Science and Technology Efforts and Programs Relating to the

Prevention, Mitigation, and Treatment of Blast Injuries

FY13 REPORT TO THE EXECUTIVE AGENT

DoD Blast Injury Research Program Coordinating Office • US Army Medical Research and Materiel Command

Acknowledgements

DoD Agency, Office or Service	DoD Agency, Office or Service
Army Public Health Command (APHC)	Office of the Air Force Surgeon General
Army Research Laboratory (ARL)	Office of the Armed Forces Medical Examiner (OAFME)
Combat Casualty Care Research Program (CCCRP)	Program Executive Office (PEO) Soldier
Defense Advanced Research Projects Agency (DARPA)	Tank Automotive Research, Development, and Engineering Center (TARDEC)
Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury (DCoE)	Uniformed Services University of Health Sciences (USUHS)
Defense and Veterans Brain Injury Center	US Army Aeromedical Research Laboratory (USAARL)
Hearing Center of Excellence (HCE)s	US Army Medical Materiel Development Activity (USAMMDA)
Joint Improvised Explosive Device Defeat Organization (JIEDDO)	US Army Medical Research Materiel Command (USAMRMC) Telemedicine & Advanced Technology Research Center (TATRC)
Joint Trauma Analysis and Prevention of Injury in Combat (JTAPIC)	US Army Natick Soldier Research, Development and Engineering Center (NSRDEC)
Marine Corps Systems Command (MCSC)	US Army Natick Soldier Systems Center (NSSC)
Military Infectious Diseases Research Program (MIDRP)	US Army Tank Automotive Research, Development and Engineering Center (TARDEC)
Military Operational Medicine Research Program (MOMRP)	US Army Test and Evaluation Command (ATEC)
Naval Health Research Center (NHRC)	USAMRMC Clinical and Rehabilitative Medicine Research Program (CRMRP)
National Intrepid Center of Excellence (NICoE)	USAMRMC Combat Casualty Care Research Program (CCCRP)
Naval Medical Research Center (NMRC)	US Navy Bureau of Medicine and Surgery (BUMED)
Naval Surface Warfare Center (NSWC) Carderock	Vision Center of Excellence (VCE)
Office of Naval Research (ONR)	Walter Reed Army Institute of Research (WRAIR)

Executive Summary

The Department of Defense (DoD) sponsors medical research programs aimed at advancing the DoD's capability to prevent, mitigate, and treat blast injuries. Established in 2006, the Blast Injury Research Program has played a key role in coordinating blast injury research and leveraging expertise from within the DoD, nationwide and internationally. This Report to the Executive Agent highlights the activities undertaken in fiscal year 2013 by the Blast Injury Research Program, the DoD and other federal agencies, academia, industry, and international partners to advance the knowledge and address current gaps in prevention, detection and treatment of blast-related injuries.

Among the key research accomplishments reported are:

- Mine-Resistant Ambush Protected (MRAP) vehicles are designed to survive improvised explosive device attacks and ambushes. Loading casualties into and out of the current MRAP MaxxPro ambulance is time consuming and labor intensive. To solve this issue, researchers at the Tank Automotive Research, Development, and Engineering Center have designed an upgraded system that requires less than a minute to move a casualty into or out of the MRAP vehicle.
- The Unites States (US) Navy Bureau of Medicine and Surgery sponsored research at the University of Utah to explore the effects of blast overpressure on intracranial pressure (ICP) and with the blood-brain barrier (BBB) breakdown in a rat model. This Report to the Executive Agent highlights the activities undertaken in fiscal year 2013 by the Blast Injury Research Program, the DoD and other federal agencies, academia, industry, and international partners to advance the knowledge and address current gaps in prevention, detection and treatment of blast-related injuries.
- The Marine Corps Systems Command and Office of Naval Research sponsored a Small Business Innovative Research effort by InfraScan, Inc. to develop a hand-held screening device that uses near-infrared technology to screen patients for intracranial bleeding. The "Infrascanner" provides a new capability to provide rapid triage for head injuries, particularly closed head injuries. The device can identify patients most likely to have increased ICP as well as those who would most benefit from immediate referral to a computed tomography scan and neurosurgical intervention.
- Researchers at the US Army Aeromedical Research Laboratory compiled ocular injury data from several published sources and constructed ocular injury risk curves based on equations developed to assess all ocular injuries as a function of a single blast exposure variable. This work has resulted in the development of procedures for the evaluation of eye protection devices using the Facial and Ocular Countermeasure for Safety headform with an improved eye surrogate.
- As part of the Military Photomedicine Program managed by the US Air Force Office of Scientific Research, researchers at Massachusetts General Hospital are developing a light-activated tissue repair technology for improved care after traumatic injuries, including peripheral nerve repair, sealing of penetrating eye wounds, blood vessel anastomosis, and the sealing of skin wounds. The technology, called Photochemical Tissue Bonding (PTB), rapidly forms a water-tight tissue-to-tissue seal by crosslinking proteins between tissue surfaces without additional proteins or glues. PTB is not cytotoxic or inflammatory, thus producing less fibrosis, scarring, and adhesions than sutured repair.

- The US Army Medical Materiel Development Activity-sponsored researchers at Stanford University, in partnership with Neodyne Biosciences, completed a pivotal trial of a novel, stress-shielding bandage to reduce surgical scars. The device is a silicone-based polymer which reduces tension on the surgical incision during immediate healing and early remodeling, effectively improving the local wound-healing environment. A sterile version of the bandage is expected to be available within the next year.
- Researchers from the Defense and Veterans Brain Injury Center, in collaboration with researchers from the Walter Reed National Military Medical Center, National Intrepid Center of Excellence, and Center for Neuroscience and Regenerative Medicine, utilized diffusion tensor imaging (DTI) to assess neurocircuitry in Service members who had sustained a TBI while deployed, for comparison to non-deployed military controls. DTI results were examined in relation to post-traumatic stress disorder and post-concussion symptoms. The data suggest that the networks of the fronto striatal circuit and the frontal-limbic circuit are the most vulnerable to military-related injury and may also have a role in the development of neuropsychological symptoms frequently seen in military patients with TBI.
- Researchers at the Center for Bionic Medicine at the Rehabilitation Institute of Chicago, supported by the Telemedicine and Advanced Technology Research Center (TATRC), have created a thought-controlled bionic leg. This is the first time that the movement of a prosthetic leg can be controlled by signals from its owner's brain. This is achievable since surgeons connect healthy nerves to the prosthesis, which is controlled by a computer chip similar to those used in modern smartphones. Brain signals travel to sensors that are attached to the prosthetic leg and the neural activity is detected by the leg's computer chip. The brain signals are immediately analyzed, decoded, and converted to instruction, which directs the limb to move in whatever manner it needs.

Among the key on-going initiatives and activities described in this report are:

- **Joint Trauma Analysis and Prevention of Injury in Combat (JTAPIC) Program.** JTAPIC is a DoD Program with Executive Agent responsibility to collect, integrate, analyze, and store operations, intelligence, materiel, and medical data to inform solutions that prevent or mitigate injury during the full range of military operations.
- **Military Health System Blast Injury Prevention Standards Recommendation (MHS BIPSR) Process.** The MHS BIPSR process ensures that the DoD is using the best available and biomedically valid standards for assessing weapon system health hazards and developing combat platform occupant and individual blast protection systems.
- **Blast-Related Data Collection and Analysis.** The DoD is collecting, and developing improved means to collect data on Service members' exposure to blast and impact during both combat and training, and linking these data to medical risks such as concussion and TBI. Understanding the blast environment and injury risks to which Service members are exposed is critical to providing the best protection to avoid injury, and the best treatment should injuries occur.
- **North Atlantic Treaty Organization (NATO) Human Factors and Medicine (HFM) Panel: HFM-234 Research Task Group (RTG) on Environmental Toxicology of Blast Exposures: Injury Metrics, Modeling, Methods and Standards.** The HFM activity was formed to promote international collaboration and standardization to address critical research needs such as physics-based modeling of animals and humans in relevant blast environments, blast exposure monitoring methods and metrics, and standardized protocols for blast injury research.

The significant research accomplishments, initiatives and activities highlighted in this annual report reflect the highly collaborative research efforts and knowledge sharing coordinated though the DoD Blast Injury Research Program Coordinating Office.

Foreword from the Director

Conventional and low-tech explosive weapons, including improvised explosive devices (IED), have caused most of the combat injuries in recent conflicts. Medical researchers have made considerable advances over the past year in developing technologies and procedures to prevent, treat, and mitigate the effects of these weapons. For example, computational modeling of the lower extremities and lumbar spine has revealed a link between the acceleration of a combat vehicle's deforming floor plate and the amount of bone damage sustained in the foot and ankle regions of the vehicle's occupants during an underbody blast event. New techniques may facilitate the development of diagnostic tools for mild traumatic brain injury (mTBI); for example, scientists have developed a novel wearable sensor that can detect impact events that may lead to mTBI. Advances in hemorrhage control and damage control surgery have helped reduce the percentage of our warfighters dying from "survivable" wounds to a record low. In the area of composite tissue transplantation, surgeons performed a fourth successful face transplant in April 2013. Researchers have also developed a technology called photochemical tissue bonding, which seals traumatic and surgical skin wounds without suture-induced inflammation and scarring.

Despite these advances, many challenges remain. Among these are understanding the mechanisms of blast-related mTBI; developing guidelines for standardizing blast injury research, which is typically interdisciplinary in nature; establishing common animal models and biomedically valid computational models of blast exposure and the resulting injuries; continuing to improve hemorrhage control and resuscitation; providing access to historical blast injury research data; and identifying blast injury prevention standards to support the continued development and testing of safe weapons and effective combat platform occupant and individual protection systems.

This report describes the efforts of the Department of Defense (DoD) Blast Injury Research Program to address the entire spectrum of blast injury challenges during fiscal year 2013 and highlights significant accomplishments during this period. These accomplishments illustrate what can be realized when diverse medical, operational, and materiel development communities within the DoD eliminate traditional mission stove pipes, break down communication barriers, establish effective partnerships, and leverage the vast biomedical research expertise that resides not only within the DoD but in other federal agencies, academia, and industry, both within the United States and in other nations.

This compilation of initiatives and accomplishments informs the Executive Agent (EA) and shares information with the many organizations that comprise the DoD Blast Injury Research Program. Information sharing encourages collaboration, prevents duplication of effort, and fulfills the underlying objective of the congressionally mandated DoD Blast Injury Research Program. I am pleased to present this report to the EA on behalf of the vast network of dedicated professionals who are the foundation of the DoD Blast Injury Research Program.

Michael J. Leggieri, Jr.
Director, DoD Blast Injury Research
Program Coordinating Office

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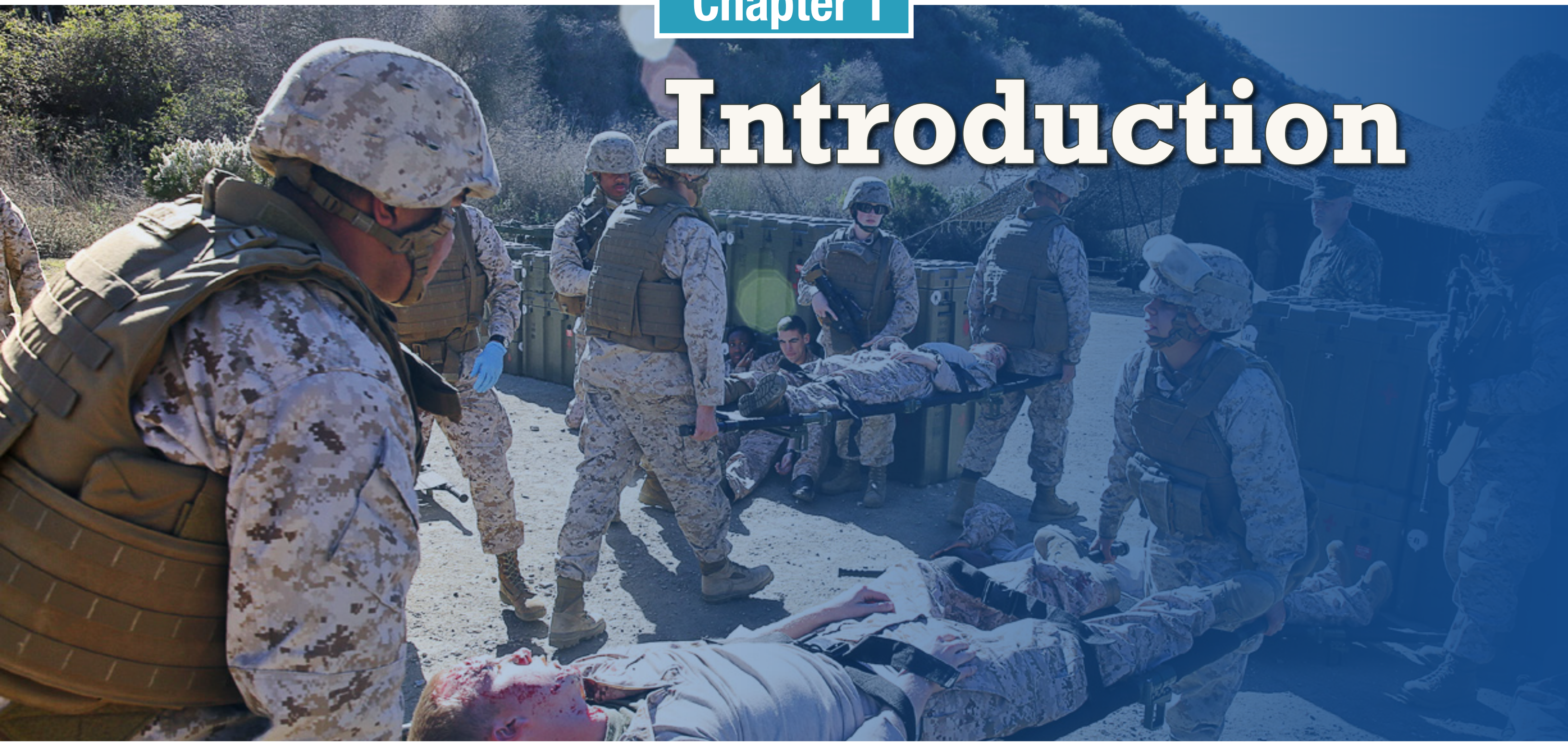
Chapter 1

Introduction



> "The United States is now winding down the longest period of sustained combat in our history, but America's obligations to those who answered the call to serve are only beginning."
>
> Veterans Day Message, As Written by Secretary of Defense Chuck Hagel, Washington, D.C.,
>
> Monday, November 11, 2013

Operations in Afghanistan and Iraq, worldwide terrorist bombings, the advent of novel explosives, and the growing use of IEDs have resulted in a significant number of blast-related casualties. In 2006, Congress directed the Office of the Secretary of Defense (OSD) to designate an Executive Agent (EA) to be responsible for coordinating and managing the medical research efforts and programs of the Department of Defense (DoD) relating to the prevention, mitigation, and treatment of blast injuries. In response to this direction, the DoD issued DoD Directive (DoDD) 6025.21E, "Medical Research for Prevention, Mitigation, and Treatment of Blast Injuries," on July 5, 2006 (see Appendix B) that designated the Secretary of the Army as the DoD EA and assigned program oversight to the Assistant Secretary of Defense for Research and Engineering (ASD(R&E)). As shown in **Figure 1-1**, the Secretary of the Army delegated authority and assigned responsibility to execute EA responsibilities to the Assistant Secretary of the Army for Acquisition, Logistics, and Technology ASA(ALT), and the ASA(ALT) further delegated authority and assigned program responsibility to the Commander, United States (US) Army Medical Command (USAMEDCOM). The DoDD also assigned additional responsibilities within the DoD as shown in **Figure 1-2**.

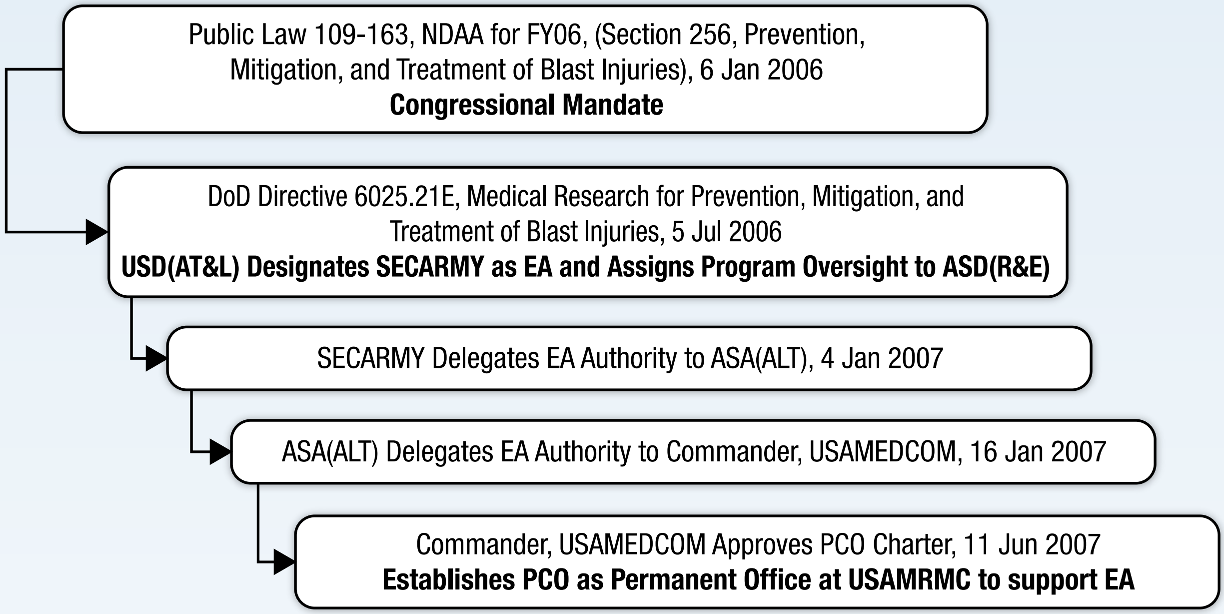


Figure 1-1: Assignment of EA Authority*

* The DoDD directed the Armed Services Biomedical Research Evaluation and Management Committee to facilitate coordination and prevent unnecessary duplication of effort within DoD biomedical research and development (R&D) and associated research areas.

Responsibilities and Functions	ASD(R&E) (ASBREM Chair)	ASD(HA) (ASBREM Co-Chair)	SECARMY (EA)	SECNAV & SECAF	USUHS	CJCS	USSOC	JIEDDO
Oversee EA	X							
Approve Blast Injury Research Programs	X							
Ensure New Technology is Transitioned to DoD Components	X							
Assist in Requirements Development and Needs Assessment	X	X		X			X	X
Approve MHS Blast Injury Prevention, Mitigation, and Treatment Standards		X						
Ensure MHS Information Systems Support the EA		X						
Share Blast Injury Research Information as Broadly as Possible			X					
Program, Budget, and Execute ASD (R&E)-Approved Programs			X					
Support Joint Database for Improving Protection Systems (JTAPIC)			X					X
Recommend MHS Blast Injury Prevention, Mitigation and Treatment Standards			X					
Appoint ASBREM Reps			X	X	X	X	X	X
Coordinate all Blast-Injury Efforts and Requirements Through the EA				X	X	X	X	X

Figure 1-2: Program Responsibilities and Functions

SECARMY=Secretary of the Army; SECNAV=Secretary of the Navy; SECAF=Secretary of the Air Force; USUHS=Uniformed Services University of the Health Sciences; CJCS=Chairman of the Joint Chiefs of Staff; USSOC=United States Special Operations Command; JIEDDO=Joint Improvised Explosive Device Defeat Organization; MHS=Military Health System; JTAPIC=Joint Trauma Analysis and Prevention of Injury in Combat; ASD(HA)=Assistant Secretary of Defense for Health Affairs

The Blast Injury Research Program Coordinating Office (PCO) was subsequently established within USAMEDCOM at the US Army Medical Research and Materiel Command (USAMRMC), Fort Detrick, Maryland, to assist the EA in coordinating and managing blast injury-related DoD medical research efforts and programs. The PCO coordinates and manages relevant DoD medical research efforts and programs, identifies blast injury knowledge gaps, shapes medical research programs to fill identified gaps, facilitates collaboration among diverse communities both within and outside of the DoD (as shown in **Figure 1-3**), and widely disseminates blast injury research information. The activities of the PCO are further described in Chapter 2.

Figure 1-3: Breadth of the PCO's Coordinating Responsibilities

Defining Blast Injuries

The term "blast injury" includes the entire spectrum of injuries that can result from exposure to an explosive weapon. The DoD Blast Injury Research Program uses the Taxonomy of Injuries from Explosive Devices as defined in DoDD 6025.21E (**Figure 1-4**) to characterize such injuries.

This taxonomy assigns blast injuries to five categories—Primary, Secondary, Tertiary, Quaternary, and Quinary—based on the type of injury. Primary blast injuries result from the high pressures created by the blast itself. These high pressures, known as blast overpressure, can crush the body and cause internal injuries. Primary blast injuries are the only category of blast injuries that are unique to blast. Secondary blast injuries result when the strong blast winds behind the pressure

Unique to Blast

PRIMARY

- Blast lung
- Eardrum rupture and middle ear damage
- Abdominal hemorrhage and perforation
- Eye rupture
- Non-impact, blast-induced mild traumatic brain injury

SECONDARY

- Penetrating ballistic (fragmentation) or blunt injuries
- Eye penetration

TERTIARY

- Fracture and traumatic amputation
- Closed and open brain injury
- Blunt injuries
- Crush injuries

QUATERNARY

- Burns
- Injury or incapacitation from inhaled toxic fire gases

QUINARY

- Illnesses, injuries, or diseases caused by chemical, biological, or radiological substances (e.g., "dirty bombs")

Figure 1-4: Types of Blast Injuries per DoDD 6025.21E

front propel fragments and debris against the body and cause blunt force and penetrating injuries. Tertiary blast injuries result from the strong winds and pressure gradients that can accelerate the body and cause the same types of blunt force injuries that would occur in a car crash, a fall, or a building collapse. Quaternary blast injuries are the result of other explosive products (such as heat and light) and exposure to toxic substances from fuels, metals, and gases that can cause burns, blindness, and inhalation injuries. Finally, quinary blast injuries refer to the clinical consequences of "post-detonation environmental contaminants," including chemical, biological and radiological (e.g., dirty bombs) substances.

Key Program Features

The Blast Injury Research Program is addressing critical medical research gaps for blast-related injuries. The program is leveraging new extramural blast injury research partnerships with DoD medical research laboratories to achieve a cutting-edge approach to solving blast injury problems. Medical research products include medical standards for enhanced personal protective equipment (PPE). The program is addressing the concept of "reset" for warfighters in redeployment, ensuring return-to-duty readiness (or healthy return to civilian life for citizen Soldiers, Sailors, Airmen, and Marines). One of the program's major areas of focus is the improvement of battlefield medical treatment capabilities to mitigate neurotrauma and hemorrhage. Finally, the program is modernizing military medical research by bringing technology advances and new research concepts into DoD programs (**Figure 1-5**).

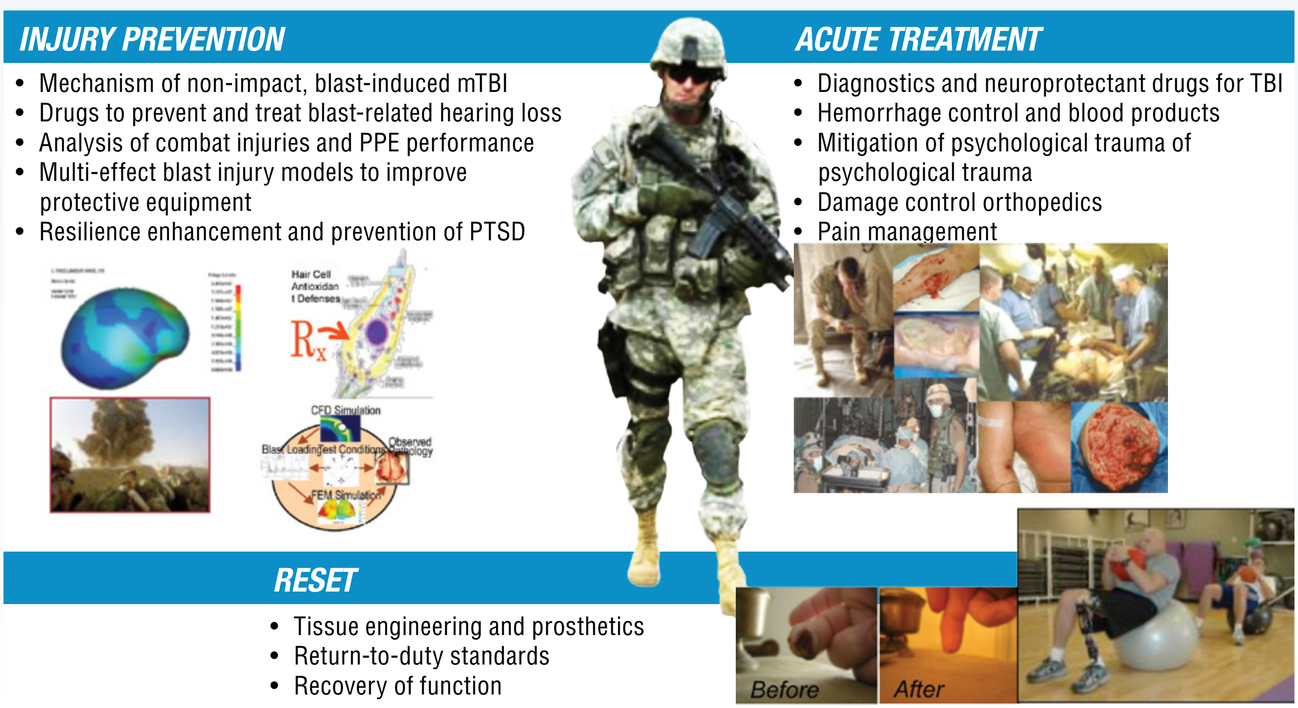


Figure 1-5: Scope of Blast Injury Research Program Areas

Key Research Topics

The Blast Injury Research Program is focusing on filling key gaps in the blast injury knowledge base. Key research topics by program area include:

Injury Prevention

Injury Prevention mitigates the risk of blast injuries by providing medically based design guidelines and performance standards for individual and combat platform occupant protection systems; comprehensive injury surveillance systems that link injury, operational, and protection system performance data; tools to identify individual susceptibility to injury; and individual resilience training to prevent or mitigate injuries.

Acute Treatment

Acute Treatment mitigates injury by providing immediate treatment across the spectrum of blast-related injuries through improved diagnostic tools, health care provider training, wound care, and medical treatment outcomes analysis.

Reset

Reset mitigates disability by providing a biomedically based performance assessment capability for return-to-duty in redeployment and following injury, restoring full performance capabilities in redeployed individuals, and restoring function and ability to seriously injured Service members with prosthetics. The term "reset" acknowledges a concept that extends beyond rehabilitation to include all activities necessary to return injured Service members to duty or to productive civilian life.

Funding

Medical research within the DoD is supported through multiple organizations and funding sources. The main types of funding are the President's Budget (PB) and Congressional Special Interest (CSI) appropriations. Traditionally referred to as "core," PB funds represent the DoD/President's planned budget. A key aspect of DoD core research programs is that research is "requirements driven." The research is focused on improving or filling a gap in the force's capabilities in preventing and treating injury and restoring function. CSI funds are adjustments to the PB that reflect congressional priorities. CSI funds are often directed by Congress to topics that relate to the DoD core programs—for example, traumatic brain injury (TBI) and orthopedic trauma. Through participation by key members of core research programs and clinical/research subject matter experts (SMEs) in vision setting, program announcement topic decisions, and proposal funding selection, the DoD core programs leverage CSI funding toward filling capability gaps. Blast injury research is funded by both PB and CSI funds.

Some of the key CSI-funded programs are listed in **Table 1-1** along with their focus areas for fiscal year 2013 (FY13). These programs, funded through the Defense Health Program (DHP), are managed by the USAMRMC. Core funding programs of the DoD Services and agencies are discussed as follows.

Service and Agency Programs

The Army, Navy, Air Force, and Defense Advanced Research Projects Agency (DARPA) each have ongoing core research programs related to blast injury. These programs sponsor research both internally, within DoD laboratories and clinical centers, and externally, within academia and industry. The research areas include injury surveillance, combat casualty care (CCC), wound infections, military operational medicine (MOM) (prevention and return-to-duty), and clinical and rehabilitative medicine (CRM). In FY10, the Office of the Assistant

Secretary of Defense for Health Affairs (OASD(HA)) established a core R&D program to enhance the related medical R&D programs of the Services and DARPA, accelerating the transition of medical technologies into products, and knowledge into new standards of care. The current emphasis of that program is on the Secretary of Defense's stated priorities of post-traumatic stress disorder (PTSD), TBI, prosthetics, restoration of eyesight and advancing eye care, and other conditions directly relevant to battlefield injuries as well as other ailments that affect both Service members and their Families. Coordination of Service and agency programs is achieved through joint oversight and management committee structures, such as Joint Technology Coordinating Groups under the Armed Services Biomedical Research Evaluation and Management (ASBREM) Committee and Joint Program Committees (JPCs) under the DHP.

The DoD has also established key research institutes and clinical Centers of Excellence (CoEs) to advance solutions to blast injury-related problems. For example, the Armed Forces Institute of Regenerative Medicine (AFIRM), managed by the USAMRMC, is focused on innovative technologies and approaches to harness the body's repair and regenerative mechanisms to treat severe injuries (http://www.afirm.mil/). Based on the success of the first 5-year program, the DoD awarded the AFIRM II as a follow-on effort in FY13 (**Table 1-2)**. The Bridging Advanced Developments for Exceptional Rehabilitation (BADER) Consortium, funded by the Peer Reviewed Orthopaedic Research Program (PRORP) and led by the University of Delaware, was established to improve orthopaedic rehabilitation of warfighters with significant limb injuries (**Table 1-3**).

Numerous DoD CoEs focused on improving the clinical care capabilities have been created in response to congressional requirements within National Defense Authorization Acts. These centers look for ways to improve care via new and updated clinical practice guidelines (CPG),

Table 1-1: FY13 Focus of CSI Programs with Blast Injury-Related Research

CSI Program	Program Focus
Psychological Health and TBI Research Program	Focuses on the research and development of assessment tools, methods, assistive devices, training strategies, and clinical applications (specifically those which target return-to-duty, cognitive self-management, evidence-based retraining focused on compensatory strategies, and/or daily functioning) that show promise in ameliorating cognitive deficits due to TBI and/or its co-morbidities such as stress disorders. The program considers the development of interventions or therapies to protect and/or restore neuronal function following TBI in the acute (first week), subacute (>1 week to 3 months), and chronic (≥ 3 months from time of injury) phases of care. Other areas of concentration are alternatives to current opioid analgesics for management of severe pain by medic/corpsman on the battlefield and in remote locations; management of acute and chronic pain under the care of a clinician in non-deployed settings; and identification of pain generators. Also addressed are hearing loss/dysfunction, balance disorders, and tinnitus within the areas of etiology of injury, diagnostics, mitigating dysfunction, restoration and rehabilitation. The mitigation and treatment of visual dysfunction associated with TBI is another program focus.
Peer Reviewed Orthopaedic Research Program (PRORP)	Supports military-relevant orthopaedic research. Areas of emphasis include optimizing long-term functional outcomes for amputee and Limb Salvage (LS) patients; preventing or mitigating post-traumatic osteoarthritis; surgical interventions for spine fractures and instability; physical or occupational therapy interventions; improving secondary health effects (e.g., joint contracture, obesity, cardiovascular disease, poor bone health) that follow reduced mobility; improving long-term socket performance and fit of prosthetics; improving moisture management and residual limb skin care at the prosthetic socket interface; and minimizing surgical site infections. Also considered is the establishment of bone, joint, and soft tissue health guidelines for training and therapeutic interventions.
Spinal Cord Injury Research Program (SCIRP)	Concentrates on areas related to the management of acute spinal cord injury (pre-hospital, en route care, and early hospital management) and issues (for example, deep vein thrombosis, infection and pressure ulcers), and best practices for interventions and musculoskeletal health during the first year after Spinal Cord Injury (SCI). Also addressed are issues occurring at any time after SCI such as bladder, bowel and sexual dysfunction; neuropathic pain and sensory dysfunction; functional deficits; and the ambulatory and non-ambulatory clinical benefits of exoskeletal systems.
Vision Research Program	Addresses vision rehabilitation strategies and quality-of-life measures, vision restoration, and mitigation and treatment of traumatic injuries, war-related injuries, and diseases to ocular structures and the visual system. Also addressed are mitigation and treatment of visual dysfunction associated with TBI, and modeling and simulation (M&S) of traumatic ocular injury.
Peer Reviewed Medical Research Program	While many of the topics are not blast-related, FY13 solicitations for research and clinical trials included topics of post-traumatic headache, composite tissue transplantation, nanomedicine for drug delivery science, post-traumatic osteoarthritis, and tinnitus.
Joint Warfighter Medical Research Program	This program augments and accelerates Department of Defense and Service medical requirements, and continues prior year initiatives that are close to achieving the prioritized military medicine objectives. FY13 investments were in the areas of regenerative medicine, tinnitus, neurotrauma, TBI, hemorrhage, surgical simulation, and prosthetics.

More information on these programs can be found at http://cdmrp.army.mil/; for the Vision Research Program, please visit http://www.tatrc.org/.

policy recommendations, understanding injury and outcome trends, and informing research sponsors as to the needs and requirements of the clinical communities. CoEs that have a focus on blast injury include the Defense Centers of Excellence (DCoE) for Psychological Health and Traumatic Brain Injury (PH/TBI), the Extremity Trauma and Amputation Center of Excellence (EACE), the Hearing Center of Excellence (HCE), the Pain Center of Excellence, Defense and Veterans Center for Integrative Pain Management, and the Vision Center of Excellence (VCE). Details on the HCE and VCE are depicted in **Tables 1-4** and **1-5**, respectively. The PCO also works with many other programs, research institutes, and centers to facilitate the coordination of blast injury research.

Upcoming Chapters

The following chapters highlight research efforts aimed at advancing the DoD's capability to prevent, mitigate and treat blast injury. The DoD Blast Injury Research PCO plays a key role in coordinating blast injury research, promoting partnerships and collaborations, and in sharing and disseminating blast injury knowledge and information. Key updates in this report include a discussion of the Joint Trauma Analysis and Prevention of Injury in Combat (JTAPIC) Program's efforts to collect and analyze operational incident and accident information to inform solutions for the prevention or mitigation of blast injury as well as a discussion of current research focused on monitoring blast exposures. Also presented are the PCO's participation in the NATO Human Factors and Medicine (HFM) Panel efforts specifically focused on understanding blast injury and translating scientific discoveries into blast injury mitigation measures, and the PCO's role in the MHS Blast Injury Prevention Standards Recommendation (MHS BIPSR) Process. Throughout this report, scientific advancements, improvements in standards of care, and the development of products to treat, diagnose, and prevent blast injuries are highlighted. Finally, at the conclusion of this report are blast injury research recommendations as well as research directions and focus areas that will help to define the path forward for blast injury research.

Table 1-2: Armed Forces Institute of Regenerative Medicine II

Armed Forces Institute of Regenerative Medicine II

http://www.afirm.mil/

Cooperative agreement established September 2013

Performers:

- Warrior Restoration Consortium, under the Wake Forest University School of Medicine (Wake Forest Baptist Medical Center)

Stakeholders with Oversight Role:

- USAMRMC*
- Office of Research and Development–US Department of Veterans Affairs (VA)
- Uniformed Services University of the Health Sciences
- Office of Naval Research (ONR)*
- National Institutes of Health (NIH)*
- Air Force Medical Service*
- OASD(HA)*

** Provides financial support*

History of the AFIRM (2008-present):

The AFIRM was established by the DoD in 2008 as a multi-institutional, interdisciplinary network of scientists with the mission of accelerating the development of new products and therapies to treat severe injuries suffered by US Service members. Research under the AFIRM was conducted through two independent research consortia working with the US Army Institute of Surgical Research (USAISR). One research consortium was led by Rutgers, the State University of New Jersey, and the Cleveland Clinic (Rutgers–Cleveland Clinic Consortium), while the other was led by Wake Forest University Baptist Medical Center and The McGowan Institute for Regenerative Medicine in Pittsburgh (Wake Forest–Pittsburgh Consortium). The AFIRM focused on developing strategies to replace or regenerate human cells, tissues, or organs to restore or establish normal function. The original goal of the program was to have one product in one patient in one clinical trial by the end of the funding period. The following are examples of the AFIRM's major accomplishments:

- **Projects:** A robust portfolio of approximately 64 projects spanning 5 focus areas
- **Clinical Trials:** Eight (8) active clinical trials; more than 200 patients treated under clinical protocols; and 6 clinical trials in development
- **Patents:** Forty-five (45) patent disclosures filed, and 19 patents awarded
- **Publications:** For FY13, 183 peer reviewed and 139 non-peer reviewed publications
- **Products:** A new bandage to reduce surgical scarring, proven in an AFIRM clinical trial, received US Food and Drug Administration (FDA) clearance and now is available for clinical use
- **Promising:** A Phase I/II clinical trial of a skin substitute for use in severe burns completed enrollment; early results are very promising

Refining Priorities and Focus:

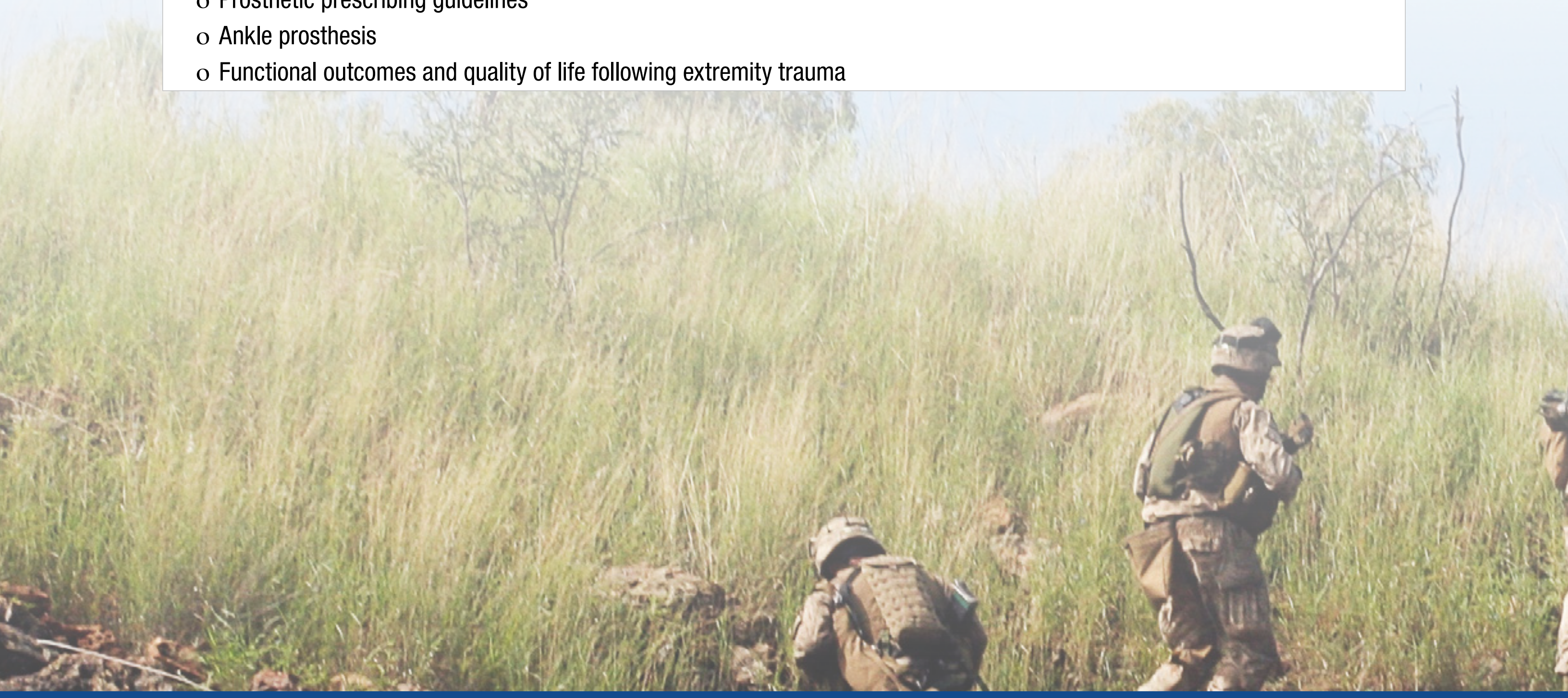
AFIRM (2008-2014)	
Limb repair	Craniofacial repair
Burn repair	Scarless wound repair
Compartment syndrome	

AFIRM II (2014-)	
Extremity regeneration	Craniomaxillofacial regeneration
Skin regeneration	Composite tissue allotransplantation and immunomodulation
Genitourinary/lower abdomen reconstuction	

Therapies developed by the AFIRM II program are intended to aid traumatically injured Service members and civilians. The research will address trauma and restoration of function in each of the following 5 focus areas: extremity regeneration, craniomaxillofacial regeneration, skin regeneration, composite tissue allotransplantation and immunomodulation, and lower abdomen and genitourinary/lower abdomen reconstruction. The goals of the program are to fund basic through translational regenerative medicine research and to position promising technologies and therapeutic/restorative practices for entrance into human clinical trials.

