ANNUAL REPORT TO CONGRESS

Efforts and Programs of the Department of Defense Relating to the Prevention, Mitigation, and Treatment of Blast Injuries

January 2008

Executive Summary

Section 256 of the National Defense Authorization Act (NDAA) for Fiscal Year 2006, Public Law 109-163, provides that the Secretary of Defense shall submit a report on the efforts and programs of the Department of Defense (DoD) relating to the prevention, mitigation, and treatment of blast injuries. The report is to include the following elements of information:

1. A description of the activities undertaken under this section during the 2 years preceding the report to improve the prevention, mitigation, and treatment of blast injuries.
2. A consolidated budget presentation for DoD biomedical research efforts and studies related to blast injury for the 2 fiscal years (FY) following the year of the report.
3. A description of any gaps in the capabilities of the Department and any plans to address such gaps within biomedical research related to blast injury, blast injury diagnostic and treatment programs, and blast injury tracking and monitoring activities.
4. A description of collaboration, if any, with other departments and agencies of the federal government and with other countries during the 2 years preceding the report in efforts for the prevention, mitigation, and treatment of blast injuries.
5. A description of any efforts during the 2 years preceding the report to disseminate findings on the diagnosis and treatment of blast injuries through civilian and military research and medical communities.
6. A description of the status of efforts during the 2 years preceding the report to incorporate blast injury effects data into appropriate programs of the DoD and into the development of comprehensive force protection systems that are effective in confronting blast, ballistic, and fire threats.

Appendix B shows the crosswalk between the required information from Section 256 of the NDAA for FY 2006, Public Law 109-163 and the FY 2007 Annual Report.

As presented in this report, during the previous 2 years the DoD has made significant progress in coordinating and advancing medical research programs focused on preventing, mitigating, and treating blast-related injuries. (See Appendix C, Taxonomy of Injuries from Explosive Devices.) The blast program coordinating office, on behalf of the Executive Agent, has developed a consolidated budget for FY 2008, 2009, and 2010 for DoD biomedical research efforts and studies that address validated knowledge gaps and capability needs. Numerous collaborative efforts with other departments and agencies of the federal government and with other countries have enabled the Department to optimize scientific growth and productivity in this area, as well as resource sharing. The Department's efforts to disseminate findings on the prevention, diagnosis, and treatment of blast injuries, and on the rehabilitation of blast-injured service members through civilian and military research and medical communities have resulted in significant improvements in the way we prevent blast injuries and in the way we care for blast-injured service members. Finally, the Department has worked very hard to incorporate blast injury effects data into "end user" programs focused on the development and implementation of comprehensive force health protection systems.

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Chapter 1
Introduction

Background. Section 256 of the National Defense Authorization Act for Fiscal Year 2006, Public Law 109-163, directed the Secretary of Defense to designate an Executive Agent (EA) to coordinate and manage the medical research efforts and programs of the Department of Defense (DoD) relating to the prevention, mitigation, and treatment of blast injuries. (See Appendix B, Crosswalk Between Required Information and the FY 2007 Annual Report.) The DoD issued DoD Directive (DoDD) 6025.21E "Medical Research for Prevention, Mitigation, and Treatment of Blast Injuries on July 5, 2006. The Directive designates the Secretary of the Army (SECARMY) as the DoD EA, assigns responsibilities governing coordination and management of the blast injury research program, and directs the Armed Services Biomedical Research Evaluation and Management (ASBREM) Committee to facilitate coordination and prevent unnecessary duplication of effort within DoD biomedical research and development and associated enabling research areas. The SECARMY delegated authority and assigned responsibility to execute EA responsibilities to the Assistant Secretary of the Army (Acquisition, Logistics, and Technology) [ASA(ALT)] on January 4, 2007, and ASA(ALT) delegated authority and assigned program responsibility to the Commander, U.S. Army Medical Command (USAMEDCOM), on January 16, 2007. The Commander USAMEDCOM established the Blast Injury Research Program Coordinating Office (PCO) at the U.S. Army Medical Research and Materiel Command (USAMRMC) in a charter dated, June 5, 2007. (See Chapter 2, DoD Blast Injury Research Program Coordinating Office.)

Defining "Blast Injury." The term "Blast Injury" creates much confusion. Simply stated, "blast injury" includes the entire spectrum of injuries that can result from exposure to an explosion. The DoD Blast Injury Research Program uses the Taxonomy of Injuries from Explosive Devices as defined in DoDD 6025.21E to characterize such injuries. This taxonomy assigns blast injuries to five categories—Primary, Secondary, Tertiary, Quaternary, and Quinary—based on the mechanism 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 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 front propel fragments and debris against the body and cause blunt and penetrating injuries. The strong winds and pressure gradients can also accelerate the body and cause the same types of blunt force injuries that would occur in a car crash or a fall. These are known as tertiary blast injuries. Quaternary blast injuries are the result of other explosive products, such as heat, light, and toxic gases, that can cause burns, blindness, and inhalation injuries. Finally, quinary blast injuries refer to the clinical consequences of "post-detonation environmental contaminants" including bacteria, radiation (dirty bombs), and tissue reactions to fuel and metals. (See Appendix C, Taxonomy of Injuries from Explosive Devices.)

