (i.e., inside the blood vessel) approaches to hemorrhage control and the management of shock

# JTCG – 7: Medical Radiological Defense

Radioactive materials are widely distributed in governments and civilian organizations worldwide for industry and medicine; are used in large quantities in power generation; and are in nuclear weapons in numerous countries. Radiation and nuclear risks represent a threat to U.S. forces and U.S. facilities as well as harm to American and international individuals and governments. The threat of injury from exposure to radiation emanating from radiological isotopes or a nuclear detonation under a variety of scenarios (e.g., RDD ["dirty bomb"], IND) could have catastrophic consequences upon the individual warfighter and the military's capacity to wage war.

Radiation, in the purest sense, is a physical means of transferring sufficient energy to a biologic target to initiate a series of biochemical reactions at the cellular level that result in massive cell injury and death, leading to immediate multiple organ system dysfunction, known as Acute Radiation Syndrome (ARS), and later occurring effects in survivors of ARS, such as lung injury and cancer. These injurious biochemical reactions can, to some extent, be interrupted and limited, as well as reversed, by measures to promote cellular recovery and regeneration.

Medical Radiological Defense (MRD) is comprised of Service representatives from the United States Army, Navy, and Air Force. JTCG–7 contributes to the planning and RDT&E activities of the discovery and development of materiel and knowledge that reduce medical capability gaps relevant to radiation health effects, enhance military readiness in a radiation environment, and enhance medical capabilities against radiation exposure. The principal focus today is the R&D of medical countermeasures to prevent or treat the effects of ARS.

# End-state Vision

MRD has the following end-state vision:

- Pharmaceutical protection against radiation injury to allow sustained military operations under the threat of radiation exposure
- Diagnostic methods and devices to rapidly and accurately identify casualties in need of immediate, delayed, and chronic medical care
- Pharmaceutical mitigators/treatments and therapies to limit radiation injury and promote regeneration/healing to reduce morbidity/mortality from radiation and to restore the fighting strength
- Pharmaceutical intervention to prevent delayed or chronic injury from radiation exposure (e.g., leukemia) to reduce long-term military medical care expense
- Detailed mechanistic understanding of radiation injury to promote faster development of, and the Food and Drug Administration's approval of, new products
- Improved medical response to mass casualties by using the full medical spectrum of advanced medical care, utilizing existing and newly developed pharmaceuticals to obtain maximal survival, both acutely and from long-term consequences of ionizing radiation exposure

## Strategic Drivers

MRD research is driven by the critical role that radiation preparedness plays in the Globally Integrated Health Services concept and by the explosion of knowledge in basic radiation biology at the molecular level. This knowledge is used to explore novel solutions in the MRD programs' three pillars: prevention, detection, and treatment.

### **Research Focus Areas**

The research focus areas of MRD are as follows:

- Novel pharmaceuticals for prevention, mitigation, and treatment
- Diagnosis by using biophysical dosimetry methods and devices
- Basic molecular radiation biology
- Enabling technologies, including qualified animal models for product development
- Development of a medical response capability that incorporates specific existing and novel therapeutics to maximize both acute and long-term recovery

# JTCG – 8: Clinical and Rehabilitative Medicine

The Clinical and Rehabilitative Medicine (CRM) research program focuses on developing knowledge and materiel products to reconstruct, rehabilitate, and provide definitive care for injured SMs. The goal is to return the SM to duty and restore their quality of life. Primary research focus areas include Neuro-mus-culoskeletal Injury (prosthetics, assistive devices, and rehabilitation and reintegration strategies), Pain Management (battlefield, acute, and chronic), and Regenerative Medicine, Vision, Hearing, and Balance Dysfunction.

## End-state Vision

Support the provision of evidence-based clinical, regenerative, and rehabilitative management of patient impairments, functional limitations, and barriers to participation following insult or injury to the musculoskeletal, sensory, nervous, or integumentary systems. The goal of JTCG-8 is to return the injured SM to duty and optimize their quality of life.

## Strategic Drivers

CRM receives guidance from multiple sources:

- Coordinated Concept of Operations
- Force 2025 and Beyond
- Defense Health Agency Joint Program Committee (JPC) Charter for CRMRP/JPC-8 OSD
- U.S. Army CRMRP ICD
- Joint Force Health Protection ICD

### **Research Focus Areas**

The research focus areas of CRM are as follows:

- Neuro-musculoskeletal Injury Rehabilitation
- Pain Management (Acute/Chronic/Battlefield)
- Regenerative Medicine and Transplants
- Sensory Systems (Visual, Auditory, and Vestibular)

# JTCG – 9: Medical Chemical and Biological Defense

The Medical Chemical and Biological Defense (MCBD) program is focused on the research, development, testing, and evaluation of diagnostics, prophylaxis, and therapeutics against chemical and biological threats of security concern to include novel and emerging threats. The program employs a requirements-driven process to achieve a portfolio of scientifically based, layered, FDA approved medical countermeasures (MCM) to protect the warfighter and maintain maximal global operational capability with minimal morbidity and mortality.