Table 1-3: BADER Consortium

Bridging Advanced Developments for Exceptional Rehabilitation (BADER) Consortium *http://www.bader-c.org/*
Cooperative agreement established September 2011
Performers: • University of Delaware, Department of Kinesiology and Applied Physiology (Lead) • Harvard Medical School and the Spaulding National Running Center • Mayo Clinic • University of Texas
Collaborators: • San Antonio Military Medical Center–Center for the Intrepid • Naval Medical Center Portsmouth • Walter Reed National Military Medical Center (WRNMMC) • Naval Medical Center San Diego
The BADER Consortium is a multi-institutional consortium that works in concert and partnership with military Medical Treatment Facilities (MTFs), VA centers, and academic and industry leaders to conduct innovative, high-impact, clinically relevant research. The BADER Consortium will create an infrastructure of relationships among the participating organizations, allowing the consortium to operate as an independent entity for clinical trials. The overarching goal is to strengthen evidence-based orthopaedic rehabilitation care that results in optimal functional outcomes for each wounded warrior.
Organization: The omnibus consortium model system, as opposed to a project centric model, focuses on the rapid forming and execution of many projects within broad research initiative areas. It avails to investigators unique human resources recruitment processes, incorporates innovative strategies including an omnibus Cooperative Research and Development Agreement (CRADA) and is uniquely suited as a vehicle for technology companies to propose clinical trials for highly advanced technologies. **Figure 1-6** shows the structure of the BADER Consortium, which includes a coordinating center along with clinical research and scientific cores.
Accomplishments: • Developed research focus (gap) areas in partnership with the DoD and the VA's EACE • Established partnerships with the Veterans Affairs and National Institutes of Health • Initiated clinical research projects regarding: o Improving amputee gait o Prosthetic prescribing guidelines o Ankle prosthesis o Functional outcomes and quality of life following extremity trauma



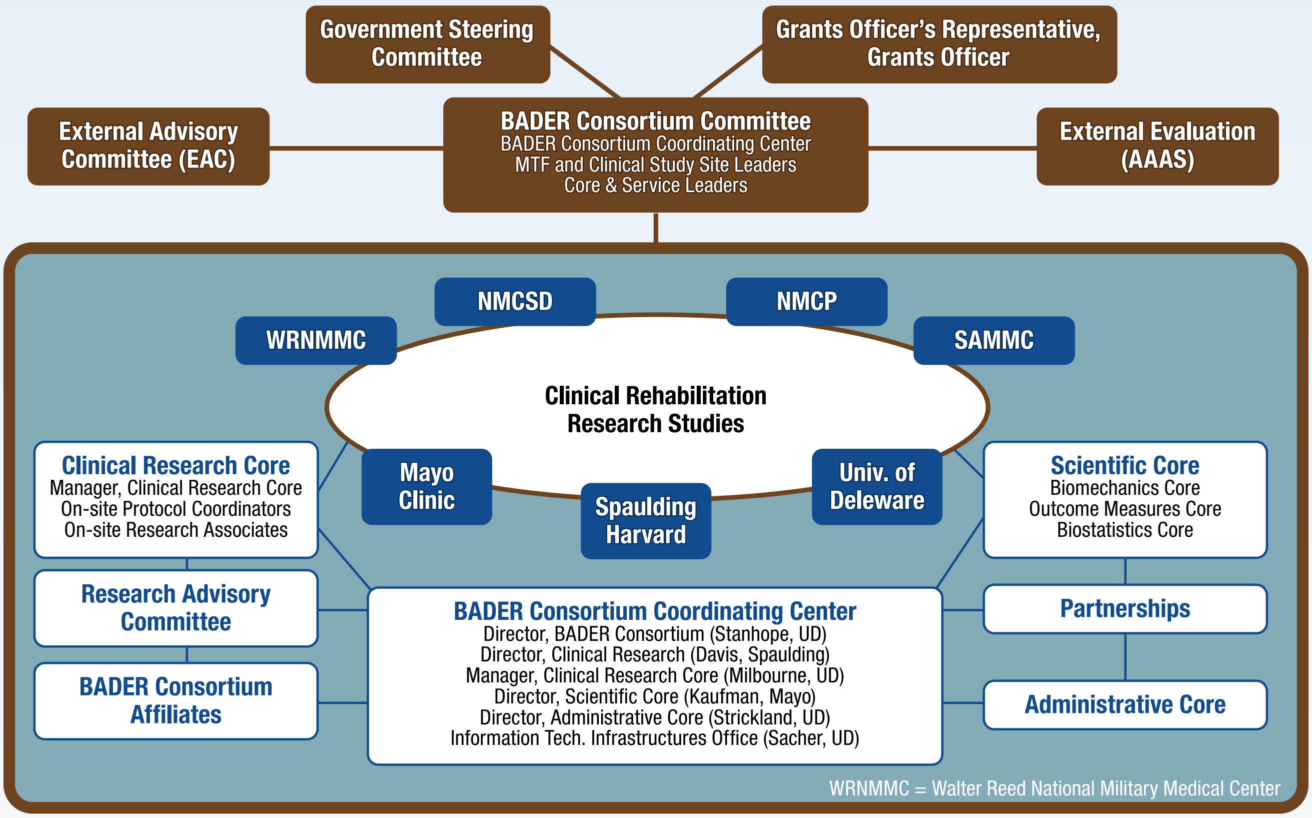


Figure 1-6: BADER Consortium Organizational Structure

AAAS=American Association for the Advancement of Science; WRNMMC=Walter Reed National Military Medical Center; NMCSD=Naval Medical Center San Diego; NMCP=Naval Medical Center Portsmouth; SAMMC=San Antonio Military Medical Center

Table 1-4: Hearing Center of Excellence (HCE)

HCE DEPARTMENT OF DEFENSE HEARING CENTER OF EXCELLENCE *http://hearing.health.mil/*
Mission: The HCE seeks to enhance readiness and continuously improve the health and quality of life of Service members and veterans through advocacy and leadership in the development of initiatives focused on the prevention, diagnosis, mitigation, treatment, rehabilitation and research of hearing loss and auditory–vestibular injury, including audio–vestibular dysfunction often related to traumatic brain injury.
Structure: The HCE is organized into five interactive directorates: Operations, Prevention & Global Outreach, Clinical Care and Rehabilitation, Research, and Informatics.
Key Initiatives: • **Auditory Research Working Group (ARWG)** – The ARWG leverages technical experts across the DoD, VA, and NIH, and academic and industry partners to optimally utilize registry and data sharing capabilities. • **Pharmaceutical Interventions for Hearing Loss (PIHL) Working Group** – This is a collaborative group of DoD, VA, NIH, academic and industry interests focused on standardizing research methods and reporting standards, and coordinating DoD interests related to pharmaceutical development strategies. • **Comprehensive Hearing Health Program (CHHP)** – This program is designed to prevent noise-induced hearing loss through effective education, monitoring, training, and hearing protection access, fitting and use. • **Joint Hearing Loss and Auditory System Injury Registry (JHASIR)** – Development of the JHASIR remains a top priority for the HCE. The JHASIR will identify and track every case of auditory injury and hearing loss in fulfillment of National Defense Authorization Act requirements. • **DoD Hearing Conservation Working Group (HCWG)** – The HCE continues to work as a unified team with the HCWG and VA representatives to develop acquisition strategies for central purchase of hearing protection devices and tactical communication and protection systems. • The HCE leads a **North Atlantic Treaty Organization (NATO)** research technical group effort to optimize hearing loss prevention, treatment, rehabilitation and reintegration of Soldiers with acoustic trauma, which includes developing a standardized data collection process for comparing and identifying best practices.
Recent Accomplishments: • Completion of critical Data Sharing, Data Use, and Data Transfer Agreements between all relevant informatics systems. • Provided a unified voice as a cohesive, large-scale hearing health improvement network. • Facilitated and enhanced existing programs and systems for hearing conservation, enterprise auditory care, and focused auditory-vestibular research. All programs target Readiness/Prevention and Care/Rehabilitation outcomes as primary measures of effectiveness. • Developed a suite of educational tools (i.e., posters, tri-folds, videos) and released a hearing loss prevention web and social media campaign to increase Service member awareness of the natural asset of hearing, the devastating effects of noise on hearing, and the insidious nature of this invisible injury. • Formalized and continues to develop partnerships with national specialty academies and Hearing Health advocates, supporting four events in 2013. • Accomplished a Memorandum of Agreement for a centralized Institutional Review Board (IRB) with the USAMRMC.

Table 1-5: Vision Center of Excellence (VCE)

Vision Center of Excellence *http://vce.health.mil/*
Mission: The VCE has been charged with improving the care of military personnel and veterans affected by eye injuries and diseases, including visual dysfunctions related to TBI, and developing a Defense and Veterans Eye Injury and Vision Registry (DVEIVR) to track eye injuries and to promote research into treatment, rehabilitation and restoration.
Structures: The VCE is organized into six functional areas: Information Management and Informatics; Technology; Education, Training, Simulation and Readiness; Clinical Care Integration; Research and Surveillance; Rehabilitation and Reintegration
Key Initiatives: • Monthly worldwide ocular trauma video-teleconference which links theater ophthalmologists with subsequent providers across the full continuum of care, as well as agencies and organizations that influence casualty care along that continuum • Development of a centralized repository of clinical ocular and related data, DVEIVR, that pertains to Service Members and Veterans with eye trauma, vision injuries, and disorders • Participation in Department of Defense Vision Research Program and Clinical and Rehabilitative Medicine Research Program by identifying research gaps, establishing strategic directions and evaluating research proposals • VIZEST Workgroup which facilitates collaboration and dissemination of information among the stakeholders in blast injury community. VIZEST workgroup is responsible for reviewing and providing guidance related to the DVEIVR, including but not limited to informing the data requirements and data model
Recent Accomplishments: • Subject Matter Expert (SME) input regarding eye injuries to PEO-Soldier program at their Combat Eye Protection Integrated Process Team meeting, February 2013 • Coordination of effort and expert guidance on treatment of blast-induced ophthalmic injuries from the terrorist IED bombing at the Boston Marathon on 15 April 2013 and the industrial explosion in West, TX • Organization of a special symposium 'Blast eye injuries: lessons learned from Boston, West, TX, Iraq, and Afghanistan" at the American Academy of Ophthalmology's Annual Scientific Symposium, November 2013 • Collaboration with the Department of Health and Human Services' Office of Emergency Management to discuss coordination and response to the ocular injuries resultant from natural or civil disasters (such as the Boston Marathon bombing and the West, TX explosion) • Dissemination of the information about vision-related funding opportunities through 2013 Vision Research Program resulted in 90% increase in the number of submitted proposals

Chapter 2

DoD Blast Injury Research Program Coordinating Office

MISSION:

Coordinate the DoD blast injury research investment, on behalf of the EA, to ensure critical knowledge gaps are filled, avoid costly and unnecessary duplication of effort, and accelerate the fielding of prevention and treatment strategies by leveraging existing knowledge and fostering collaboration and information sharing among the world's blast injury experts.

VISION:

A fully coordinated DoD blast injury research program as envisioned by Congress and directed by the Secretary of Defense that delivers timely and effective blast injury prevention, mitigation, and treatment strategies to our warfighters today and in the future.

The DoD medical research community has a long history of conducting medical research on blast-related injuries and has produced tremendous advances in battlefield medicine that are responsible for preventing blast injuries and saving the lives of blast-injured Service members. This research has also produced biomedically valid blast injury prediction models and performance standards that serve as the basis for combat platform occupant and personal protection system designs, as occupational exposure standards for blast-producing weapon systems, and as survivability assessment tools and metrics for combat platform occupant survivability assessments.

Researchers in other federal agencies, academia, and industry have also made significant contributions to the study of blast injury prevention, mitigation, and treatment. The PCO is taking full advantage of the body of knowledge and expertise that reside both within and outside of the DoD to solve complex blast injury related problems.

Key PCO Functions

The PCO coordinates and manages its responsibilities to the EA through its five primary activities (**Figure 2-1**). These key functions are detailed below.

Identify Blast Injury Knowledge Gaps

The study of blast injury is complex involving various research disciplines and approaches. It is critical for program managers and researchers to understand where to focus their attention and to the information gained from research projects. The PCO uses various means to identify knowledge gaps, including:

- **State-of-the-Science Meetings.** The PCO instituted the International State-of-the-Science Meeting Series to assist in identifying knowledge gaps pertaining to key blast injury issues. These focused meetings help determine what is known and what is not known regarding a particular blast injury topic. See Chapter 7 for more information on the meeting series.
- **DoD Brain Injury Computational Modeling Expert Panel.** An expert panel has been established to assess the state of research in computational modeling of non-impact blast-induced mild traumatic brain injury (mTBI) to identify critical knowledge gaps, develop a research roadmap to address the gaps, and monitor progress in resolving the knowledge gaps. See Chapter 7 to learn more about this effort.
- **NATO HFM Panel Activities.** The PCO participates in and leads NATO HFM technical activities that bring together the international community interested in blast injury research. These activities serve as a sharing mechanism to understand what knowledge gaps exist among our NATO allies and how they are being addressed. With the PCO director as the chair, a new HFM Technical Activity (HFM-234) was established on Environmental Toxicology of Blast Exposures: Injury Metrics, Modeling, Methods, and Standards. See Chapter 6 to learn more about this effort.

Figure 2-1: PCO Functions

Disseminate Blast Injury Research Information

The PCO serves as a resource to members of the DoD, other federal agencies, academia, and industry regarding blast injury research and programs. Some of the mechanisms used to provide this resource include:

- **Website.** The Blast Injury Research Program website (https://blastinjuryresearch.amedd.army.mil) provides up-to-date research information and allows individuals and organizations to submit blast injury-related questions directly to the PCO. The website contains information on programs and initiatives, accomplishments, meetings, and past reports. In FY13, major upgrades were made to the website to enhance the site's usability for information sharing throughout the blast injury research community.
- **Responding to Inquiries.** The PCO provides coordinated responses to scientific and programmatic inquiries regarding blast injury research and effects from all levels, including Congress, DoD and Service component leadership, other DoD organizations, industry, and academia. Products provided to DoD leadership include programmatic information, review of policy and guidance recommendations, and status reports on active projects.

- **Meetings.** The PCO actively seeks out stakeholders, within DoD and with partner nations, to inform them of the DoD's efforts in blast injury research as well as to learn about their programs, problem sets, and initiatives. Some of these efforts are described in the "Recent PCO Activities" section in this chapter.
- **Linking Researchers.** The PCO is able to use its network of research programs and knowledge of active blast injury research to link researchers from government, academia, and industry in support of blast injury research efforts.

Shape Research Programs to Fill Knowledge Gaps

To help inform and shape research programs and to ensure blast injury knowledge gaps are addressed in DoD medical research programs, PCO leadership participate as voting members and/or interact with numerous research program planning and management committees, including:

- **JPCs.** The JPCs, with membership from the component Services, VA, NIH, the science and technology community, and the operational and requirements community, are responsible for developing research program plans and program announcements, reviewing research proposals for programmatic relevance, and evaluating research progress.
- **Joint Technology Coordinating Groups (JTCGs).** The JTCGs, organized under the ASBREM Committee, are responsible for coordinating medical research programs across the Services, including programs that address blast injury research topics in the areas of Infectious Disease, MOM, CCC, and CRM.
- **Integrating Integrated Product Teams (IIPTs).** The IIPTs were created to implement a team approach to manage biomedical science and technology throughout the USAMRMC. IIPT membership consists of personnel from the combat development community and SMEs from DoD, academia, and other organizations. The IIPTs are responsible for advising the USAMRMC Research Area Directors on the current focus and future direction for ongoing research efforts.
- **Research Advisory Committees (RACs).** PCO participation on RACs helps to inform the researchers and sponsoring programs of new developments and related efforts. For example, in March 2013, the PCO participated in the ONR stakeholders update meeting for the Advanced Requirements for Crew Safety (ARCS) project. The main objective of the ARCS program is to provide the military vehicle requirements developer with validated, quantitative, medically based crew survivability requirements that the acquisition, design, and testing community can use to verify a survivable vehicle design.

Promote Information Sharing and Partnerships

The blast threat and respective mitigation solutions are multidisciplinary problems that require the continued interaction of diverse organizations across the DoD to be successful. In the past, many of these organizations may have only approached the problems from their own individual perspectives. The PCO is actively engaged in linking organizations and establishing and maintaining partnerships to ensure this success. The following is one critical partnership that is developing:

- **NATO HFM-234 on Environmental Toxicology of Blast Exposures: Injury Metrics, Modeling, Methods, and Standards.** With the PCO director as the chair, a new HFM-234 was established in October 2012. This effort focuses on advancing the state-of-knowledge, standardizing research methods, and building an evidence-based approach for blast injury analysis and medical care improvements across the NATO countries. See Chapter 6 to learn more about this effort.

Facilitate Collaboration Within and Outside of the DoD

Information and research capabilities related to blast injury research can be found both within and outside of the DoD. Through collaboration, the programs can advance toward solutions more quickly. The following examples detail how collaboration is critical for DoD and, ultimately, for enhanced warfighter survivability.

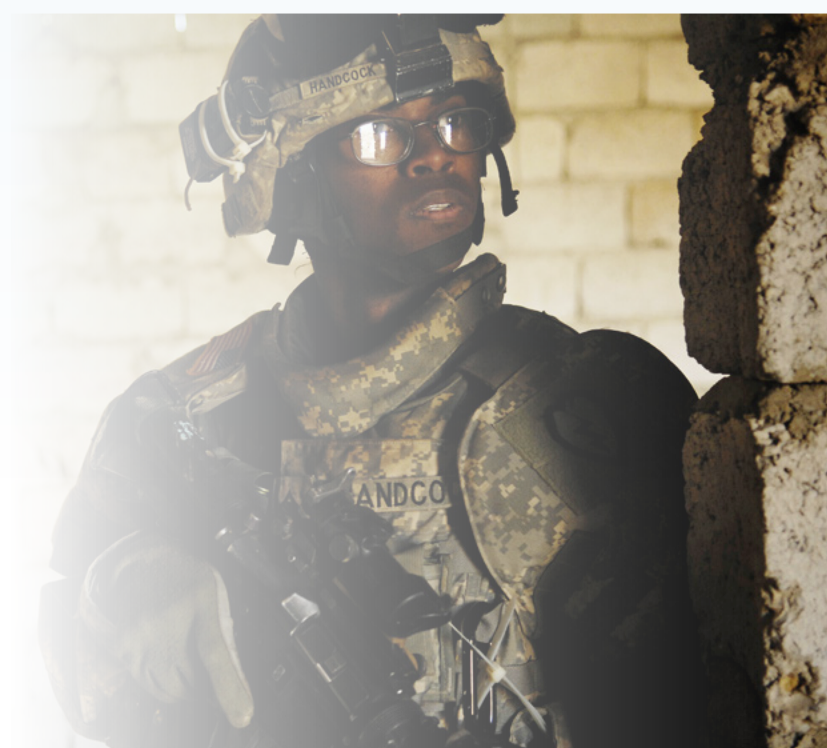
- **Recommending Blast Injury Prevention Standards, Including Protective Equipment Performance Standards for the DoD.** The PCO, in collaboration with the Johns Hopkins University Applied Physics Laboratory (JHU/APL), a University Affiliated Research Center and DoD trusted agent, has developed an unbiased, inclusive, stakeholder-driven process for identifying and recommending MHS Blast Injury Prevention Standards. This process, known as the MHS BIPSR process, fulfills a key responsibility of the EA and ensures that the DoD is using the best available, biomedically valid standards to develop safe weapon systems, survivable combat platforms, and effective protection against blast-related threats. See Chapter 5 for more on the MHS BIPSR process.
- **Sharing USAMRMC Injury Models with the Navy.** The objective of the Navy's Human Injury Treatment (HIT) M&S project is to provide the Navy Live Fire Test and Evaluation (LFT&E) community with a computer modeling tool for ship survivability assessments. The PCO has established a Memorandum of Understanding between the ONR and the USAMRMC that enables the transfer of USAMRMC injury prediction models to ONR for insertion into the HIT toolset. In return, ONR will provide formal verification and validation of the USAMRMC models. The current version of the HIT model contains the USAMRMC's blast lung injury and toxic gas inhalation injury prediction models. In November 2012, the PCO Director participated in the Integrated Product Team (IPT) meeting which demonstrated the HIT model, and reviewed FY12 accomplishments and FY13 plans. The HIT model is on schedule to transition to the Navy LFT&E community at the end of FY14.
- **Leveraging Expertise from Industry, Academia, and Federal Agencies to Solve Difficult Blast Injury Problems.** The PCO continues to establish and expand relationships to coordinate efforts, conduct collaborative activities, obtain needed expertise, and solve problems. Through interactions with other organizations, working groups, and meetings, the PCO has developed an extensive network that it can call on to support the program's efforts. Examples include the DoD Brain Injury Computational Modeling Expert Panel, the State-of-the-Science Meeting Series, and the MHS BIPSR process.

Recent PCO Activities

Since its inception, the PCO has made significant progress in effectively coordinating and participating in DoD blast injury research. Examples of FY13 activities in the which the PCO participated include:

Identifying Blast Injury Research Knowledge Gaps

- **Allied NeuroSensory Warrior Related Research (ANSW2R).** The ANSW2R effort was initiated by the Hearing Center of Excellence to study combined injury patterns and treatments of these injuries across specialties, Services, and the continuum of care. The overall goal of ANSW2R is to improve the translation of bench-to-bed rehabilitation and reintegration for our wounded warfighters. A meeting was held in October 2012 to outline objectives for assessing current research portfolios, and to develop a business plan for integrating neurosensory research and expected outcomes with projected milestones. The PCO is participating in the ANSW2R effort as a stakeholder.
- **Literature and Med-Bio Data Analytics.** The DARPA Defense Sciences Office-organized workshop "Literature and Med-Bio Data Analytics" in November 2012 focused on identifying research and technology to rapidly exploit the exploding amount of data and information in biology/medicine and related areas to accelerate biology research. The participants included academic, industry and government SMEs from a variety of disciplines including natural language processing for biology and medical literature, data mining of large disparate biomedical data sets, and biologists. The discussion centered on the state-of-the-art in tools, approaches in mining large databases, open systems/forums for data sharing, predictive mechanistic models, access and frameworks. Recommendations from the workshop included sharing of medical data with a broader group of researchers, fast creation of databases, merging medical and clinical information, creation of communities, interactive publications, and promoting public-private partnerships.
- **VIZEST Vision Registry.** In February 2013, the PCO participated in a meeting with the DoD VCE-sponsored VIZEST Vision Registry Stakeholder Workgroup. This group is developing a comprehensive vision registry containing eye trauma data that can be used to guide the development of effective eye injury prevention, diagnosis, mitigation, treatment and rehabilitation strategies. The discussion focused on knowledge gaps pertaining to the existence and mechanisms of primary blast-induced eye injuries. The PCO highlighted similarities to primary blast-induced brain injury, and urged the group to consider that lessons learned from the brain injury research programs, including animal model shortcomings, also apply to eye trauma research. The PCO and JTAPIC will continue to participate in future workgroup discussions to identify potential collaborative opportunities within the DoD Blast Injury Research community.



- **Translating Knowledge Gaps into Active Research.** The PCO participates in a number of program planning and review activities that support shaping and guiding research programs to resolve knowledge gaps that have been identified. In FY13, these activities included:
  - Attending the American Institute of Biological Sciences review of the Military Operational Medicine Research Program portfolio and plans on Concussion Dosimetry/mTBI Assessment and Interventions research.
  - Serving as a voting member of the FY13 Armed Forces Institute of Regenerative Medicine II (AFIRM-II) programmatic review meeting to select proposals for establishing the AFIRM-II effort, a $75 million program focused on basic through translational regenerative medicine R&D which will build on the success of the concluding AFIRM-I program.
  - Serving as a panel member at the USAMRMC Military Operational Medicine Research Program (MOMRP)/Joint Program Committee for Military Operational Medicine (JPC-5) 2nd Annual In-Progress Review (IPR) of Defense Health Program-funded research on Injury Biomechanics, including several research topics relating to blast injuries such as blast-related brain, eye, and auditory injuries, and injuries caused by under body blast.
  - Participating in several medical research program planning activities, including the JPC-5 FY13 PH/TBI Basic and Applied Psychological Health Research Program pre-application review, the JPC-5 Programmatic Review and Business Meeting, the JPC-6 (Combat Casualty Care) Traumatic Brain Injury Research Award proposal review, and the JPC-6 FY13 TBI and Neurotrauma Programmatic Reviews.
  - Participating in various IIPT meetings, including: the USAMRMC MOMRP IIPT's FY16-20 Unfunded Requirements prioritization review, the JPC-8 and Center for Regenerative Medicine IIPT business meeting, and the USAMRMC MOMRP IIPT meeting.
  - Conducting a PCO strategic planning meeting to identify weaknesses and gaps in the PCO's support of EA's responsibilities, and to develop a road map for objectives over the next 5 years. New objectives that were identified include holding a follow-on Blast Injury Research Planning Meeting to re-baseline what gaps remain, implementing sharing of historical blast research data, and establishing a Blast Injury Program Coordinating Board comprising members from key stakeholder communities identified in DoDD 6025.21E.

- **Non-Impact Blast-Induced Mild Traumatic Brain Injury (mTBI).** The PCO began planning for the fourth State-of-the-Science meeting, which is anticipated to occur in Fourth Quarter (4Q) FY14. The possible injury mechanism(s) underlying mTBI caused by exposure to a blast event without secondary or tertiary head impact remains a key knowledge gap. See Chapter 7 for more information on the meeting.

Promoting International Cooperation and Collaborative Activities

Not all knowledge of blast injury prevention, mitigation, and treatment resides within the United States. Therefore, the PCO hosts international experts and participates in international meetings to facilitate an exchange of information and ideas, pursue opportunities to leverage the research and experience from other countries, and explore opportunities for developing common standards for future joint operations. Some of the efforts are described in the following bullets.

- **Israel.** The 2012 Shoresh Conference on Military Medicine was held at Fort Detrick, Maryland, on October 16, 2012. This was the 16th Shoresh conference held between the United States and Israel; the conferences are the primary venue for exchange of information under the US–Israel Data Exchange Agreement for Military Medicine. The PCO Director participated in this meeting, particularly in discussions on non-impact, blast-induced mTBI. The Director provided a briefing on the value of computational modeling to study blast injury that included historical examples of studies on blast injury mechanisms as well as an overview of the establishment and activities of the DoD Brain Injury Computational Modeling Expert Panel, a major effort undertaken by the PCO to guide research to develop a validated, computational model of blast-induced mTBI.
- **France.** In October 2012, the PCO Director briefed senior French military medicine leadership on the DoD Blast Injury Research Program. The French delegation was led

by Maj. Gen. Didier Lagarde, Director of the Defense Biomedical Research Institute, and included Brig. Gen. Daniel Garin, Scientific Director, Institut de Recherche Biomedicale des Armees (Armed Forces Biomedical Research Institute), and Brig. Gen. Lionel Bourdon, Deputy for Forces Medico-Surgical Support. The briefing was an update on initiatives previously introduced to this delegation at the 2nd Franco-American Research Workshop on War Traumatism (2010), and it covered the JTAPIC Program, Battlefield Exposure Sensor Data Analysis, and the MHS BIPSR Process, as well as the newly established NATO HFM-234 Research Technical Group (RTG) Technical Group on Environmental Toxicology of Blast Exposures: Injury Metrics, Modeling, Methods and Standards.

- **India.** The PCO and the Defense Threat Reduction Agency (DTRA) jointly chaired a meeting of the Medical and Chemical, Biological, Radiological and Nuclear (CBRN) Working Group of the India-US Joint Technical Group (JTG) meeting #15 on January 25, 2013. The India-US JTG is the senior bilateral forum between the DoD and Indian Ministry of Defence for discussion and coordination of defense research and production matters involving defense equipment cooperation, including cooperation in research and development, production, procurement and logistics support. Participation included the Defence Research and Development Organization (Ministry of Defence, India), USAMRMC, DTRA, DARPA, and other Service organizations. The co-chairs of JTG #15 approved the following Joint Medical and CBRN Working Groups proposed areas for continued interaction, coordination, and discussion: Soldiers in extreme field environments, advanced sensor technologies for real-time Soldier wearable applications, human performance optimization, a multidrug-resistant organism repository and surveillance network, radiation countermeasures, and mTBI. Areas of interest for mTBI are mathematical modeling and imaging, chronic effects of TBI, blast tube studies to characterize blast-induced neurotrauma, understanding blast mechanism of injury, and blast dose-response end points. The next steps are to establish project agreements for selected topics and work out the framework for a 3–5 year roadmap for cooperation under the JTG.

Providing Support to DoD Leadership

Part of the PCO responsibility is to support DoD leadership with information and assessments to respond to blast injury issues. A few examples of such support are:

- **Annual Report to the Executive Agent.** The PCO prepares this report on the science and technology efforts and programs relating to the prevention, mitigation and treatment of blast injuries. The report summarizes efforts of the entire DoD Blast Injury Research Program, addressing the full spectrum of blast injury challenges, and highlights significant accomplishments. In addition to informing the EA, this compilation of initiatives and accomplishments is intended as a means for information sharing. The report is available on the Blast Injury Research Program website (https://blastinjuryresearch.amedd.army.mil).
- **Informing Leadership.** In support of the EA, the PCO Director briefed Dr. David Smith, Deputy Assistant Secretary of Defense for Force Health Protection and Readiness at OASD(HA) and Dr. Patrick Mason, Director of Human Performance, Training, and Biosystems Directorate, OASD(R&E), on EA authorities and responsibilities as well as OASD(HA) responsibilities for recommending and approving blast injury prevention standards. The MHS BIPSR process was a key aspect of the briefings.
- **Coordinating Requests for Information (RFIs).** The Blast Injury Research PCO responded to a Joint Improvised Explosive Device Defeat Organization (JIEDDO) request, via the Blast Injury Research Program website, for RFIs on the "average medical cost of a Soldier wounded by an IED event." The PCO coordinated with the JTAPIC Program Management Office and the Program Analysis and Evaluation (PA&E) Office at the Office of

the Surgeon General (OTSG)/USAMEDCOM. Neither office had data packaged on the average medical costs for wounded warfighters; therefore, a recommendation was made to have JIEDDO send a request through OTSG/USAMEDCOM channels, or to PA&E, to request a study to answer the question. The PCO also provided a publication to assist JIEDDO in scoping and framing their request.

- **Protection from TBI.** The PCO, in coordination with the USAMRMC Research Area Directors for Military Operational Medicine and Combat Casualty Care Research, prepared an information paper for senior Army leaders from the Surgeon General's Office addressing concerns regarding the effects of body armor and combat helmets on primary blast injury (PBI). Recent studies of the Advanced Combat Helmet (ACH) with pads have shown that the ACH attenuates blast shock waves. However, with respect to preventing TBI, the significance of the ACH's ability to attenuate blast shock waves is unknown because the existence and mechanisms of blast-induced TBI without head impact are unknown. The information paper highlights that a critical knowledge gap is being addressed by the DoD programs regarding the injury mechanisms underlying blast-induced mTBI without secondary or tertiary head impact.
- **USAMEDCOM Complex Battle Injury Action Officer Working Group.** The PCO briefed the MHS BIPSR Process to the USAMEDCOM Complex Battle Injury (CBI) Action Officer Working Group (CBI-AOWG). The CBI-AOWG is charged with developing a comprehensive CBI campaign plan to implement the recommendations from the Dismounted Combat Blast Injury report. The campaign plan will address all aspects of CBI to prevent, protect against, and mitigate blast injuries; optimize long-term outcomes for severely wounded warriors and their families with the ultimate goal to provide the best possible rehabilitation and long-term reintegration opportunities for our warriors and their families as they return successfully to duty or civilian life. The MHS BIPSR process supports the protection aspect of the CBI campaign plan by addressing the needs of all Services for biomedically valid MHS Blast Injury Prevention Standards in the development and testing of safe weapons, and effective combat vehicle crew and individual protection systems.

PCO in the News

- **Mathematical Models of Blast-Induced TBI: Current Status, Challenges and Prospects.** A review article co-authored by Dr. Raj Gupta, PCO Deputy Director, was published in May 2013 in the journal Frontiers in Neurotrauma. The article provides a brief overview of blast wave physics, injury biomechanics, and the neurobiology of brain injury as a foundation for a more detailed discussion of multiscale mathematical models of primary biomechanics and secondary injury and repair mechanisms. The article summarizes the current state-of-the-art models of blast waves and head/brain biomechanics for the development of a PBI model. The conclusion is that mathematical modeling could play a major role in advancing our understanding of brain injury mechanisms and help in neurodiagnostics, treatment and protection. The article may be found at http://www.frontiersin.org/Neurotrauma/10.3389/fneur.2013.00059/full.

Informing Protective Equipment Development

The medical research community has always played a role in the development of individual and combat platform occupant blast protection equipment and systems by providing materiel developers with biomedically valid injury criteria, performance standards, and testing methods. The PCO continues to strengthen and expand this collaborative relationship as illustrated in the following activities:

- **Burn Injury Prediction Tool.** In December 2012, the PCO participated in a meeting of interested stakeholders to plan a strategy for creating an improved burn injury prediction tool for the development and performance testing of flame-resistant clothing. Existing testing methods are useful in comparing the relative performance of fabrics, but they do not provide information on the probability that a fabric will prevent a specific type or degree of burn injury. The Natick Soldier Research Development and Engineering Center (NSRDEC) identified this capability gap in 2011. Since then, the PCO has engaged stakeholders from NSRDEC, the Product Manager Soldier Clothing and Individual Equipment, the Air Force Research Laboratory, and the USAMRMC to address this gap. With appropriate modifications, the burn injury prediction tool, BURNSIM, may meet

NSRDEC's needs and research proposals are under review for modifying BURNSIM.

- **Behind Armor Blunt Trauma.** In December 2012, the PCO staff participated in a behind armor blunt trauma update meeting hosted by the USAMRMC MOMRP. This meeting updated representatives from the DoD and Army test and evaluation (T&E) communities on current medical research efforts to create improved methodologies for the development and performance testing of combat helmets and body armor. The goal is to ensure that products from research and development will meet the needs of the T&E community. MOMRP's efforts include developing human skull fracture injury criteria for focused blunt impacts to the head and a modified clay testing methodology for predicting the probability and severity of blunt injuries behind body armor. The PCO was recently made aware of similar efforts sponsored by the ONR, and plans to engage the MOMRP and ONR project sponsors to ensure that all of these efforts are synchronized.
- **Combat Eye Protection.** The PCO serves on the Military Combat Eye Protection (MCEP) IPT sponsored by the Product Manager Soldier Protective Equipment. Traumatic eye injuries represent about 12%–15% of casualties in Operations Iraqi Freedom and Enduring Freedom. The MCEP program focuses on protecting the eye from external threats and hazards, providing vision correction for MCEP and encouraging MCEP use, and providing training while leveraging Soldier feedback to reduce injury and improve designs. The PCO's continuing participation on the MCEP IPT provides an opportunity to highlight key blast injury issues on behalf of the DoD EA.

- **Ballistic Helmet Testing.** The OSD Director, Operational Test and Evaluation, tasked the National Research Council to determine the adequacy of military ballistic helmet testing procedures. The committee was interested in hearing about the PCO's initiatives to identify and fill knowledge gaps associated with potential brain injuries from exposure to primary blast overpressure without head impact. The PCO referred the study director to the US Army Aeromedical Research Laboratory (USAARL) for their technical expertise on helmet performance testing with respect to head and brain injury prevention, and USAARL participated in the committee meeting in April 2013.
- **Modeling & Simulation Methodologies for Survivability Improvements.** In an effort to understand and predict the threat scenarios and injury potentials, and to develop improved protective measures, the PCO submitted a Small Business Innovative Research (SBIR) topic to develop a Human Body Model for Computational Assessment of Blast Injury and Protection. The objective was to design, develop and demonstrate an anatomically consistent, articulated human body model for the computational assessment of explosion blast injury loads, body responses, casualty estimation, and PPE. During the preparation phase of the topic, the PCO office met with MOMRP and Program Executive OÍffice (PEO) Land Systems' US Marine Corps Mine Resistant Ambush Protected (MRAP) vehicle and AutoCell Survivability Lead representatives to coordinate development of an articulated human body model for the computational assessment of blast injury and protection and the ongoing efforts regarding the use of Corvid's high fidelity computational physics (HFCP) models. The Corvid's HFCP models aim to aid in the design and evaluation processes required to meet survivability objectives for several platforms as well as shot-line selection for Live-Fire events. Ongoing efforts are investigating the effect of mine blasts on crew survivability metrics and continuing the development of a physics-based model that will assist in the design of safety components devised to mitigate injuries sustained by individuals riding in tactical wheeled vehicles. There may be a need to develop an articulated human body model for the computational assessment of blast injury and protection.
- **Draft Military Standard (MIL-STD)-1474E DoD Design Criteria Standard, Noise Limits.** The PCO, representing the DoD EA for Blast Injury Research and coordinating comments from USAMRMC medical research programs, reviewed the Draft MIL-STD-1474E (DoD Design Criteria Standard, Noise Limits) which specifies the maximum permissible noise levels produced by military systems and the test requirements for measuring these levels. This MIL-STD is used to support health risk acceptance decisions in the acquisition process and ultimately to protect Service members. The PCO is concerned from both the USAMRMC medical research and blast injury research EA perspectives that this standard's provision for allowing different noise injury criteria for Army systems versus joint systems, including criteria that have not been fully validated, may not afford an equal level of protection to all Service members who may be using similar systems. In September 2013, the PCO, representing the DoD EA for Blast Injury Research, non-concurred with comment on the draft MIL-STD to the MIL-STD proponent at the Aviation and Missile Research Development and Engineering Center.
- **Hazard Analysis for Dismounted Stryker Mobile Gun System and Tank Crews.** The PCO facilitated Army Health Hazard Assessment (HHA) Program support for US Army Training and Doctrine Command (TRADOC) Capability Manager-Live (TCM-Live). TCM-Live was interested in learning about the minimum safe distance for blast overpressure and noise hazards for dismounted Stryker Mobile Gun System and Tank crews who perform dismounted breaching operations under a requirement established by the Maneuver Center of Excellence. To answer this question, the HHA Program at the Army Public Health Command will collect blast

overpressure and impulse noise data to assess potential health hazards.

Advancing Science and Medicine

The PCO's role in informing research/program managers and fostering collaborations contributes to advancing science and medicine related to blast injuries. The following are examples of how the PCO facilitates these advancements:

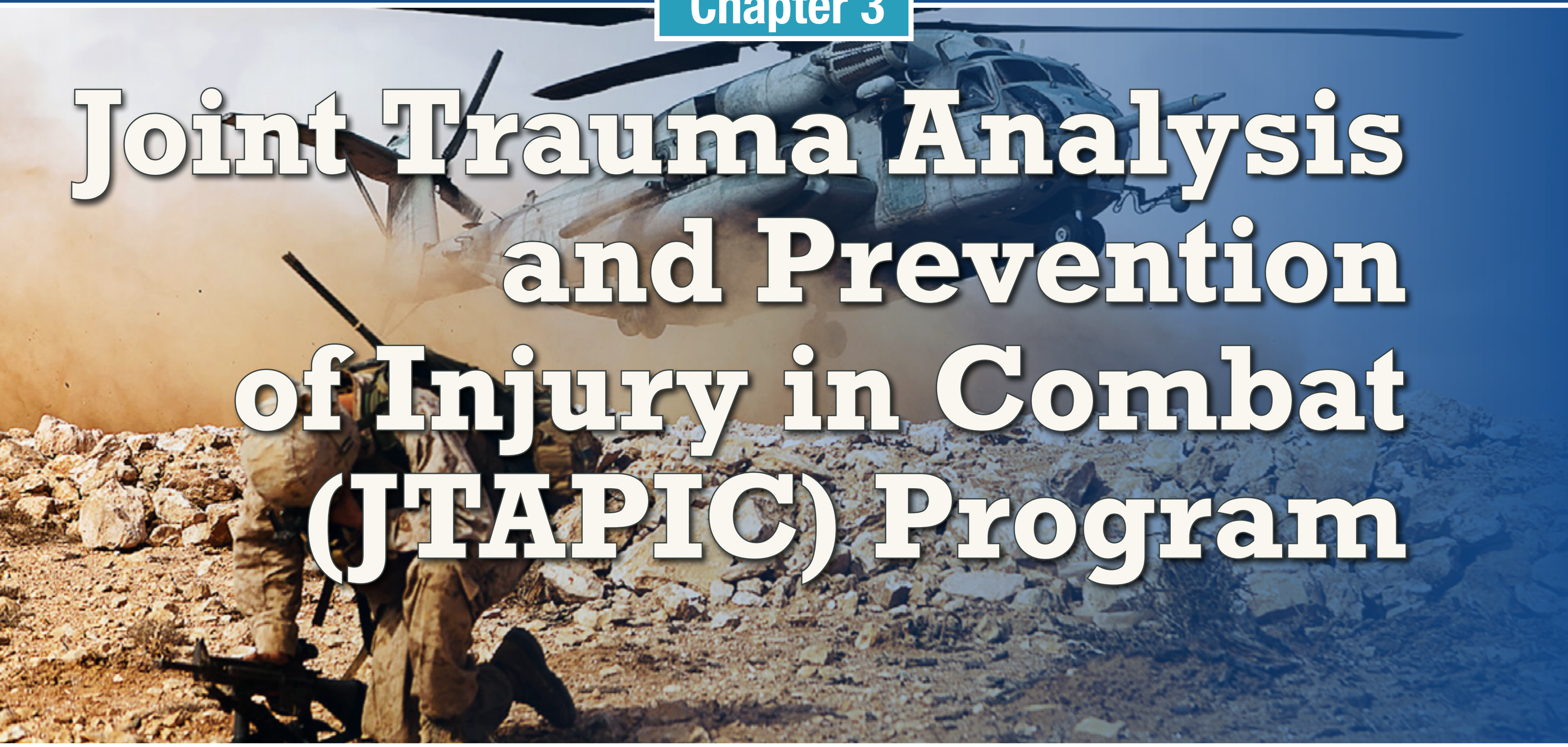
- **Antimicrobial Textiles for Control of Wound Infections in Field and Hospital Settings.** The PCO is managing a SBIR program that is seeking to develop antimicrobial finishes for textiles. Antimicrobial textiles could be used for military uniform and medical textiles (e.g., anti-infective wound dressings, hospital textiles, bedding, medical devices). Phase I projects focused on chemical functionality for application to textiles and achieving antimicrobial activity, while Phase II efforts will focus on characterizing functionality on a variety of textiles. By the end of FY13, one effort was transitioned into Phase II.
- **Blast-Induced TBI – Experimental Approach Using Animal Models.** In December 2012, the PCO and Combat Casualty Care Research Program (CCCRP) jointly hosted a presentation and discussion by Dr. N. Chandra, Elmer-Koch Professor of Engineering from the College of Engineering, University of Nebraska-Lincoln (UNL) as part of the DoD Neurotrauma Grand Rounds. The UNL work examines the role of animal placement location in the blast shock tube and the biomechanical load experienced by the animal. Their studies using rats discovered that the biomechanical load on the brain and internal organs in the thoracic cavity (lungs and heart) varied significantly depending on the animal placement location. The results have significant implications for the study of blast injury and the associated injury mechanisms, and the research accomplishment is described further in Chapter 8.
- **Vision Center of Excellence (VCE) VIZEST Work Group Meetings on Vision Injury Topics.** The PCO participates in the VIZEST Working Group Meetings to maintain the visibility and raise awareness of blast injury issues. The ongoing meeting series includes presentations and discussions by health care providers, engineers, program analysts, and data modelers from the VCE, VA, AMEDD, academia, and industry. Recent topics have included a glaucoma data model, the collection of indicators for the development of glaucoma following ocular trauma, uveitis case overviews, and a SBIR for the measurement of the corneal and sclera surface for the purpose of automating ocular surface protection to improve outcomes in various diseases, treatments and following injury (with patient trials expected to begin in FY14).
- **Neuronal Information Processing and Injury Under Blast Pressure Loading.** The PCO initiated a new collaborative effort with the US Army Research Laboratory (ARL) (Weapons and Materials Research Directorate) to understand the spatial and mechanical changes in model neurons at the cellular level under external stimulus, especially pressure waves. The short-term objective of the project is to develop a physically based three-dimensional (3D) optical monitoring technique with the help of theoretical modeling and experiments to study information processing of neuron clusters under blast pressure loading. The long-term goals are to understand the detailed neuronal injury mechanisms by which blast waves impact brain cells and to develop a multiscale cellular analysis and simulation tool in 3D capable of predicting the effect of applied blast impact loading conditions and translate these loads into neuronal injury.