Key Program Features. This new DoD program is addressing critical medical research gaps for blast-related injuries and will fully address traumatic brain injury (TBI) and post-traumatic stress disorder (PTSD) research. The program is leveraging new extramural blast 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 new concept of "reset" for warfighters in redeployment, ensuring return-to-duty (RTD) readiness (or healthy return to civilian life for citizen Soldiers). 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 the DoD programs.

Key Research Topics. The blast injury research program is focused on filling gaps in the blast injury knowledge base. Key research topics by program area include:

- **Injury Prevention.** Determining if a link exists between primary blast and mild traumatic brain injury (mTBI); developing drugs to prevent and treat blast-related hearing loss; analyzing combat injuries and PPE performance; developing multi-effect blast injury models to improve protective equipment; and developing strategies that enhance psychological resilience and prevent PTSD.
- **Acute Treatment.** Developing diagnostics and neuroprotectant drugs for TBI; developing hemorrhage control and blood products; developing treatments for psychological trauma; developing medical procedures for damage-control orthopedics; and devising innovative strategies for improved pain management.
- **Reset.** Advancing tissue engineering and prosthetics; improving recovery of function; and developing RTD standards.

Key Program Accomplishments. The Blast Injury Research Program has achieved great success during the past 2 years as illustrated by key accomplishments reported by DoD organizations, other federal agencies, academia, and industry. Chapter 4 provides a comprehensive listing of these key blast injury research accomplishments. Three examples of key accomplishments that are having a global impact on the prevention, mitigation, and treatment of blast injuries are the establishment of the Joint Trauma Analysis and Prevention of Injury in Combat (JTAPIC) Project, the performance of baseline neuropsychological assessments of deploying Soldiers, and the fielding of the battlemind training program.

- **JTAPIC.** The JTAPIC Project is a partnership among the intelligence, operational, materiel, and medical communities with a common goal to collect, integrate, and analyze injury and operational data. These analyses improve our understanding of our vulnerabilities to threats and enable the development of improved tactics, techniques, and procedures and materiel solutions that will prevent or mitigate blast-related injuries. The JTAPIC partners include the U.S. Army National Ground Intelligence Center, Anti-Armor Task Force, Office of the Armed Forces Medical Examiner, U.S. Army Project Manager Soldier Equipment, U.S. Army Research Laboratory (ARL), U.S. Army Aeromedical Research Laboratory (USAARL), U.S. Army Institute of Surgical Research, Naval Health Research Center (NHRC), Marine Corps Systems Command (MARCORSYSCOM), and the Air Force Surgeon General's Office. Although still in its infancy, the JTAPIC Project has already made a difference in the way we protect our warfighters from blast-related injuries. For example, the Project has established an effective, near-real time process for collecting and analyzing data from blast-related combat incidents. Using this process and sophisticated fragment analysis procedures, the Project was able to confirm the presence of prominent threat weapons of interest to the intelligence community. Using incident, injury, and virtual autopsy data, the Project was able to identify potential vulnerabilities in operational procedures and to rapidly convey those vulnerabilities to commanders in theater. The JTAPIC Project has provided actionable information to combat vehicle Program Managers (PMs) that has led to the modification of vehicle equipment, such as seats designed to prevent or mitigate blast-related injuries. The Project is currently analyzing performance data related to specific modifications to the up-armored high-mobility, multipurpose wheeled vehicles (HMMWV or Humvee) to determine the effectiveness of those modifications. Finally, the JTAPIC Project has begun to collect damaged PPE, such as body armor and combat helmets, for analyses that will provide PPE developers with the information they need to develop improved protection systems.
- **Neuropsychological Assessment Baselines.** The Army has begun performing baseline neuropsychological assessments of deploying Soldiers using the Automated Neuropsychological Assessment Metrics (ANAM). These baseline neuropsychological data may help make it possible to identify any neuropsychological changes that may occur during deployment. As of September 24, 2007, 12,235 Soldiers had taken the ANAM prior to deploying (101st Airborne

Division, 1st Armored Division, and 45th Infantry Brigade Combat Team, Oklahoma City, Oklahoma).