### End-state Vision

To provide a robust portfolio of scientifically based medical countermeasures that ensures DoD operations are unconstrained by Chemical, Biological, Radiological, and Nuclear effects. Achievement of DoD unconstrained operations will be based upon the layered approach utilizing the below concepts:

- Operationally relative scientific based requirements
- Rapid far forward diagnostics
- A polypharmaceutical approach throughout the continuum of healthcare care
- Rapid and agile MCM production through the use of the Advanced Development Manufacturing capability
- Leveraging platform technologies

## Strategic Drivers

MCBD receives guidance from many sources as the program is in direct support of the Defense-Wide Chemical Biological Defense Program (CBDP). Direction and goals are drawn from the National Security Strategy, the National Defense Strategy, and the Joint Chiefs of Staff's National Military Strategy. Guidance is further defined by the Defense Planning Guidance and the Joint Service Priorities, which are considered in the development of the annual DoD Chemical and Biological Defense Program Planning Guidance distributed by the Deputy Assistant Secretary of Defense for Chemical and Biological Defense.

## **Research Focus Areas**

CBDP medical research areas align to one of the following Core Capability Areas:

- Biological Therapeutics
- Chemical Therapeutics
- Biological Prophylaxis
- Chemical Prophylaxis
- Medical Diagnostics
- Basic Research
- Enabling Technology

# Appendix C: Joint Concept for Health Services Implementation

Armed Services Biomedical Research Evaluation and Management (ASBREM) Community of Interest (CoI) members are advancing progress toward Joint Concept for Health Services (JCHS) implementation through biomedical research and development (R&D). ASBREM JTCGs currently are contributing R&D products and concepts to support nine (9) of the sixteen (16) JCHS Concept Required Capabilities, as illustrated in Table 3.

JCHS Concept Required Capabilities	JTCGs						
	BI/HIST	MID	MOM	CCC	MRD	CRM	MCBD
2. Joint Theater-Directed Coordination,				•	•		
Synchronization & Medical S.A.							
3. Monitor Patient Outcomes, Assess	•		•	•	•		
Clinical Effects, & Adapt Operations	· ·				•		
5. Medical Mitigation of the	•	•	•		•		•
Environment		•					· ·
7. Medical Treatment	•		•	•		•	
Facilities							
8. Patient Evacuation	•			•			
9. Patient Management	•	٠	•	•	•	•	٠
12. Joint & Service Medical Education &	•		•	•	•		
Training							
13. Joint Medical R&D	•	٠	•	•	•	•	•
15. Global Health Services Network	•		•	•			

Table 3. JCHS Mapped to the JTCGs

Besides advancing other Concept Required Capabilities, ASBREM coordinates work toward these Concepts Required Capabilities (JCHS document, 2015, p. 17): Enhance the ability to advance the state of medical science, technologies, and practices in areas relevant to GIO and to ensure the most promising medical solutions are developed and fielded for the future Joint Force.

- Improve support for basic medical research directed toward greater knowledge and understanding of the fundamental principles of science and medicine that are relevant to the improvement of health services capabilities
- Improve joint refinement of biomedical technology concepts and ideas into potential solutions to military health and performance problems with a view towards evaluating technical feasibility and Joint Force Requirements
- Improve support of promising medical technology candidate solutions that are selected for initial safety and efficacy testing in small–scale human clinical trials regulated by the U.S. Food and Drug

Administration (FDA) prior to licensing for human use. This includes examining promising medical technology candidate solutions for initial safety and efficacy testing

- Improve Advanced Component Development support for medical products that are regulated by the U.S. FDA and the accelerated transition of FDA licensed and non-licensed (or FDA-unapproved) products and medical practice guidelines to the military operational user through clinical and field validation studies
- Improve development and demonstration of medical commodities delivered from Advanced Component Development efforts that are directed at meeting validated requirements prior to full-rate initial production and fielding, including initial operational test and evaluation and clinical trials
- Improve support for enhancement activities for fielded medical products and the pre-planned improvement of fielded medical products, including information management/information technol-ogy systems.

# Appendix D: Abbreviations and Acronyms

A2/AD	Anti-Access/Area-Denial
ADAG	Advanced Development Advisory Group
AFMS	Air Force Medical Service
ALS	Amyotrophic Lateral Sclerosis
AOC	Army Operating Concept
ARS	Acute Radiation Syndrome
ASBREM	Armed Services Biological Research, Evaluation and Management
<b>BI/HIST</b>	Biomedical Informatics & Health Information Systems and Technology
CBDP	Chemical Biological Defense Program
CCC	Combat Casualty Care
Col	Community of Interest
CONOPS	Concept of Operations
CRM	Clinical and Rehabilitative Medicine
DHA	Defense Health Agency
DoD	Department of Defense
ExCom	Executive Committee
FDA	Food and Drug Administration
GAO	Government Accountability Office
GIHS	Globally Integrated Health Services
GIO	Globally Integrated Operations
HITI	Health Information Technologies and Informatics
HSD	Health Service Delivery
HSS	Health System Support
ICD	Initial Capabilities Document
IM	Information Management
IT	Information Technology
JCB	Joint Capabilities Board
JCHS	Joint Concept for Health Services
JPC	Joint Program Committee
JROCM	Joint Requirements Oversight Council Memorandum
JTCG	Joint Technology Coordinating Group
MCBD	Medical Chemical and Biological Defense
MHS	Military Health System
MID	Military Infectious Disease
MOM	Military Operational Medicine
MRD	Medical Radiological Defense
MTF	Medical Treatment Facility
NMS	National Military Strategy
OSD	Office of the Secretary of Defense
POI	Point of Injury
PTSD	Post-traumatic Stress Disorder

- R&D Research and Development
- RDT&E Research, Development, Testing, and Evaluation
  - S&T Science and Technology
  - SLAG Senior Leadership Advisory Group
  - SM Service Member
- STAG Science and Technology Advisory Group
- TBI Traumatic Brain Injury
- U.S. United States