Linking with Other Federal Agencies and Industry

- **Long-term Health Effects of Blast Exposure.** The VA is sponsoring the Institute of Medicine (IOM) Committee on "Gulf War and Health: Long-term Effects of Blast Exposures." The VA tasked this committee to conduct a comprehensive review of acute and long-term health consequences among Gulf War veterans, and to advise on disability compensation. The Committee is interested in the findings from the PCO's International State-of-the-Science Meeting on Non-impact, Blast-induced mTBI, and on the activities of the DoD Brain Injury Computational Modeling Expert Panel. In February 2013, the PCO Director provided a briefing on the PCO's efforts to fill knowledge gaps pertaining to the possible injury mechanism(s) underlying mTBI caused by exposure to a blast event without secondary or tertiary head impact. At the IOM Committee's request, the PCO provided a comprehensive list of DoD-funded studies on the long-term health effects from blast exposure and copies of selected publications to address specific inquiries.

Chapter 3

Joint Trauma Analysis and Prevention of Injury in Combat (JTAPIC) Program



MISSION

To collect, integrate, analyze, and store operations, intelligence, materiel, and medical data to inform solutions that will prevent or mitigate injury during the full range of military operations.

The JTAPIC program was established at USAMRMC, Fort Detrick, Maryland, in July 2006 to assist in fulfilling portions of the Secretary of the Army's EA responsibilities under DoDD 6025.21E ("Medical Research for Prevention, Mitigation and Treatment of Blast Injuries"). Prior to the establishment of the JTAPIC program, military organizations focused on improving warfighter survivability individually rather than collaboratively. The medical community focused on battlefield medicine and increasing warfighter survivability by using the best medical and treatment modalities available. Protective equipment developers focused on performance specifications and the development of process improvements under testing conditions because few articles were returned for analysis from killed in action (KIA) or wounded in action (WIA) events. When an article was returned, the analysis was performed without the benefit of full knowledge of the operational context—understanding what happened to the warfighter, and what he or she was doing at the time of injury—or the injuries sustained by the warfighter. When vehicle improvements were fielded in Operation Iraqi Freedom (OIF), there was no formal process to provide vehicle developers with relevant contextualized medical information on combat injuries that could allow them to understand how well vehicles protected the occupants. Conversely, for the medical community, no formal process existed for providing medical injury data associated with combat operations to nonmedical users,

Table 3-1: JTAPIC Partner Organizations and Associated Charter Responsibilities

Partner Organization	Unique Responsibilities
US Army Aeromedical Research Laboratory	Provide analysis of aircraft and vehicle injury patterns.
Dismounted Incident Analysis Team (Army)	Collect dismounted operations and intelligence incident data; provide subject matter expertise and analysis
Current Operations Analysis Support Team (Marine Corps)	Provide Marine Corps-related operations research analysis and subject matter expertise
National Ground Intelligence Center (Army)	Collect mounted operations and intelligence incident data; provide forensic vehicle analysis, information management support and services, subject matter expertise, and analysis
Marine Corps Intelligence Agency	Provide Marine Corps-related intelligence analysis and subject matter expertise
Armed Forces Medical Examiner System	Collect KIA injury data; provide KIA injury coding, subject matter expertise, and analysis
Naval Health Research Center	Collect WIA injury data; provide WIA injury coding, subject matter expertise, and analysis
Joint Trauma System	Provide WIA traumatic injury subject matter expertise and analysis
Army Research Laboratory	Provide forensic evidence (ballistics, fragments, other metals, etc.) analysis, experimentation support and services, comparative analysis between life-fire tests and operational events, survivability and lethality M&S support and services, information management support and services, subject matter expertise, and analysis
Project Manager, Soldier Protective Individual Equipment (Army)	Collect damaged PPE; provide PPE analysis and subject matter expertise
Product Manager, Infantry Combat Equipment (Marine Corps)	Collect damaged Marine PPE; provide PPE analysis and subject matter expertise

such as combatant commanders, materiel developers, and requirement developers.

To streamline and enhance joint Service information sharing and collaboration for the analysis and prevention of injuries in combat, the JTAPIC program was established as a joint “matrix” partnership (**Table 3-1**) in fall 2006 and formalized in 2012. The medical, materiel, operations, and intelligence SMEs stay embedded in their parent organization while their support and service to the JTAPIC mission is managed and coordinated by the JTAPIC PMO.

As shown in **Figure 3-1**, the JTAPIC program links medical, intelligence, operational, and materiel information to improve the understanding of vulnerabilities to threats and to enable the development of improved Tactics, Techniques, and Procedures (TTPs) and materiel solutions that will prevent and/or mitigate traumatic injuries. The integrated analysis that occurs within the JTAPIC partnership strives to provide actionable decision support to inform prevention or mitigation solutions across the doctrine, organization, training, materiel, leader development, personnel, facility, and policy (DOTMLPF-P) domains that will prevent or mitigate traumatic injuries relative to all military operations and ultimately, in combat.

JTAPIC was recognized in February 2013 by the Assistant Secretary of Defense (Research and Technology) for its contributions to The Technical Cooperation Program. JTAPIC contributed to creating a community of interest within the Land Systems Group, Action Group 3, aimed at mitigating battlefield trauma through a Soldier-centric approach to survivability. JTAPIC's contributions expedited national procurement activities that significantly contributed to saving warfighters' lives or reducing the severity of their injuries.

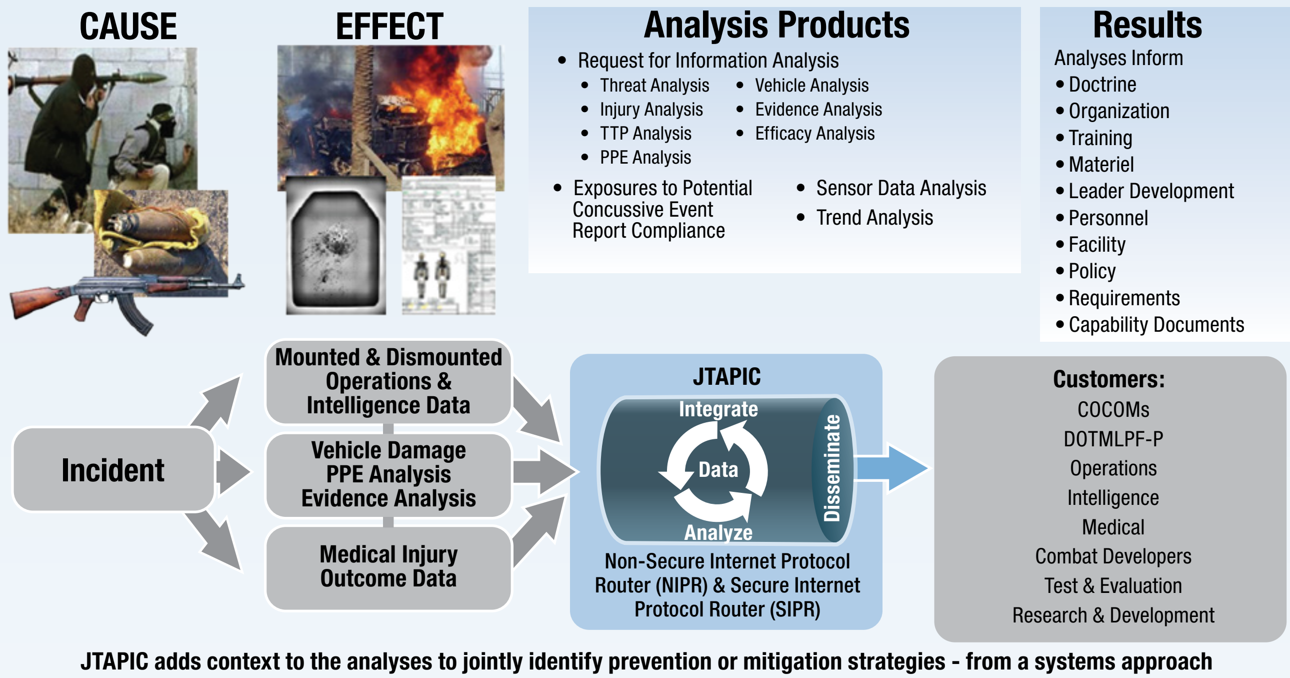


Figure 3-1: JTAPIC Operational Concept

Program Structure

The overall organization of the JTAPIC PMO is shown in **Figure 3-2.** JTAPIC funds personnel that are embedded in 11 separate and geographically disperse partner organizations. Eight team members staff the PMO at Fort Detrick. Approximately 64% of JTAPIC partner organizations are nonmedical and 54% are not Army.

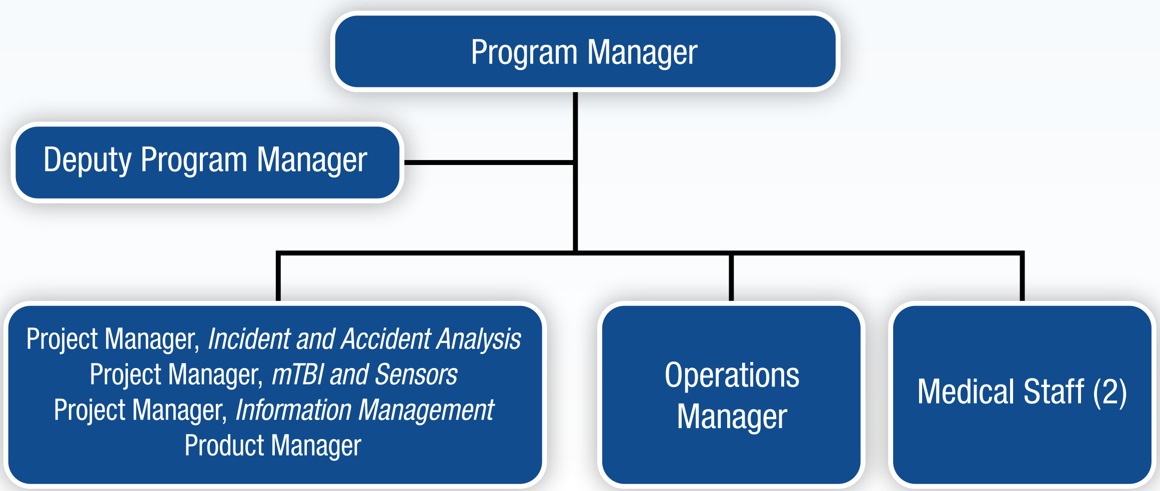


Figure 3-2: JTAPIC PMO Structure

Decision Support

The JTAPIC program is in a unique position to provide a comprehensive analysis of any casualty-causing operational event. The information collected, integrated, and analyzed is distributed to appropriate DOTMLPF-P domain customers to provide objective, relevant, and timely decision support for those who create solutions to prevent or mitigate injury. **Table 3-2** describes the types of decision support provided. Examples of support provided by JTAPIC in FY13 are described below.

Event Analyses

Event analyses are initiated from COCOM inquiries or when unusual or emerging events are flagged during trend or other monitoring. Members of the operational, intelligence, materiel, and medical communities then integrate their data, analyze the event for injury causation and potential mitigation strategies, and report the results and recommendations to the appropriate customers.

- **Gunshot Wound Analysis:** In July, a JTAPIC gunshot wound (head injury) analysis assisted PEO Soldier in gaining approval to procure the Enhanced Combat Helmet (ECH). The ECH will provide improved head protection when compared to the protection afforded by the ACH.
- **Support to Accident and Combat Aviation Communities:** USAARL continued providing accident data collection and analysis support to both the MRAP Joint Program Office and the U.S. Army Aviation and Missile Research, Development, and Engineering Center Tank Automotive Research, Development, and Engineering Center (TARDEC) communities by publishing Technical Reports (TR) to support customers in need of injury metrics: 1) TR 2013-12 Ocular Battle Injuries among US Military Personnel, 2002-2011 included data that indicates explosive blast injury was the leading cause of military eye injuries during the past decade (2002 through 2011). This finding reinforces the need for military personnel to wear protective eyewear at all times during training and combat. 2) TR 2013-13 Injury to Occupants of US Army High Mobility Multipurpose Wheeled Vehicle (HMMWV) Rollover Accidents, 1989-2007 reported the results of a collaborative study revealing that wearing occupant restraints could have saved 69% of Soldiers' lives lost from being unrestrained in HMMWV rollover accidents. TR 2013-14 Prevention of Injury in MRAP Vehicle Accidents concluded that during the time period studied five standardized causes and outcomes classified as road

Table 3-2: Type of Decision Support Provided by the JTAPIC Program

	Sentinel Event	Event Analysis	Trends	RFI
Purpose	First time occurred; significantly beyond expectations	Of interest, unusual, emerging	Monitor aggregate data for emerging outcomes, story untold, question not asked, and efficacy analysis	Inform materiel or nonmateriel capability or requirement documents
Frequency	Immediate as identified	Weekly, Monthly	Monthly, Quarterly	As requested
Production Time	Usually 3–10 days	Usually >30 days	Usually >30 days	Usually 1–6 months; can be 72 hours (Congress)
Deliverable	Analysis notification memo	Analysis notification as required	Trend chart with analysis and contextualization	Email, memo, product briefs, analysis, recommendations
Customer	Varies across DOTMLPF-P	Varies across DOTMLPF-P	Varies across DOTMLPF-P	Requester and Stakeholders

hazard, rollover, vehicle issues, personnel, and driver response contributed to 80 percent of MRAP accidents resulting in injury. Rollovers are the deadliest and costliest Army MRAP accident type.

- **Blast Exposure Sensors:** JTAPIC collects and analyzes the 2nd Generation Helmet-Mounted Sensor System data. The helmet sensor is designed to be an operational tool for leaders to identify early when a Service member has been exposed to environmental forces that may result in injury. The sensors indicate exposure, not injury, and are not medical devices. When fully operational, an amber or red sensor recording in theater is used to inform someone in the chain of command that a Service member must be referred for a concussion evaluation. The concussion evaluation results should be recorded in the electronic health record (e-HR). JTAPIC uses the sensor data to 1) identify Service members that may have been exposed to a potential concussive event, 2) review the Service member's e-HR to determine if the Service member was evaluated for a concussion, 3) add operational information to contextualize the sensor event, and 4) match the sensor data to the e-HR entry to inform the dose-response curve. An informed dose-response curve provides a predictive tool regarding how likely a Service member may be injured/concussed as a result of his/her exposure to predefined environmental forces (namely acceleration). JTAPIC is prepared to collect and analyze DARPA Blast Gauge data as well. As a result of an Army directed requirement, Service members in theater wearing a helmet-mounted sensor will also wear a blast gauge starting near April 2014. More on the DoD's blast exposure sensor efforts can be found in Chapter 4.

Trends

- **Monitoring Concussion Exposure Reporting:** JTAPIC has been measuring compliance with the requirement for Services and COCOMs to submit a monthly exposure tracking report to JTAPIC per DoD Instruction 6490.11, Policy Guidance for Management of Mild Traumatic Brain Injury/Concussion in the Deployed Setting, September 2011, paragraphs 6e and 8b, respectively. The monthly report transitioned to weekly reporting in January 2013 to provide real-time feedback and an opportunity to follow-up with Service members that had not been evaluated for a concussion or were followed-up subsequent to the initial concussion evaluation. The weekly compliance reviews have resulted in 1) improved management of Service members exposed to a potential concussive event in theater, 2) improved documentation in the electronic health record (from <60% prior to July 2013 to >80% from July through early November 2013), 3) improved understanding of the policy and associated practices between organizations, and 4) improved data collection of Service members exposed to potential concussive events across all Services (Defense Casualty Information Processing System and environmental sensors became additional data sources around June 2013).
- **Multiple Exposure and Multiple Concussion Report:** In October, JTAPIC released the first Multiple Exposure and Multiple Concussion report to US Central Command (CENTCOM), Health Affairs, Force Health Protection and Readiness, and Service TBI offices to inform and assist CENTCOM and the Services in managing their Service members exposed to a potential concussive event or diagnosed as concussed two or more times in 12 months. Reporting frequency will continue on a monthly basis.

Requests for Information

- **Total RFIs:** JTAPIC responded to 51 Requests for Information (RFIs) in FY13 that were distributed to various customers to include but not limited to the Congressional Liaison Office, JIEDDO, materiel and nonmateriel development organizations, test and evaluation organizations, as well as capability requirements offices to help inform decisions.
- **Support to Warrior Injury Assessment Manikin (WIAMan) Program:** JTAPIC provided data from more than 100 Service

member blast exposure events for the WIAMan extramural collaboration between the Director of Operational Test and Evaluation of the Office of the Secretary of Defense, and automotive industry, university, and medical community attendees. The support provided by JTAPIC will assist the WIAMan Project Office in designing the most effective anthropomorphic test device (ATD) for understanding the limits of the human body in an underbody blast environment to ultimately improve force protection.

- An RFI can be submitted at *http://jtapic.arl.army.mil/*; for additional information, send an email to *usarmy.detrick.medcom-usamrmc.list.jtapic@mail.mil*.

Way Forward

The JTAPIC program will continue to collect operational incident and accident information to timely inform solutions that can prevent or mitigate traumatic injury. Expertise provided by the 11 partner organizations results in the actionable products that our customers have come to use and value in their decision-making process to prevent or mitigate injury across the full range of military operations.

Chapter 4

Monitoring Blast Exposure

Understanding the blast environment and injury risks to which Service members are exposed is critical for providing the best protection to avoid injury, and the best treatments should injuries occur. This knowledge aids COCOMs and medical personnel in decision-making, informs equipment design, and guides protection technology and research investments. The DoD is actively collecting—and developing improved means to collect—data on Service members' exposure to blast and impact, both in combat and during training, and linking these data to medical risks such as concussion and TBI. A critical aspect of these efforts is to identify and measure the physical forces (acceleration and overpressure) that are encountered by the individual warfighter, using sensors placed on the warfighter and/or vehicle. These force data (dose) can then be combined with data on injuries (response). Dose-response curves or predictive models are being developed by the DoD to inform protective equipment development, and operational and medical decision-making. This chapter highlights technologies currently employed and under development, key DoD policies and directives influencing data collection, the data collection and analysis process, the use of the e-HR, and some initial findings that are influencing the path forward.

Policies and Directives

The DoD has established policies and directives related to the detection, tracking, and management of blast injury, particularly concussion and TBI, in order to ensure the best protection and treatment courses of action, as well as to inform operational decision-making for commanders. A key policy is DoD Instruction (DoDI) 6490.11, DoD Policy Guidance for Management of Mild Traumatic Brain Injury/ Concussion in the Deployed Setting, described in the side box. JTAPIC is working with the Army TBI Program Director at the OTSG and the DCoE to modify the current policy to include a fifth referral criteria (sensor referral) for medical evaluation due to exposure to a potentially concussive event.

Role of the JTAPIC Program

The JTAPIC program supports both the implementation of policy and guidance for the management of mTBI/concussion and the analysis of data from blast exposure sensors. The program collects the Blast Exposure and Concussion Incident Report (BECIR) from COCOM and measures COCOM compliance with the DoDI. In addition, the JTAPIC program correlates sensor data with injury data in the e-HR and collaborates with the DCoE on mTBI analysis. The data collected is shared with the DCoE, Defense and Veterans Brain Injury Center (DVBIC), the Deputy Assistant Secretary of Defense for Force Health Protection and Readiness, and the CENTCOM Surgeon's Office. As the JTAPIC program is the DoD repository for all sensor data from the Services, program officials have worked with the US Forces-Afghanistan (USFOR-A) and CENTCOM Surgeons, and the OTSG to develop and implement the USFOR-A theater policy for referral and documentation following sensor indications of exposure to a blast event. Concurrent work focused on implementing how and where to document the exposure in the e-HR to support correlating exposure and injury data.

DoDI 6490.11, Policy Guidance for Management of Mild Traumatic Brain Injury/ Concussion in the Deployed Setting, September 18, 2012

- Outlines the responsibilities, requirements, and procedures for the identification, tracking and medical treatment of Service members exposed to potentially concussive events, including blast events
- Defines a potentially concussive event requiring mandatory rest periods, medical evaluations, and reporting of exposure as the following (but not limited to) and requires:
  - Involvement in a vehicle blast event, collision, or rollover
  - Presence within 50 meters of a blast (inside or outside)
  - A direct blow to the head or witnessed loss of consciousness
  - Exposure to more than one blast event (directs medical evaluation)
- Provides guidance for commanders to assess and medically refer Service members
- Identifies reporting requirements, including monthly reports to JTAPIC
- Provides medical evaluation and treatment guidance – use of most current guidance from the DCoE
- Directs further medical evaluations to be conducted for recurrent concussions (three concussions within 12 months, or when clinically indicated)

Figure 4-1 summarizes the flow of data and analyses which JTAPIC supports.

The JTAPIC program also evaluates the implementation of sensor data-related policies and processes. For example, in December 2012, JTAPIC in conjunction with the Project Manager, Helmet Sensor at PEO Soldier, and Army TBI Program Director at OTSG visited the Operation Enduring Freedom (OEF) theater to review sensor implementation and effectiveness; verify that units wearing helmet sensors received the USFOR-A Fragmentary Order, and were prepared to comply with it; verify that all Service members with an amber or red helmet sensor reading are getting medically evaluated for concussion (despite an apparent lack of documentation); discuss sensor implementation processes with unit

Combined Data Sources Flow (mTBI)

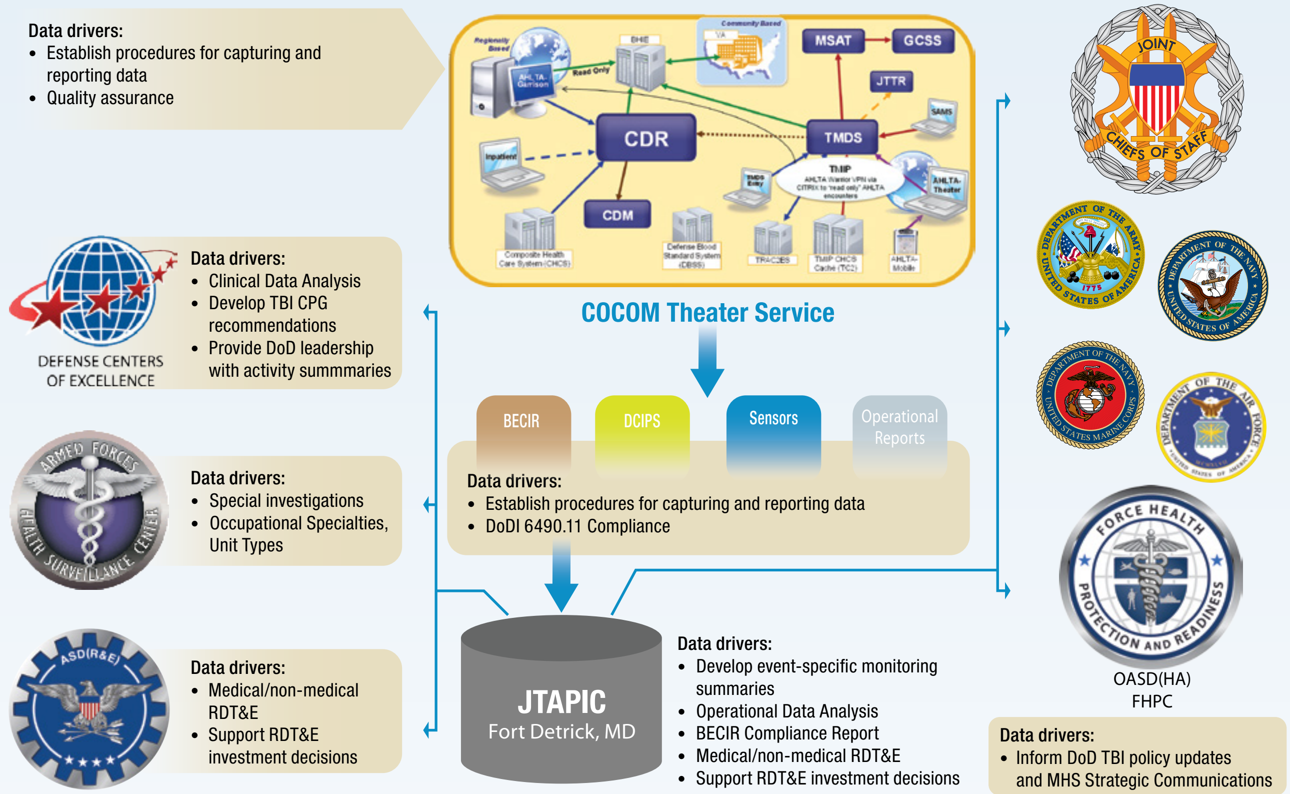


Figure 4-1: Data Flow to JTAPIC for mTBI per DoDI 6490.11 and Data/Analysis Sharing

Armed Forces Health Longitudinal Technology Application=AHLTA; Bidirectional Health Information Exchange=BHIE; Clinical Data Mart=CDM; Clinical Data Registry=CDR; Combatant Commanders=COCOMS; Defense Civilian Intelligence Personnel System = DCIPS; Doctrine, Organization, Training, Materiel, Leadership and Education, Personnel, Facilities and Policy=DOTMLPF-P; Global Combat Support System=GCSS; Joint Theater Trauma Registry=JTTR; Medical Situational Awareness in the Theater=MSAT; Research, Development, Testing, And Evaluation=RDT&E; Shipboard Automated Medical System=SAMS; Theater Medical Data Store=TMDS; Theater Medical Information Program=TMIP; Transportation Command Regulating and Command & Control Evacuation System=TRAC2ES; Virtual Private Network=VPN

leaders, sensor field support technicians, and medical personnel at Military Treatment Facility (MTFs) and Concussion Care Centers; and close information gaps to help further the capability to collect, analyze, and correlate sensor data.

The JTAPIC program seeks to improve the effectiveness of data collection and analysis, including recommendations for updating policies. See Chapter 3 for more on the JTAPIC program.

Blast Monitoring Systems – In Use

DARPA Blast Gauge

DARPA previously contracted with BlackBox Biometrics to complete the development of a small, lightweight, and inexpensive blast dosimeter. The DARPA Blast Gauge is used to indicate whether a Soldier has experienced a blast or impact event, and can help identify individuals requiring medical evaluation. The gauge measures pressure, 3-axis acceleration at the sensor location, and the time of event. The gauge includes overpressure exposure-level status lights (red, yellow, or green) and can be attached to helmets, gear, or other mounting points on the warfighter, with the primary attachment points being the non-firing shoulder, opposite side chest, and the nape pad (**Figure 4-2**). The sensor is commercially available from BlackBox Biometrics (http://

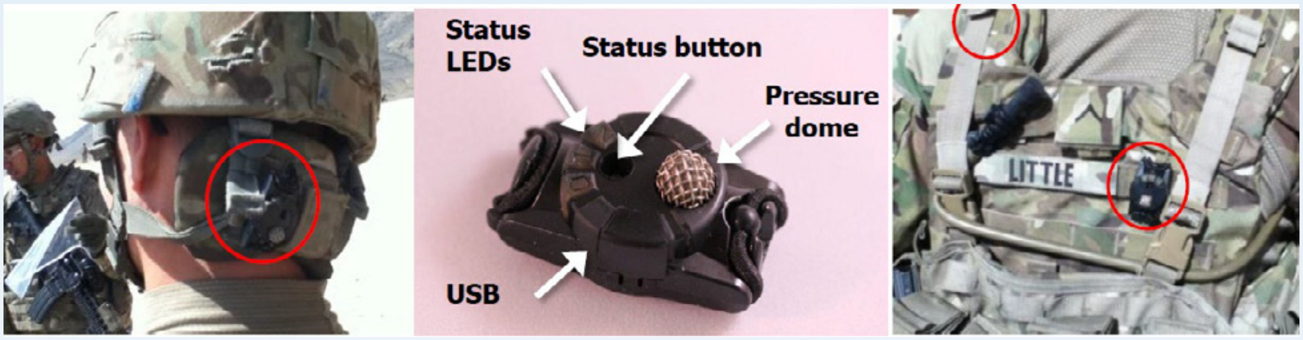


Figure 4-2: DARPA Blast Gauge

blastgauge.com/; NSN 6665-01-606-7851). Over 150,000 DARPA Blast Gauges have been sent to units since its release in 2011 for use in training and combat operations, including Afghanistan, and 800 sensors have been fielded to the Australian Army and Special Operations Forces.

HEADS

In 2007, PEO Soldier's Product Manager Soldier Protective Equipment (PM SPE) fielded the first-generation (Gen I) helmet-mounted sensor system (HMSS). The Gen I HMSS recorded helmet acceleration and pressure from impacts and explosions, and the data obtained led to numerous improvements. The second-generation (Gen II) HMSS, or HEADS, is a self-contained transducer, records and stores both linear and rotational accelerations to the helmet, and has an added overpressure trigger to detect when Soldiers are exposed to high-energy-induced blast impulses and impacts. The sensor is mounted internally in the crown of the ACH, ECH, or Combat Vehicle Crewman Helmet (**Figure 4-3**). Although the sensor is not yet commercially available, approximately 17,000 HEADS sensors have been fielded to military units since its release in 2012, and currently it is being used in Afghanistan.

Integrated Blast Effects Sensor Suite (I-BESS) Program

The I-BESS is an integrated, wireless system for use by both mounted and dismounted Soldiers that measures acceleration and overpressure associated with blast events. The sensor was designed using government-owned and commercially available data-processing architectures and software, making it expandable and upgradeable in the future. The system includes a Soldier Body Unit (SBU), which collects blast information on an individual Service member, and a vehicle system, which contains floor- and seat-mounted accelerometers to collect information on vehicle blast engagements (**Figure 4-4**). The Peltor headset features triaxial linear accelerometers and angular rate sensors to capture the kinematics of the human head during a blast event. Event-driven data collected from the I-BESS are ultimately transferred to the US Army Test and Evaluation Command (ATEC) Black Box system. The I-BESS was fielded in 2012 to Afghanistan; 42 vehicle systems are to be outfitted and 700 SBUs distributed.

Figure 4-3: HEADS Helmet Mounted Sensor System

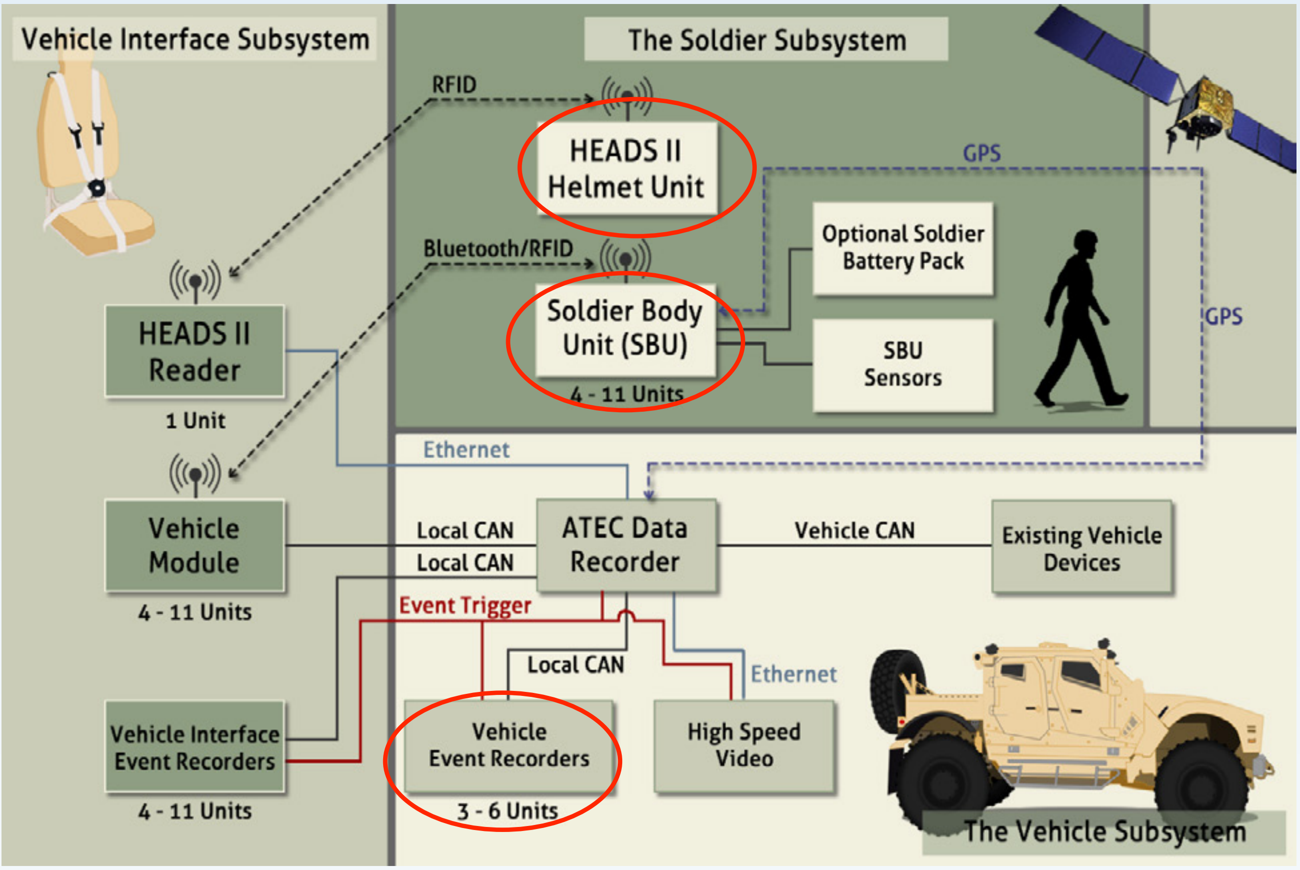


Figure 4-4: Integrated Blast Effects Sensor Suite

Ongoing R&D and Evaluations

Evaluation of Sensors by the US Marine Corp Warfighting Laboratory

Under the direction of the Assistant Commandant of the Marine Corps, the Marine Corps Warfighting Laboratory (MCWL) is performing an independent evaluation of blast sensors for use in the Marine Corps. In FY12, MCWL began the evaluation with a Limited Technical Assessment (LTA) of two types of blast sensors: the US ARMY's Gen II HMSS and DARPA's Blast Gauge system. The LTA concluded that the DARPA Blast Gauge sensors were ready for inclusion in an End User Evaluation (EUE), but the Gen II HMSS would not be included due to observed high variability in both acceleration and pressure recordings given identical inputs, along with false triggers, erroneous date/time stamps, and radio frequency identification issues.

Starting in FY13, and with the plan to continue on through 2QFY14, DARPA Blast Gauge sensors are undergoing an EUE in theatre with 2nd EOD Company 8th ESB. When the EOD company returns, data will be evaluated and an EUE report will be generated to provide recommendations on the way forward.

Shock Impact & Explosive Limits Dosimetry (SHIELD) System

The US Army Medical Materiel Development Activity (USAMMDA) is sponsoring a new dosimetry system being developed by Oceanit (**Figure 4-5**). Several prototype dosimeters have been constructed and tested on multiple test runs in full-scale shock tubes. The sensor distinguishes three blast intensities (30, 45, and 60 psi). The rupture threshold of the dosimeters can be tuned to any relevant value (low, medium, and high) by modifying the

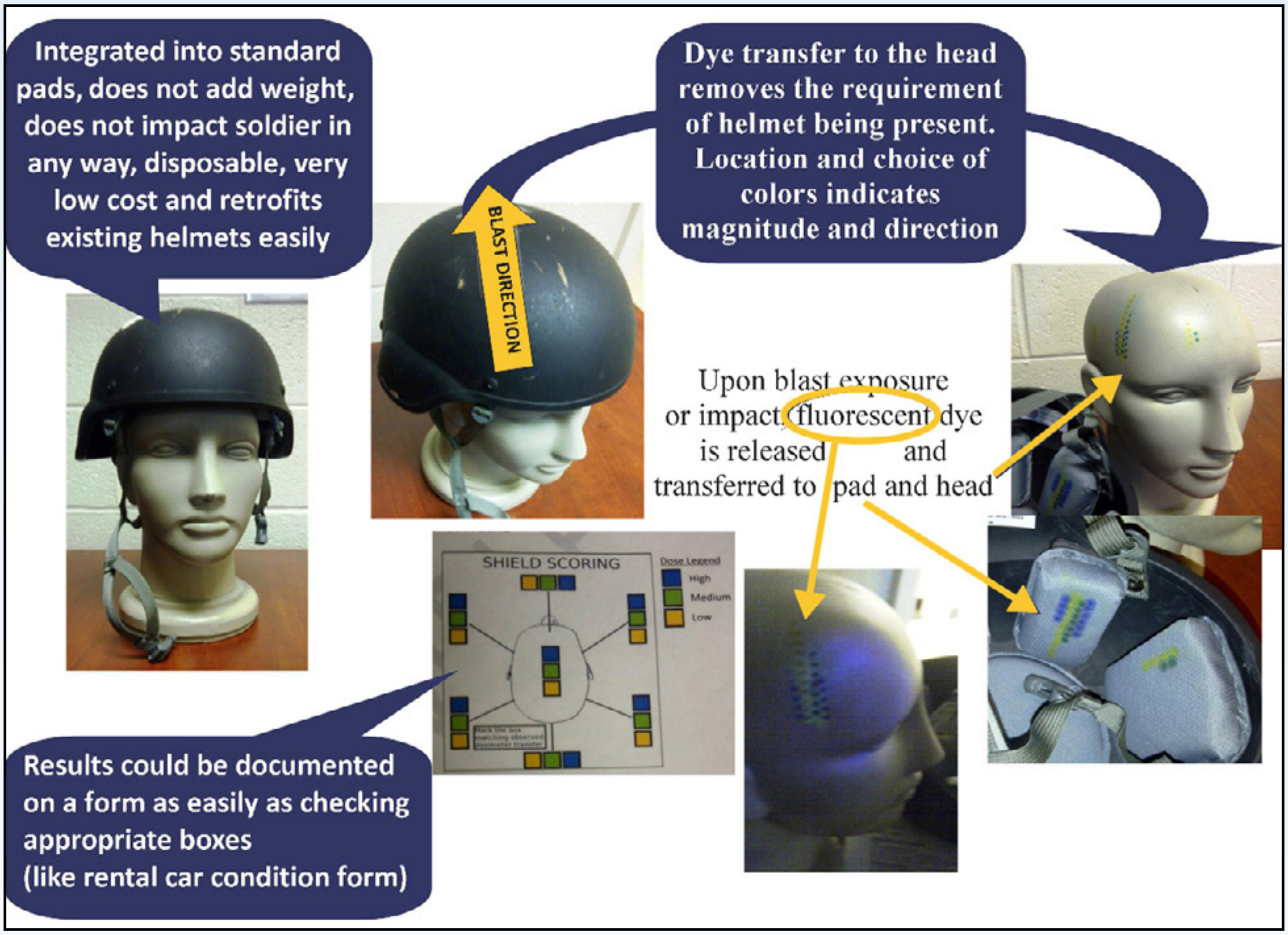


Figure 4-5: SHIELD System Dosimeters

microstructure properties. The dosimeter is also capable of recording concussive impact and distinguishing the relative force of the impact. The dosimeter indicates intensity and direction of the event through the transfer of a color dye. The dyes are also detectable with an ultraviolet penlight for discovery under tactical conditions, and the pads are easily retro-fitted into all combat helmets. To test the dosimeter's ability to register concussive impact, impact testing was conducted with the prototype dosimeter sandwiched between a helmet pad and scalp surrogate. Weights were dropped from varying heights to simulate impact. The results showed successful transfer of dye to the anatomical headforms.

Low Power Microelectromechanical Systems Acceleration Sensors

NSRDEC is sponsoring the development of a novel three-axis acceleration threshold sensor to detect impact events that could lead to mTBI and TBI. The sensor is being developed by the US ARL, as part of the Helmet and Electronics and Display System - Upgradeable Protection Army Technology Objective, to detect impact events. The wearable sensor package fits the earbud form factor (5 mm diameter) and operates in an ultralow power state until an impact acceleration event occurs. Eight normally open three-axis acceleration threshold switches that vary in threshold sensitivity (nominally 30-300g's) detect impact through switch closure and the electronics process, and transmit the data package via Bluetooth™. Post processing via handheld smartphone and or PC will enable the end user to determine whether medical treatment is necessary. The form factor reduction and battery life improvements are potential advantages of the proposed design. Preliminary battery life evaluations show that the sensors can detect and transmit up to five TBI-like events over a one month period of operational time before requiring recharging. NSRDEC plans to incorporate this sensor in their CY14 helmet experiments.

Standards for Ground Vehicle Sensor Systems

The Tank Automotive Research Development and Engineering Center (TARDEC) Ground System Survivability (GSS) Exterior Blast Mitigation Technology Team is developing standards for sensors systems for use in combat and tactical vehicles. The purpose of these systems is threefold: to detect blast, crash, and rollover events and provide a trigger signal to active protection systems; and to record data during these events. The trigger signal will provide the ability to use active protection systems that can significantly reduce injury in catastrophic events, such as deploying an airbag during a crash. The data recorded during these events can be used to better understand what the vehicle and occupants are experiencing, and can be used to improve vehicle design, improve testing, and design better safety systems. The standards developed will be able to be adapted to all military vehicles for use in both war time and peace.

Technology-Enabled Capabilities Demonstration Brain in Combat – Concussion Dosimetry

The USAMRMC sponsors the Technology-Enabled Capabilities Demonstration (TECD) Brain in Combat. This TECD was intended to take medical technologies from late research development and demonstrate these in a relevant environment to determine technologies that should go forward into advanced development. A major challenge is determining technologies that could be used by leaders to determine if a Soldier could return to duty or should be referred to the medic for further evaluation. Concussion dosimetry is the development of algorithms to determine the probability of injury that could be associated with the energy absorbed by an environmental sensor either from acceleration/deceleration or from blast overpressure.

USAMRMC and the Maneuver Center of Excellence are working to evaluate the various technologies in relevant operational environments. After discussions with Maneuver Battle Laboratory, the Airborne School, and Basic Training Brigades, it was determined that airborne training and basic combatives were two of the best environments to study acceleration sensors to evaluate the energies absorbed during the various training events throughout the duration of these courses. These efforts would utilize sensors currently in use by the Army in theater (Gen II helmet), and also investigate the use of various sensors used in athletics programs from high schools, universities and the National Football League.