- **Battlemind Training.** USAMRMC neuropsychology researchers developed and are fielding and validating a new training program, Battlemind Training, to help Soldiers cope with the stresses and strains of deployment and ease the transition from a combat environment to home. Battlemind refers to a Soldier's inner strength to face fear and adversity in combat, with courage. Battlemind training teaches Soldiers to use this inner strength to help them transition. This training is being integrated into the Army Deployment Cycle Support program. The Battlemind Training I module has been incorporated into the Army's Deployment Cycle Support Contingency Plan, and the Battlemind Training II module has been incorporated into the post-deployment health re-assessment process as well.

Chapter 2
DoD Blast Injury Research Program Coordinating Office

Background. The Commander USAMEDCOM established the Blast Injury Research PCO at the USAMRMC in a charter dated June 5, 2007. The mission of the PCO is to assist the DoD EA in fulfilling his responsibilities and functions in accordance with DoDD 6025.21E by coordinating and managing relevant DoD medical research efforts and programs related to the prevention, mitigation, and treatment of blast injuries.

Why a coordinated program? The DoD medical research community has been conducting medical research on blast-related injuries for decades. These decades of research have produced tremendous advances in battlefield medicine that are responsible for saving the lives of many blast-injured service members on today's battlefields. This research has also produced biomedically valid blast injury prediction models and performance standards that serve as the basis for crew and personal protection system designs, as occupational exposure standards for blast-producing weapon systems, and as survivability assessment tools and metrics for combat vehicle crew survivability assessments. In addition to DoD contributions to solving blast injury problems, researchers in academia and industry have also made significant contributions to the study of blast injury prevention, mitigation, and treatment. The DoD Blast Injury Research Program will take full advantage of the body of knowledge and expertise that resides both within and outside of the DoD to solve complex blast injury problems. Specific examples are provided in Chapter 5, Key Components of the Blast Injury Research Program.

Blast Injury Research Program Coordinating Office Accomplishments. Since its inception, the PCO has worked hard to establish and manage a coordinated blast injury research program. The following are examples of key accomplishments that have contributed to the success of the Program:

1. **Identification of Blast Injury Research Knowledge Gaps.** The PCO organized a DoD blast injury research planning meeting in July 2006 to assess the state of the science and to identify knowledge gaps in blast injury research. This meeting had wide representation from across the DoD, other federal agencies, academia, and industry. The gaps identified include: determining if a link exists between primary blast and mTBI; developing drugs to prevent and treat blast-related hearing loss; analyzing combat injuries and PPE performance; developing multi-effect blast injury models to improve protective equipment; developing strategies that enhance psychological resilience and prevent PTSD; developing diagnostics and neuroprotectant drugs for TBI; developing hemorrhage control and blood products; developing treatments for psychological trauma; developing medical procedures for damage control orthopedics; devising innovative strategies for improved pain management; advancing tissue engineering and prosthetics; and developing RTD standards. Many of these gaps were validated during the Congressionally Directed Medical Research Programs (CDMRP) PTSD/TBI stakeholders and vision setting meetings described in Chapter 5. The PCO has used these gaps to develop a prioritized listing of Program funding requirements. As funds become available, the PCO will solicit research proposals that address these key gaps.

2. **Research Program Management Taxonomy.** The PCO established a simplified research program management taxonomy that includes three main categories of blast injury research: Injury Prevention, Acute Treatment, and Reset.

   - *Injury Prevention* mitigates the risk of blast injuries by providing medically based design guidelines and performance standards for individual and crew protection systems, by providing comprehensive injury surveillance systems that link injury, operational, and protection system performance data, by developing tools to identify individual susceptibility to injury, and by developing individual resilience training to mitigate or prevent injuries. (See Chapter 4 for a list of key Injury Prevention accomplishments.)

- *Acute Treatment* mitigates injury by providing acute and definitive treatment across the spectrum of blast-related injuries through improved diagnostics, health care provider training, wound care, and medical treatment outcomes analysis. (See Chapter 4 for a list of key Acute Treatment accomplishments.)
- *Reset* mitigates disability by providing biomedically based performance assessment capability for RTD in redeployment and following injury; by restoring full performance capabilities in redeployed individuals; and by restoring seriously injured service members with prosthetics and regenerative medicine. 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. (See Chapter 4 for a list of key Reset accomplishments.)

Subcategories within each of the major categories of the taxonomy address specific research thrust areas. The thrust areas within the Injury Prevention category are Injury Surveillance, Individual Resilience Training, Protection Standards, and Personalized Medicine. The Acute Treatment category includes Medical Treatment Outcomes Analysis, Health Care Provider Training, Wound Care, and Diagnostics. The Reset category includes Return-to-Duty Standards, Individual Retraining, Advanced Prosthetics, and Regenerative Medicine. Together, these major categories and thrust areas of blast injury research are designed to mitigate the risk of injury and to mitigate the short- and long-term outcomes of injury, including disability.