The Training and Doctrine Command (TRADOC) became aware of these efforts and, in conjunction with USAMRMC, is developing a sensor program for the training environment. They are in the process of establishing its methodology, including identifying the best sensors, appropriate training environments, and who should actually be wearing the determined environmental sensors (students or cadre). Of interest for inclusion is blast overpressure work with the Artillery at the Fire Centers of Excellence, Fort Sill, Oklahoma. Further discussions with the Army G3/5/7 (Operations and Plans) and the Army Requirements and Resourcing Board General Officer's Steering Committee on a more holistic approach to the wearing/use of sensors—throughout the Army's widely varying training environments—led to recommendations for considering additional sites in the studies. Army Study Funds were requested to support these efforts.

The USAMRMC lead laboratory is the USAARL due to its extensive experience with aviation helmet safety and its work with Fort Benning in neck injury. The Walter Reed Army Institute of Research (WRAIR) plans to perform the blast overpressure work at Fort Sill with the Artillery School, based on its extensive history of blast research including recent work done with breacher training. Breaching requires the team to blow a hole into the wall of a building to allow Soldiers a tactical advantage to rush inside either to capture their targets or to secure the building. USAARL is developing protocols and completing laboratory studies, and WRAIR has been able to shift one of its existing protocols to the work at Fort Sill. Pilot studies at the Fort Benning and Fort Sill sites are expected to begin in January 2014.

As part of the TECD, the US Army's MOMRP is sponsoring research by L-3 Communications in collaboration with others to understand the sequence of mechanisms that lead to concussion in order to build a model that can accurately predict credible damage parameters that correlate with concussion indicators. Mathematical modeling is being used to link the external forces with stresses and strains in the brain. **Figure 4-6** provides an overview of the effort. The model being developed is not specific to a particular exposure sensor.

Environmental Sensors in Training – USAARL

TRADOC has a requirement to field head impact environmental sensors to Army Soldiers in training environments. The overall goal for the project is to collect data on the exposure conditions that may result in documented TBI and then use this data to establish reliable dose-response correlations. USAARL's involvement in the process is significant, including activities such as laboratory evaluations of the sensors, methodology for fielding the sensors, and performing concussion assessments on the trainees (with several Soldier population sizes, from 10–20 up to 400). As shown in **Figure 4-7,** the effort is focused on both accelerative environments (Airborne Training and Combatives during Basic Training) and overpressure environments (Heavy Artillery). At this time, the sensors of interest include the PEO-S PM SPE-sponsored Gen II HMSS, the DARPA Blast Gauge, and the SIMBEX Head Impact Dosimeter (a USAARL-sponsored SBIR effort), Reebok Checklight and the X2 XPatch.

Currently, USAARL is performing a laboratory evaluation of the sensors mentioned above and is preparing for several pilot studies involving

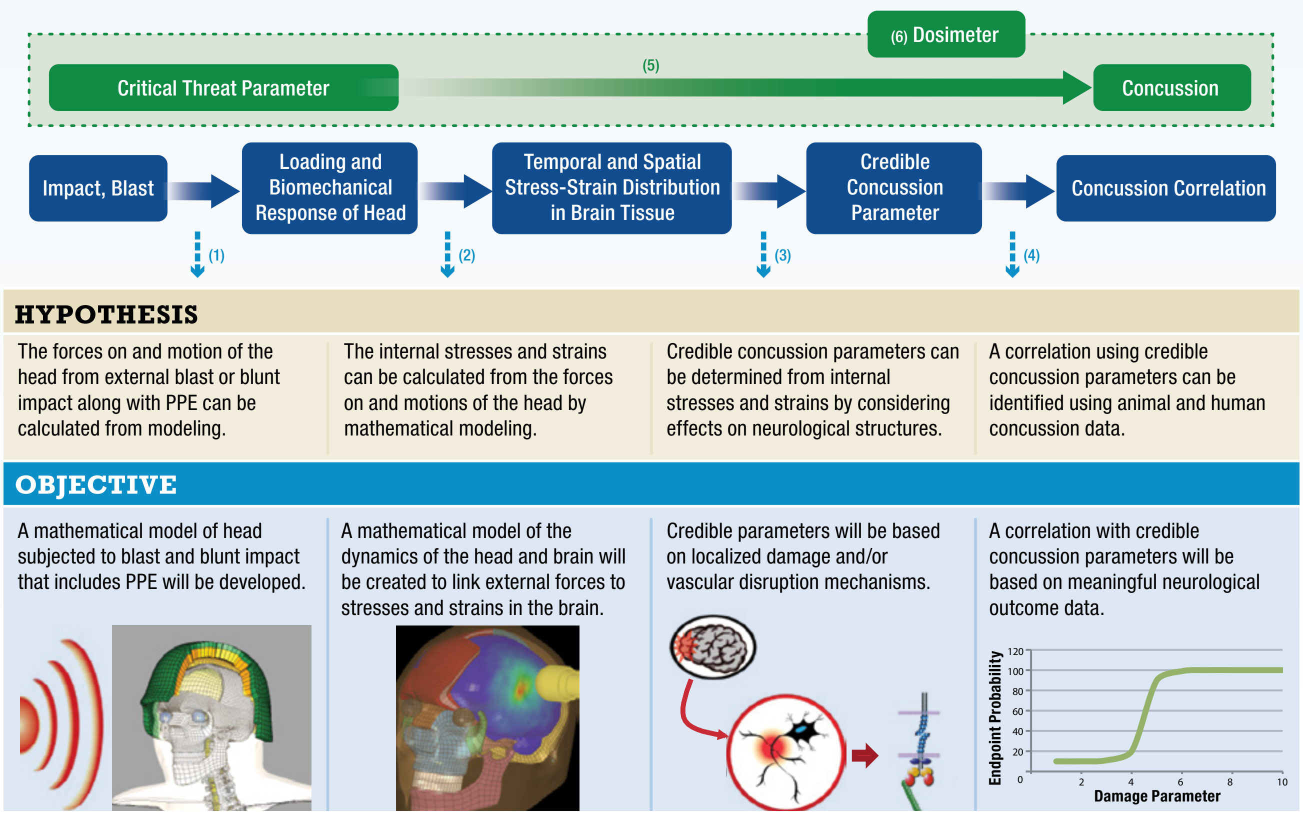


Figure 4-6: MOMRP Concussion Dosimetry Research Effort

Airborne Training and Combatives training at Fort Benning, Georgia. The purpose of these evaluations is to (1) validate the technical performance of the sensors against the lab grade instrumentation in a variety of controlled exposure conditions and (2) determine whether they provide sufficient information so that they can be used with existing head injury metrics. Several tests are being performed, including indirect impacts using a minisled (ensuring that the retention system of the ACH is not changed with the addition of the sensor and simulating impacts to the chest and body), direct impacts using a drop tower (ensuring that the blunt impact protection for the ACH is not changed with the addition of the sensor and simulating impacts directly to the head/helmet) and mass properties (center of gravity, moments of inertia, etc.). Additionally, the environmental sensors are being evaluated to determine whether it is possible to correlate the output they provide with any known head injury metrics (i.e., Head Injury Criteria, Gadd Severity Index, accurate peak linear acceleration or peak rotational velocity, etc.). Several injury metrics exist for evaluating the possibility of a head injury due to acceleration; however, the head acceleration or rotational velocity is often unknown or derived from non-ideal conditions for military operational and training environment exposures.

Following the lab evaluations, USAARL will conduct a form and fit pilot test of the sensors using the Training Cadre from each of the environments. This will allow the cadre to gain familiarity with the sensors in order to assess any potential interference with the training environment or their normal operating procedures. USAARL will also determine best approaches for access to the trainees for distribution and recovery of the sensors. A second pilot study will instrument a small population of trainees (10–20) in both environments with sensors to (1) determine appropriate sensor trigger levels and the

Figure 4-7: Overpressure and Acceleration Exposure in Training Environments

incidence of false triggers and missed impacts, (2) perform a comparison between different sensors, and (3) provide information to support developing best practices for the logistics of incorporating environmental sensors into military training environments (e.g., Soldier access, sensor distribution/recovery, data recovery). Future activity being planned includes incorporating techniques for assessing concussion (i.e., the Military Acute Concussion Evaluation (MACE) Exam, the Automated Neuropsychological Assessment Metrics (ANAM), and other neurocognitive, vestibular, and vision assessments) into larger scale studies. The goal is to develop a robust injury threshold in conjunction with an environmental sensor(s) (measuring force exposure severity from a blast or impact) to be transitioned to a dosimeter that identifies likelihood of injury based solely on the exposure level.

Sensor Data Analysis

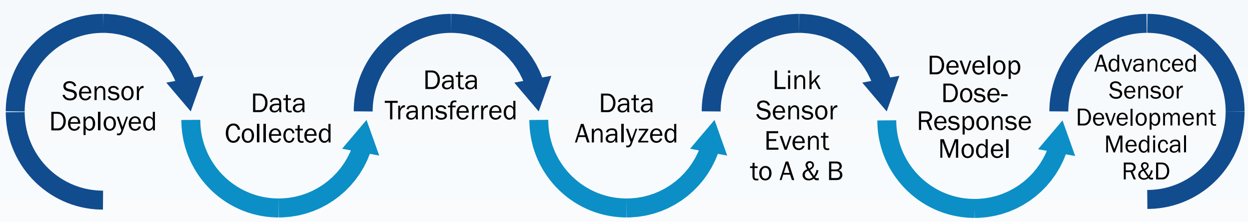
Process

As shown in **Figure 4-8**, the process encompasses sensor deployment through data analysis and development of next generation sensor technologies. JTAPIC uses the sensor data to inform the Services about Service members exposed to potentially concussive events, or those that have been exposed multiple times. JTAPIC also matches the exposure data to medical encounter data on injuries in order to refine current injury threshold levels. The process also supports line and medical requirements (**Table 4-1**).

Sensor Data Collection

The currently fielded sensor systems are at varying stages in the data collection and analysis process. Data is collected on the measured overpressure or acceleration event.

- **DARPA Blast Gauge:** This sensor was deployed in July 2011 and linking of the sensor event to medical encounter and operational data has begun. DARPA receives gauges in theater or by mail from units and downloads the data which is then transferred to JTAPIC or DARPA partners for analysis. A Service member's chain is typically notified



A=Medical Encounter; B=Operational Environment

Figure 4-8: Sensor Data Analysis Process

Table 4-1: Line and Medical Requirements Supported by Sensor Data Collection and Analysis

Line Requirements
Identify Service members with amber or red sensor output
Ensure Service members are evaluated by medical personnel
Report information into the BECIR module within CIDNE*

* CIDNE=Combat Information Data Network Exchange

Medical Requirements
Document all encounters in the electronic health record to include International Classification of Diseases, Ninth Revision (ICD-9) codes and three sensor questions
Utilize the MACE when screening for concussion
Utilize the Concussion Management in Deployed Settings algorithms

of events via medical personnel, or the gauge can be accessed locally by command. In FY13, JTAPIC was working with DARPA on strategies to receive data from all Services.

- **Gen II HMSS/HEADS:** This sensor was deployed in June 2012 and the effort has progressed to the dose-response model development stage. Data is collected by Brigade Combat Team (BCT)-embedded field service technicians following known events (or every 30 days) and transferred to PEO Soldier electronically. BCT data collectors notify the Service member's chain of command of blast exposure events.
- **I-BESS:** This sensor system was deployed in September 2012 and data collection is underway. Data is stored in the vehicle data recorder and is removed by data collectors for transfer via the Army's Test and Evaluation Vision Digital Library System to the JTAPIC program for analysis. There is no chain of command notification of events at this time.

Electronic Health Records

JTAPIC conducted an analysis of data from June 2012 through July 2013. There have been 12,761 helmet sensor events documented for the period, and the distribution of red/amber/green exposures are shown in **Figure 4-9**. Only a very limited number of Service members had corresponding entries in the e-HR (**Table 4-2**). The medical personnel performing concussion evaluations also document in the e-HR whether a sensor was worn, the type of sensor, and if the referral was due to sensor output.

JTAPIC also reviews deployed e-HRs to determine if a Service member on the BECIR was diagnosed with a concussion. JTAPIC found that ~35% of the BECIR entries do not have an e-HR entry documenting concussion evaluation. JTAPIC, the CENTCOM Surgeon's Office, and the USFOR-A Surgeon's Office are collaborating to improve concussion evaluation documentation in the e-HR.

Dose-Response Model

A critical component of the blast sensor efforts is developing biomedically validated models to

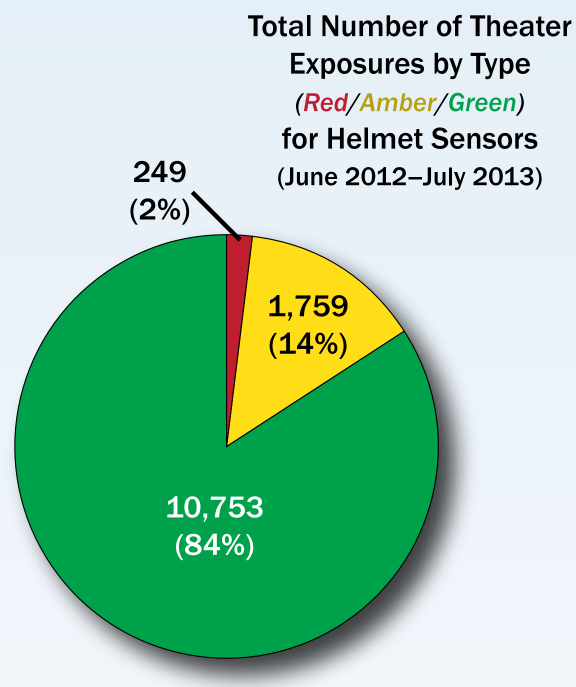


Figure 4-9: Distribution of Helmet Sensor Exposures

	Red	Amber	Green
Number of Service Members (SMs) Exposed	231	1,459	5,950
Number of SMs Exposed with Matching e-HR Entry	6	14	9
Number of SMs Exposed with Matching e-HR Entry and Diagnosed Concussed/ mTBI	1	3	3

Table 4-2: Corresponding Entries of Service Members to the e-HR

correlate the dose received by the sensor to injury potential, as the raw sensor data only indicates exposure to something that might cause injury. Further, a correlation between overpressure and mild TBI has not been proven by research to date. Therefore, sensor data that can be matched to a Service member's e-HR are being used to establish a dose-response model. If there is a correlation between the sensor and medical data, then the sensor data will serve to validate or refine the current sensor injury thresholds. JTAPIC completed a preliminary data analysis in November 2013, and work on the model is continuing.

Way Forward

Going forward, a key focus for the various sensor research, development and fielding efforts will be developing and refining the dose-response models. Improvements are needed in the data capture and analysis process to ensure all data from the sensors, event details and medical record are collected and linked in a timely manner. Additionally, efforts are underway to "train the way we fight" and expand sensor deployments to Army and Marine Corps units in garrison and training bases. The initial goal is to focus on usability (i.e., whether the sensors and gauges interfere with training in any way), but researchers will also assess new sensor technologies. Sensor technologies are evolving, and the expectation is that, ultimately, there will be greater integration of the data with other monitoring technologies.

Chapter 5

MHS Blast Injury Prevention Standards Recommendation Process

DoDD 6025.21E assigns to the EA the responsibility to "Provide medical recommendations with regard to blast-injury prevention, mitigation, and treatment standards to be approved by the OASD(HA)." The MHS BIPSR process is a DoD process designed to address this requirement. The process provides all Services with an unbiased, stakeholder-driven critical assessment methodology for recommending biomedically valid MHS Blast Injury Prevention Standards to protect against the entire spectrum of blast injuries. These standards can range from simple dose-response curves and injury thresholds that address single components of blast insults (e.g., peak force) to complex algorithms and models that address multiple components of blast insults (e.g., force-time history).

The MHS Blast Injury Prevention Standards play a critically important role in the development of safe weapon systems, survivable combat platforms, and effective protection systems (**Figure 5-1**). It is important to note that the MHS BIPSR process is not a research program and does not develop new injury criteria or injury prediction tools. The process, however, does inform research by identifying gaps where no suitable standards currently exist.

Figure 5-1: The MHS Blast Injury Prevention Standards for Safe Weapons, Survivable Combat Platforms, and Effective Protection Systems are Developed with the Aid of the Medical Research, Test and Evaluation, and Materiel Development Communities.

Three communities participate as partners in the development of a standard: the medical research, test and evaluation, and materiel development communities (**Figure 5-1**). The test and evaluation community and materiel developers are often presented with standards from various sources and with varying states of biomedical validity. To meet the needs of the DoD, an unbiased and inclusive process was implemented in which a broad community of SMEs is recruited to identify and thoroughly assess the biomedical validity and applicability of medical standards to DoD-unique problems.

The MHS BIPSR Process

The MHS BIPSR process is an unbiased, inclusive, stakeholder-driven process for identifying and assessing MHS Blast Injury Prevention Standards that support weapon system health hazard assessments, combat platform occupant survivability assessments, and protection system development. Notably, the MHS BIPSR process addresses the entire spectrum of blast injuries and blast injury threats described in the DoDD. The MHS BIPSR process seeks to ensure that the DoD uses the best available, scientifically sound, and biomedically valid standards that will protect our Service members from blast injuries.

The PCO developed the MHS BIPSR process to support a key EA responsibility to recommend MHS Blast Injury Prevention Standards for approval by the OASD(HA). The medical research, test and evaluation, and materiel development communities have been actively involved in the development and application of this process. There are two key components in the process to identify and approve MHS Blast Injury Prevention Standards:

- **Recommendation Process.** An unbiased and inclusive process, under the authority of the EA, for identifying and thoroughly assessing the MHS Blast Injury Prevention Standards with a focus on biomedical validity and applicability. This process reaches out to a broad community of SMEs in the DoD, other federal agencies, academia, industry, and other nations.
- **Approval Process.** A formal process for advising the EA on the MHS Blast Injury Prevention Standards to recommend to the OASD(HA) for approval and DoD implementation.

The PCO contracted with the JHU/APL, a University Affiliated Research Center and DoD-trusted agent, to serve as an independent agent to develop and execute the MHS BIPSR process. Key characteristics of the MHS BIPSR process include:

- **Involvement of stakeholders** from the test and evaluation, materiel development, medical research, and operational communities, who remain active throughout the process
- **SME panels** that are broad-based, non-advocacy groups composed of individuals from academia, industry, DoD, and other federal agencies
- **Consensus building** to recommend the best, biomedically valid standards that meet the needs of the DoD stakeholders
- **Identification of capability gaps and research needs** when suitable standards do not exist, which informs research programs that can potentially provide the needed solutions

The major pillars of the MHS BIPSR process include: (1) reviewing existing capabilities through a systematic literature survey, (2) developing data collection mechanisms, (3) developing evaluation criteria, (4) evaluating candidate standards, (5) holding a consensus-building meeting for stakeholders to share information, (6) deriving and executing scenario-based test cases and executing the tests for the identified candidate standards (where applicable), and (7) developing recommendations for the MHS Blast Injury Prevention Standards and evaluating the process.

Testing the MHS BIPSR Process – Toxic Fire Gas Inhalation (TGI) Exemplar

The viability of the MHS BIPSR Process was tested using TGI as an injury domain exemplar. TGI was selected as the exemplar because it would allow the focus of the effort to remain on the evolution of the process rather than on the complexities of the insult. Assessment of the MHS BIPSR TGI exemplar focused on injury prediction tools that determine injury and performance outcomes from inhalation exposure to mixed gases. These tools could be used to assess warfighter survivability in combat vehicles, ships, aircraft, or enclosures where inhaled gases may be a threat, and to assess warfighter health risks associated with the use of weapon systems that produce toxic gases. The exemplar served to verify the MHS BIPSR process. It also provided a set of lessons learned that are being incorporated into the MHS BIPSR process to enhance subsequent implementation and resulting products.

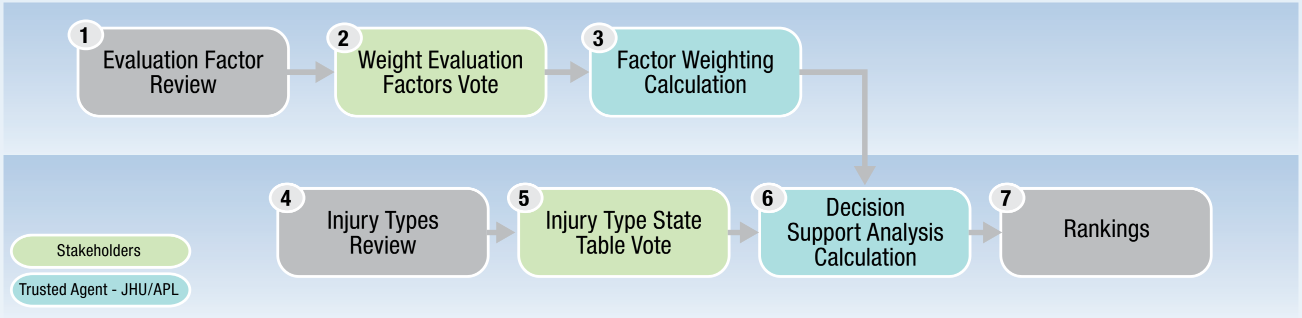


Figure 5-2: Blast Injury Type Prioritization and Selection Methodology

Stakeholder Participation

In FY12-13, the PCO sponsored and chaired a series of three MHS BIPSR process stakeholder meetings in which participants reviewed the MHS BIPSR process and the prioritization and selection methodology to identify the MHS Blast Injury Prevention Standards that should be reviewed by the MHS BIPSR process (**Figure 5-2**). This methodology relied on several key components, including:

- **Blast Injury Types** for which MHS Blast Injury Prevention Standards would be developed.
- **Evaluation Factors** that provide the means for the stakeholders to assess the relative criticality of the blast injury type in terms of such issues as frequency of occurrence, impact on readiness, and resource requirements.
- **State Tables** that provide the stakeholders with an objective basis for rating the blast injury types. A "grade" is given based on pre-agreed-upon state definitions or levels, thus removing unintended bias.
- **Weighting Values** that allow the assessment to emphasize characteristics and/or evaluation factors that are more critical.

The first step in the selection methodology proved to be the most difficult to establish. The Blast Injury Types proposed for evaluation were initially focused on a list of 16 Blast Injury Types defined in a 1989 report by WRAIR[1], which included:

- Cervical Spine Injury
- Dermal Burns
- Eye Injury
- Facial Bone Fracture
- Hearing Impairment
- Lower Extremity Injury
- Lumbar Spine
- Mild TBI (Impact Concussion)
- Moderate to Severe TBI
- Rib Fracture and Internal Injury
- Skull Fracture
- Thoracic/Abdominal Internal Organ Injuries
- Toxic Gas Impairment
- Tympanic Membrane Rupture
- Upper Extremity Injury
- Vision Impairment

BIPSR Stakeholder Meetings Summary

April 2012
Reviewed the proposed MHS BIPSR process and sought stakeholder feedback to enhance its efficiency and value to the DoD. Concluded that the overall MHS BIPSR process is structurally sound and does not require modification.

August 2012
Solicited stakeholder input on the Blast Injury Types, Evaluation Factors, and State Table definitions to be used for a future prioritization exercise. Conducted three surveys to refine the Blast Injury Type list and survey Stakeholders for needed MHS Blast Injury Prevention Standards.

April 2013
Presented and discussed the results from the revised MHS BIPSR Blast Injury Type Prioritization Methodology, and identified the MHS BIPSR Blast Injury Type that would be the first to undergo MHS BIPSR process implementation. Lower Leg Extremity Injury was selected.

[1] The proposed blast injury type list to be prioritized was based on the Technical Report, "Medical Evaluation of Non-fragment Injury Effects in Armored Vehicle Live Fire Tests: Instrumentation Requirements and Injury Criteria," WRAIR, September 1989.

Stakeholders quickly realized that the categorization of injury types has evolved since the publication of the WRAIR report, resulting in coverage gaps (e.g., genitourinary blast injuries) and shifts in perspective from individual organs and bones toward regions of the body (e.g., lower extremity, thoracic/abdominal internal organ injuries). Also, important injury types for which the science is immature, such as mTBI caused by exposure to a blast event without secondary or tertiary head impact, were not considered since the lack of maturity in the science impacts the ability to identify a standard and would undermine a MHS BIPSR process review. Other injury type taxonomies were considered, and the group ultimately developed a new list, the MHS BIPSR Blast Injury Type List, that would be used going forward (**Table 5-1**).

After detailed analysis of stakeholders' comments, concerns and recommendations, the PCO and JHU/APL decided to pursue a revised path forward. This new path included further revision of the Evaluation Factor definitions and State Tables, based on stakeholder input. It also included the development of a set of three surveys to (1) collect MHS BIPSR stakeholder feedback on the revised Evaluation Factors, (2) determine weighted values for the Evaluation Factors, and (3) refine the Blast Injury Type list and survey stakeholders for needed Blast Injury Prevention Standards.

Table 5-1: MHS BIPSR Blast Injury Type List Compared to Other Injury Taxonomies

<table>
<tr><th>1989 WRAIR Blast Injury Type</th><th>AIS* Body Regions</th><th>ICD-9 Body Areas</th><th>Barell Matrix Body Regions</th><th>MHS BIPSR Blast Injury Type List</th></tr>
<tr><td rowspan="3">Mild TBI (Impact Concussion)
Moderate to Severe TBI
Skull Fracture</td><td rowspan="3">Head</td><td rowspan="6">Head</td><td rowspan="3">Head</td><td>Mild TBI (concussive)</td></tr>
<tr><td>Moderate to Severe TBI</td></tr>
<tr><td>Skull Fracture</td></tr>
<tr><td rowspan="3">Eye Injury
Vision Impairment
Tympanic Membrane Rupture
Hearing Impairment
Facial Bone Fracture</td><td rowspan="3">Face</td><td rowspan="3">Face</td><td>Ocular</td></tr>
<tr><td>Face (includes Oral and Maxillofacial)</td></tr>
<tr><td>Auditory</td></tr>
<tr><td>Rib Fracture and Internal Injury
Thoracic Internal Organ Injuries
Toxic Gas Impairment</td><td>Thorax</td><td rowspan="3">Torso</td><td>Thorax</td><td>Thorax (includes Rib Fracture, Chest, Internal Organs, Toxic Gas Inhalation)</td></tr>
<tr><td rowspan="2">Abdominal Internal Organ Injuries</td><td rowspan="2">Abdomen</td><td rowspan="2">Abdomen/Pelvis</td><td>Abdomen</td></tr>
<tr><td>Pelvic/Urogenital</td></tr>
<tr><td>Cervical Spine Injury</td><td>Neck</td><td>Neck</td><td>Neck</td><td>Neck</td></tr>
<tr><td>Lumbar Spine</td><td>Spine</td><td>Spine/Back</td><td>Spine</td><td>Spine/Back (includes C-Spine, T-Spine, L-Spine, Sacrum/Coccyx, Spinal Cord)</td></tr>
<tr><td>Upper Extremity</td><td>Upper Extremity</td><td>Upper Extremity</td><td>Upper Extremity</td><td>Upper Extremity</td></tr>
<tr><td>Lower Extremity</td><td>Lower Extremity</td><td>Lower Extremity</td><td>Lower Extremity</td><td>Lower Extremity</td></tr>
<tr><td>Dermal Burns</td><td>External</td><td>Burn</td><td>External</td><td>Dermal Burns</td></tr>
</table>

* AIS=Abbreviated Injury Scale

Stakeholder Survey #1 –Evaluation Factors and Associated States

The first survey was designed to obtain stakeholder input to determine the Evaluation Factors and associated State Tables that would be used to identify the first two MHS Blast Injury Prevention Standards to undergo MHS BIPSR Process Review in FY13. Based on the discussions of the original Evaluation Factors presented at the August 2012 Stakeholder Meeting, six Key Evaluation Factors were identified:

- **Blast Injury Prevalence Rate:** The number of cases of a given blast injury type expressed as a percentage of the total number of blast injuries.
- **Impact on Operational Readiness:** The time for a Service member to return to duty.
- **Treatment Resources:** The distribution of medical resources and capabilities required to provide Service members phased roles of medical care from the point of injury to the US support base and beyond.
- **Rehabilitation Resources:** Resources required to support Service member's rehabilitation beyond immediate treatment resources. These resources may include therapy, pharmaceuticals, or devices needed to reset for quality of life.
- **Maturity of the Science:** For a particular injury type, the maturity of the science is determined based on the existence of established standards (e.g., MIL-STD-1474E noise limit design criteria). In the absence of established standards, the degree to which biomedically valid injury mechanisms have been established in the peer-reviewed scientific literature or assessment methodologies based on the established injury mechanisms have been developed and are being applied in the assessment of injury risks.
- **Disability Percentage:** Designated disability percentage assigned to an injury type, used to calculated disability benefits. Disability percentage is always rounded up to even 10% increments.

There was consensus from the stakeholders who responded to the survey that all six Evaluation Factors were relevant in determining the first two MHS Blast Injury Prevention Standards that will undergo MHS BIPSR process review (**Table 5-2**). The Rehabilitation Resources Evaluation Factor received the lowest percentage of agreement; however, there was still consensus among 73% of the responding stakeholders.

Table 5-2: Summary of Evaluation Factor Responses

Evaluation Factor	Agree	Disagree	Abstain	Total	% Agree
(a) Blast Injury Prevalence Rate	25	1	0	26	96
(b) Impact on Operational Readiness	25	1	0	26	96
(c) Treatment Resources	25	1	0	26	96
(d) Rehabilitation Resources	19	3	4	26	73
(e) Maturity of the Science	22	2	2	26	85
(f) Disability Percentage	21	2	3	26	81

Based on input received on the survey, definitions for two Evaluation Factors (Treatment Resources and Maturity of the Science) were revised for additional clarity.

Table 5-3: Stakeholder Responses to Survey #2

Evaluation Factor	Weighting
Impact on Operational Readiness	3.3
Blast Injury Prevalence Rate	2.6
Treatment Resources	2.2
Maturity of the Science	2.1
Rehabilitation Resources	1.1
Disability Percentage	1

Stakeholder Survey #2 – Weighting of Evaluation Factors

The second survey was designed for stakeholders to provide input on the relative weights of the six Evaluation Factors in order to facilitate prioritization of Blast Injury Types. The survey contained 15 Choice Sets with pairwise comparisons of the Evaluation Factors. For each Choice Set, stakeholders were asked to select the Evaluation Factor that they believed to be most important and therefore should be assigned a greater weight. The pairwise Choice Set approach was used to reduce the unintended bias found in traditional surveys. The weightings defined as a result of this survey were used in the statistical calculations to determine the first two Blast Injury Types that will undergo MHS BIPSR process review. The survey also contained a space at the end for comments.

The most important Evaluation Factor was determined to be Impact on Operational Readiness, which had an impact 3.3 times greater than that of Disability Percentage, the lowest-weighted Evaluation Factor (**Table 5-3**). The Evaluation Factors ranked second through fourth (Blast Injury Prevalence Rate, Treatment Resources, and Maturity of the Science) were closely located in the middle of the weighting curve of Stakeholder priority, while the last two Evaluation Factors (Rehabilitation Resources and Disability Percentage) were closely located at the part of the curve with the lowest relative priority (**Table 5-3**).

Stakeholder Survey #3 – Blast Injury Types and Blast Injury Prevention Standards Needs

The primary goals of the third survey were to (1) gain stakeholder concurrence on the MHS BIPSR Blast Injury Type List, and (2) have stakeholders identify any MHS Blast Injury Prevention Standards that are needed by their particular Community or Service. The original Blast Injury Type list was revised based on stakeholder input from the August 2012 Stakeholder Meeting, and the Blast Injury Prevalence Rate data supplied by the JTAPIC report. The feedback received from the third survey was used to further refine the MHS BIPSR Blast Injury Type List.

The Stakeholders' Standards Needs identified by the survey included:

- TBI (included in Head/Neck category)
- Dental (included in Face category)
- Lung (included in Thorax category)
- Hearing Impairment (included in Auditory category)
- Skull (included in Head/Neck category)
- Spine (included in Spine/Back category)
- Toxic Gas Inhalation (included in Thorax category)
- Pelvis (included in Pelvic/Urogenital category)

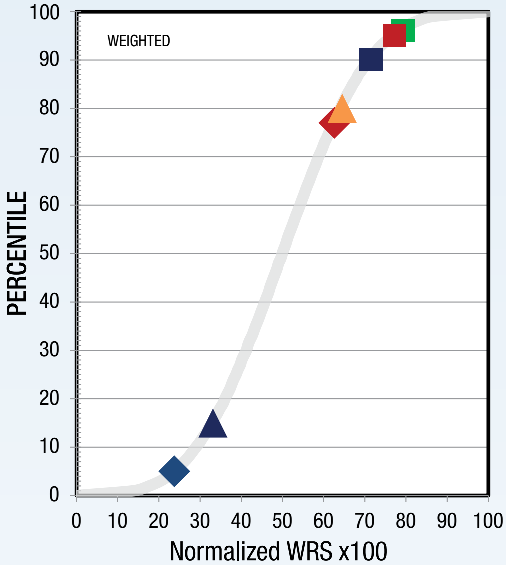
The Stakeholders' Standards Needs were consistent with the revised MHS BIPSR Blast Injury Type List (**Table 5-4**).

Consolidation and Analysis of Survey Data

JHU/APL compiled the feedback from the three Stakeholders' surveys and further revised the Evaluation Factor definitions and State Tables. JHU/APL also executed the sixth step in the Blast Injury Type Prioritization and Selection Methodology (as shown earlier in **Figure 5-2**). The Stakeholders held a web-based virtual meeting in April 2013 to (1) review the results of the revised MHS BIPSR Blast Injury Type Prioritization Methodology, and (2) identify

Table 5-4: Correlation of Standards Needs to Blast Injury Types

Revised MHS BIPSR Blast Injury Type List	Standards Needs Identified
Head & Neck Body Regions	
• Mild TBI	9
• Moderate to Severe TBI	9
• Skull Fradture (includes Penetrating Brain Injury)	6
• Ocular (includes Vision Impairment)	7
• Face (includes Oral and Maxillofacial Fractures)	6
• Auditory (includes Tympanic Membrane Rupture, Inner Ear, and Hearing Impairment)	7
• Neck (does not include Cervical Spine)	5
Thorax *(includes Chest, Rib Fractures, Internal Injuries, Sternum, Heart and Lungs, Toxic Gas Inhalation)*	7
Abdomen	3
Pelvic/Urogenital	4
Spine/Back *(includes C-spine, T-spine, L-spine, Sacrum/Coccyx, Spinal Cord)*	7
Upper Extremity	4
Lower Extremity	6
Dermal Burns	2



	Injury Type	nWRS x100	%
	Mild TBI	23.76	5
	Moderate to Severe TBI	62.63	77
	Skull Fracture	0	0
	Ocular *(includes Vision Impairment)*	0	0
	Face *(includes Oral and Maxillofacial)*	0	0
	Auditory *(includes Tympanic Membrane Rupture)*	33.15	15
	Neck	0	0
	Thorax *(includes Rib, Fracture, Chest, Internal)*	0	0
	Abdomen	64.55	80
	Pelvic/Urogenital		
	Cervical Spine	71.58	90
	Lower Extremity *(includes Hip, Upper Leg, Thigh, Knee, Lower Leg, Ankle, Foot, Toe)*	79.36	96
	Upper Extremity *(includes Shoulder, Arm, Clavical, Scapula, Elbow, Forearm, Wrist, Hand and Fingers)*	77.25	95

Figure 5-3: Prioritization Methodology Results Identified the Top MHS BIPSR Blast Injury Types.

the MHS BIPSR Blast Injury Type that would be the first to undergo MHS BIPSR process implementation. The meeting was hosted by the PCO Director and Deputy Director. Participants included representatives of the Medical, Test & Evaluation, Materiel Development, and Operational communities.

JHU/APL introduced a Blast Injury Type Prioritization Methodology that incorporated Stakeholder input but removed any unintended bias. This methodology employed a mathematical analysis using Stakeholder Evaluation Factors (determined in Survey #1; see page 5-6), the Stakeholder Weightings (determined in Survey #2; see page 5-7), and Evaluation Factor State Tables (levels assigned to the Evaluation Factors based on available information from authoritative sources to provide Stakeholders with an objective basis for rating the Blast Injury Types). Each Evaluation Factor was also assigned a weight based on the results of Survey #2. A weighted raw score (WRS) was determined for each level for an Evaluation Factor, and then normalized (nWRS) based on the number of levels for a given Evaluation Factor. The nWRS values were distributed using a maximum information entropy technique to select a probability density function consistent with the available blast injury information without unintended bias.

First Blast Injury Types Identified for MHS BIPSR Process Implementation

The graph in **Figure 5-3** shows the cumulative probability distribution curve of percentile ranking versus nWRS. The legend for the graph is shown on the right side of **Figure 5-3**. Notably, the Blast Injury Types that are located higher and further right on the curve are considered higher priority. The data analyses revealed the following types of blast injuries:

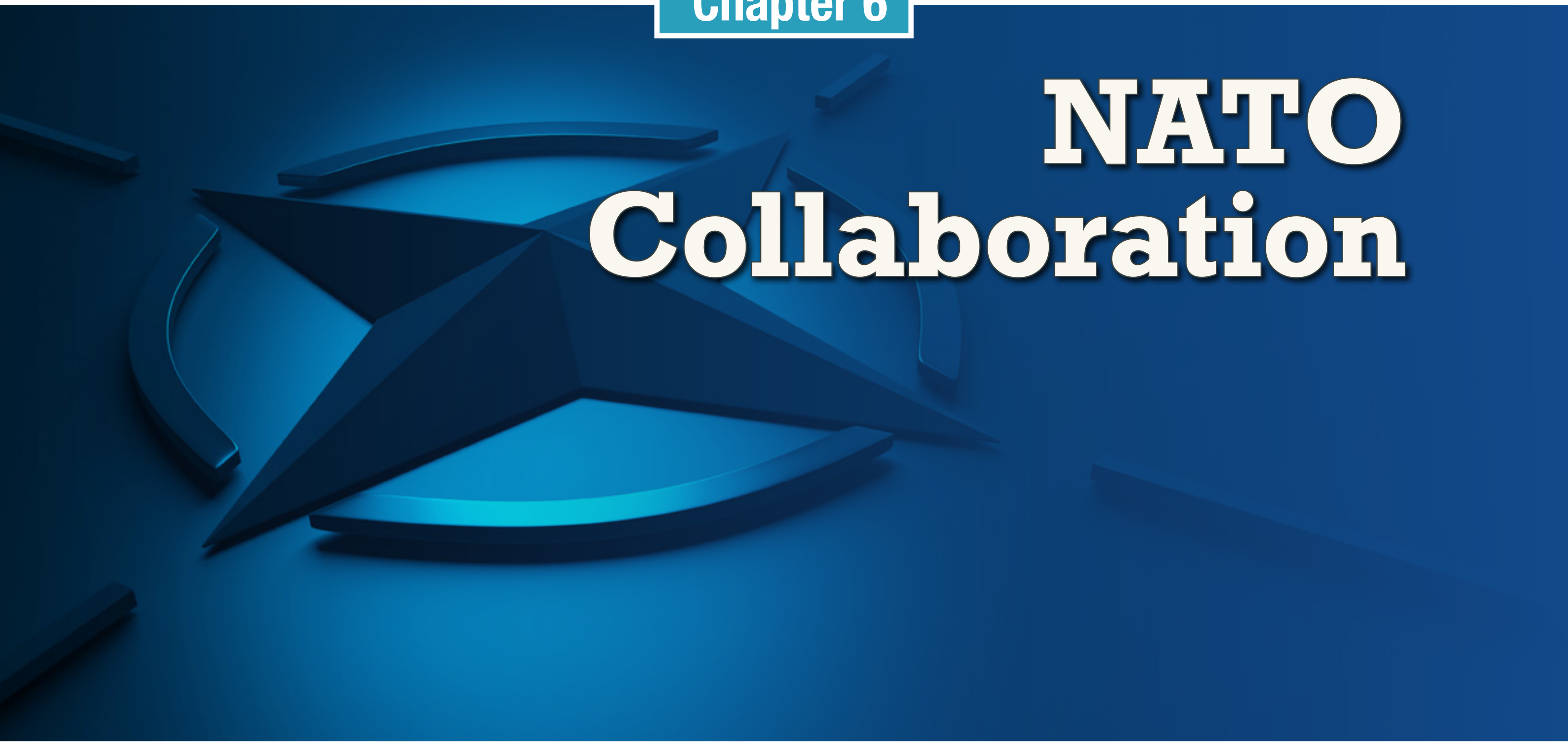
1. Lower Extremity (includes hip, upper thigh, thigh, knee, lower leg, ankle, foot, and toes)
2. Upper Extremity (includes shoulder, arm, clavicle, scapula, elbow, forearm, wrist, hand, and fingers)
3. Cervical Spine
4. Abdomen
5. Moderate to Severe TBI
6. Auditory (includes tympanic membrane)
7. mild TBI

Based on these results and the results of a "Pick Two" exercise that was conducted at the August 2012 Stakeholder Meeting (which identified "Lower Extremity Injury" and "Moderate to Severe TBI" as the two highest priority Blast Injury Types), the April 2013 Stakeholder Meeting concluded with the selection of **Lower Extremity** as the first Blast Injury Type to be considered by the MHS BIPSR process.

Way Forward

The next step in the MHS BIPSR process is to form a focused Stakeholder Committee to define the requirements for the Lower Extremity MHS BIPSR Blast Injury Type and identify relevant information from other projects that can be leveraged by the MHS BIPSR process to avoid duplication of effort. The defined requirements will be used to drive a focused literature review for Lower Extremity Blast Injury Types to identify existing Standards, relevant Candidate Standards, and SMEs. Based on these identified SMEs, a SME panel for the Lower Extremity Blast Injury Type will be established. An initial SME panel meeting will be conducted in the near future to begin identifying Candidate Standards for assessment and consideration. The SME panel will, over the course of the MHS BIPSR process, define a Candidate Standard Assessment Information Template that will be used to collect Candidate Standard Assessment Information via an information-sharing repository. This process will not involve any new research but will instead identify existing gaps that could require future research by others.

Chapter 6



NATO Collaboration

NATO's forces regularly sustain attacks from blasts or explosions by IEDs, land mines, and rocket-propelled grenades. Blast injury has become a significant source of casualties in current NATO operations. Advances in military PPE have allowed individuals to survive blasts that in previous eras of military combat would not have been survivable.

The PCO continues to be involved in collaborative activities with NATO to understand blast injury and translate the scientific discoveries into blast injury mitigation measures. The PCO and NATO members recognized the need to assess the state-of-the-science in the international community regarding blast injury and to facilitate information sharing and collaboration. Several related HFM RTG activities, including HFM-175, -193, -198, and the Research Symposium (RSY) HFM-207, have been organized to advance the state-of-the knowledge.

HFM Panel

The mission of the HFM Panel is to provide the science and technology base for optimizing health, safety, protection, well-being, and performance of the human in operational environments with consideration of affordability. This involves understanding and ensuring the physical, physiological, psychological, and cognitive compatibility among military personnel, technological systems, missions, and environments. This is accomplished by exchange of information, collaborative experiments and shared field trials.

A new NATO technical activity, HFM-234 "Environmental Toxicology of Blast Exposures: Injury Metrics, Modeling, Methods, and Standards," was subsequently proposed and approved. The activities leading up to and including the launch of HFM-234 are described in this chapter.

HFM-175: Medically Unexplained Physical Symptoms (MUPS) in Military Health (Apr 2008 – Apr 2012)

The goal was to develop an operational definition of MUPS in military setting; identify approaches that NATO partners use to diagnose deployment-related health problems; determine what is known about MUPS among NATO partners; explore how diagnostic tools could be improved; and formulate Best Practices Guidelines for how to identify, treat, manage and return Soldiers to duty.

HFM-193: Mild Traumatic Brain Injury in a Military Operational Setting (Nov 2009 – Jan 2013)

The objectives were to describe current existing clinical practice for all participating NATO countries; provide a summary of current research projects and predicted target dates for completion; identify existing gaps in knowledge; and elucidate principles for best practices.

HFM-198: Injury Assessment Methods for Vehicle Active and Passive Protection Systems (Jan 2010 – Jan 2013)

The purpose was to define an injury assessment method for quantifying collateral damage effects for dismounted Soldiers and civilians, and for active (hard kill) protection systems, with a focus on blast overpressure and fragment effects; and define injury assessment method for mounted Soldiers subjected to IED threat with a focus on acceleration and impact effects.

HFM-207 Symposium: A Survey of Blast Injury Across the Full Landscape of Military Science

The HFM-207 Symposium: *A Survey of Blast Injury Across the Full Landscape of Military Science* revealed the importance of a systematic approach to understanding blast injuries much like the well-established approach used to solve the classical toxicology problem where the etiology of the injury requires an understanding of the dose, mechanism of delivery of the dosage, and dose-response endpoints. Also recognized was the pressing need for a multidisciplinary approach to addressing non-penetrating blast injuries to the brain that result in a host of symptoms with vague etiology (see the FY12 Report to the EA for full details).

In addition, the Technical Evaluation Report emphasized the continued multinational exchanges of scientific and technical advances to respond to blast threat and blast injuries. The first recommendation identified a future need for a recurring technical exchange venue on blast injury and its mitigation to address advances in medicine and personal protection and their synergy. The second recommendation highlighted the need for the development of a Technical Activity Proposal (TAP) to explore the concept of "the Toxicology of Blast Injury" and suggested to focus the activity on several difficult problems including standardizing animal models, common dose-response methods, route of exposure methods, computational models, dose regimens to human medical endpoints (surgical trauma to mTBI spectrum), and methods for translational research leading to medical products and/or physical protection products.

HFM-207 Symposium: A Survey of Blast Injury Across the Full Landscape of Military Science

Halifax, Canada, October 3-5, 2011
Co-chairs: United States (PCO) and Canada (Defence Research and Decampment Canada (DRDC)-Suffield)

Blast-related injury to the brain is particularly complex to diagnose and treat, so the symposium focused on ways to (1) increase the understanding of blast injury in military operations, (2) explore and describe the range of blast injuries seen in current NATO operations, and (3) delineate some of the medical treatment strategies now being used. Representatives from nine nations set forward 45 technical papers that addressed the Program Committee's five key themes:

- Defining the Problem
- The Complexity of Blast Injury
- Studying Blast Injury Mechanisms
- Studying Blast-Induced Head Injury
- Mitigating Blast Injuries: Materiel

HFM-234 Technical Activity: Environmental Toxicology of Blast Exposures: Injury Metrics, Modeling, Methods, and Standards

To address the above recommendation and to develop a specific NATO activity devoted to the toxicology of blast exposure, a TAP titled Environmental Toxicology of Blast Exposures: Injury Metrics, Modeling, Methods and Standards was approved in October 2012 which resulted in the establishment of a new NATO Science & Technology Organization (STO) HFM Panel RTG.

A kick-off meeting of the RTG was held on July 1-2, 2013, in Paris, France, at the STO Collaboration Support Office. Twelve Technical Team (TT) members participated in the meeting, representing nine NATO nations. Mr. Leggieri, Director, Blast Injury Research PCO and Chair of the RTG, summarized the purpose of the meeting, which was to present the guidelines for the upcoming three years of work, review the TAP, and establish a Program of Work.

LTC Ron Verkerk of the Research and Technology Agency, presented information on the NATO Science and Technology (S&T) community, North Atlantic Council, Non-NATO S&T partners, and the mission of positioning S&T investment as a strategic enabler of the knowledge and technology of the defense of NATO nations and partners. He then focused on the HFM panel mission to optimize the health, safety, well-being, and performance of the human in the operational environment. He subsequently highlighted the HFM panel management, requirements, TAP, and specific activities to complete during the planning phase and the working phase, and recommendations for Program format, reports, publications, and STO website resources available to RTG.

Technical Activity Proposal Review

Mr. Leggieri presented the background information on HFM-207 RSY including objectives, lessons learned, and the Technical Evaluation Report leading to the establishment of the HFM-234 RTG. He discussed the recommendation and the submission of the TAP to establish a framework for a new multidisciplinary research area on the environmental toxicology of blast.

Discussion pursued that included authority of NATO standard, implementation across NATO nations, general guidelines, validation of models such as human, animal, mechanical, physiological, cell-based, in vitro, and standards for measurements.

In addition, he discussed the composition of the TT members, participating nations (**Figure 6-1**), HFM-234 (RTG) TAP objectives (**Table 6-1)**, and topics and anticipated deliverables of the RTG in the form of technical reports and specific recommendations. He presented the list of participating member nations and noted that Dr. John Glenn, Principal Assistant for Research and Technology, USAMRMC and US HFM Panel Voting Member, is the HFM-234 (RTG) Panel Mentor.

Table 6-1: Technical Activity Proposal Objectives

TAP Objectives
The RTG will establish a framework for a new interdisciplinary research area on the environmental toxicology of blast. In addition, the RTG will: • Build an evidence-based outline for NATO standards for blast injury analysis; • Examine opportunities for improvements in the standards of medical care for blast injury; • Explore advancing the state-of-practice in computational modeling of blast injury in relevant operational environments; and, • Explore standardized animal models and toxicology research protocols that could be adopted by R&T programs across NATO.

HFM-234 Participating Nations

Mr. Michael Leggieri, Chair Dr. Raj Gupta, Secretary USAMRMC Dr. Ibolja Cernak University of Alberta, Canada **UNITED STATES**	Mr. Steven Bjarnason DRDC Suffield Dr. Lucie Martineau Dr. Simon Ouellet DRDC Valcartier **CANADA**
Dr. Hans Orru University of Tartu **ESTONIA**	Dr. Jean-Claude Sarron DCSSA **FRANCE**
Drs. Dan Bieler, Amulf Willms, and Axel Franke German Armed Forces Central Hospital, Koblenz **GERMANY**	Mr. Mat Philippens TNO **THE NETHERLANDS**
Mr. Stian Skriudalen Mr. Jan Arild Teland Norwegian Defense Research Establishment **NORWAY**	Dr. Marten Risling Karolinska Institutet **SWEDEN**
Dr. Emrys Kirkman Dr. Sarah Watts DSTL **UNITED KINGDOM**	

Objective: To establish a framework for a new multidisciplinary research area on the environmental toxicology of blast that can be implemented across NATO nations, and provide validation guidelines for research models and standards for measurements.

Figure 6-1: HFM-234 Participating Nations

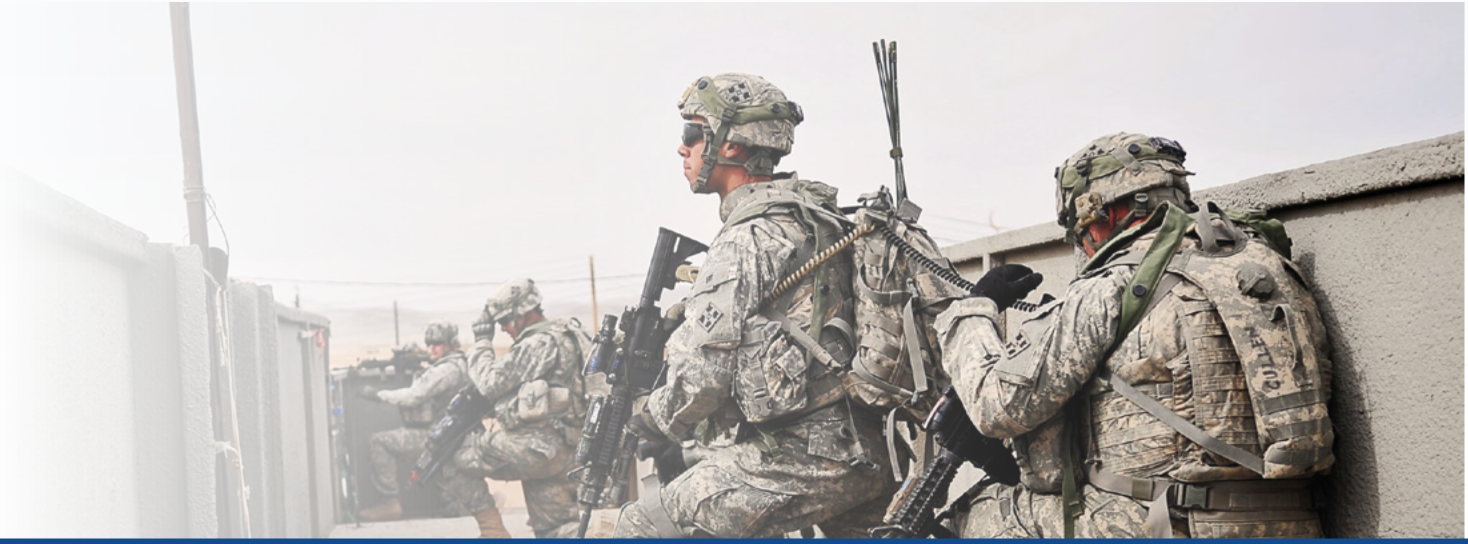
Central Army Health Service Directorate=DCSSA; Defence Research and Development Canada=DRDC; Defence Science and Technology Laboratory=DSTL; The Organization for Applied Science Research=TNO

Development of Toxicology Framework

Dr. Raj Gupta, Deputy Director, Blast Injury Research PCO and the HFM-234 Secretary, highlighted the topics for review, specific requirements of the Program of Work, and the need for review and revision of the TAP topics. Following discussion, the TT members decided to first develop an integrated Toxicology Framework to address the objectives as outlined in the Technical Activity Proposal and Terms of Reference. The following bulleted list summarizes the dialogue, in-depth discussion, and deliberations of the TT members for developing the toxicological framework.

Defining the Program of Work

The discussion during the development of the toxicology framework and identification



of associated gaps was used as the basis for the overall development of the HFM-234 (RTG) Program of Work (summarized in the table below). The TT members volunteered to conduct and/or host various activities/workshops/meetings in coordination with their respective organizations.

The TT members agreed that all workshops will be 2–3 days in duration, with the majority of time devoted to the specific purpose and objectives of the workshop as identified in the Program of Work. The last half-day of each workshop will be reserved for the TT members' discussion and deliberations, to assess the progress and status of various activities, and to plan for future activities.

Generally, each workshop will examine the current status of the blast injury toxicology S&T, with specific focus as reflected in the Program of Work. Participating scientists, clinicians, operators, and regulators drawn from the international, military, academic, and industrial communities will be asked to present their scientific, technical, clinical, and/or regulatory efforts and participate in working groups, as appropriate.

HFM-234 Program of Work

Table 6-2 outlines the series or meetings and activities that have been arranged in a sequence guided by a common strategy to address a specific set of questions and identify scientific gaps, and the suggested/recommended guidelines specific to the objectives and focus of the workshop.

Table 6-2: HFM-234 Activities

HFM-234 (RTG): Program of Work			
Activity/Workshop	**Month/Year**	**Purpose**	**Host/Location**
Meeting #1	1–2 Jul 2013	HFM-234 (RTG) Kick-off	STO/CSO (Paris)
Dictionary of Terms	Ongoing	Develop a dictionary of commonly used terms with definitions (Virtual-Core working group to develop an initial list and distribute to TT members)	Canada (Virtual)
Meeting #2	10–12 Dec 2013	Develop recommendations for collecting data necessary for conducting epidemiological studies	USA (Frederick, Fort Detrick, MD)
Meeting #3	20–22 May 2014	Develop guidelines to reproduce blast exposure conditions in the laboratory	Canada (Medicine Hat)
Meeting #4	7–9 Oct 2014	Technical Task Group to synthesize workshops, computational modeling, and review dictionary	Estonia (Tallinn)
Meeting #5	12–14 May 2015	Develop recommendations for standardized animal models and a roadmap for dose-dependent curves	Sweden (Stockholm)
Meeting #6	19–21 Jan 2016	Review draft report	England (Porton Down)

Dictionary of Terms

TT members recognized that establishing reporting standards for collaborative research requires a common “dictionary” of terms and their meanings. An activity to collect and distribute such a dictionary through the Virtual-Core working group was assigned at the kick-off meeting, with follow-on updates as needed until complete. Dr. Ibolja Cernak serves as the lead for this working group, which includes members from the United Kingdom (Dr. Emrys Kirkman) and the Netherlands (Mr. Mat Philippens). A working version of the dictionary will be made available to all TT members to annotate and expand as work on the Program of Work continues.

HFM-234 (RTG) Meeting #2: Recommendations for Epidemiological Study Data Collection

The PCO planned the first in a series of focused working meetings under the auspices of the NATO Technical Team (HFM-234) on "Environmental Toxicology of Blast Exposures: Injury Metrics, Modeling, Methods and Standards." This first meeting was held in December 2013 at Fort Detrick, and focused on developing recommendations for collecting the data necessary for conducting epidemiological studies of blast injury.

Participating nations provided information on their current guidelines for conducting blast injury epidemiological studies. TT members discussed the types of data needed to conduct epidemiological blast injury studies. These discussions focused on (1) defining parameters of interest to track initial exposure to blast, (2) identifying the types of data needed to link biological outcome to blast exposure, (3) defining parameters of interest related to the use of sensors in these types of studies, and (4) optimizing existing databases for blast injury epidemiological studies. These discussions helped TT members draft recommendations for blast injury epidemiological study data collection guidelines. Additional information on the outcomes of this meeting will be included in the FY14 report to the EA.

Way Forward

The toxicological approach represents a new paradigm for the study of blast injury. The TT members will be able to draw upon the depth of experience and range of expertise represented in this international collaboration to refine the objectives and methods that will ultimately lead to new advances.

Chapter 7

Blast Injury Knowledge Gaps

> "The National Research Action Plan demonstrates a dedication across multiple agencies to close critical research and care gaps, both in the military and civilian sector."
>
> Terry M. Rauch, Ph.D.,
>
> Director, Defense Medical Research and Development Program, Office of Force Health Protection and Readiness Programs

A key role of the Blast Injury Research PCO in support of the EA is to identify blast injury knowledge gaps and shape research programs to fill these gaps. The Blast Injury Research PCO is planning to conduct a comprehensive review and assessment (R&A) of DoD R&D programs and related efforts to mitigate blast injury. In preparation for this R&A, this chapter provides a look back at the state of the science in FY06. The knowledge gaps are correlated with the current ongoing research efforts aimed at filling those gaps. The Presidentially directed National Research Action Plan (NRAP) for TBI, PTSD, and suicide prevention research is also described in this chapter. Additionally, two key Blast Injury Research PCO-initiated efforts are highlighted: the State-of-the Science meeting series and the effort to develop computational models for non-impact blast-induced mTBI.

FY06 Blast Injury Research Planning Meeting

The USAMRMC sponsored a DoD Blast Injury Research Planning Meeting in Frederick, Maryland, on July 10, 2006. The objective of the meeting was to map out the gaps that exist in the current and planned DoD investment in blast injury research. Representatives from medical and nonmedical organizations known to have an investment in Research, Development, Test, and Evaluation programs relevant to blast injury prevention, mitigation, and treatment were invited to participate. The meeting consisted of a series of presentations on past, current, and future blast injury research programs; an open discussion of blast injury knowledge gaps; and a closed discussion among the panel members to develop a list of medical research priorities to close the gaps and to develop a proposed strategy for the future management and coordination of the program. The 2006 meeting identified the highest priority, overarching knowledge gap as the need for epidemiological data that would help define the blast injury problem – including linking operational/incident and medical databases, and analyses of PPE performance. Such data would be critical to identifying additional knowledge gaps and focusing R&D efforts to resolve those gaps.

Knowledge Gaps

Tables 7-1 through 7-4 show the knowledge gaps in the areas of protection, diagnostics, treatment, and reset/return-to-duty, respectively. The tables also highlight key ongoing and newly initiated research efforts that are addressing these gaps. Through activities such as program coordination, expert panels, state-of-the-science meetings, program R&A meetings, and international collaboration, the Blast Injury Research PCO is identifying additional knowledge gaps as well as refining existing gaps.

Protection from Blast Injury

Table 7-1: Blast Injury Knowledge Gaps and Key Current Activities Related to the Area of Protection

Knowledge Gaps Identified in 2006
Incident and Injury Linkages: Analyze the effect of blast on body armor and subsequent injury.
Data Collection: Collect more detailed incident and injury data, including more detailed autopsy data.
Databases: Develop robust epidemiological databases; standardize data definitions prior to merging of data.
Individual Differences: Determine the effects of age, gender, and size on PPE performance.
Neck Injuries: Determine the incidence of neck injuries and develop protection strategies.
TBI Effects: Determine whether there is a TBI associated with primary blast.
Primary and Synergistic Effects: Determine the synergistic effects of primary and secondary blast injuries on tissue response and wound healing.
Repeat Exposures: Determine the effects of repeated blast exposures on areas besides the brain.
Case Identification Methods: Develop a better means of identifying cases of blast injury, especially those with milder injuries. (Unless the clinician is alerted to look for it, many brain injuries will be missed clinically.)
High-rate Mechanical Properties for Biological Tissues: Determine how animal and human tissues respond to high rates of strain such as those experienced in blast injuries.
Environmental Injury Models: Model the effects of inhaled toxic gases, including smoke and aerosols, associated with blast events.
Models: Standardize and validate surrogate test models and nomenclature; develop a brain injury model; develop injury criteria.

Key Current Relevant Activities
Through JTAPIC, linking principal in-theater and autopsy medical databases and determining incidence and severity of blast exposures in OIF.
Through JTAPIC, linking medical databases with PPE performance and incident databases to enable thorough analyses of PPE performance.
Determining whether there is a TBI associated with primary blast.
Characterizing high-rate mechanical properties for biological tissues and soft materials.
Developing predictive constitutive and damage models.
Standardizing and validating surrogate test models, nomenclature, and databases.
Developing synthetic materials to mimic behavior of biological tissues.

Diagnostics of Blast Injury

Table 7-2: Blast Injury Knowledge Gaps and Key Current Activities Related to the Area of Diagnostics

Knowledge Gaps

Improved Clinical Data for Mild Injuries: Develop and gain approval for field screening tests sensitive to mTBI and vet through a nationally recognized panel; collect better clinical data on which to base a specific diagnosis of blast, PTSD, or other type of injury; develop a means to predict chronic injuries before they occur; determine the extent of subtle head injuries; and conduct basic research to determine whether blast overpressure can cause mTBI.
Dosimeters to Record Biodynamic Forces Acting on the Head: Develop a dosimeter that can be worn in the combat helmet to measure and record the forces acting on the head during a blast exposure.
Expand the Use of Biomarkers and Study Effects of Multiple Concussions: Identify biomarker(s) of TBI that can distinguish mTBI from PTSD-like symptoms; develop a diagnostic tool, perhaps biomarkers that can predict the effects of multiple concussions; and identify biomarkers that can be used as prognostic indicators of lung/internal organ damage.

Key Current Relevant Activities

Developing field screening tests sensitive to mTBI.
Expanding the capability for greater specificity with biomarkers of TBI.
Enhancing biomarker indicators for prognostic indicators of lung/internal organ damage.

Treatment of Blast Injury

Table 7-3: Blast Injury Knowledge Gaps and Key Current Activities Related to the Area of Treatment

Knowledge Gaps

Clinical Practice Guidelines: Conduct translational research validation for field clinical practice guidelines, especially for actions taken during the "platinum 10 minutes" and vet through nationally recognized expert panel.
Neuroprotectants: Develop better neuroprotectants for acute head injuries ranging from severe penetrating injuries to mTBI; develop additional solutions for increased ICP.
Facial Injuries: Develop acute treatments of facial and eye injuries to mitigate damage and enhance repair (a better means of treating facial injuries is needed, as there are social implications) and consider how acute treatment affects longer-term reconstruction of the face and follow-on cosmetic surgery.
Animal Models: Develop a better crosswalk between animal models and human treatment studies; study mechanical effects at the moment of impact and the molecular pathways behind the response to the impact.
Freeze-Dried Human Plasma: Develop better methods of getting freeze-dried human plasma to the medic on the battlefield.

Key Current Relevant Activities

Conducting translational research validation for field clinical practice guidelines.
Developing improved neuroprotectants for acute head injury, including solutions for increased ICP.
Developing acute treatments of facial and eye injuries to mitigate damage and enhance repair.

Reset/Return-to-Duty Following Blast Injury

Table 7-4: Blast Injury Knowledge Gaps and Key Current Activities Related to the Area of Reset/Return-to-Duty

Knowledge Gaps
Limbs: Explore new technologies in tissue regeneration as a possible means of repairing injured limbs and replacing lost limbs.
Therapy: Conduct more physical and occupational therapy research.
Hearing Loss Studies with NIH: Coordinate with other agencies, especially NIH agencies, for cochlear hair cell protection and repair, and acute protection/restoration of hearing following impulse noise exposure.
Auditory Injury: Consider a longitudinal study on hearing loss in conjunction with the VA; determine whether there is a correlation between hearing loss and cognitive performance decrements; improve screening of troops for hearing losses; and ensure collaboration between parallel service efforts on hearing loss.
Drugs to Treat Hearing Loss: Accelerate research on drugs to treat noise-induced hearing loss and to regenerate cochlea hairs.

Key Current Relevant Activities
Advancing tissue regeneration methods, limb and other prosthetics, and repair and restoration of oral, dental and craniofacial tissues.
Coordinating research with other agencies, including the NIH, on cochlear hair cell protection and repair/restoration of hearing following impulse noise exposure.
Developing approaches to improve longer-term outcomes in concussive brain injury.
Developing criteria for withdrawal from duty for recovery and return to duty after concussive head injury/exposure.

National Research Action Plan

A limited understanding of underlying mechanisms of PTSD, the long-term consequences of TBI, and warning signs for tragic outcomes such as suicide has hampered progress in the prevention, diagnosis, and treatment of these conditions. On August 31, 2012, President Barack Obama issued an Executive Order directing the DoD, VA, US Department of Health and Human Services (HHS), and the Department of Education (henceforth referred to as "the agencies") to develop a NRAP on PTSD, other mental health conditions, and TBI to improve prevention, diagnosis, and treatment. The Executive Order also called for the establishment of a comprehensive longitudinal study of 100,000 Service members focused on PTSD, TBI, and related injuries. To attain these goals, the agencies were urged to improve data sharing as appropriate, and with the appropriate privacy and confidentiality protections, and harness new tools and technologies (e.g., electronic health records).

Representatives of the agencies drafted the NRAP and delivered it to the White House on April 30, 2013. The White House released the final version of the NRAP on August 10, 2013. The NRAP outlines coordinated research efforts to accelerate discovery of the causes and mechanisms underlying PTSD, TBI, and other co-occurring outcomes such as suicide, depression, and substance abuse disorders. The plan describes research to rapidly translate what is learned into new effective prevention strategies and clinical innovations such as biomarkers to detect disorders early and accurately, and efficacious and safe treatments to improve function and quality of life and to promote community participation and reintegration.

The agencies currently hold regularly scheduled meetings to discuss and share new findings, reassess goals, and update collaborative activities. Specific follow-up actions related to TBI are presented in the following time frames (excerpted from the NRAP).

Immediate Actions (within 1 year)

- Complete the current DoD-CDC-Brain Trauma Foundation mTBI/concussion classification project to clarify what is known and unknown about mTBI, and the critical gaps that need to be addressed. Identify a process for developing a clinically relevant system to replace the current mild/moderate/severe nomenclature.
- Increase the inventory of scarce research resources (e.g., tissue samples, blood, and cerebrospinal fluid), facilitating access for scientific purposes (with appropriate human subjects' protections related to privacy and confidentiality). To accomplish this, the agencies will leverage existing pathology archives to initiate development of a virtual tissue (brain) repository for TBI research. Activities will also include (1) incorporating appropriate agreements either between the investigator and resourcing agency (material transfer agreement) or between agencies (interagency agreement) and (2) processes for securing consent to obtain brain tissue from donor (premortem) or representative (postmortem).
- Facilitate coordination of portfolio analysis and collaboration on research projects of shared interest by exploring the possibility of participation of the DoD and National Institute on Disability and Rehabilitation Research in the NIH Electronic Research Administration system, which provides support for the full life cycle of grants administration functions for the NIH, VA, and several other agencies.
- Determine whether point-of-injury blast and impact sensors can be correlated to mechanism and severity of brain injury.
- Establish an interagency working group to review and report on existing and novel diagnostic tools and treatments for TBI to improve the evidence base for TBI management.
- Coordinate within and between agencies involved in the Brain Research through Advancing Innovative Neurotechnologies initiative to ensure a balance of basic and translational science so that more maturely developed technologies can be utilized clinically as soon as possible.
- Continue to support clinical trials that are evaluating the effectiveness of therapies to improve outcomes and quality of life following TBI.

Short-Term Actions (2–4 years)

- Support research focused on systematically characterizing blast neuropathology related to military service, and comparing and contrasting it to the neuropathology of impact TBI. Test neuroimaging technologies to establish a means of identifying pathobiological markers of TBI regardless of mechanism in Service members and Veterans. If there are verifiable and clinically significant differences between blast- and impact-induced TBI, develop scalable animal and in vitro models, if feasible, to identify and leverage biological pathways for study of therapies and the process of recovery.
- Develop a better understanding of the quantitative relationship between the level or number of repetitions of blast exposure and severity of TBI in animal models and humans.
- Determine whether co-occurring and pre-existing conditions exacerbate impact- and blast-related neuropathology.
- Develop initiatives for basic and clinical research focused on increasing the understanding of mechanisms of recovery after TBI and discovering ways to harness neuroplasticity to improve outcomes. See **Figure 7-1** for an overview of hypothesized mechanisms of brain injury resulting from blast exposure.
- Support validation studies of proteomic, imaging, neurophysiologic, and other potential biomarkers and diagnostic tools using the TBI common data elements (CDEs), the Federal Interagency Traumatic Brain Injury Research (FITBIR) Informatics System and existing TBI clinical networks (e.g., Transforming Research and Clinical Knowledge in TBI, Traumatic Brain

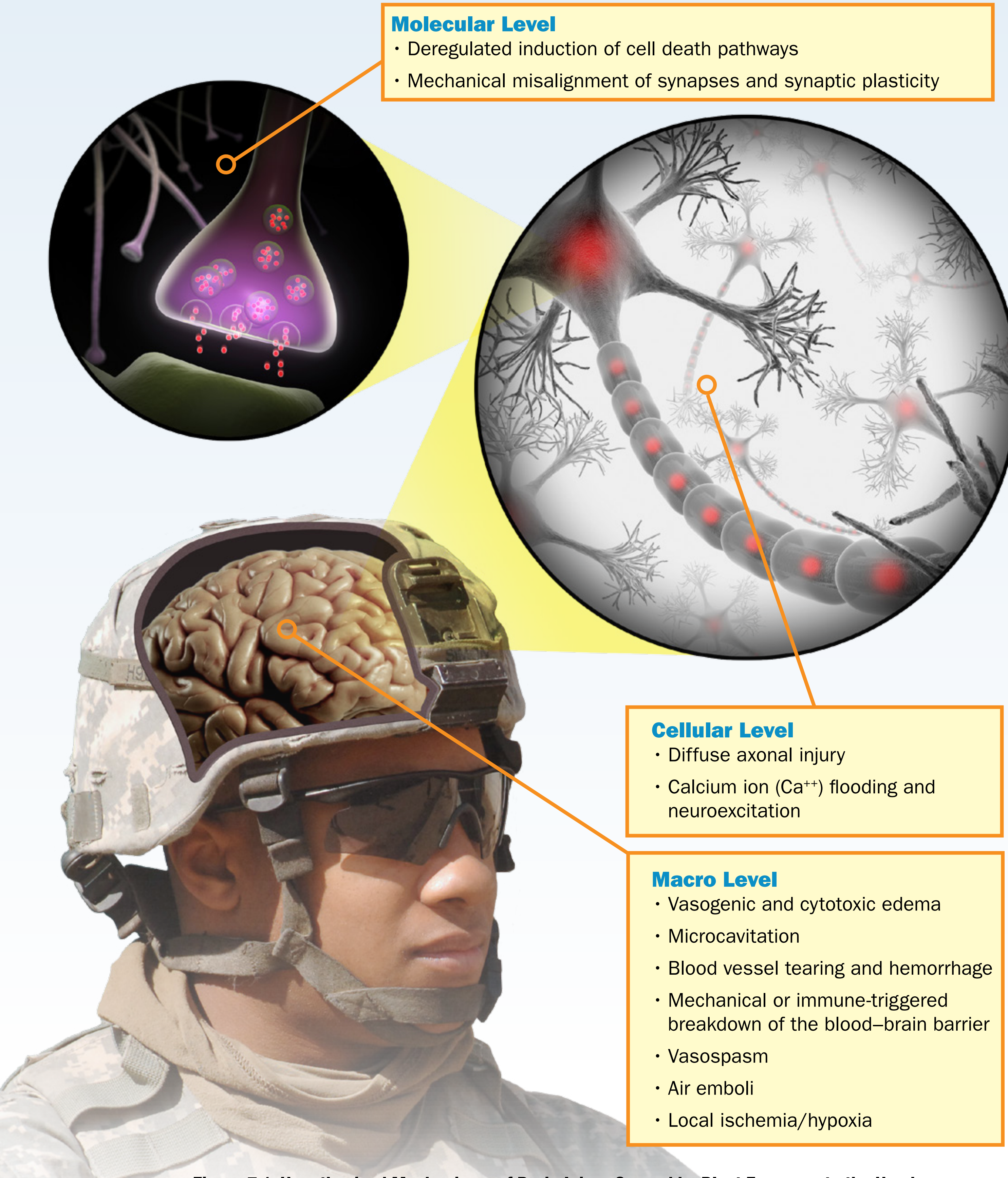


Figure 7-1: Hypothesized Mechanisms of Brain Injury Caused by Blast Exposure to the Head

Injury Model Systems Centers Program (TBIMS), Chronic Effects of Neurotrauma Consortium (CENC), and VA Centers of Excellence). These studies may focus on early diagnosis, neuroanatomic correlation of symptoms, classification of degrees of injury, markers of neural patterns of good recovery vs. poor recovery, or biomarkers in studies of therapeutic target engagement.

- Continue to support the FITBIR Informatics System as a national resource for TBI research and enhance the system to include with appropriate consent advanced analytical tools, pipelines for importing and exporting data (especially neuroimaging data); electronic data capture for emergency rooms, intensive care units, sports fields, and battlefields; and legacy data.
- Promote collaboration, meta-analysis and sharing of de-identified individual TBI study data in CDE format across agencies through the population of existing federal databases with FITBIR data, where possible, appropriate, and permissible. Activities to support this collaboration include implementing the use of global unique identifiers, the TBI CDEs, and consent forms that allow for data sharing across agencies for new studies, when possible, appropriate, and permissible.
- Develop efficient, affordable, comprehensive, valid, and sensitive tools for assessing functional outcomes and quality of life over time. Evaluate the utility of the NIH Toolbox for Assessment of Neurological and Behavioral Function, the Neuro-Quality of Life (QOL), the TBI-QOL, and other tools that meet scientific standards to improve clinical assessment and enable measurement of treatment effectiveness specific to the TBI population.

Long-Term Actions (5–10 years)

- Develop a more precise system for classifying and staging TBI to enhance diagnosis and prognosis, and enable targeted therapies and personalized medicine. The approach will be to (1) support natural history and other prospective, observational studies, and (2) share data from these studies, with appropriate privacy protections, to enable computational analysis of large, high-quality data sets that include impact and blast injuries, military and civilian populations, acute and chronic phases, and the entire spectrum of age, severity, and the continuum of care.
- Determine the acute and chronic effects of TBI as well as the genetic, gender, ethnic, and environmental (epigenetic, socioeconomic, and cultural) protective and risk factors that influence susceptibility to injury and subsequent outcomes including the development of chronic traumatic encephalopathy, Alzheimer's and other neurodegenerative diseases. The approach will be to utilize new and existing longitudinal research initiatives (e.g., CENC, TBIMS National Database, and Million Veteran Program) to study the chronic effects of TBI, including medical, neurological, psychiatric, and psychosocial complications, and to study genetic and epigenetic protective and risk factors.
- Identify causal relationships between post-traumatic alterations in brain function and symptoms, functional outcomes, and quality of life through greater integration of basic and clinical research. Integrate preclinical and clinical research to investigate causal relationships for all ages, injury types, and severities and for acute, subacute, and chronic stages. This will provide a foundation for developing targeted treatments and pharmacodynamic biomarkers.
- Evaluate promising pharmacological and nonpharmacological treatments, including rehabilitation treatments for their ability to increase functional outcomes such as community participation and reintegration.
- Develop and test models for optimal team-based, integrated treatment of TBI and co-occurring conditions to improve upon the existing practice of independently treating biological targets and/or symptoms of each condition.
- Conduct research on the social, psychological, and economic effects of deployment-related TBI on military families and on communities. Diverse indicators of family and community well-being should be examined.

- Conduct research on the long-term health needs of Service members and Veterans with TBI and the resources needed for long-term care and planning.

The NRAP's aspirational vision for TBI research is to identify evidenced-based therapies that are effective in maximizing short- and long-term health and function, community participation and reintegration for persons with TBI in civilian and military populations, including Service members, Veterans, and their families. Effective treatments, including rehabilitation treatments, would be personalized to address the specific type of injury and co-occurring conditions (especially substance related), considering patient preferences for care. A clinically relevant classification system for TBI across the spectrum of injury severities, age, gender, and chronic conditions, including mild single and repetitive injuries would be available to advise patients about their diagnosis, prognosis, and treatment options. More sensitive, reliable, and efficient tools ("gold standards") would be available for evaluating the effectiveness of treatments on an individual's physical, cognitive, and psychosocial functioning and quality of life.

International State-of-the-Science Meeting Series

The Blast Injury Research PCO established a State-of-the-Science Meeting Series in 2009 to assist in identifying knowledge gaps pertaining to key blast injury issues. These are narrowly focused meetings that help determine what is known and what is unknown about a particular blast injury topic. These meetings are designed to bring together the world's top researchers from academia, DoD, other government organizations, and industry to share their expertise in helping focus future research investments that address these gaps.

The Blast Injury Research PCO intends to hold at least one meeting per year that critically assesses the state of the science and provides vital evidence needed to prevent, mitigate, and treat blast-related injuries. Meeting topics are selected based on input from representatives of the CoEs and Joint Technology Coordinating Groups 5, 6, and 8 (Military Operational Medicine, Combat Casualty Care, and Clinical Rehabilitative Medicine, respectively).

Since its inception, three State-of-the-Science meetings have been hosted, and two meetings are being planned for FY14. Highlights of these meetings are presented in the following paragraphs, and meeting summaries can be found on the DoD Blast Injury Program website at https://blastinjuryresearch.amedd.army.mil.

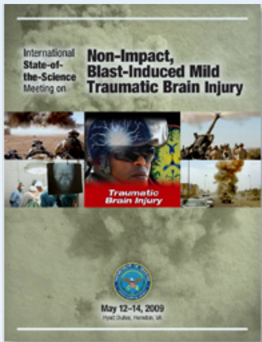
Upcoming: Non-Impact, Blast-Induced Mild Traumatic Brain Injury (4QFY14)

Non-impact blast exposures occur when warfighters are close enough to an explosion to experience the high pressures created by the blast itself, but are far enough away to avoid penetrating injuries caused by fragments and blunt impact injuries caused by debris or by whole-body translation. The mTBI caused by exposure to a blast event without secondary or tertiary head impact remains a key knowledge gap.

The DoD Blast Injury Research PCO hosted the first International State-of-the-Science Meeting on Non-Impact, Blast-Induced Mild Traumatic Brain Injury in May 2009 (see below). The PCO will assess the progress that has been made since that meeting by hosting the International State-of-the-Science Meeting on Mild Traumatic Brain Injury Exposure Sensor Thresholds in September 2014. Approximately 100 SMEs from the DoD, other federal agencies, academia, industry, and the international community will be invited to participate.

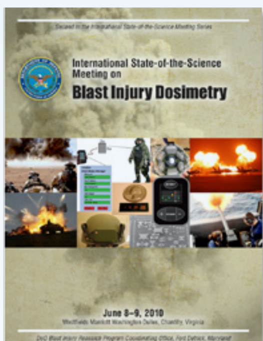
Past: Non-Impact, Blast-Induced Mild Traumatic Brain Injury, May 2009

Participants at the first International State-of-the-Science Meeting on Non-Impact, Blast-Induced Mild Traumatic Brain Injury examined research focused on the relationship between blast exposure and non-impact, blast-induced mTBI, and they formally recommended standardizing



research methods to facilitate data sharing; improving documentation; establishing a common repository for data for all research models; sharing findings through peer-reviewed literature; supporting brain injury and psychological health recommendations; developing an evaluation platform for use close to the battle front; encouraging interdisciplinary interactions; promoting safety; and setting up Integrated Product Teams to keep abreast of progress and recommend new areas of research.

Past: Blast Injury Dosimetry, June 2010



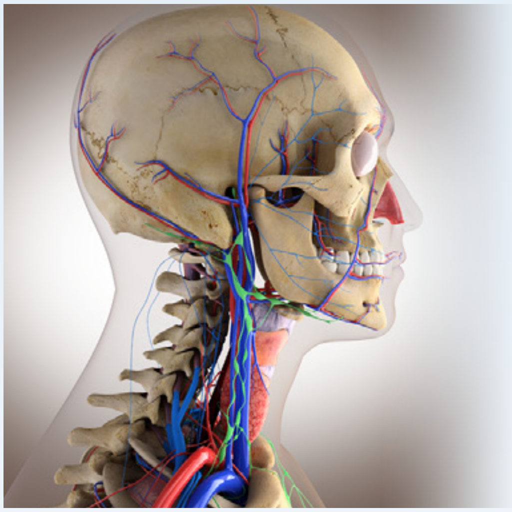
Warfighters are routinely exposed to blast-related insults in training and in combat. These insults range from occupational exposures associated with the use of weapon systems to potentially lethal exposures from explosive enemy weapons in combat. Through blast injury dosimetry, the DoD is seeking a way to objectively record and document these blast-related exposures and to correlate the exposures with acute injuries or chronic health effects.

After reviewing the DoD's blast dosimeter development efforts and prioritizing research gaps, the participants recommended that 1) a central testing site employing uniform methods be established to evaluate new and historic studies to enable standardizing methods and measurements; 2) field sensors only when the connection between the data and a specific injury is clear; 3) ensure that sensors do not impede the warfighters' efficiency, on or off the battlefield; 4) establish a task force of SMEs to review sensor data collected to date, and establish a calibration regimen that incorporates the upper and lower limits of survivable injury; 5) expand the Breacher olfactory response studies; and 6) conduct a biomedical literature search of human effects models to discover any correlations for blast injury. The participants agreed to proceed with the second-generation helmet-mounted sensors and a concussion screening tool that is well-tested, with the goal of collecting as much data as possible from blast exposures to help identify research areas.

Past: Blast-Related Tinnitus, November 2011

Tinnitus is defined as noise or ringing in one or both ears when no external sound is present. It can be a chronic, debilitating condition. Tinnitus most often results from either acoustic trauma or head and neck injury, which are prevalent injuries in current conflicts.

Starting out, participants identified a number of fundamental knowledge gaps to be addressed, such as evaluating the impact of tinnitus on operational readiness, assessing the quantity and quality of data already collected in existing government medical databases and registries, discovering onset and progression factors through large-scale longitudinal studies, identifying pre-existing risk factors before and after injury, evaluating connections – if any – between tinnitus and other cognitive/ psychological disorders, and standardizing animal and experimental models, procedures and equipment. Participants saw several promising areas for Applied Research and Technology Development, such as identifying candidate pharmacologic strategies for early interventions, and developing improved imaging techniques and better objective diagnostic and assessment tools to help in the diagnosis and characterization of tinnitus. In the area of Clinical Research, participants' recommendations were made to develop standard protocols and measures for conducting tinnitus-related clinical studies, characterize the performance of existing technologies to diagnose and characterize tinnitus, and conduct well-designed human studies of existing and novel therapies for preventing and treating hearing loss and tinnitus.



Developing Computational Models of Non-Impact, Blast-Induced Mild Traumatic Brain Injury

We currently have a limited understanding of the possible injury mechanism(s) underlying mTBI caused by exposure to a blast event without secondary or tertiary head impact. Numerous hypotheses of the mechanisms of brain injury caused by blast exposure to the head have been proposed, including: blood vessel tearing and hemorrhage, mechanical or immune-triggered breakdown of the blood–brain barrier, vasospasm, air emboli, microcavitation, diffuse axonal injury, vasogenic and cytotoxic edema, local ischemia/hypoxia, oxidative stress and reactive oxygen species, mechanical misalignment of synapses and synaptic plasticity, calcium ion (Ca++) flooding and neuroexcitation, and deregulated induction of various cell death pathways. The approaches of in vitro (cell culture) studies, in vivo (animal) testing, and analysis of clinical (human) data are useful and necessary, but these are slow, expensive, and often nonconclusive, thus limiting the availability of tools for the rapid evaluation of various blast-related mTBI injury hypotheses. Physiology-based mathematical modeling tools of blast-induced head injury may provide a framework to guide experimental testing, interpret data, and scale animal data to humans in the effort to elucidate injury mechanisms and determine the effectiveness of protective or treatment strategies.

Until recently, researchers have not studied high-fidelity computational modeling of blast-related brain injury. Modeling blast mTBI and the resulting trauma is extremely difficult as it involves a range of disciplines, including gas and structure dynamics, biomechanics, physiology, pathology, biology, biochemistry, and time and space scales. Considerable progress has been made in DoD-sponsored models during the past few years. Most of these efforts are unique and represent novel distinct approaches. However, existing software tools and computational models of TBI still have numerous limitations, and some major challenges remain to be solved in blast wave brain TBI models.

Based on the findings and recommendations from the first International State-of-Science Meeting on Non-Impact, Blast-Induced mTBI (see above), the DoD Blast Injury Research PCO established the DoD Brain Injury Computational Modeling Expert Panel. This panel brings together subject matter experts from the engineering, medical research, blast physics, and clinical medicine communities to:

- Assess the state-of-the-art in computational modeling to understand the injury mechanism of blast-induced mTBI
- Integrate ongoing DoD research efforts
- Leverage ongoing efforts by other organizations (Department of Transportation, NIH, etc.)
- Accelerate the transition of preventive and treatment strategies

The PCO anticipates that this focused effort will be the first step in leveraging and integrating results of individual projects to generate a unified solution that may result in development and validation of one or more accurate computational models of blast-induced mTBI. It is anticipated that these models will expedite prevention and treatment strategies for blast-related mTBI by providing a framework for understanding injury mechanisms, guiding experimental testing, interpreting data, and scaling animal data to humans. Through a series of five focused meetings (summarized in the FY12 Report to the EA), which included presentations by SMEs and workshop sessions that covered specific computational modeling challenges, the Expert Panel has developed a roadmap for research.

Computational Modeling Research Roadmap

As noted above, computational modeling of non-impact, blast-induced mTBI is very difficult, involving a range of disciplines (e.g., biomechanics, physiology, and biology), lengths (subcellular to macroscopic), and time scales (microseconds to weeks). Validated multidisciplinary models are needed that integrate blast explosion physics, anatomical- and image-based human body geometrical models, human body biodynamics, tissue biomechanics, and several physiological models. Physiology-based computational/mathematical modeling tools of blast head injury may provide a framework to understand injury mechanisms, guide experimental testing, interpret data, and scale animal data to humans to study both blast wave TBI mechanisms and the effectiveness of protective or treatment strategies. Overall, data from the engineering/physical research area have to be united with data from the medical world.

Key aspects of developing the model will include characterizing blast injuries; developing in vitro and in vivo models leading to field testing and clinical trials; and correlating these data with the blast insult, damage/injury, and clinical data/observations. An enterprise approach is envisioned to achieve these objectives. The enterprise (depicted in **Figure 7-2**) will serve to (1) set priorities, (2) integrate research, and (3) create a framework for sharing. The structure will consist of CoEs, a Program Integrator, and a national database/repository. The Program Integrator will coordinate data flow between the CoEs and will ensure quality and control the database. The CoEs will involve teams of researchers from a variety of fields, including blast physics, biomechanics, materials, biology, engineering, and medicine. The goals of the enterprise are to set the broad research agenda and prioritize specific research challenges, set a framework for the sharing of information and resources, provide quality assurance, minimize duplication and free resources for novel research, keep the work focused on the solution, and evolve with the research.

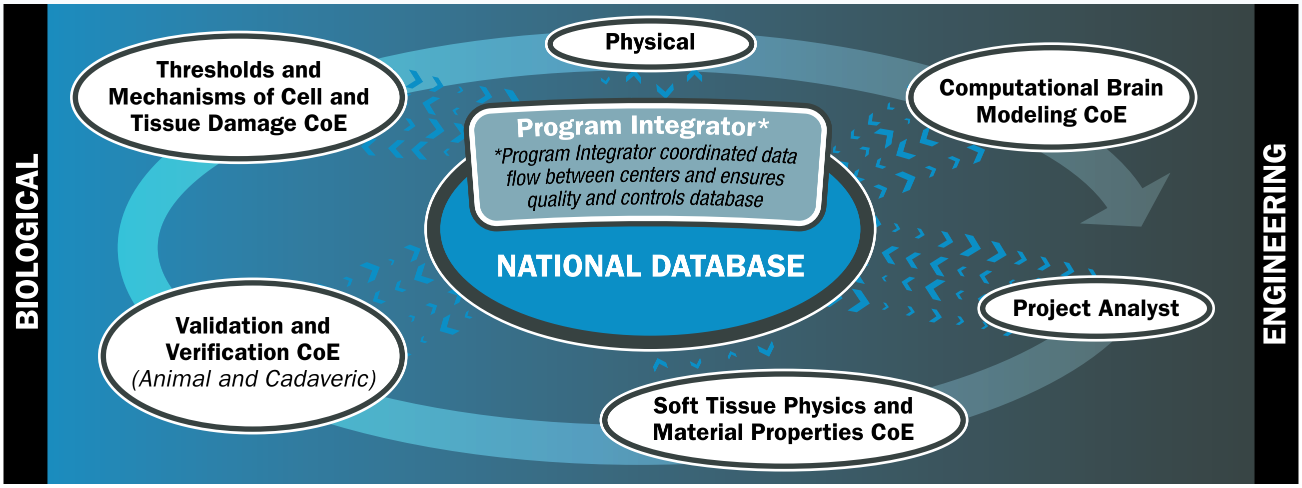


Figure 7-2: The Computational Blast-Induced mTBI Modeling Enterprise

Chapter 8

Key Research Accomplishments

The Blast Injury Research PCO was established to coordinate the large number of relevant efforts that contribute solutions to the injury problems associated with blast threats. The US Army, Navy, Air Force, and other DoD organizations sponsor and conduct blast injury research. Many other federal agencies, as well as academia and industry, also play key roles in solving blast injury problems. A sampling of FY13 accomplishments is reported in this chapter. These accomplishments highlight the diversity of efforts and organizations that are committed to providing Soldiers, Sailors, Airmen, and Marines with the very best blast injury prevention, mitigation, and treatment solutions.

From Research to Fielded Products

V-Xtract Fieldable Vehicle and Metric Suite Extensions

The Vehicle Extrication Trainer (V-Xtract) is a portable, rugged, reconfigurable and reusable prototype training system. US ARL–Human Research and Engineering Directorate (HRED), Simulation and Training Technology Center (STTC) created the V-Xtract as a SBIR project in FY09. The V-Xtract program uses the Army's disposed vehicles as physical training mock-ups. The system satisfies training requirements by prototyping realistic blast cues and combat replicated scenarios (e.g., simulated blast from an IED). V-Xtract tracks trainee performance to provide automated after-action review feedback to Soldiers. The system employs advanced, specialized M&S training technologies. ARL-HRED, STTC's research plan is focused toward transitioning V-Xtract to the PEO for Simulation, Training and Instrumentation commencing in 2015. Overall, it is anticipated that V-Xtract will provide combat lifesavers and medics with the skills needed to effectively extricate and care for casualties in the event of vehicle rollovers.

Abdominal Aortic Tourniquet for Uncompressible Hemorrhage

While substantial advances in tourniquets have been made in recent years with regard to their ability to stop blood loss from a casualty's limbs, an ongoing issue has been treating uncompressible hemorrhage in areas where a normal tourniquet cannot be applied. Researchers at Trinity Medical Center and Georgia Regents University have developed the abdominal aortic tourniquet (AAT) to stop the flow of blood in casualties experiencing upper thigh, pelvic, or groin injuries, which are areas that regular tourniquets cannot reach. Approved in October 2011 by the FDA, the AAT fastens around the abdomen over the belly button, and air is pumped by hand into its wedge-shaped bladder, which places pressure on the major arteries passing to the lower torso. The AAT can also be used to stop junctional hemorrhage in the shoulder area, although the research team has not yet received FDA approval for its use in that manner. While the AAT is primarily used by special operations forces, the device is available commercially for conventional units. Overall, the AAT has been instrumental in helping Service members survive wounds that previously would not have been survivable.

Developing a Novel Bandage to Reduce Scarring

Investigators at Stanford University, in partnership with Neodyne Biosciences, have completed a pivotal trial of a novel, stress-shielding bandage to reduce surgical scars. The device is a silicone-based polymer which reduces tension on the surgical incision during immediate healing and early remodeling, effectively improving the local wound-healing environment. Neodyne Biosciences is in the early stages of commercializing a non-sterile version of the bandage in several sizes. A sterile version will be available within the next year. Reducing the size of cutaneous scars may improve both function and appearance of reconstructions following trauma.

Injury Prevention – Injury Mechanisms

Developing Computational Tools to Understand How Blast Loading Affects Brain Tissue

Researchers at ARL are developing the computational tools needed to understand how macroscale loading from a blast event is translated to microscale damage within brain tissue. Their finite element model incorporates various length scales into full head simulations by including anisotropic constitutive laws informed by diffusion weighted imaging, a magnetic resonance imaging (MRI) technique that allows in vivo tracking of axonal fiber bundles in the white matter of the human brain. The researchers performed massively parallel simulations to investigate diffuse axonal injury patterns during blast loading of a dismounted body. They developed a fiber segment-based degradation method to provide a more detailed description of where damage may occur along white matter pathways. This technique was implemented to improve the connectome neurotrauma model for use with finite element blast simulation data. This effort will enhance our understanding of how blast waves are transmitted through the brain leading to neuronal injuries, which will assist in the development of enhanced protection for the Soldier's head to help prevent causalities.

Synthesizing Pressure-sensitive Bionanomaterials to Serve as a Dosimeter for TBI

Pressure-sensitive bionanomaterials have the potential to serve as a standard "dosimeter" in TBI research programs, unifying the broad research efforts in determining pressure-induced neuronal damage, biomarkers, and, ultimately, the fundamental mTBI initiation mechanism. Researchers at ARL designed and synthesized multiple protein-nanocluster fluorescent hybrids with tailorable pressure sensitivity ranges and calibrated these to correlate fluorescence emission intensity with impacting with pressure. They also demonstrated the in situ synthesis of these nanoclusters by a living neuron, directly incorporating the pressure-sensitive materials within the native neuronal proteins.

Developing Improved Personal Protective Equipment for Service Members

Scientists at ARL have developed experimental methods to measure the rate-dependent mechanical response of single ultra-high molecular weight polyethylene (UHMWPE) micron-scale fibers. This effort will enable the development of improved PPE for the dismounted warrior. UHMWPE material is used extensively by the Army in Soldier PPE as well as in vehicle armor to protect against high-rate blast and impact loading. The ability to understand the fiber response will enable enhanced understanding of the behavior of UHMWPE composites, thereby improving the ability to optimize manufacturing methods and potentially advance the protection capabilities of lighter weight armors for Soldiers. Furthermore, this experimental method will be used to characterize additional novel fibers and develop new or refined versions of existing multi-scale composite material modeling concepts.

Identifying Mechanisms of Blast Overpressure Injury

Repetitive exposure to blast results in alterations in the central nervous system and, in particular, brain damage related to behavioral and/or cognitive changes. Investigators at the Research Operations Integration Medicine Research & Development Center are seeking to identify and characterize the injury mechanisms associated with exposure to blast overpressure, including molecular and functional markers of brain damage. In addition to investigating the relationship between the frequency of exposure to multiple low levels of blast overpressure, the researchers are assessing the threshold levels of single and repetitive blasts that are associated with metabolic and functional indices of brain damage. The main goal is to identify specific biomarkers and associated cognitive (functional) outcome. The researchers are also examining (1) non-invasive pupillometry to identify deviations in pupillary size, asymmetry and reactivity, and possible intracranial lesions associated with blast overpressure as well as to test potential therapeutics such as antioxidants; (2) the effects of blast on complement, mitochondrial gene expression and function, and changes in the endothelial glycocalyx; (3) the effects of hyperbaric oxygen (HBO2) on blast-injured animals; and (4) the association of blast and post-traumatic headache, the most common sequela associated with head injury. It is anticipated that the data from these studies may result in a better understanding of the mechanisms associated with blast-induced injury and support improved prevention, mitigation, and treatment strategies.

Characterizing Behavioral and Protein Expression Changes following Blast Exposure

Researchers at the Naval Medical Research Center (NMRC) and the James J. Peters VA Medical Center in the Bronx, New York, are collaborating to examine the behavioral and physiological alterations associated with exposures to repeated low level (75 kPa) blast overpressures. Rodents are subjected to 3 x 75 kPa (one blast per day), and the animals are evaluated for neurological impairments and alterations in stress and anxiety using a battery of established tests that are sensitive to the aforementioned dimensions. Behavioral assessments include the Morris water maze test, the open field test, and the delayed match to place testing, among others. The researchers will evaluate the animals' brains for abnormal protein that is aggregated and neurofibrillary tangles (tauopathy) and for associated changes in proteins associated with anxiety. They will determine the pathogenic response in brain tissue by gross pathology, genomic analysis (focusing on genes related to oxidative stress, apoptosis, and immune response), and proteomic studies (lipid peroxidation, protein oxidation and nitration). It is anticipated that a greater understanding of the behavioral and physiological effects of low level blast exposure will provide the information necessary for the development of more sensitive and specific diagnostic tests and potential treatments.

Understanding the Effects of Traumatic Insults on Brain Structure and Function

There is a great need for better understanding of the effect of mechanical loading (such as explosive blast) on the structure and function of brain cells. Currently, brain injury from a realistic blast is mainly studied at the whole brain or whole animal level. Researchers at ARL are aiming to gain insight into cellular damage thresholds and mechanisms, as well as build an accurate predictive injury multi-scale model (sub-cellular to cellular level) for the study of neuronal injury mechanisms following realistic blast events. They are fabricating three dimensional cultures of neurons and supporting cells using a biocompatible nanofibrous scaffold, and targeting the neural membrane with bioconjugated sensing particles to study neurotransmitter (glutamate) release in real time. They are exposing the cultures to different levels of explosive blast and examining the cellular structural and functional changes. Data on pressure profiles, cellular viability, glutamate concentration, and membrane permeability changes are being collected to build multi-

scale predictive models. The researchers are also taking advantage of the high performance computing capabilities available at ARL to build numerical models to capture the impact of blast waves on a single neuron membrane followed by a simplified neuron network. The M&S approach is to build a finite-element model of a simplified neuron-network with each component represented by a visco-hyperelastic constitutive representation. At the sub-cellular level, while it is well known that exposure of biological cells to shock waves causes damage to cell membranes, it is currently unknown by which mechanisms the damage is caused, and how it depends on physical parameters such as shock-wave velocity, shock-pulse duration, or shock-pulse shape. The researchers are developing a coarse-grained model of the simplified cellular membrane (lipid vesicle) to elucidate the general principles of the cellular damage induced by shock waves. The insights gained from this work may prove to be useful in the diagnosis, prevention, and treatment of brain injuries. In addition, the data may enable the development of significantly improved PPE to potentially prevent or minimize the effects of mTBIs.

Evaluating Fracture Criteria for Human Bones at Blast and Ballistic Loading Rates

Researchers at ARL are conducting a comprehensive research program aimed at understanding the fracture response and developing fracture criteria of human cortical bones at different loading rates, including loading rates representing battlefield blast. These experimental fracture criteria are to be used in computer simulation of the human during blast and impact loading to understand the bone fracture thresholds and fracture mechanisms under battlefield loading conditions. It is anticipated that this effort will enable greater understanding of how accelerative loads are transmitted through the body, leading to skull and other bone fractures. It will support the development of enhanced Soldier protection technologies that should reduce fracture-related injuries.

Identifying the p11 Pathway as a Novel, Therapeutic Target

Researchers at Rockefeller University have identified molecular pathways associated with the development of clinical depression. Depression is a frequent co-morbid condition of TBI, PTSD, suicide ideation, the neurodegeneration associated with Parkinson's disease, and other neurodegenerative and psychiatric disorders. The researchers identified a pathway resulting in modulation of serotonin receptors by the protein p11. This pathway suggests a potential therapeutic intervention point for depression, whether presenting alone or as a co-morbid condition. The effect of p11 in modulating serotonin receptor availability as well as its action as a transcription factor in the hippocampus provides initial support for development of pharmaceutical regulators of p11 activity to both prevent/treat depression, and to provide support for continued neurogenesis in the hippocampus, a requirement for sustained cognitive function. Of particular interest is the fact that p11 expression in the brain is matched in magnitude and direction by p11 leukocyte transcript expression, making a blood sample suitable for identification and for monitoring p11 central nervous system status.

Performing Realistic Blast Experiments Underwater

Researchers at the ARL created a novel platform to perform realistic blast experiments with neurons underwater, which is the first time this type of experiment has been done (**Figure 8-1**). The researchers detonated charges in air, outside the aquarium, and 45.5 inches above the ground. They measured the shockwave overpressure duration at various distances from the explosive charge center using pressure gauges that were mounted and positioned face-on to the blast. They exposed PC12 neurons to realistic blast waves of 42 and 209 psi. They assessed neuronal viability and membrane permeability 24 hours post-blast. Neurons without exposure to any blast waves served as controls. The researchers' preliminary results revealed no significant changes for cells subjected to the 42 psi blast wave. They found a significant increase in cell death and membrane permeability for cells subjected to the 209 psi blast wave. There was also a significant increase in glutamate levels in cells subjected to the higher pressure blast wave. The researchers also fabricated electrospun nanofibrous scaffolds for the 3-D culture of neurons from a variety of polymeric materials. They cultured the neurons on the scaffolds and assessed viability and morphology. They observed good alignment of neurites (growing tips of neuronal processes) with the fiber axis. Work is underway to enable real-time imaging of the neurons during blast exposure. The insights gained from this work may enable the development of significantly improved PPE to minimize the incidence of mild traumatic brain injuries in our warfighters.

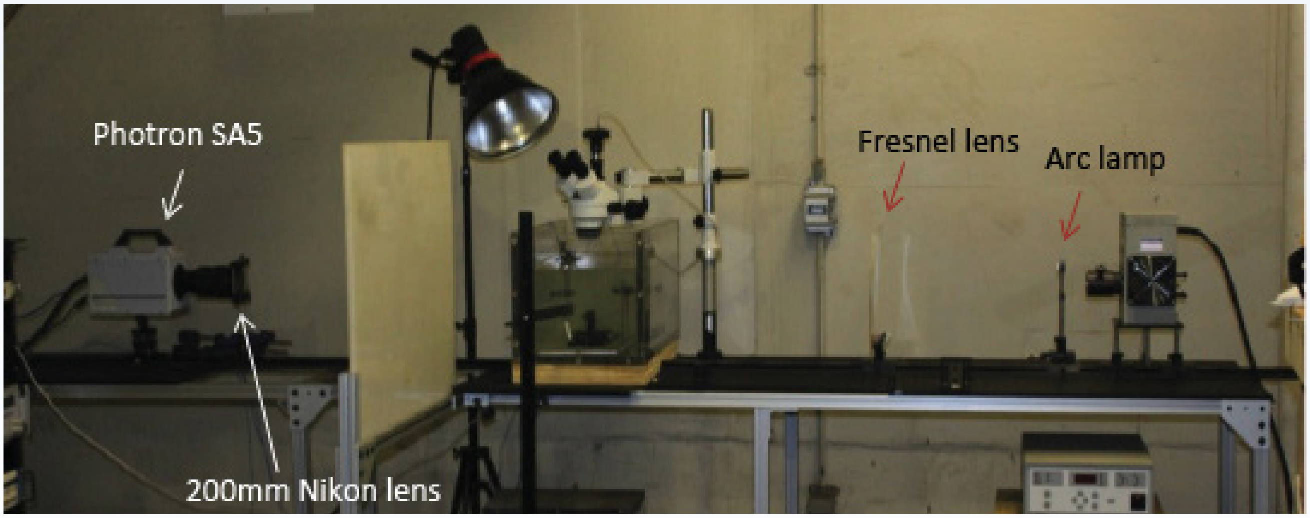


Figure 8-1: A Modified Aquarium Setup for Performing Blast Experiments Underwater

Injury Prevention – Injury Models

Warrior Injury Assessment Manikin (WIAMan) Project; Creating an Enhanced Capability for Predicting and Assessing UBB Injury Risk for LFT&E

WIAMan is an Army-led R&D effort to create a greatly enhanced capability to assess the risk of injury to mounted soldiers that are subjected to the vertical accelerative loading environment caused by a UBB attack. The WIAMan project is conducting original medical research and is also designing and demonstrating a biofidelic prototype ATD specifically for UBB testing. A Senior Steering Group co-led by The Director of Operational Test and Evaluation of the Office of the Secretary of Defense and ASD(R&E) provides oversight for the project. In FY13, the Senior Steering Group directed a restructuring of the project to streamline it and increase efficiency. The ARL, under the Research, Development, and Engineering Command, is the home of the newly-formed WIAMan Project Management Office, which is now responsible for execution of all parts of the project, including medical research and ATD development. Under oversight of the WIAMan Program Management Office, execution of the medical research associated with WIAMan has been transitioned from the Army to the JHU/APL. In FY13, extramural medical research and test plans from eight universities were reviewed and approved by the WIAMan Program Management Office and several body-region specific research activities were initiated. A key technical accomplishment in FY13 was the completion of an initial series of experiments to determine the differences in response between a human and an ATD in an explosively-driven, LFT&E-representative environment. This test series utilized a unique accelerative loading fixture, which was purpose-built for the WIAMan program and which allows the use of small amounts of explosive to impart vertical accelerative loads in a controlled fashion. This test series demonstrates a stark difference in the kinematic response of a human when compared to that of a current ATD in a UBB environment. Aspects of the response of the current ATD are likely not representative of actual loads experience by human during the course of such an event. These observed and documented differences highlight the critical need to continue this type of work in order to enhance the DoD's understanding of the human response to the UBB environment and to build a injury risk assessment capability. Such knowledge will form the basis for significantly improving UBB LFT&E capabilities and building better, more protective vehicle platforms for our Soldiers, Sailors, Airmen, and Marines.

Investigating Injuries to Armored Vehicle Personnel Subject to Blast: Preliminary Study with Emphasis on Lower Extremity Fractures

Investigators at the University of Virginia are, in coordination with the WIAMan PMO, working toward simulating the Under Body Blast (UBB) environment in a laboratory setting in order to study lower extremity musculoskeletal injuries due to high rate blast loading.

In 2013, they completed the design, construction, and validation of ODYSSEY, a UBB horizontal accelerator. With this validated experimental model, they developed preliminary hind-foot injury criteria as well as a lumped-mass finite element model, which will inform equipment to be designed to best prevent musculoskeletal injuries due to UBB events. The researchers will validate the lumped-mass finite element model in FY14. Both the rate of load as well as resulting injuries seen in UBB events are different from those observed in automotive intrusion. It is anticipated that the capability to model lower extremity injury during UBB events will help predict and prevent blast injury within military vehicles.

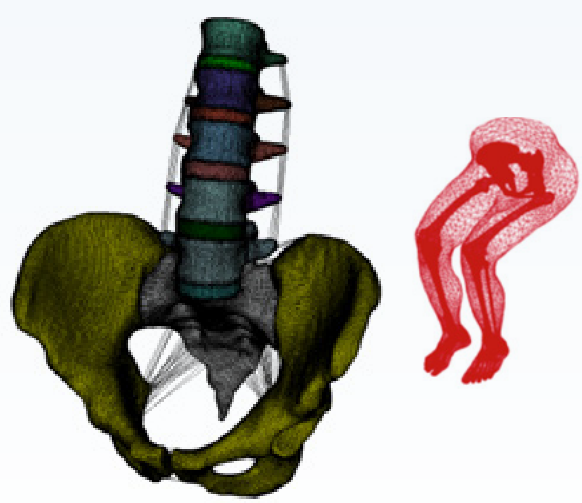


Figure 8-2: A Model of the Lumbar Spine, Sacrum, and Pelvis and a Full Lower-Extremity Model for a Seated Vehicle Occupant

Building and Refining Computational Models of Accelerative Injuries to the Lower Extremities and Spine

The UBB to military vehicles can cause severe injuries to the lower extremities and spine of vehicle occupants, which can result in permanent disability, limb amputation, or death. In an effort to understand and prevent such injuries, ARL researchers have built high-resolution, computational finite element models of the lower extremities and lumbar spine (**Figure 8-2**). Previous years' work demonstrated a link between the acceleration of a deforming floor plate and the amount of bone damage sustained in the foot and ankle region during an UBB event. Current work includes refining these anatomical models, and beginning the process of exploring the extraordinarily large phase space of material parameters, constitutive models, and failure criteria relevant to building a virtual human. This research seeks to develop validated models of the human body for the purpose of studying injury mechanisms experienced during UBB. It is anticipated that this information will provide added insight to the protection design process, potentially leading to more effective protection equipment for Soldiers and helping to reduce the occurrence and severity of injuries experienced in theater.

Biometric Modeling of Dismounted Complex Blast Injury (DCBI)

The USAMRMC teamed with the Physical Optics Corporation of Torrance, CA to develop a pelvic model that would have multi-sensory data as part of the SBIR program. This system addresses the need for a biometric model to study the effects of dismounted complex blast injury (DCBI) on the pelvis, abdomen, and genitals. It is based both on a numerical model for predicting blast effects resulting from different impact forces and on an anatomically correct physical model with a number of sensors providing comprehensive information about the blast effect as well as data to validate the numerical model. The biometric DCBI model provides the medical research community with a needed tool to study DCBI.

Developing Shock and Blast Mitigation Strategies to Protect Vehicle Occupants

Engineers at the Analysis and Evaluation Technology Division of the US Army Armament Research, Development and Engineering Center (ARDEC) have been modeling blast against various vehicles to determine a means of better protecting the occupants. Using a variety of tools, such as the Abaqus Coupled Eulerian-Lagrangian method, fluid-structure interactions were captured during the blast event. Explosive detonation and the resulting soil/fragment impact created shock loads on the vehicular structure. ARDEC has also worked with Corvid Technologies in blast mitigation for the MRAP All-Terrain Vehicle. Corvid Technologies created a large, macroscale model of the MRAP vehicle undergoing a blast event and provided the transient displacements of the roof, which ARDEC used in a high fidelity Gunner Protection Kit (GPK) model. This effort resulted in the fielding of a reinforcement kit for the GPK. ARDEC continues to investigate blast/structure interaction for vehicles and other structures to better protect the occupants. Constitutive modeling for soils and detonation products are being researched, and Smooth-Particle Hydrodynamics are also being evaluated and applied. Additional work is being performed in modeling pressed explosives as a composite structure as well. The culmination of these efforts will provide insight into shock and blast mitigation strategies within the structure or vehicle.

Determining the Response of Hybrid III Manikin Foot Vinyl Rubber to Blast and Impact Loading

Researchers at ARL are conducting a comprehensive research program to mathematically represent the response of existing and novel blast-impact manikin materials at different loading rates, including blast loading rates. Mathematical models have been obtained that represent the response of foot vinyl-rubber from a Hybrid III manikin to use in computer codes. Initially, a refined version of the Hybrid III manikin will be used to understand the human response during blast and impact loading. Overall, these loading rate-dependent mathematical models are needed to conduct computer simulation of the anthropomorphic manikins that are being designed by the US Army to understand the injury thresholds of Soldiers under blast and ballistic impact loading for the design of novel protection equipment.

Preventing Violent Explosive Neurologic Trauma (PREVENT) Program

The Preventing Violent Explosive Neurologic Trauma (PREVENT) program illuminated the causes of blast-induced TBI, an injury that while previously described in the warfighter population, has been referred to as a potential “hidden epidemic” in the current conflict. PREVENT used a variety of modeling techniques based on in-theater conditions to assess potential TBI caused by blast in the absence of penetrating injury or concussion. Research worked to create a model that can be directly correlated to the epidemiology and etiology of injury seen in returning warfighters, and attempted to determine the physical and physiological underpinnings and causes of the injury. Raw data was collected from in-theater blast gauges, along with medical and event reports to form a comprehensive analysis. As part of the mitigation and treatment strategy, candidate therapeutics were tested in order to alleviate inflammation from both acute and chronic injury.

The absence of definitive evidence of explosive blast mTBI in the exposed warfighter is partly because available diagnostic techniques were not sensitive enough to detect the “mild” injury found in mTBI. In order to understand the injury processes, DARPA PREVENT developed sophisticated techniques and hardware to achieve sufficient sensitivity to detect mTBI. Such advancement was quite necessary for developing targeted therapies.

The overall aim of DARPA PREVENT was to construct a model of blast brain injury relevant to the warfighter, with the objective of gaining an understanding of this disease so that meaningful effective therapies could be identified. The program aimed to develop a large animal model (swine) and small animal model (rodent) of blast mTBI to study mechanisms of injury, neuropathology, molecular biomarkers, and neurocognitive changes, as well as novel non-invasive diagnostic tools to detect and study explosive blast mTBI in the human and the large animal model sufficient to detect and identify extent, distribution, and severity of mTBI from explosive blast in warfighters. Additionally, the program aimed to identify likely candidates among FDA approved drugs for therapeutic treatment of explosive blast mTBI.

Advanced magnetic resonance spectroscopic imaging techniques were developed to study alterations in brain metabolites resulting from explosive blast exposures in both the warfighter and the large animal model. These techniques involved the development of sophisticated hardware on a 7T magnet to produce a capability to conduct increased signal to noise ratio spectroscopic imaging of the human hippocampus. Using these techniques, DARPA PREVENT discovered for the first time unequivocal evidence of organic brain injury in the hippocampus due to explosive blast in warfighters as well as clear differentiation of injury to this brain area from blast compared to the injury in PTSD without blast, providing an objective method for differential diagnosis.

DARPA PREVENT provided additional evidence that single exposures are associated with less hippocampal injury than multiple exposures. Large animal imaging studies revealed injury in the hippocampus similar to that in the warfighter. This injury was detected only 6-8 months post blast suggesting an ongoing amplification of an initial injury. Multiple blast exposures resulted in enhanced injury. This PREVENT swine model produced neuropathological signs of injury and produced several critical pieces of evidence such as significant astrocyte activation more in multiple exposure animals than single exposures. Activated astrocytes can be involved in a number of other pathological functions, one in particular being the release of inflammatory and pro-inflammatory molecules. DARPA PREVENT proteomic studies revealed the upregulation of several inflammatory molecules in the hippocampus raising the possibility that explosive blasts may trigger an initial inflammatory response in the brain which secondarily triggers slow neuronal injury and death. Another unique finding of PREVENT is a pattern of axonal injury around the ventricles (Periventricular axonal injury) which differs from the classical patterns of diffuse axonal injury reported for TBI in the literature.

PREVENT Screening of FDA-approved drugs for treatment of mTBI and mTBI with hemorrhagic shock has identified minocycline as a promising therapeutic agent. Cognitive and neuropathological assessments in models show significant improvement from injury with treatment.

Developing an End-to-End Concussion Prediction Model

Mild TBI/concussion is a pervasive injury from traumatic exposures that can have immediate effects on a warfighter's performance, as well as chronic medical consequences. Researchers at L-3 Communications/Jaycor, sponsored by the MOMRP program, have made progress in several critical areas toward the development of an integrated end-to-end concussion prediction model. These advancements include: (1) refining the human finite element analysis of skull and brain to better understand the mechanical effects of impact loading on specific brain regions; (2) refining the micro-mechanics model of a single axon to understand how macroscopic tissue strains and strain-rates translate to localized regions of axonal strain; and (3) expanding the neurophysiology model to understand how acute, mild injury impacts sodium channels and subsequent axonal signal transmission. Overall, these studies are intended to deliver an algorithm that outputs the probability of concussion when head acceleration is provided as input.

Blast-Induced TBI – Experimental Approach Using Animal Models

Researchers at UNL are examining the role of animal placement location (APL) in a blast shock tube, and the biomechanical load experienced by the animal. The key findings of their work are: (1) APL plays an important role in the biomechanical loading experienced by the animal; (2) Friedlander waves implicated in TBI are best replicated inside the shock tube. Thus, for APLs deep inside the shock tube, the load experienced by the animal is purely due to the blast wave, and is not influenced by the three-dimensional nature of the events occurring at the exit of the shock tube; (3) near and outside the exit of the shock tube, an expansion wave significantly degrades the blast wave profile, and the remaining flow is ejected as a subsonic jet wind. Thus, the loading experienced by the animal is mainly non-blast jet-type loading; (4) due to subsonic jet wind effects at the exit of the shock tube, the animals are tossed when free, and the lung is heavily loaded when animal motion is constrained. This, in turn, can change injury type and severity and medical outcome; (5) surface and intracranial pressures vary linearly with incident pressures; and (6) validated numerical simulations indicated that the major wave transmission pathway to the rat brain is through the skull. The rat snout plays only a secondary role in biomechanical loading of a rat by diffracting the blast wave toward the eye socket and skull. Overall, these animal studies are helping the scientists to determine some of the potential mechanisms underlying brain damage associated with blast exposure.

Injury Prevention – Protective Equipment

Developing the Soldier Protection System: The Next Generation of Protective Gear

The PM SPE received a Milestone B approval in 2013 for entrance of the Soldier Protection System (SPS) program into the Engineering and Manufacturing Development phase. The SPS program is an integrated system of vital torso, head, and extremity subsystems to provide protection against multiple threats associated with blunt trauma, ballistic projectiles, fragmentation munitions, IEDs, and indirect fire. The SPS is designed to be worn by both mounted and dismounted Soldiers during the full spectrum of combat operations. As with the Pelvic Protection System's (PPS's) Protective Under-Garment and Protective Outer-Garment (for details, see the FY12 Report to the Executive Agent), the SPS includes protection for the pelvis, femoral arteries, and lower abdominal organs. PM SPE continues to leverage all Soldier input, feedback and ongoing PPS assessments while working with industry to ensure the constant evolution and incremental improvements of pelvic protection, and to improve the overall user acceptability and rate of wear by reducing the aerial density and weight, in an effort to improve ballistic performance. These advancements have already influenced requirements for the next generation of pelvic protection. Overall, the SPS will be the future system fielded to Soldiers to protect the user against a variety of threats, including blast.

Designing a User-preferred Blast Protection Harness

The US Army Natick Soldier RD&E Center began defining the materials, system design, and human performance trade space associated with providing blast debris protection to the urogenital, perineal, and femoral regions of both male and female warfighters in order to provide the prescribed protection while maximizing mobility, compatibility with current gear, and user acceptance. The effort includes two parallel tasks: (1) Trade space concept prototyping and user evaluation, and (2) materials characterization using the ARL/UK sand cannon. The trade space concept prototyping and user evaluation task involved evaluation of the following design variables: level of protection (via number of protective fabric layers); area of coverage; placement on the body (i.e., under the trouser, integrated within the trouser or over the trouser); fit; and adjustability. Concepts were designed using a fixed protective material (i.e., Kevlar KM2, woven), using either two or seven layers of KM2, and fit to a size medium trouser only. When evaluated in a "worst case" environment (i.e., hot, humid, ~4 hours of wear/session), the preferred 2-layer concept was the boxer, due to its comfort, weight, mobility and pocket access. However, during the after-action review, the favored concept was the 360° trouser; users preferred to have the full thigh/urogenital/perineum protection built-in so that it was always with them. The favored 7-layer concept was the harness, due to its comfort, weight, mobility, low bulk, wound care access and breathability. It was also highly favored with respect to ease of use, pocket access and stability. The materials characterization task led to the determination that 5–6 layers of Kevlar would provide a high level of protection against an 8-gram grit load at reasonably high velocity. The researchers also determined that fine weave Kevlar appeared to perform slightly better than ballistic Kevlar. They filed a non-provisional patent application to protect the user-preferred, 7-layer blast protective harness concept. PEO-Soldier began evaluating the harness concept in late 2013.

Developing Robust, Predictive Underbody Blast Methodology for the Test and Evaluation Community

The ARL's Survivability/Lethality Analysis Directorate (SLAD) serves as leader of the multi-agency UBB methodology (UBM) for the T&E program. Engineers from SLAD compiled results from numerous live-fire UBB events in order to investigate correlations in the data from floor-mounted accelerometers and lower leg responses from ATDs. The accelerometer data were characterized into a number of different metrics typically used for UBB analysis, and preliminary correlations were developed and documented. SLAD also completed analysis of experimental data generated by ARL's Weapons and Materials Research Directorate (WMRD), a UBM program partner, to validate a one-dimensional seat and occupant model. The model is a fast-running tool to estimate lower spine response using the dynamic response index criteria. SLAD also demonstrated for the first time the use of finite element modeling coupled with reduced-order modeling approaches to directly support live-fire test planning for the Joint Light Tactical Vehicle program. Results focused on the potential for injury to the lower leg and spine, with a secondary focus on vehicle damage. The findings were used to select shot locations for future live-fire events. All of these projects are part of a comprehensive multi-year plan to develop a robust predictive UBM that will aid the T&E community by improving live-fire test planning, enhancing vehicle design to mitigate blast, and expanding data available to Army vehicle evaluators (beyond that provided by limited live-fire testing). The ultimate result will be improved warfighter survivability.

Designing Novel Materials to Protect Against Blast and Ballistic Threats

ONR protection against mTBI has focused on the use of High Strain Rate Sensitive Polymers, specifically, polyurea as part of an effort focused on the development of materials against blast and ballistic threats. Combining light-weight polymers with Kevlar have been shown to divert and dissipate blast waves away from the brain as well as improving protection of the brain from ballistic and blunt trauma. Helmets treated with polyurea have been proven to be effective against blast-induced mTBI through testing on instrumented manikins, and the helmet (at no weight increase) has an improved ballistic limit compared to the standard helmet. The materials for these experiments were supplied by the DuPont Corporation under a Cooperative Research and Development Agreement (CRADA).

A number of blast mitigating technologies have been identified through this research effort that limits blast exposure including the use of highly rate-sensitive polymers, sculpting the shape of the polymer, perforated plates, inclusions such as tungsten carbide particulates, and the use of ballistic cloth fabric and membrane rupture. Novel perforation geometries have included inclined holes for diverting blast waves as well as investigating internal surfaces to promote blast reflections. Emphasis in FY13 was on delineating the underlying causes of brain-induced pressures and accelerations at the base of the skull in tests on manikins instrumented with pressure gauges and accelerometers. The best correlation was observed with acceleration levels, implying an equivalent impact type event over a region of the skull. Another finding from this study indicated that little pressure was transmitted through the helmet. Meetings with researchers from the University of Pennsylvania, Duke University, and Columbia University under an Army Research Office-Multidisciplinary University Research Initiative supported the possible mechanism of skull deflection as being most relevant to TBI injury.

A Naval Surface Warfare Center Carderock Division (NSWCCD)-supported In-House Laboratory Independent Research effort, which included components supported by ONR, investigated the effects of blast waves on perforated plates. Diaphragms containing foils with polymer, mounted over the perforations improved the blast wave-mitigating effects. Additionally, Kevlar cloth mounted over the perforated plates gave further improvements.

Integration of the polymer into the current helmet, while keeping the weight within acceptable levels is promising, and ballistic requirements were met, but must undergo testing to meet all of the requirements (PEO Soldier and US Marine Corps). ONR and NSWCCD are currently working with DuPont Inc., under a CRADA agreement, and evaluations indicate that the cost is reasonable for incorporating this technology into existing protective equipment.

Developing a Head Protection System Model

Researchers at the ARL are developing a head/helmet model to understand the load transfer to the head-wearing combat helmet that is subjected to ballistic and blast threats. They are modeling the interaction between the threat and the helmet, subsequent load transfer to the head through the air and pads, and consequent deformation and stresses in the brain. Their strategy for characterizing helmet behavior is to calibrate a composite model to match ballistic data in the range of interest. The researchers carried out instrumented flat plate ballistic experiments, and calibrated a computational model to match back face deformation profile, composite damage, and penetration limit. They will model the effect of helmet curvature and impact obliquity as more experimental data are available. The researchers also established a fluid structure interaction model to study blast wave impingement on the helmet and subsequent load transfer to the brain through composite shell, pad, skull, and cerebrospinal fluid. Overall, this effort will result in an enhanced understanding of how ballistic loads are transmitted through the brain, which could lead to the development of enhanced protection to the Soldier's head to prevent casualities.

Developing an Improved Modular Ballistic Protection System

The Modular Ballistic Protection System (MBPS) is composed of multiple ballistic panels that are attached to the inside of a tent frame using an energy-absorbing connection system. With assistance from the University of Maine, the Deployable Force Protection (DFP) Technical Focus Team developed and tested a promising ballistic strike face material in a MBPS-X prototype. Test observers included the technical lead for the Passive Protection Team of DFP as well as the Demonstration Lead of the entire DFP. The MBPS-X prototype with the strike face material was subjected to multiple indirect fire threats from various foreign countries. The system performed very well against the target threats for an expeditionary protection system. The results were encouraging because the material solution tested is rapidly deployable and extremely low in cost in relation to the level of protection it provides. Overall, this could provide the warfighter with greater protection for the most common indirect fire threats found in expeditionary base camps, resulting in reduced casualties.

Occupant Protection: Occupant Accommodation Tools to Predict Solider Postures

TARDEC GSS Interior Blast Mitigation Technology Team worked with the University of Michigan Transportation Research Institute (UMTRI) to conduct the Seated-Soldier Project. 300 Soldiers on three military bases over a four month period were measured and scanned in various garb levels in order to complete the study. The purpose of the study was to: 1) determine how increased gear encumbrance worn by Soldiers affects their seating position and 2) develop tools that will allow military ground vehicle seat developers to properly design seats for 90% of the Soldier population. Data gathered will ensure that Soldier space claims will be outlined for current and future vehicle programs so there will be adequate accommodation for Soldiers while ensuring performance and safety. The initial development of accommodation tools used to predict soldier postures will improve future designs and workstations. Tools to be developed include: occupant accommodation models for driver and crew positions, JACK Manikins, Pro-E Manikins, a hip-point/seat reference tool and procedure to allow the vehicle to be properly design around the occupant, and other tools that may have not been realized. Results of the Seated Solider Study were presented at the ARC 2013 Annual Review and June 2013 TARDEC Research and Technology Integration Town Hall. Data will also feed into updating MIL-STD-1472 and developing the WIAMan anthropomorphic test device.

Occupant Protection: Development of Cargo Retention Technologies for use in Military Vehicle Interiors, for Occupant Protection from Injury during an Underbody Blast, Crash or Roll-over Event

TARDEC GSS Interior Blast Mitigation Technology Team is researching and developing cargo retention technologies to secure cargo such as basic issue items and weapons stowed inside military vehicles, to prevent occupant injury due to loose cargo which can become dangerous projectiles during an underbody blast, crash or roll-over event. The goals of the project are; (1) to identify commercially available cargo retention technologies which are capable of securing cargo in military vehicles; (2) developing and testing cargo retention technologies which provide a means for securing basic issue items stowed in military vehicle interiors, inherent with high forces of underbody blast event; and (3) creating and publishing military vehicle cargo retention design guidelines and military product specifications used for procurement and fielding of all future military vehicle cargo retention technologies. These goals are achieved through: i) market research, and ii) component level testing and vehicle level testing, such as drop tower, environmental, vibration, durability, human factors and User evaluations, and vehicle blast/road tests. During FY12-13, strategic market research of existing technologies and specifications are complete, as well as drop tower testing for the attachment tracks, assault pack retainers, fire extinguishers and barrel down weapon mount. Additionally, an innovative design for a metallic wall barrel down weapon mount is complete and an innovation disclosure (for patent application) has been submitted to TARDEC for a ballistic resistant military vehicle weapons case. Future work planned in FY14-16 is to continue development of cargo retention technologies for all basic issue items and evaluate the retention technologies for utilization in military ground vehicles.

Occupant Protection: Interior Trim Energy Absorption Material, for Occupant Protection from Injury during an Underbody Blast, Crash or Roll-over Event

TARDEC GSS Interior Blast Mitigation Technology Team is researching and developing interior trim energy absorption materials for use in military vehicles to protect the vehicle occupant from head injury during an underbody blast, crash or roll-over event. The goals of the study are: (1) to identify commercially available interior trim energy absorption materials which provide the needed occupant head impact protection;

(2) to develop materials to bridge gaps in commercial material capabilities; (3) to develop a standard military head impact test procedure for evaluating energy absorption materials for i) evaluation using a fixture, and ii) evaluation in a vehicle; (4) to develop U.S. Army military vehicle interior trim energy absorption material design guidelines and product specifications, intended for all future procurement of military vehicle interior trim energy absorption materials; and (5) to verify the performance of vehicle integrated interior trim energy absorption material components through the Occupant Centric Platform Technology-Enabled Capabilities Demonstrator (OCP TECD) vehicles. These goals are achieved through: i) market research of materials and existing standards and ii) component level testing and vehicle level testing, such as head impact, environmental, vibration, durability, human factors and User evaluations, and vehicle blast/road tests. During FY12-13, strategic market research of existing materials and specifications are complete. In November 2012, the Head Impact Laboratory became operational and measurement systems analysis using a stand along fixture is complete and passed. To date, over 80 commercial material variants are head impact tested and flame, smoke and toxicity testing is complete for the top energy absorption materials. Future work planned in FY14-17 includes: i) use a questionnaire for tactical market research of materials and specifications, ii) design and fabricate vehicle interior trim energy absorption material for integration into a military ground vehicle, iii) test vehicle components and materials for head impact, environment, vibration, durability, flame, smoke and toxicity, human factors performance and user evaluations, iv) develop materials to fill commercial capability gaps and v) draft guidelines and specifications for interior trim energy absorption materials and components.

Occupant Protection: Sensors Systems Development Aims to Reduce Occupant Injuries During Ground Vehicle Blast Events

TARDEC GSS Exterior Blast Mitigation Technology Team is developing standards for sensors systems for use in combat and tactical vehicles. The purpose of these systems is three-fold: to detect blast, crash, and rollover events and provide a trigger signal to active protection systems; and to record data during these events. The trigger signal will provide the ability to use active protection systems that may significantly reduce injury in catastrophic events, such as deploying an airbag during a crash. The data recorded during these events can be used to better understand what the vehicle and occupants are experiencing, and can be used

to improve vehicle design, improve testing, and design improved safety systems. The standards developed will be adaptable to all military vehicles for use in both war time and peace.

Occupant Protection: Energy Attenuating Flooring Development Aims to Reduce Occupant Injuries During Ground Vehicle Blast Events

TARDEC is in the process of researching and developing Energy Attenuating ground vehicle flooring concepts. TARDEC developed a one-of-a-kind live-fire evaluation fixture capable of evaluating unique blast attenuating floor systems and aftermarket pads/blast mats. The fixture was used for comparing attenuating concepts with a controlled input which simulates the loading at vehicle floor system attachment points versus center of floor. TARDEC designed and fabricated 2 flooring concepts capable of controlling blast loading into the tibia. This effort led to a better understanding of the benefit of flooring systems that use either deforming metal or an arrangement of friction hinges to control blast loading and structural loading while taking into consideration the performance sensitivity of the foot placement. To accomplish this TARDEC conducted live fire blast evaluations on the 2 concepts at a targeted and fleet representative input accelerative load. Structural durability testing was also conducted for various drive vibration profiles and weight configurations to gain insight into the ruggedness of the flooring concepts when subjected to road loads and to identify and any issues. Future work planned in FY14-16 is to continue development of Energy Attenuating ground vehicle flooring concepts and create relevant specifications for Energy Attenuating ground vehicle flooring concepts.

Ground Vehicle Structures: Development of Decoupled Blast Mitigation and Active Blast Mitigation Underbody Solutions Aim to Reduce Occupant Injuries During Ground Vehicle Blast Events

TARDEC is researching and developing two novel approaches to reduce the loads transmitted

through vehicle structure, to the occupant interfacing subsystems (floors & seats), and ultimately to the occupant during a blast event. The first approach is a decoupled hull-to-cab integration mechanism. The goal of this decoupling mechanism is to reduce the high peak accelerations of the cab and stretch out the duration of the blast loading for a relatively more gradual acceleration of the cab and its occupants. TARDEC led a team to design, fabricate, and evaluate a series of decoupling mechanism concepts. The TARDEC team then down selected to the best performing concept which is now being integrated onto a specific military vehicle system. The second approach involves the firing of active countermeasures that applies a downward force opposite the blast. This active blast mitigation integration involves: i) a sensor suite to detect the blast, ii) processing algorithm to distinguish the blast and firing of the countermeasures, iii) countermeasure design/integration/tuning to apply necessary counter force as intended to the vehicle structure. As the technologies are further matured, the active blast mitigation technology combined with the decoupled hull-to-cab integration mechanism has the potential to greatly reduce the acceleration of the vehicle cab compared to existing rigid/non-active vehicle designs.

Developing Self-Sealing Fuel Tanks

In FY13, the Program Manager for the Light Armored Vehicle (LAV) completed development and testing of multiple role variant self-sealing fuel tanks. These fuel tanks contain a self-sealing component that enables sealing of damage from behind armor effects from blast events and overmatch events that penetrate the fuel tank. It is anticipated that this will minimize potential secondary fire events that could injure LAV crews and damage LAVs.

Developing a Torso Surrogate Device for Estimation of Armor System Performance for Torso Protection against Blast Overpressure Threats

Work initiated under the Army Technology Objective titled Soldier Blast and Ballistic Protective System Assessment and Analysis Tools (D.SO.2008.04) resulted in the development of a torso surrogate device for estimation of armor system performance against blast threats. Specifically, NSRDEC funded work with JHU/APL to modify the Human Surrogate Torso Model (HSTM) for protective equipment performance assessment against blast overpressure threats. A multi-phase testing approach was used to analyze the response of the device to both ideal and complex live-fire blast testing. The HSTM is built to include individual torso components with a detailed skeletal structure, the major thoracic and abdominal organs, lower gastrointestinal tract, mediastinum, flesh, and skin. The internal organs, including heart, lungs, liver, and stomach, are composed of silicone-based biosimulant materials targeting the density, durometer, and bulk modulus of human organs. The HSTM includes an instrumentation suite comprised of pressure sensors in each of the major organs, accelerometers, a custom developed displacement sensor, and load cell. The system was found to be rugged, repeatable and able to discriminate between test conditions including blast scenario, charge weight, and the presence of PPE. Overall, this effort has resulted in the development of a test device that has the potential for use to estimate blast torso protection performance of armor systems or armor designs.

Improving Mine-Resistant Ambush Protected Vehicles

MRAP vehicles have been designed to survive IED attacks and ambushes. However, it requires a substantial amount of time and labor to load casualties into and out of the current MRAP MaxxPro ambulance. To solve this issue, researchers at the TARDEC have designed the MRAP MaxxPro Plus long wheelbase vehicle with a litter assist system to be retrofitted from the MaxxPro Dash DXM variant of MRAP vehicles. Loading and unloading will be much safer and easier with this newly upgraded system, requiring under a minute to get a casualty into or out of the vehicle. Researchers at USAMMDA have been working with Navistar Defense to retrofit MRAP MaxxPro vehicles with an independent suspension system that improves off-road mobility and evens out the ride which may help to prevent further damage to casualties, especially to those who have sustained a TBI.

Navy Advanced Requirements for Crew Safety (ARCS) Program

The ARCS program, sponsored by the Naval Surface Warfare Center/ONR, has been focused on defining medically based crew safety requirements that are quantitative and relate to operationally relevant criteria using a new Military Combat Injury Scale (MCIS) and associated Military Functional Incapacity Scale (MFIS) and their relation to the injury criteria, and where possible, on developing Vehicle Response Survivability Curves (VRSC) that relate vehicle motions to various levels of incapacity due to blunt trauma. The MCIS effort concluded that reliable injury risk curves for the selected MCIS injuries as predicted by Hybrid III responses could not be generated for the majority of the injury criteria. Some of the key findings of the VRSC effort indicated that horizontal seat loading is significant and can be of the same magnitude and high rate as the vertical; and the blast-induced vehicle roll and horizontal loading can have a large effect on injury. This effort should lead to the development of improved vehicle designs with enhanced occupant protection.

Acute Treatment – Diagnostics

Advancing Soldier Medicine: Prevention, Diagnostics and Far-Forward Care

The Institute for Soldier Nanotechnologies (ISN) strategic research thrust in Soldier medicine addresses the bottom-up design of nanomaterials and nanostructures targeted toward providing technologies to enhance medical protection, provide a means of diagnosis, and be adaptable to far-forward care. The researchers are developing a portable platform for the long-term storage and rapid reconstitution of lyophilized drugs and therapeutics. They completed fluid dynamic and molecular interaction studies, which have led to the development of models for dissolution within various microfluidic chamber designs. Overall, the researchers are designing the rapid reconstitution packages to provide rapid availability of therapeutics under conditions of environmental extremes. Using a nanolayer approach, the researchers are also developing a multilayer composite system designed to assemble thrombin, other hemostatic agents, and antimicrobials in a dry film form. They have developed and tested chemistry and deposition techniques to enable stable incorporation of a hemostatic peptide into the multilayered platform. The researchers have engaged research personnel from USAISR to collaboratively investigate the efficacy of these multilayered films in providing controlled release of therapeutics. Specifically, the ISN and USAISR will be examining the potency of hemostatic films for stopping traumatic blood loss in a porcine liver model. Overall, the researchers' multilayered platform for incorporating clotting, wound healing, and antimicrobial agents could provide a well-controlled means of delivering optimal sequential release of these agents.

Developing a Device to Screen for Intracranial Bleeding

Researchers at InfraScan Inc. have developed a hand-held screening device that uses near-infrared technology to screen patients for intracranial bleeding. The "Infrascanner" provides a new capability to provide rapid triage for head injuries, particularly closed head injuries. The device can identify patients most likely to have increased intracranial pressure. It can be used to identify those who would most benefit from immediate referral to a computed tomography scan and neurosurgical intervention. The Marine Corps Systems Command (MCSC) and ONR sponsored the development effort through the SBIR program. A multi-center clinical trial provided the data needed for FDA certification of the Infrascanner.

The Blast Load Assessment – Sense and Test (BLAST) Program

The BLAST program is a Force Health Protection Enabling Capability under the Future Naval Capabilities program. Currently in its first year of funding, researchers working on this ONR-funded program are developing three inter-related products. The first is a blast sensor that measures and records the intensity of a blast event as experienced by the warfighter. The second is an assessment tool that can quantitatively determine the effect of the blast event on the brain's function. The third product can mathematically integrate these data to provide stand-down guidelines for personnel that have been exposed to any size blast event. Together, these products are expected to improve unit health and operational effectiveness by replacing mandatory stand-downs with selective removal of only injured personnel and allowing them time for proper recuperation and treatment.

Improving the Tactical Combat Casualty Care Card

The JTS and the DoD Trauma Registry data collection have helped to improve trauma care at forward surgical teams and combat support hospitals in Iraq and Afghanistan. There is still a need, however, for data collection and analysis to improve performance at the prehospital level of care. The Committee on Tactical Combat Casualty Care (TCCC) has released an updated version of the TCCC card in an effort to improve the documentation of pre-hospital care on the battlefield.

While the revised card continues the simple format of the previous card, it incorporates numerous modifications that will allow better documentation of pre-hospital care. For example, there are new sections that record the use of junctional tourniquets, document pain level, and indicate supraglottic airway use. The updated card also includes spaces for the documentation of an eye shield, combat pill pack usage, hypothermia prevention equipment, type of chest seal, and type of supraglottic airway. The card will also record a better definition of mechanism of injury, among other improvements.

Acute Treatment – Epidemiology

Developing the MCIS and MFIS for Injury Severity Coding of Combat Casualty Injuries

The Naval Health Research Center (NHRC) has completed system revisions and initial validation studies on the MCIS/MFIS system, with funding from the ONR and in collaboration with military and private partners. The system will be used to develop better methods to predict the impact of combat trauma on combat effectiveness with special reference to ground and shipboard combat. The MCIS/MFIS lexicon specifically describes combat trauma injuries from the military perspective and translates them into impact on functional capabilities. In validation tests, the new system reduced the descriptive complexity by 87%, increased the injury descriptive details in eight key areas (e.g., multiple amputations, penetrating injuries to the face), and provided functional capacity scales that quantify impact on the casualty's ability to carry out mission responsibilities. MCIS/MFIS will support the development of ground and ship systems to minimize crew injuries, maximize the benefits of available medical care, and estimate a damaged vehicle/ship's fighting capability to support tactical decisions.

Identifying Acute Symptoms and Associated Outcomes Following Combat Blast Mild Traumatic Brain Injury

Assessment of acute mTBI symptoms after a combat blast could aid diagnosis and guide follow-up care. The NHRC in San Diego, California, conducted a retrospective cohort study with 1,656 service personnel who experienced a combat blast-related mTBI in Iraq. The most common acute mTBI symptoms were headache (62.8%), loss of consciousness (LOC; 34.5%), and tinnitus (33.2%). LOC was predictive of PTSD, while altered mental status and previous blast history were predictive of post-concussion syndrome. While no acute symptoms were associated with discharge outcomes, injury severity was associated with disability discharge. Understanding the importance of assessing cognitive status immediately after a blast provides an empirical clinical practice guideline for medical personnel in diagnosing mTBI and referring injured Service members for follow-up care.

Examining the Relationships among Injury Severity, Post-Traumatic Stress Disorder, and Career Outcomes following Combat Blast Injuries

Blast injuries are now the most common wounds faced by warfighters. In this study, researchers at the NHRC described career performance outcomes of 4,255 male Service members after combat blast injuries, and examined the relationship between injury severity and the type of Service discharge. The researchers found that initial injury severity was associated with adverse career performance outcomes. They also determined that adverse career performance outcome proportions were higher in Service members with a PTSD diagnosis. This study has led to a better understanding of the role that injury severity and PTSD diagnosis have on functional outcomes, which can transition to improved rehabilitation management in Service members injured by blasts.

Developing Ocular Injury Risk Curves to Assess Blast-Related Ocular Injuries

Secondary blast injury, caused by flying debris or fragments, is a particular threat to the eyes, even when Army-authorized protective eyewear is worn. Currently, authorized protective eyewear is evaluated against the same protective ophthalmic standards created for industry by the American National Standards Institute, but are not evaluated against the magnitude of blast mechanisms to which warfighters are exposed during combat. Researchers at USAARL compiled ocular injury data from several published sources and constructed ocular injury risk curves based on equations developed to assess all ocular injuries as a function of a single blast exposure variable. This work has resulted in the development of procedures for the evaluation of eye protection devices using the Facial and Ocular Countermeasure for Safety headform with an improved eye surrogate.

Documenting Potential Health Effects of Repeated Blast Exposure in Operational Breaching Personnel

Breacher's injury studies focus on military and law enforcement dynamic entry personnel who use explosives as a means of gaining access to barricaded or hardened structures. Researchers at WRAIR and NMRC completed data collection for their Breacher injury survey at two military and one civilian law enforcement training sites. They incorporated additional test venues and utilized additional surveillance data as well as improved data collection at new time points (including new data from participants who served as a larger comparison group and control subjects). These studies continue to comprise neurocognitive, neurophysiological, neuroanatomical, toxicological, and auditory system assessments and detailed characterization of the physical environment of the exposure to blast (e.g., pressure, noise level). They are aimed at creating a supporting, lower-fidelity surveillance effort on a larger cohort of personnel who have completed Breacher training. In a collaborative effort between WRAIR and NIH, patients have also been evaluated using advanced brain imaging technologies (e.g., fMRI). The preliminary data indicate that blast exposure is associated with changes in neurocognitive performance and that the observed changes in performance results are cumulative. These studies are facilitating the development of a valid human study model for repetitive, low-level blast exposure and clearer descriptions of the behavioral and physiologic effects of said exposure, thereby allowing for the development of more sensitive and specific diagnostic tests.

Correlating Traumatic Injury to the Head with Molecular Genetic Risk Factors in Parkinson's Disease

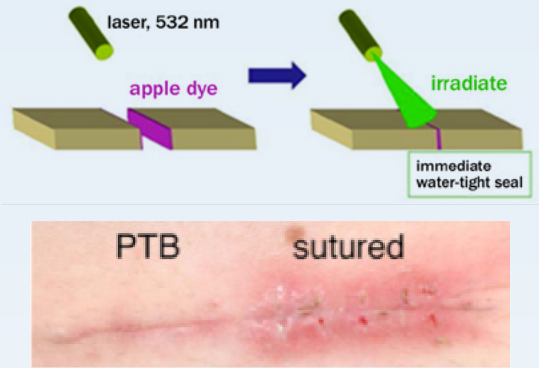
Traumatic injury to the head has been correlated with the later development of neurodegenerative conditions, including Alzheimer's disease and Parkinson's disease. Not all Service members suffering a traumatic injury to the head will progress to long-term neurodegeneration. It is necessary to know what factors outside the characteristics of the injury parameters influence development of long-term health problems. In a large dataset of Parkinson's patients with a known history of a traumatic injury to the head, researchers at the National Institute of Aging's Laboratory of Neurogenetics evaluated whether known Parkinson's disease loci contain risk alleles enriched in TBI/Parkinson's disease as opposed to non-TBI/Parkinson's disease. They identified eight single nucleotide polymorphisms across two loci that were statistically significant after meta-analyses. By identifying rare polymorphisms in the genetic sequence of individuals with Parkinson's disease that have a history of traumatic injury to the head, this work provides a means of further characterizing individuals at increased risk for long-term health problems following a traumatic injury to the head. Additional work with a larger cohort is necessary to validate the findings.

Characterizing Relationships between Acute Care Evaluations and Health Outcomes

Researchers at NMRC, collaborating with scientists at the Naval Experimental Dive Unit and the Naval Medical Center-Portsmouth, have undertaken efforts to characterize combat blast-related concussions in Service members who have served in OEF. This is a retrospective, observational database review of patients treated at the Concussion Restoration Care Center in Helmand Province. The purpose of the study is to characterize combat-related concussions in the acute setting and determine if the clinical information gathered is associated with health outcomes post-deployment. Specifically, the researchers aim to delineate the important features of combat-related concussions: symptoms, neurocognitive status following concussion, factors that may impact outcomes and treatments. This work may be instrumental in developing and testing new treatment algorithms. Future work is oriented towards understanding balance/vestibular deficits following blast concussion.

Developing Clinical Practice Guidelines for Preventing and Managing Infections Associated with Combat-related Injuries

The DoD–VA Trauma Infectious Disease Outcomes Study is led by the Infectious Disease Clinical Research Program and funded by the Military Infectious Diseases Research Program (MIDRP). The multiple DoD and VA medical treatment facility research study is designed to produce evidence based data for the development of CPGs for prevention and management of deep soft tissue infections (DSTIs) associated with combat-related injuries. The researchers are investigating clinical outcomes from current management of DSTIs in combat-related injuries. At initial inpatient hospitalization, skin and soft tissue infections (SSTIs) accounted for more than 40% of infections associated with combat-related injuries. Eighty-five percent (85%) of the SSTIs were DSTIs. Initial analyses have evaluated the number/rate of DSTIs as well as initial antibiotic regimens. This information is currently under review to determine how clinical practice can be modified to improve outcomes. Overall, it is anticipated that a new CPG on prevention and management of DSTIs will lead to improved outcomes related to both infections and healing in cases of combat-related wounds.



Epidermal sealing of excision with PTB (left) and sutures (right) 2 weeks post surgery.

Figure 8-3: Photochemical Tissue Bonding

Conducting Real-time Casualty Analysis

The NHRC provides the JTAPIC Program Office with a weekly analysis of all combat casualties occurring in the previous 7 days in overseas contingency operations. These WIA casualties are gathered from various operational data bases, including Combined Information Data Network Exchange, Significant Action Reports, Medical Situation Awareness in Theater, and the Defense Casualty Information Process System. For each wounded Service member, the medical data from these sources is thoroughly reviewed at NHRC and a clinical profile is developed describing the injury characteristics of the casualty. Each casualty's injuries are then coded on various diagnostic and injury severity taxonomies by registered nurses. In addition to injury analyses conducted at NHRC, these detailed clinical profiles are then made available to the JTAPIC partnership for additional analysis where tactical data (e.g., weapon type, explosive weight, strike point) are matched to the profiles. This mapping of medical to tactical data allows vehicle and personal protective equipment developers to design targeted modifications to improve vehicle and PPE, thereby reducing the frequency and severity of injury. Because of the common requirement for medical data, NHRC participates in nearly every JTAPIC partnership analysis. Since January 2013, NHRC has provided the DoD with 2,703 detailed clinical profiles of casualties injured in overseas contingency operations. In addition, NHRC medical staff reviewed 4,936 casualty medical records for compliance with directives associated with the Blast Exposure and Concussion Incident Report for current theater operations. The immediate availability of these data permits rapid responses to identify and defeat new and emerging threats, directly reducing casualty rates.

Genitourinary Injury Analysis Prepared for JTAPIC

Although genitourinary (GU) injury accounts for a relatively small proportion of all battle injury (2%), it has become a concern. As a result, pelvic protection equipment has been issued to all Services. In a report, the NHRC described the state of the documentation on adherence to PPS in injured Service members and examined the temporal relationship between GU injury and fielding of PPS. Data from the report are being used by the personal protective equipment development community to reduce and or mitigate the devastating clinical, psychological, and reproductive effects of GU injury. There has been a steady decline of GU injury as a proportion of all battle injury during the study's time period, but this cannot be definitively attributed to PPS due to the paucity of data and other factors also affecting GU injury. An examination of GU injury in Service members with lower extremity amputations reveals no declining trend. NHRC continues its ongoing efforts to monitor GU injury.

Acute Treatment – Hemorrhage and Blood

Conducting Damage Control Resuscitation (DCR) Research

The CCCRP's DCR task area focuses on the conceptual development, discovery, and early studies of new candidate physiological replacement fluids, drugs, and/or biological agents for the treatment or prevention of secondary injury resulting from shock occurring as a result of battlefield injury. Progress is being made in three research areas: Intracavitary and Junctional Hemorrhage; Hemorrhage Control of Coagulopathic Bleeding; and Improved Resuscitation Strategy. Regarding the Intracavitary and Junctional Hemorrhage area, the researchers have (1) established efficacy and acute safety criteria for evaluating control devices for junctional hemorrhage (bleeding from the areas at the junction of the trunk and its appendages); (2) validated a manikin model for assessing the differential performance of junctional devices; (3) developed a model of exsanguination shock (shock due to blood loss) in swine to prepare for aortic balloon occlusion studies for the control of non-compressible hemorrhage; and (4) collaborated with DARPA on their Wound Stasis program. Regarding the Hemorrhage Control of Coagulopathic Bleeding area, the researchers have (1) established large soft tissue/coagulopathy swine model criteria to evaluate hemostatic dressings and devices (i.e., those that are designed to stop bleeding); and (2) established a model of coagulopathy (inability of blood to clot, leading to prolonged bleeding) to evaluate new biologic hemostatic dressings. Regarding the Improved Resuscitation Strategy area, the researchers have (1) validated swine hemorrhage/trauma models to assess the efficacy of blood components, inhibitors of the complement (innate immune) system, and anti-shock drugs to monitor bleeding volume, inflammatory response and survival time; and (2) validated rat microcirculation studies to assess macro- and micro-circulatory criteria for improved resuscitation fluids. Overall, these research efforts should lead to decreased battlefield deaths due to uncontrolled hemorrhage.

Developing a System for Extended Storage of Red Blood Cells

In partnership with USAMMDA, Hemerus Medical LLC received FDA approval of the New Drug Application for its SOLX® System (LEUKOSEP® HWB-600-XL Leukocyte Reduction Filtration System for Whole Blood with CPD Anticoagulant and SOLX® Additive) on April 25, 2013. The SOLX® system, developed under the Red Blood Cell Extended Life Program, is a whole blood collection system that produces leuko-reduced red blood cells and plasma. Red blood cells produced by the SOLX® System demonstrate improved cell quality for a storage period of 42 days, theoretically reducing complications that may be associated with red blood cell storage lesions. This system has been approved in the US by the FDA for 6-week red blood cell storage. Data show that it could store red blood cells for at least 2 weeks longer, which could potentially decrease product loss due to outdating during military deployments. Overall, the SOLX® System could improve the safety and efficacy of therapeutic red blood cell transfusions as well as patient outcomes.

Conducting Coagulation and Blood Research

The CCCRP's Coagulation and Blood Research task area is focused on decreasing battlefield mortality due to hemorrhage by providing diagnostic and therapeutic solutions to treat the coagulopathy of trauma (COT) with safe and effective blood products delivered far-forward. Research efforts over the past year included COT and platelet product development. Regarding COT, the researchers developed a rat model of coagulopathy and demonstrated its similarity to human coagulopathy. In addition, they determined that red blood cells mitigate the effects of acidosis (too much acid in body fluids) on coagulation. Platelets are needed for normal blood clotting. The researchers have characterized a platelet function defect in a rat model of COT. In addition, they screened emergent platelet storage technologies and identified the leading technology (refrigeration, no agitation). They also characterized the addition of magnesium to improve the bloodclotting function of citrate-stored platelets. CCCRP collaborated with USAMMDA to develop and field new long-term stored platelet products (frozen and freeze-dried) and freeze-dried plasma. The overall goal of these research efforts is to restore normal blood clotting at early time points in warfighters who have a potentially life-threatening hemorrhage.

Improving the Mobile CareGuide Sensor Platform

Researchers at Reflectance Medical, Inc., (RMI) sponsored by the CCCRP, have developed the Mobile CareGuide™ sensor platform to noninvasively and continuously assess patient metabolic status. The Mobile CareGuide sensor allows medical personnel to obtain tissue measurements of pH and oxygen without a blood sample. This now helps the medics decide more quickly who will go into shock. The original Mobile CareGuide 1100 received FDA clearance in July 2012, the second generation Mobile CareGuide 2100 was approved by the FDA in December 2012, and the latest version of the device, the Mobile CareGuide 3100, received FDA clearance in July 2013. As noted on RMI's website, CareGuide is expected to help clinicians manage patients with cardiac dysfunction both in and out of the hospital, with the goal of reducing treatment costs by avoiding or shortening hospital visits.

Conducting Tactical Combat Casualty Care (TCCC) Research

The CCCRP's TCCC task area seeks to optimize combat casualty care by providing clinically-focused, evidence-based and tactically valid technology and procedural solutions for improving the survival of combat casualties and other victims of trauma, targeting the out-of-hospital setting. Several TCCC research projects have yielded results during the past year. One project focuses on the development of a portable, real-time, non-invasive resuscitation monitoring device with built-in decision support that would guide medical personnel during resuscitation of injured soldiers from the battlefield through to the hospital. The researchers have completed the development of an initial algorithm for resuscitation monitoring, which will be ported to three devices in the near future. They hope to attain the first FDA-cleared monitor by FY14. In another project, researchers are studying the regulation of blood flow in the brain during simulated hemorrhage. Specifically, they are characterizing the effect of inspiratory breathing on responses of blood flow and oxygenation in the brain during continuous bleeding in individuals with high and low tolerance to hemorrhage. During the past year, they have begun to collect data. In another project, researchers are conducting a preclinical evaluation of a decision-support medical monitoring system for early detection of heart failure during blood loss in humans. During the past year, they completed experiments on six subjects. Overall, it is anticipated that products arising from these research projects will lead to earlier interventions due to the earlier identification of patients with differential tolerance to hemorrhage, improved triage decisions, guided resuscitation, and reduced morbidity and mortality in severe trauma casualties.

Acute Treatment – Wound Infection, Repair and Stabilization

Conducting Clinical Trials in Burns and Trauma

Researchers funded by the CCCRP's Clinical Trials in Burns and Trauma task area are making progress on a variety of clinical studies. They are (1) developing a blood filtration system for the treatment of septic shock in trauma patients; (2) elucidating the impact of rehabilitation procedures and rehabilitation time on the contracture of burn scars during the wound-healing process; (3) determining whether a restrictive blood transfusion protocol is better than a traditional transfusion strategy that maintains hemoglobin concentrations at higher levels; and (4) comparing the clinical performance of the ReCell® cell spraying device with that of split-thickness meshed skin grafts (which contain parallel rows of staggered slits) for the treatment of second degree burns. Collectively, these studies support the overall goal of improving functional survival among those service members who sustain a burn injury and/or mechanical trauma.

Comparing Health Outcomes for Combat Amputee and Limb Salvage Patients Injured in the Iraq and Afghanistan Wars

Treatment of military combatants who sustain leg-threatening injuries remains one of the leading challenges for military providers. To help inform physicians regarding the health outcomes of surgical amputation versus limb savage (LS) for the most serious leg injuries, the NHRC conducted a retrospective analysis of health records for patients who sustained serious lower extremity injuries in the Iraq and Afghanistan conflicts between 2001 and 2008. Of the 788 patients studied, 74% had an amputation during the first 90 days post injury; 10% had an amputation more than 90 days post injury; and 15% had leg-threatening injuries without amputation, or LS. Injury data and health outcomes were followed for 24 months. After adjusting for group differences, NHRC found that, in the short term, early amputation was associated with reduced rates of adverse health outcome complications (e.g., infections, substance abuse, and post-traumatic stress disorder), relative to late amputation and/or LS. Most evident was that late amputees had the poorest physical and psychological outcomes, including prolonged infections and pain disorders. These findings indicate the need for separate health care pathways for early and late amputees and LS patients, since these patients face differing clinical consequences.

Conducting Craniomaxillofacial (CMF) Trauma Research

Scientists funded by the CCCRP's CMF Trauma Research task area are developing solutions to mitigate dental disease in service members and optimize treatment of CMF battlefield injuries with the goal of returning the service members to full function. Their approach involves research in the areas of epidemiology, basic science, prevention, and treatment. For example, the researchers are continuing to develop an epidemiological model of dental emergency rates and diagnoses of soldiers in a theater of operations. It is anticipated that the results of these research efforts will lead to improved pre-deployment dental readiness policies, dental classification changes, and clinical preparation of soldiers for deployment. In another study, researchers are evaluating treatments to prevent the development of bacterial biofilms (groups of microorganisms that stick to each other on a surface) in combat wounds. They found imipenem to be the most effective agent against *K. pneumoniae* biofilms both in vitro and in wounds. The research team also developed a topical delivery system for the controlled release of antimicrobials. Results of this research effort should help to mitigate impaired healing caused by the biofilm infection of combat wounds. Other researchers have developed an inflamed wound model exhibiting prolonged inflammation. They are evaluating inflammatory mediators as treatments. In another study, researchers are characterizing the *Pseudomonas* wound infection response to antimicrobial treatments. Their microarray analyses of Pseudomonas-infected wounds showed extensive inflammatory responses evident 24 hours after active infection, compared to uninfected wounds. It is anticipated that the results of these research efforts will help to mitigate the effects of inflammation on wound scarring in our warfighters.

Using Light-Activated Tissue Repair to Treat a Wide Range of Injuries

As part of the Military Photomedicine Program managed by the Air Force Office of Scientific Research, a light-activated tissue repair technology is being developed by the Wellman Center for Photomedicine at Massachusetts General Hospital for improved care after traumatic injuries, including peripheral nerve repair, the sealing of penetrating eye wounds, blood vessel anastomosis, and the sealing of skin wounds. The technology, called Photochemical Tissue Bonding (PTB), rapidly forms a water-tight tissue-to-tissue seal by cross-linking proteins between tissue surfaces without additional proteins or glues. A light-sensitive, FDA-approved dye is applied, and the surfaces are placed in contact followed by exposure to a green clinical laser that does not cause thermal damage (**Figure 8-3**). PTB is not cytotoxic or inflammatory, thus producing less fibrosis, scarring, and adhesions than sutured repair. A recent breakthrough in PTB technology occurred in its use in repair of blood vessels. A very thin dissolvable glass has been used as a stent on which to place the two blood vessel ends. The rigid stent completely dissolves in the blood stream (after bonding) in less than 15 minutes. Although excessive scarring and

long procedure times are still challenges for repair of traumatic and surgical skin wounds, PTB has demonstrated potential to improve outcomes in a wide range of injuries and is being further developed.

Improving Cutaneous Skin Coverage Following Severe Burn Injury

Researchers at Wake Forest University (funded through AFIRM) are collaborating with researchers at USAISR and Stratatech Corporation to conduct a multicenter clinical trial to assess the safety, tolerability, and efficacy of prolonged exposure to increasing amounts of a single application of StrataGraft skin tissue (compared to autografts) in deep partial-thickness burns. StrataGraft is a living, meshable, suturable human skin substitute that reproduces many of the structural and biological properties of normal human skin. Data obtained from the first clinical trial cohort suggests that StrataGraft works to facilitate wound closure and is replaced as the patient's own cells close the wound. This result has prompted the initiation of two additional cohorts, one of which doubles the area of burn treated with StrataGraft, and the other which looks at the use of cryopreserved material. Both additional cohorts completed enrollment in FY13. This technique is a promising alternative approach for cutaneous skin coverage after extensive burn injuries.

Conducting Extremity Trauma Research

Extremities are the most commonly injured body part. The injuries are primarily penetrating soft tissue wounds and open fractures resulting from high energy sources, and are fraught with complications that can lead to poor outcomes and late amputations. The CCCRP's Extremity Trauma task area is focused on developing and evaluating ways to care for acute injuries, prevent infection, and heal/regenerate injured or lost tissue to return the injured Warrior to full function. Researchers at USAISR are leading the Skeletal Trauma Research Consortium, which seeks to describe the clinical issues, reduce complications, and increase the return-to-duty rate, particularly for those who have undergone limb salvage. Results from their recent "Return to Run" study revealed that more than 50% of soldiers who completed the program returned to duty. Researchers working in this task area have also been developing and evaluating guidelines and therapies to prevent and treat wound

complications in combat casualties. As part of this effort, they found that incorporation of D-amino acids (a biofilm dispersal agent) into a bone graft prevents it from becoming contaminated by the UAMS-1 clinical strain that is a high producer of biofilms. This will promote healing of the wound and reduce complications. Researchers in this task area have also engineered muscle constructs for the repair of traumatic volumetric muscle loss (VML). They found that only 50% of donor minced muscle tissue is needed to achieve comparable functional recovery as would be attained with 100% replacement of the tissue lost with VML. Researchers in this task area are also improving cellular therapies for bone trauma using injectable scaffolds for bone regeneration. They found that injectable constructs show cellular deposition in vitro, and lovastatin promotes accelerated bone growth in vivo. They note that the combination of these elements could provide a valuable system for efficient bone growth. Overall, it is anticipated that the results of these research efforts will reduce complications associated with extremity injuries, increase rates of limb salvage, improve clinical outcomes, and improve return-to-duty rates for our warfighters.

Developing a Treatment to Limit Burn Injury Progression

Burn injuries often become larger in the 2–3 days following injury. This can greatly complicate treatment and outcomes for patients, and to date there is no therapy to stop this process. Investigators at Stony Brook University, funded through AFIRM, found that a single intravenous infusion of a novel molecule derived from fibronectin, P12, could attenuate burn injury progression in both rodents and pigs, even under hypoxic conditions. The group is completing the preclinical studies necessary to support an Investigational New Drug application to the FDA. A clinical trial is expected in the next 2–3 years. An effective treatment to prevent burn injury progression may reduce scarring, contractures, infection, disability, and possibly mortality from serious burn wounds.

Acute Treatment – TBI Treatment

Demonstrating Cortical Thinning in Warfighters with Blast-related mTBI

Researchers from DVBIC, in collaboration with researchers from the University of Texas at San Antonio Health Science Center, have demonstrated thinning of the cortical area of the brain in a small cohort of blast-injured mTBI patients. Twelve (12) US Service members

with blast-related mTBI were compared to 11 demographically matched Service members without TBI. All subjects underwent MRI examination, and the T1-weighted anatomic images were processed using the Free Surfer suite of tools. Group comparisons controlling for age demonstrated distinct cortical thinning in two left hemispheric structures (left superior temporal and frontal gyri) for the blast-injured Service members. Behavioral analyses of those two clusters demonstrated three significant behavioral/cognitive sub-domains, each associated with audition and language. Post-hoc analyses of clinical records demonstrated significant abnormal audiology reports for the blast-injured Service members. This suggests that the cortical thinning may be related to injury to the external auditory system rather than direct injury to the brain from the blast. Overall, the researchers demonstrated the potential to define unique regions of interest and functional correlations that may be used to design future studies. Although additional replication of the study results is needed in larger cohorts, this study is one of the first to demonstrate statistically significant cortical thinning in blast-injured mTBI patients.

Assessing Rehabilitative Quality of Life Outcomes in Injured Service Members

The NHRC initiated a 6-year longitudinal study to assess rehabilitative QOL outcomes in injured US Service members to better understand the consequences of combat injury, TBI, and PTSD on long-term health and readiness. The Wounded Warrior Recovery Project is supported by the US Navy Bureau of Medicine and Surgery (BUMED) and could draw upon a reservoir of more than 50,000 injured military personnel. Enrollment began in FY13 and is expected to continue throughout FY14 and FY15. This prospective study administers surveys every six months to gauge physical and mental health, as well as QOL of both active US military personnel and those that have separated from the military. Thus far, 723 injured Service members have enrolled in the study and over 100,000 survey responses have been collected.

Conducting Brain Trauma Neuroprotection Research

Researchers funded by the CCCRP's Brain Trauma Neuroprotection research task area conduct basic and applied research leading to (1) reduced death and residual disability caused by brain injury in combat through improved diagnostics, and (2) the discovery, development and implementation of novel therapeutic strategies including pharmaceuticals, hypothermia, and neural stem cell transplantation. The researchers have made progress on numerous research projects. They established a platform to study concussions associated with injury from projectiles. They also established a polytrauma animal model for the evaluation of individual and combined insults. They completed the first non-convulsive seizure combination drug study. They initiated a new study focused on the effects of combination drug therapy on the brain's ability to reorganize and re-establish connections following TBI. They also initiated preliminary studies of treatments for post-TBI epilepsy. The overall goal of these research efforts is to improve clinical outcomes of casualties with mild, moderate or severe traumatic brain injuries.

Demonstrating Altered Neurocircuitry in Service Members Sustaining a TBI

Researchers from the DVBIC, in collaboration with researchers from the WRNMMC, National Intrepid Center of Excellence (NICoE), and Center for Neuroscience and Regenerative Medicine (CNRM), utilized diffusion tensor imaging (DTI) techniques to assess neurocircuitry in 37 US Service members who had sustained a TBI while deployed, compared to 14 non-deployed military controls. Subjects sustained mTBI with 17 through a blast mechanism and 20 through a non-blast mechanism. DTI results were examined in relation to PTSD and post-concussion symptoms. Findings from this study suggest that the networks of the fronto-striatal circuit and the frontal-limbic circuit (particularly the cortico-striato-thalamo-cortical circuit) are most vulnerable to military-related injury and may also have a role in the development of neuropsychological symptoms frequently seen in military TBI patients.

Functional MRI in the Investigation of Blast-related Traumatic Brain Injury

Researchers from the DVBIC, in collaboration with researchers from WRNMMC, NICoE, and CNRM, performed a review of the application of fMRI to investigate blast-related TBI (bTBI). The review summarized recent bTBI publications with discussions of various elements of blast-related injury and resting state fMRI. The authors provided brief reviews of some fMRI techniques that focus on mental processes commonly disrupted by bTBI, including working memory, selective attention, and emotional processing. Given the heterogeneous nature of bTBI and its high rate of comorbidity with other psychological and physical injuries, the review presented suggestions and considerations for designing fMRI studies for bTBI populations as well.

Evaluating Hyperbaric Oxgyen Intervention as a Treatment of Post-Concussion Syndrome Associated with mTBI

Researchers from the DVBIC, in collaboration with the Hunter Holmes McGuire Veterans Affairs Medical Center, conducted a randomized, double-blind, sham-controlled study on 61 Marines with a history of mTBI and post-concussion syndrome (PCS). Using the Rivermead Post Concussion Questionnaire, the researchers measured pre-HBO2 oxygen intervention outcomes as well as at two later time points. The results showed no evidence of efficacy by three months post-intervention to treat the cognitive or behavioral sequelae of PCS after combat-related mTBI. Therefore, the study results do not support the use of HBO2 to treat PCS, even at typical treatment pressures advocated by hyperbaric clinicians for mTBI.

Evaluating Blood Brain Barrier (BBB) Integrity after a TBI

BBB integrity is supposed to be compromised following a TBI, including bTBI; however, little is known about the long-term kinetics of BBB changes and its consequences. In this study, sponsored by BUMED, researchers at the University of Utah explored the effects of blast overpressure on ICP and its correlation with BBB breakdown in a rat model. Animals were exposed to either one or three blast overpressures, and ICP was monitored in two blast overpressure-exposed groups as well as a control group by a telemetric device over a 7-day period. The results demonstrated that BBB breakdown may play an important role in the mechanism of mTBI brain injury, and that an increase in ICP can be used as one of the markers of brain damage after exposure to blast overpressure. Findings may lead to novel diagnostic approaches for assessing TBI in pre-hospital and hospital settings in addition to identifying potential therapeutic approaches.

Evaluating the Effects of Interactive Metronome Therapy on Cognitive Functioning After Blast-Related Injury

In a randomized controlled pilot trial, researchers from the DVBIC randomly assigned 46 active duty Soldiers with persisting cognitive complaints following blast-related mild to moderate TBI to either receive standard rehabilitation care (SRC) or SRC plus a 15-session standardized course of interactive metronome therapy. Significant group differences were found in unadjusted analyses for Repeatable Battery for the Assessment of Neuropsychological Status index scores, as well as immediate memory and delayed memory indices, with the interactive metronome group showing significantly greater improvement at Time 2 than the SRC group. Though not all were statistically significant, effects in 21 of 26 cognitive outcome measures were consistently in favor of the interactive metronome treatment group. Therefore, the addition of interactive metronome therapy to standard rehabilitation care appears to have a positive effect on neuropsychological outcomes for Soldiers who have sustained mild-to-moderate TBI and have persistent cognitive complaints after the period for expected recovery has passed.

The Automated Neuropsychological Assessment Metrics TBI Assessment System

On June 4, 2013, the DoD Instruction 6490.13, "Comprehensive Policy on Neurocognitive Assessments by the Military Services," established the ANAM instrument as the DoD-designated neurocognitive assessment tool to be used by Office of the Secretary of Defense, the Military Departments, the Office of the Chairman of the Joint Chiefs of Staff and the Joint Staff, the Combatant Commands, the Office of the Inspector General of the DoD, the Defense Agencies, the DoD Field Activities, and all other organizational entities within the DoD. The instrument is to be used solely in its screening capacity to detect cognitive changes as part of a clinical evaluation. Determination of pre-deployment neuropsychological function is a useful means of providing a baseline for individual alterations (as opposed to population comparison) for enhanced evaluation within clinical evaluation. As such, the tool permits clinicians a means of determining specific neuropsychological domains that are related to alterations in injured individuals.

Conducting HBO2 Therapy Clinical Trials

The DoD remains committed to researching and providing evidence-based solutions for our wounded warriors. USAMMDA is leading an effort to determine if HBO2 therapy is of benefit in the treatment of chronic symptoms of mTBI or PCS. A pilot Phase II study of HBO2 for persistent post-concussive symptoms after mTBI, a study of low-dose HBO2 was completed, and the results are being prepared for release to the FDA. Another clinical trial – the mTBI Mechanisms of Action of HBO2 for Persistent Post-Concussive Symptoms study – began in September 2012 and is ongoing. Participants in this study will undergo a battery of outcome assessments at defined test intervals to determine the optimum assessment battery for future studies. The study will attempt to identify potential confounding variables in evaluating and treating PCS. An evaluation of the test–retest variability of these assessments will be explored separately in a normal study population to differentiate meaningful clinical changes within the PCS population.

Establishing the World's First Brain Tissue Repository for Studying TBI in Service Members

Due to its prevalence, TBI has been called the signature injury of the wars in Iraq and Afghanistan. TBI leads to persistent memory and mood disorders in many returning Servicemen and women, disrupting their ability to maintain a job, reintegrate into the community, and reconnect with friends and family members. The CNRM Brain Tissue Repository for TBI has been established at the USUHS in Bethesda, Maryland, to advance the understanding and treatment of TBI in warfighters. By comparing injured and uninjured brain tissue (accessed through the repository), scientists and physicians will be able to characterize the key neuropathological features of TBI and identify ways of preventing and potentially treating the adverse effects of TBI. CNRM researchers will also investigate how traumatic injury to the head leads to chronic traumatic encephalopathy (CTE), which is a progressive neurodegenerative disorder involving the accumulation of a protein called tau in cells of the nervous system within certain brain regions. Symptoms of CTE include memory loss, aggressive behavior, and suicide ideation. It is anticipated that access to the brain tissues, along with the clinical information associated with them, will allow scientists to more rapidly address the underlying biological mechanisms by which head trauma results in the development of CTE.

Reset – Transplants

Developing Reinforced Fascia for Abdominal Wall Reconstruction

AFIRM-funded scientists at the Cleveland Clinic Foundation have created a reinforced fascia-derived tissue for use in abdominal wall reconstruction. Reconstruction of the abdominal wall following trauma or traumatic sequelae is very challenging, and the outcomes are often unsatisfactory. The construct developed by these researchers offers a material with the necessary structural and mechanical properties to maintain a competent abdominal wall without the deformity and disability of an autologous donor site for the tissue. This technology has been transitioned to a semi-automated process and will be studied in a large animal model. This application is an extension of research done on a material for rotator cuff repair, which is transitioning to private industry funding for clinical trials development and execution. Reinforced fascia for abdominal wall reconstruction may provide an effective solution to a clinical challenge arising from catastrophic trauma and resuscitation for which there currently are very few options.

Performing Face Transplants to Address Catastrophic Tissue Loss in the Face

Composite tissue transplantation offers wounded warriors with severe facial disfigurement and dysfunction another option if standard reconstructive treatments are inadequate to address the extent of their injuries. Two teams of investigators managed by the Tissue Injury and Regenerative Medicine Program Management Office are conducting clinical trials of face transplantation: Cleveland Clinic Foundation (CCF) and Brigham and Women's Hospital (BWH). Surgeons at CCF have listed one patient and are waiting for a suitable donor. Surgeons at BWH have performed four face transplants, the most recent in April 2013. All four patients are experiencing return of sensation and motor function in the transplanted tissue. To those wounded warfighters who have suffered catastrophic facial injuries, facial transplants offer the possibility of restored function—chewing, swallowing, nasal breathing, oral competence, intelligible speech—and appearance, which could not be accomplished with conventional reconstructive surgery.

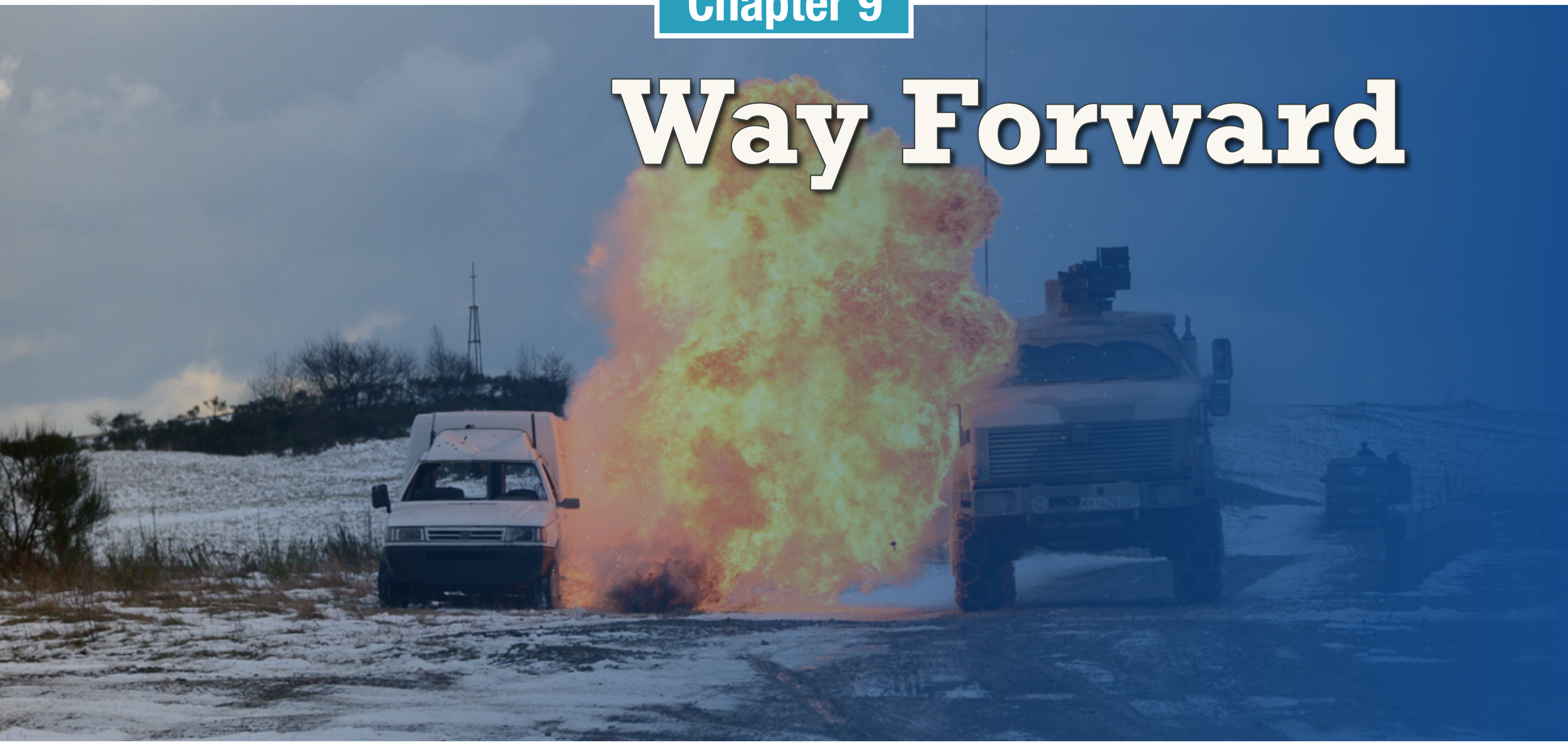
Reset – Prosthetics/Rehabilitation

Developing the World's First Thought-controlled Bionic Leg

Researchers at the Center for Bionic Medicine at the Rehabilitation Institute of Chicago have created a thought-controlled bionic leg. This is the first time that the movement of a prosthetic leg can be controlled by signals from its owner's brain. This is achievable because surgeons connect healthy nerves to the prosthesis. The prosthetic leg is controlled by a computer chip similar to those used in modern smartphones. Brain signals travel to sensors that are attached to the prosthetic leg, and the neural activity is detected by the leg's computer chip. The brain signals are immediately analyzed, decoded, and converted to instruction, which directs the limb to move in whatever manner it needs. The bionic leg soon provides an amputee with smooth transitions between sitting, walking, and climbing or descending stairs. The researchers hope to be able to make the technology available commercially within 5 years.

Chapter 9

Way Forward



The DoD Blast Injury Research Program will continue to coordinate and expedite prevention, mitigation, and treatment strategies for blast-related injuries. A number of existing and planned initiatives within the PCO during the next few years will support this goal. The PCO will also continue to identify priority areas for blast injury-related research as one of its key responsibilities.

Research Recommendations

The goal for blast injury R&D is to continue to identify, prioritize, develop, and ultimately field solutions to improve the military's capability to prevent and respond to blast injuries. Overarching goals for the primary focus areas are:

- **Injury Prevention:** Reduce the number and severity of blast-related injuries;
- **Acute Treatment:** Reduce morbidity and mortality from blast injuries and improve battlefield capabilities for treating blast injuries; and
- **Reset:** Reduce the recovery time, and increase the return-to-duty rate and quality of life for Service members with blast injuries.

Despite the many advances in research, medicine and protective equipment, there are still significant hurdles to be overcome to further improve the DoD's capability to prevent and respond to blast injury. For example, a conclusion has not yet been reached as to whether exposure to blast overpressure in the absence of a head impact event is a mechanism of mild TBI.

Figure 9-1 provides an overview of the many research directions necessary to address the complexity of blast injury. These focus areas were identified through JPC program review and other information.

Injury Prevention

Injury Mechanisms

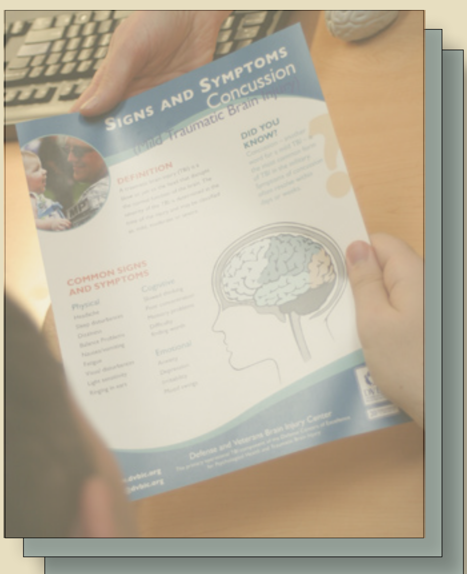
- Discover mechanisms of TBI, particularly mTBI
- Analyze effects of multiple blast exposures
- Discover mechanisms of soft and hard tissue injuries
- Discover mechanisms of sensory systems trauma
- Elucidate blast wave interactions with the body (including in conjunction with protective equipment)

Injury Models

- Develop valid computational and animal models of blast injuries
- Develop models for neural injury, particularly TBI
- Establish cross-species correlations between animal models and humans
- Complete appropriate validation for human trials

Protective Equipment

- Establish biomedically valid blast injury prevention standards for protective equipment
- Establish UBB strategies for vehicles
- Develop head protection systems to reduce injury and severity of TBI
- Develop more effective hearing and vision protection



Acute Treatment

Epidemiology

- Identify and analyze injury trends and treatment outcomes
- Direct and prioritize research to fill gaps in knowledge and capability

Diagnostics

- Develop technologies to diagnose and monitor blast injuries and injury/healing parameters during treatment
- Develop technologies to monitor blast exposure and predict the likelihood of injury
- Develop improved monitors and outcome predictors for surgery, treatment, and rehabilitation
- Develop accurate and reliable helmet-mounted and body-worn sensors for monitoring blast exposure
- Develop valid injury thresholds for use with blast exposure sensors

Hemorrhage and Blood

- Develop strategies to control non-compressible hemorrhage (e.g., from internal organ damage and bleeding)
- Develop strategies to control and counteract the cascade of injury following severe hemorrhage (e.g., coagulopathy)
- Develop replacement blood products and components
- Develop diagnostic tools for physiological and hemodynamic assessments following significant blood loss or trauma and during treatment
- Develop rapid screening technologies to help ensure safe whole blood supplies

Wound Repair and Stabilization

- Develop strategies for treating and stabilizing wounds on the battlefield, from self/buddy aid and the first responder through surgical repair and stabilization at the combat support hospital
- Develop treatment strategies to promote better wound healing and tissue regrowth
- Develop treatment strategies to reduce scar formation
- Develop treatment strategies for craniomaxillofacial injury

Figure 9-1: Blast Injury Research Directions and Focus Areas

- Develop treatments for sensory systems trauma (e.g., hearing and vision)
- Develop strategies to reduce functional sensory loss over time and to restore function

Wound Infection

- Develop strategies to prevent and treat bacterial, viral, and fungal infections
- Develop tools and practices that prevent infections and/or guide clinical wound management decisions
- Develop tools for rapid and early detection of multidrug-resistant organisms and infection
- Develop biomarkers or other molecular signatures to monitor wound healing and determine optimal treatment paths

TBI Treatment

- Develop clinical trials under the National Research Action Plan
- Develop strategies to improve early diagnosis and treatment effectiveness for PTSD and TBI
- Validate animal and computational blast injury models
- Standardize experimental apparatus and conditions for exposing animals to blast
- Develop improved clinical trial methodologies and validated tools to document treatment effects without confounding variables
- Establish whether blast exposure sensor data can be used to predict injury, particularly for mild or delayed effects
- Develop diagnostic tools and criteria for detecting TBI
- Establish biomarkers and treatment outcome measures for TBI
- Discover the mechanisms and long-term effects of TBI
- Establish the impact of pre-existing and co-occurring conditions on outcome
- Establish the relationship between multiple blast exposures and TBI
- Develop treatment and rehabilitation products
- Identify strategies to improve psychosocial impacts of living with TBI

Reset

Regenerative Medicine

- Investigate peripheral nerve injury, skin injury, scarless wound healing, vascular injury, and composite tissue allotransplantation/immunomodulation
- Investigate regeneration of nerves over long distances
- Develop improved reliability of nerve regeneration
- Develop alternatives to nerve grafts
- Develop improved re-innervation of organs and tissues
- Develop improved functional outcomes
- Develop technologies that address full-thickness burns
- Develop next-generation products that address complex architecture of the face and hands and target improvement in functional/aesthetic outcomes
- Investigate wound healing with reduced scarring
- Develop strategies for controlling inflammatory response and fibrosis in deep burn injuries
- Investigate vascular scaffolds for regrowth
- Develop alternatives to autografts
- Investigate strategies to improve the vascularization of large tissue constructs

Transplants

- Investigate strategies that reduce the consequences (adverse effects and toxicity) of long-term immunosuppressive therapy to prevent transplant rejection and improve the functioning of the transplanted tissue
- Develop strategies to improve limb and face transplant procedures
- Develop transplant strategies/technologies for smaller complex tissue units (e.g., portions of the extremities, face, or internal tissues) to restore function

Prosthetics

- Develop improved human-device interface
- Improve exteroceptive sensor integration for ease of limb function
- Improve integration of neural signals and mechanical devices for better user-intent control
- Develop strategies to improve comfort and limb health at the socket
- Investigate strategies for reducing high rejection rates of upper-extremity prostheses
- Investigate the long-term health consequences of amputation, such as heterotopic ossification (HO), reduction in bone mineral density, the development of osteoarthritis, and reduced mobility

Rehabilitation

- Improve rehabilitation of neuromusculoskeletal injuries
- Optimize rehabilitation regimens
- Develop assessment tools and outcome predictors
- Improve the human-device interface of prosthetics and orthotics
- Develop strategies for improving lost function due to burn and scar contracture
- Improve treatments for spinal cord injuries
- Investigate secondary health effects (such as osteoarthritis, HO, low back pain, fractures, and cardiovascular disease)
- Improve reintegration strategies for return-to-duty or transition to civilian life
- Improve pain management strategies at all levels of care, from the battlefield through rehabilitation

Key Initiatives in FY14

The MHS BIPSR Process

As determined by three Stakeholder meetings and three Stakeholder surveys, the MHS BIPSR process in FY14 will focus on lower extremity injuries. A focused literature review will be used to identify existing standards, relevant candidate standards, and SMEs. The goal is to identify candidate standards for consideration and assessment via the MHS BIPSR process. Additionally, a standards information repository will be developed to promote information sharing. The MHS BIPSR process will also help to identify existing gaps that require research.

Blast Exposure Monitoring

While new sensor technologies are being developed, a key aspect to be addressed in the near future is the dose-response predictive models necessary to link exposure data to injury risk. Sensor deployments are expected to expand to the garrison and training base. Improvements in data collection and analysis are also anticipated.

NATO HFM-234 Technical Activity - Environmental Toxicology of Blast Exposures: Injury Metrics, Modeling, Methods, and Standards

The HFM-234 technical team will address a wide range of topics, including physics-based modeling of animals and man in relevant blast environments, blast exposure monitoring methods and metrics, and standardized protocols for blast injury research. A program of work has been established, and planned FY14 activities include developing a dictionary of commonly used blast injury terms, developing recommendations for collecting data necessary for conducting epidemiological studies, and developing guidelines to reproduce blast exposure conditions in the laboratory.

International State-of-the-Science Meeting Series

The PCO intends to hold at least one State-of-the-Science meeting each year. The fourth meeting in the series is anticipated for 4QFY14, and the topic will be mild TBI exposure sensor thresholds. SMEs from across the DoD, other federal agencies, academia, industry and the international community will be invited to participate.

Follow-on Blast Injury Research Planning Meeting

The first DoD Blast Injury Research Planning Meeting was held at Fort Detrick, Maryland, in July 2006 to summarize the state of the science for blast injury, and to map out gaps in both the then-current and future DoD investment in blast injury research. The PCO has initiated an action to organize a DoD Blast Injury Research Planning Meeting to assess what has been accomplished, what is underway or planned, and what blast injury research gaps remain.

PCO Coordination

In carrying out its research coordination responsibilities, the DoD Blast Injury Research Program Coordinating Office will continue to facilitate collaborative research among laboratories of the DoD, other Federal agencies, academia, industry, and the international communities.

These research collaborations will enable the DoD to leverage resources and take full advantage of the body of knowledge residing within and outside of the DoD to solve complex blast injury problems, and to establish and maintain a fully coordinated DoD Blast Injury Research Program, as envisioned by Congress and directed by the Secretary of Defense.

Acronyms

3D	Three-Dimensional
4Q	Fourth Quarter
AAT	Abdominal Aortic Tourniquet
ACH	Advanced Combat Helmet
AFIRM	Armed Forces Institute of Regenerative Medicine
AIS	Abbreviated Injury Scale
ANAM	Automated Neuropsychological Assessment Metrics
ANSW2R	Allied NeuroSensory Warrior Related Research
APL	Animal Placement Location
ARCS	Advanced Requirements for Crew Safety
ARDEC	US Army Armament Research, Development and Engineering Center
ARL	US Army Research Laboratory
ARWG	Auditory Research Working Group
ASA(ALT)	Assistant Secretary of the Army for Acquisition, Logistics, and Technology
ASBREM	Armed Services Biomedical Research Evaluation and Management
ASD(HA)	Assistant Secretary of Defense for Health Affairs
ASD(R&E)	Assistant Secretary of Defense for Research and Engineering
ATD	Anthropomorphic Test Device
ATEC	Army Test and Evaluation Command
BADER	Bridging Advanced Developments for Exceptional Rehabilitation
BBB	Blood-Brain Barrier
BCT	Brigade Combat Team
BECIR	Blast Exposure and Concussion Incident Report
BIPSR	Blast Injury Prevention Standards Recommendation
BLAST	Blast Load Assessment –Sense and Test
bTBI	Blast-related TBI
BUMED	The US Navy Bureau of Medicine and Surgery
BWH	Brigham and Women's Hospital
Ca++	Calcium Ion
CBI	Combat Blast Injury
CBI-AOWG	Complex Battle Injury Action Officer Working Group
CBRN	Chemical, Biological, Radiological and Nuclear
CCC	Combat Casualty Care
CCCRP	Combat Casualty Care Research Program
CCF	Cleveland Clinic Foundation
CDE	Common Data Element
CENC	Chronic Effects of Neurotrauma Consortium
CENTCOM	US Central Command
CHHP	Comprehensive Hearing Health Program
CIDNE	Combat Information Data Network Exchange
CJCS	Chairman of the Joint Chiefs of Staff
CNRM	Center for Neuroscience and Regenerative Medicine
COCOM	Combatant Commanders
CoEs	Centers of Excellence
COT	Coagulopathy of Trauma
CPG	Clinical Practice Guidelines
CRADA	Cooperative Research and Development Agreement
CRM	Clinical and Rehabilitative Medicine
CSI	Congressional Special Interest
CTE	Chronic Traumatic Encephalopathy
DARPA	Defense Advanced Research Projects Agency
DCBI	Dismounted Complex Blast Injury
DCoE	Defense Centers of Excellence
DCR	Damage Control Resuscitation
DCSSA	Central Army Health Service Directorate
DRDC	Defence Research and Development Canada
DVBIC	Defense and Veterans Brain Injury Center
DVEIVR	Defense and Veterans Eye Injury and Vision Registry

DFP	Deployable Force Protection
DHP	Defense Health Program
DoD	Department of Defense
DoDD	DoD Directive
DoDI	DoD Instruction
DOTMLPF-P	Doctrine, Organization, Training, Materiel, Leader Development, Personnel, Facility, and Policy
DSTI	Deep Soft Tissue Infection
DSTL	Defence Science and Technology Laboratory
DTI	Diffusion Tensor Imaging
DTRA	Defense Threat Reduction Agency
EA	Executive Agent
EACE	Extremity Trauma and Amputation Center of Excellence
ECH	Enhanced Combat Helmet
e-HR	Electronic Health Record
EUE	End User Evaluation
FDA	US Food and Drug Administration
FITBIR	Federal Interagency Traumatic Brain Injury Research
fMRI	Functional Magnetic Resonance Imaging
FY	Fiscal Year
Gen I	Generation I
Gen II	Generation II
GPK	Gunner Protection Kit
GU	Genitourinary
HBO2	Hyperbaric Oxygen
HCE	Hearing Center of Excellence
HCWG	DoD Hearing Conservation Working Group
HEADS	Second Generation (Gen II) HMSS
HFCP	High Fidelity Computational Physics
HFM	Human Factors and Medicine
HHA	Health Hazard Assessment
HHS	US Department of Health and Human Services
HIC	Head Injury Criteria
HIT	Human Injury Treatment
HMMWV	High Mobility Multipurpose Wheeled Vehicle
HMSS	Helmet-Mounted Sensor System
HO	Heterotopic Ossification
HRED	Human Research and Engineering Directorate
HSTM	Human Surrogate Torso Model
I-BESS	Integrated Blast Effect Sensor Suite
ICD	International Classification of Diseases
ICP	Intracranial Pressure
IEDs	Improvised Explosive Devices
IIPTs	Integrating Integrated Product Teams
IOM	Institute of Medicine
IPR	In-Progress Review
IPT	Integrated Product Team
IRB	Institutional Review Board
ISN	Institute for Soldier Nanotechnologies
JHASIR	Joint Hearing Loss and Auditory System Injury
JHU/APL	Johns Hopkins University Applied Physics Laboratory
JIEDDO	Joint Improvised Explosive Device Defeat Organization
JPC5	Joint Program Committee for Military Operational Medicine
JPC6	Joint Program Committee for Combat Casualty Care
JPCs	Joint Program Committees
JTAPIC	Joint Trauma Analysis and Prevention of Injury in Combat
JTCGs	Joint Technology Coordinating Groups
JTG	Joint Technical Group
JTS	Joint Trauma System
KIA	Killed In Action
LAV	Light Armored Vehicle
LFT&E	Live Fire Test and Evaluation
LOC	Loss of Consciousness
LS	Limb Salvage
LTA	Limited Technical Assessment
LTC	Lieutenant Colonel
M&S	Modeling and Simulation
MACE	Military Acute Concussion Evaluation
MBPS	Modular Ballistic Protection System
MCEP	Military Combat Eye Protection
MCIS	Military Combat Injury Scale
MCSC	Marine Corps System Command
MCWL	Marine Corps Warfighting Laboratory

MFIS	Military Functional Incapacity Scale
MHS	Military Health System
MIDRP	Military Infectious Diseases Research Program
MIL-STD	Military Standard
MOM	Military Operational Medicine
MOMRP	MOM Research Program
MRAP	Mine Resistant Ambush Protected
MRI	Magnetic Resonance Imaging
mTBI	mild Traumatic Brain Injury
MTF	Military Treatment Facility
MUPS	Medically Unexplained Physical Symptoms
NATO	North Atlantic Treaty Organization
NHRC	Naval Health Research Center
NIH	National Institutes of Health
NIPR	Non-Secure Internet Protocol
NMRC	Naval Medical Research Center
NRAP	National Research Action Plan
NSRDEC	Natick Soldier Research, Development and Engineering Center
NSWCCD	Naval Surface Warfare Center Carderock Division
nWRS	Normalized WRS
OASD(HA)	Office of the Assistant Secretary of Defense for Health Affairs
OASD(R&E)	Office of the Assistant Secretary of Defense for Research and Engineering
OEF	Operation Enduring Freedom
OIF	Operation Iraqi Freedom
ONR	Office of Naval Research
OSD	Office of the Secretary of Defense
OTSG	Office of the Surgeon General
PA&E	Program Analysis and Evaluation
PB	President's Budget
PBI	Primary Blast Injury
PCO	Program Coordinating Office
PCS	Post-concussion Syndrome
PEO	Program Executive Office
PH/TBI	Psychological Health and Traumatic Brain Injury
PIHL	Pharmaceutical Interventions for Hearing Loss
PM	Project Manager
PMO	Program Management Office
PM SPE	Product Manager Soldier Protective Equipment
PPE	Personal Protective Equipment
PPS	Pelvic Protection System
PRORP	Peer Reviewed Orthopaedic Research Program
PTB	Photochemical Tissue Bonding
PTSD	Post-Traumatic Stress Disorder
PREVENT	Preventing Violent Explosive Neurologic Trauma
QOL	Quality of Life
R&A	Review and Assessment
R&D	Research and Development
RAC	Research Advisory Committee
RD&E	Research, Development, and Evaluation
RDT&E	Research, Development, Test, and Evaluation
RFIs	Requests for Information
RMI	Reflectance Medical, Inc
RTG	Research Task Group
S&T	Science and Technology
SBIR	Small Business Innovation Research
SECAF	Secretary of Air Force
SECARMY	Secretary of Army
SECNAY	Secretary of Navy
SCI	Spinal Cord Injury
SCIRP	Spinal Cord Injury Research Program
SHIELD	Shock Impact & Explosive Limits Dosimetry
SIPR	Secure Internet Protocol Router
SLAD	Survivability/Lethality Analysis Directorate
SME	Subject Matter Expert
SMs	Service Members
SNP	Single Nucleotide Polymorphism
SPS	Soldier Protection System
SRC	Standard Rehabilitation Care
SSTI	Skin and Soft Tissue Infections
STO	Science & Technology Organization
STTC	Simulation and Training Technology Center
T&E	Test and Evaluation
TAP	Technical Activity Proposal

TARDEC	Tank Automotive Research, Development and Engineering Center
TATRC	Telemedicine and Advanced Technology Research Center
TBI	Traumatic Brain Injury
TBIMS	Traumatic Brain Injury Model Systems Centers Program
TCCC	Tactical Combat Casualty Care
TCM-Live	TRADOC Capability Manager-Live
TECD	Technology Enabled Capabilities Demonstration
TGI	Toxic Fire Gas Inhalation
TR	Technical Report
TRADOC	Training and Doctrine Command
TSWG	Technical Support Working Group
TT	Technical Team
TTPs	Tactics, Techniques, and Procedures
UBB	Under Body Blast
UBM	Under Body Methodology
UHMWPE	Ultra-high Molecular Weight Polyethylene
UNL	University of Nebraska-Lincoln
USAARL	US Army Aeromedical Research Laboratory
USAISR	US Army Institute of Surgical Research
USAMEDCOM	US Army Medical Command
USAMMDA	US Army Medical Materiel Development Activity
USAMRMC	US Army Medical Research and Materiel Command
USD (AT&L)	UnderSecretary of Defense for Acquisition, Technology, and Logistics
USFOR-A	US Forces Afghanistan
USSOC	United States Special Operations Command
USUHS	Uniformed Services University of the Health Sciences
VA	US Department of Veterans Affairs
VCE	Vision Center of Excellence
VML	Volumetric Loss
VRSC	Vehicle Response Survivability Curves
V-Xtract	Vehicle Extrication Trainer
WIA	Wounded In Action
WIAMan	Warrior Injury Assessment Manikin
WMRD	Weapons and Materials Research Directorate
WRAIR	Walter Reed Army Institute of Research
WRNMMC	Walter Reed National Military Medical Center
WRS	Weighted Raw Score

Department of Defense

DIRECTIVE

NUMBER 6025.21E
July 5, 2006

USD(AT&L)

SUBJECT: Medical Research for Prevention, Mitigation, and Treatment of Blast Injuries

References: (a) Section 256 of Public Law 109-163, "National Defense Authorization Act for Fiscal Year 2006"[1]
(b) DoD Directive 5101.1, "DoD Executive Agent," September 3, 2002
(c) DoD Directive 5134.3, "Director of Defense Research and Engineering (DDR&E),"November 3, 2003
(d) DoD Directive 5025.1, "DoD Directives System," March 2005
(e) through (g), see Enclosure 1

1. PURPOSE

This Directive:

1.1. Implements Reference (a) by establishing policy and assigning responsibilities governing coordination and management of medical research efforts and DoD programs related to prevention, mitigation, and treatment of blast injuries.

1.2. Designates the Secretary of the Army, in compliance with Reference (a) and consistent with Reference (b), as the DoD Executive Agent (DoD EA) for Medical Research for Prevention, Mitigation, and Treatment of Blast Injuries according to Reference (b).

1.3. Establishes the Armed Services Biomedical Research Evaluation and Management (ASBREM) Committee. The ASBREM Committee serves to facilitate coordination and prevent unnecessary duplication of effort within DoD biomedical research and development and associated enabling research areas, to include serving as the forum for implementation of subsections (d) and (g) of Reference (a).

[1] Federal legislative information is available through the Library of Congress THOMAS site, http://thomas.loc.gov.

2. APPLICABILITY

This Directive applies to:

2.1. The Office of the Secretary of Defense, the Military Departments, the Chairman of the Joint Chiefs of Staff, the Combatant Commands, the Office of the Inspector General of the Department of Defense, the Defense Agencies, the DoD Field Activities, and all other organizational entities in the Department of Defense (hereafter collectively referred to as the "DoD Components").

2.2. Medical and associated enabling research supported by any DoD Component for prevention, mitigation, and treatment of blast injuries.

3. DEFINITIONS

As used in this Directive, the following terms are defined as follows:

3.1. Blast Injury. Injury that occurs as the result of the detonation of high explosives, including vehicle-borne and person-borne explosive devices, rocket-propelled grenades, and improvised explosive devices. The blast injury taxonomy is provided at Enclosure 2.

3.2. Research. Any systematic investigation, including research, development, testing, and evaluation (RDT&E), designed to develop or contribute to general knowledge.

4. POLICY

It is DoD policy that:

4.1. DoD research related to blast injury prevention, mitigation, and treatment will be coordinated and managed by a DoD EA to meet the requirements, objectives, and standards of the DoD Military Health System as identified by the Under Secretary of Defense for Personnel and Readiness (USD(P&R)) and the unique combat casualty care requirements of the DoD Components.

4.2. Relevant research shall take maximum advantage of the scientific and technical capabilities of industry, academia, DoD Components, and other Federal Agencies.

4.3. The ASBREM Committee will be the venue for joint and cross-Service coordination specified by Reference (a).

4.4. DoD Components will gather and share medical information related to the efficacy of personal protective equipment and of vehicular equipment designed to protect against blast injury.

5. RESPONSIBILITIES AND FUNCTIONS

5.1. The Director of Defense Research and Engineering (DDR&E), under the Under Secretary of Defense for Acquisition, Technology and Logistics, according to DoD Directive 5134.3 (Reference (c)), shall:

5.1.1. Plan, program, and execute the functions and reports mandated for the DDR&E by Reference (a).

5.1.2. Have the authority to publish DoD Issuances consistent with Reference (d) for implementation of this Directive.

5.1.3. Establish, as needed, procedures to ensure that new technology developed under this Directive is effectively transitioned and integrated into systems and subsystems and transferred to and firmly under the control of the DoD Components.

5.1.4. Chair the ASBREM Committee to coordinate DoD biomedical research (see Enclosure 3 for additional detail), and employ that entity to facilitate the DoD EA's coordination and oversight of blast-injury research as specified in Reference (a).

5.1.5. Serve as the final approving authority for DoD blast-injury research programs.

5.1.6. Oversee the functions of the DoD EA and conduct/report on related periodic assessments (per Reference (a)).

5.2. The Assistant Secretary of Defense for Health Affairs (ASD(HA)), under the USD(P&R), shall:

5.2.1. Assist the DDR&E, the DoD EA, and the Director, Joint Improvised Explosive Devices Defeat Organization (JIEDDO), with identification of related operational and research needs, assessment of relevant research efforts, and coordination of planning to resolve capability gaps through focused research efforts.

5.2.2. Be the approving authority for Military Health System prevention and treatment standards developed and proposed by the DoD EA.

5.2.3. Appoint appropriate representatives to related coordinating boards or committees established by the DoD EA.

5.2.4. Ensure that the information systems capabilities of the Military Health System support the DoD EA and the functions specified by this Directive.

5.2.5. Serve as Co-chair of the ASBREM Committee. (See Enclosure 3 for additional detail.)

5.3. The Secretary of the Army is hereby designated as the DoD EA for Medical Research for Prevention, Mitigation, and Treatment of Blast Injuries, consistent with Reference (a), to coordinate and manage relevant DoD research efforts and programs, and in that role shall:

5.3.1. Give full consideration to the Research and Engineering (R&E) needs of the DoD Components and the Director, JIEDDO, addressing those needs/requirements by:

5.3.1.1. Maintaining a DoD technology base for medical research related to blast injuries and based on the DDR&E-approved program for the DoD Components.

5.3.1.2. Performing programming and budgeting actions for all blast-injury research to maintain the R&E programs based on DDR&E-approved priorities of the DoD Components.

5.3.1.3. Programming and budgeting for blast-injury research based on analysis and prioritization of needs of the DoD Components, consistent with paragraph 5.1 of this Directive.

5.3.1.4. Executing the approved DoD blast-injury research program consistent with DoD guidance and availability of annual congressional appropriations.

5.3.2. Provide medical recommendations with regard to blast-injury prevention, mitigation, and treatment standards to be approved by the ASD(HA).

5.3.3. Coordinate DoD blast-injury-research issues with the staffs of the DDR&E, the ASD(HA), and the Director, JIEDDO.

5.3.4. Support the development, maintenance, and usage of a joint database for collection, analysis, and sharing of information gathered or developed by the DoD Components related to the efficacy of theater personal protective equipment (including body armor, helmets, and eyewear) and vehicular equipment designed to protect against blast injury.

5.3.5. Appoint a medical general or flag officer representative to the ASBREM Committee.

5.3.6. Ensure that information is shared as broadly as possible except where limited by law, policy, or security classification and that data assets produced as a result of the assigned responsibilities are visible, accessible, and understandable to the rest of the Department as appropriate and in accordance with Reference (e).

5.4. The Secretaries of the Navy and the Air Force shall:

5.4.1. Forward their respective approved blast-injury medical R&E requirements to the DoD EA for consideration and integration.

5.4.2. Appoint medical general or flag officer representatives to the ASBREM Committee and appoint representatives to any other coordination, oversight, or assessment board established by DDR&E or the DoD EA.

5.4.3. Coordinate with other DoD Components on the assignment of Joint Technical Staff Officers to Army medical research entities, research and acquisition organizations, or installations for coordination of research programming and execution needs pertaining to their Component.

5.4.4. Provide an appropriate system for identification, verification, prioritization, and headquarters-level approval of their respective blast-injury R&E requirements before submission to the DoD EA.

5.5. The President of the Uniformed Services University of the Health Sciences (USUHS), under the ASD(HA) and USD(P&R), shall:

5.5.1. Ensure that education relating to blast-injury prevention, mitigation, and treatment is included in the USUHS medical and continuing education curriculum and programs.

5.5.2. Appoint a representative to any coordination, oversight, or assessment board established by DDR&E or the DoD EA.

5.6. The Chairman of the Joint Chiefs of Staff shall:

5.6.1. Coordinate input to the DoD EA and ensure integration of the requirements processes of the Joint Capabilities Integration and Development System[2] with the processes employed under this Directive.

5.6.2. Appoint a relevant senior representative to the ASBREM Committee.

5.6.3. Appoint representatives to organizational entities of the ASBREM Committee and to any other coordination, oversight, or assessment board established by DDR&E or the DoD EA.

5.7. The Commander, U.S. Special Operations Command shall establish procedures and processes for coordination of relevant Defense Major Force Program 11 activities with those planned, programmed, and executed by the DoD EA and shall also:

5.7.1. Forward that command's approved blast-injury R&E requirements for consideration and integration to the DoD EA.

5.7.2. Appoint representatives to organizational entities of the ASBREM Committee, as appropriate, and to any other coordination, oversight, or assessment board established by DDR&E or the DoD EA.

[2] CJCSI 3170.01E, "Joint Capabilities Integration and Development System," May 11, 2005, is available at http://www.dtic.mil/cjcs_directives/cjcs/instructions.htm.

5.7.3. Coordinate with the command on the assignment of Joint Technical Staff Officers to Army medical research entities, research and acquisition organizations, or installations for coordination of research programming and execution needs.

5.7.4. Provide an appropriate system for identification, verification, and headquarters-level approval of that command's blast-injury R&E requirements before submission to the DoD EA.

5.8. The Director, JIEDDO, consistent with Reference (f), shall:

5.8.1. Support development, maintenance, and usage of a joint database for collection, analysis, and sharing of information gathered or developed by DoD Components related to the efficacy of theater personal protective equipment (e.g., body armor, helmets, and eyewear) and vehicular equipment designed to protect against blast-injury.

5.8.2. Appoint representatives to organizational entities of the ASBREM Committee, as appropriate, and to any other coordination, oversight, or assessment board established by DDR&E or the DoD EA.

5.8.3. Assist the DoD EA, the DDR&E, and the ASD(HA) with identification of related operational and research needs, assessment of relevant research efforts, and coordination of planning to resolve capability gaps through focused research efforts.

6. AUTHORITY

The DoD EA identified by this Directive is hereby delegated authority to do the following:

6.1. Obtain reports and information, consistent with the policies and criteria of DoD Directive 8910.1 (Reference (g)), as necessary, to carry out assigned responsibilities and functions.

6.2. Communicate directly with the Heads of the DoD Components, as necessary, to carry out assigned functions, including the transmission of requests for advice and assistance. Communications to the Military Departments shall be transmitted through the Secretaries of the Military Departments, their designees, or as otherwise provided in law or directed by the Secretary of Defense in other DoD issuances. Communications to the Commanders of the Combatant Commands shall normally be transmitted through the Chairman of the Joint Chiefs of Staff.

6.3. Communicate with other Federal Agencies, representatives of the Legislative Branch, members of the public, and representatives of foreign governments, as appropriate, in carrying out assigned responsibilities and functions. Communications with representatives of the Legislative Branch shall be coordinated with the Assistant Secretary of Defense for Legislative Affairs and the Under Secretary of Defense (Comptroller)/Chief Financial Officer, as appropriate, and be consistent with the DoD Legislative Program.

7. EFFECTIVE DATE

This Directive is effective immediately.

Gordon England

Enclosures – 3
E1. References, continued
E2. Taxonomy of Injuries from Explosive Devices
E3. ASBREM Committee

E1. ENCLOSURE 1

REFERENCES, continued

(e) DoD Directive 8320.2, "Data Sharing in a Net-Centric Department of Defense," December 2, 2004
(f) DoD Directive 2000.19E, "Joint Improved Explosive Device Defeat Organization (JIEDDO)," February 14, 2006
(g) DoD Directive 8910.1, "Management and Control of Information Requirements," June 11, 1993

E2. ENCLOSURE 2

TAXONOMY OF INJURIES FROM EXPLOSIVE DEVICES

E2.1.1. Primary. Blast overpressure injury resulting in direct tissue damage from the shock wave coupling into the body.

E2.1.2. Secondary. Injury produced by primary fragments originating from the exploding device (preformed and natural (unformed) casing fragments, and other projectiles deliberately introduced into the device to enhance the fragment threat); and secondary fragments, which are projectiles from the environment (debris, vehicular metal, etc.).

E2.1.3. Tertiary. Displacement of the body or part of body by the blast overpressure causing acceleration/deceleration to the body or its parts, which may subsequently strike hard objects causing typical blunt injury (translational injury), avulsion (separation) of limbs, stripping of soft tissues, skin speckling with explosive product residue and building structural collapse with crush and blunt injuries, and crush syndrome development.

E2.1.4. Quaternary. Other "explosive products" effects – heat (radiant and convective), and toxic, toxidromes from fuel, metals, etc. – causing burn and inhalation injury.

E2.1.5. Quinary. Clinical consequences of "post detonation environmental contaminants" including bacteria (deliberate and commensal, with or without sepsis), radiation (dirty bombs), tissue reactions to fuel, metals, etc.

E3. ENCLOSURE 3

ASBREM COMMITTEE

E3.1. ORGANIZATION AND MANAGEMENT

The ASBREM Committee shall:

E3.1.1. Consist of general and flag officer and Senior Executive representatives of relevant DoD Components.

E3.1.1.1. Standing members include relevant senior officials of the DoD Components. At a minimum, the DDR&E, the ASD(HA), and representatives of the DoD Components' Acquisition Executives.

E3.1.1.2. The standing membership may be expanded by invitation of the Chair when issues require senior-level coordination outside the scope of the principal members. Such invited members will include a medical flag officer from the Joint Staff, a designee of the DoD EA specified by this Directive, the Director, JIEDDO, the Director of the Combating Terrorism Technology Support Office, and others as appropriate.

E3.1.2. Be chaired by the DDR&E or Senior Executive designee and co-chaired by the ASD(HA) or Senior Executive designee.

E3.1.3. Convene at the discretion of the Chair and Co-chair.

E3.1.4. Invite the attendance of observers from DoD boards, committees or offices, or from other Federal Agencies with interests in the deliberations of the ASBREM Committee.

E3.1.5. Establish subcommittees, Joint Technology Coordinating Groups, and other entities, as required, to facilitate and execute committee business.

E3.2. FUNCTIONS

The ASBREM Committee shall:

E3.2.1. Review medical RDT&E program plans and accomplishments for quality, relevance, and responsiveness to military operational needs, the needs of the Military Health System, and the goals of Force Health Protection.

E3.2.2. Review program plans and budgets in support of the various guidance documents relevant to National Security and to the missions and functions of the Department of Defense.

E3.2.3. Provide coordination, recommendations, and support to DoD EA(s) and other DoD officials as requested, directed, or otherwise appropriate.

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