3. **Program Funding Requirements**. The DoDD 6025.21E requires the EA to perform programming and budgeting actions for all blast-injury research to maintain research programs based on the Director of Defense Research and Engineering (DDR&E)–approved priorities of the DoD components. The PCO has worked closely with organizations across the DoD to develop and staff the funding requirements for the Blast Injury Research Program for inclusion in the FY10 President's Budget. The fully funded Program will address critical blast injury research gaps, will leverage new extramural blast research partnerships with DoD medical research laboratories, will address the new concept of "reset" for warfighters in redeployment, ensuring RTD readiness (or healthy return to civilian life for citizen Soldiers), and will focus on the improvement of battlefield medical treatment capabilities to mitigate neurotrauma and hemorrhage. Key features of this programming request are:

- Increase efforts on injury mechanisms and physiological modeling of the data to produce damage risk criteria for better personal and crew protective equipment.
- Increase efforts on field resuscitation to further improve survival from the type of polytrauma typically encountered in blast injury, including fielding of freeze-dried plasma; development of new equipment and drugs for damage control resuscitation (DCR) such as controlled cooling and activation of survival mechanisms; and new neuroprotectant drugs.
- Establish research to enhance RTD (or to functionality and civilian life) for all service members following traumatic exposures such as blast events. This includes determination of scientifically based tests and standards for cognitive, emotional, and physical duty fitness; and treatment and retraining of psychomotor, cognitive, emotional, and physical deficits.
- Move rehabilitation research from annual congressional special interest efforts into focused extramural programs on regenerative medicine and reconstructive surgery; military/extramural amputee treatment and research; and ocular and auditory rehabilitation treatment and research.
- Complete the efforts initiated with the FY07 $300M congressional special interest appropriation for research on TBI and PTSD, two key gap areas associated with exposure to blast events. Typically, a medical research program requires a decade of continued effort to realize implementation of the findings of the research.
- Establish the funding base for operational and clinical research efforts that will continue indefinitely through the coordination of the new Defense Center of Excellence (DCoE) for

Psychological Health (PH) and TBI. This includes the Defense and Veterans Brain Injury Center (DVBIC) currently funded year to year through congressional special interest supplements.

- Transition programs from initial proof of concept to sustained support including the JTAPIC Project for medical assessments of key incidents that enhances military agility and survivability on the battlefield (developed and demonstrated with Joint Improvised Explosive Device Defeat Organization [JIEDDO] seed funding) and transitions discovery to advanced development for relevant Defense Advanced Research Projects Agency (DARPA) projects such field medical imaging technologies and medical evacuation concepts.

4. **Strengthening and Expanding Collaborations between the Medical Research Community and the Protection Equipment Developers.** The medical research community has always played a critically important role in the development of individual and crew blast protection equipment and systems by providing the materiel developers with biomedically valid injury criteria, performance standards, and testing methods. The PCO has strengthened and expanded this important relationship by facilitating the establishment of collaborative research projects and information exchanges between the medical research community and the individual and crew protection system developers at Tank-Automotive Research, Development, and Engineering Center, U.S. Army Natick Soldier Research, Development, and Engineering Center (NSRDEC), and ARL's Survivability/Lethality Analysis Directorate, and the PM, Joint Lightweight Tactical Vehicle (JLTV). This newly energized collaborative relationship between the medical and materiel development communities promises to yield significant improvements in the way we protect our service members from blast injuries.

Blast PCO Major Objectives. In the coming months, the PCO will focus its efforts on accomplishing the following major objectives:

1. **Establish a Program Management Strategy and Structure.** The PCO will establish a three-tiered management strategy to develop and review new research plans and to review ongoing research programs. The first level will consist of Integrating Integrated Product Teams (IIPTs) and Working Groups that will be responsible for assessing the state of the science in blast injury research and for proposing medical research studies that can fill recognized knowledge gaps. The second level of the program coordination structure will be the Joint Program Integration Panel (JPIP). The JPIP will provide programmatic reviews across the three IIPTs and recommend research plans based on programmatic relevance. The JPIP members will include representatives from the ASBREM Secretariat (Army, Navy, Air Force, the Office of the Secretary of Defense/Office of Health Affairs); Uniformed Services University of the Health Sciences (USUHS); DDR&E; the Department of Veterans Affairs (VA); the National Institutes of Health (NIH); and clinical consultants from each of the Services. The third level of the program coordination structure will be the Executive Advisory Board (EAB). The EAB will consist of Flag Officers who will be responsible for reviewing and approving research program recommendations that the USAMRMC Commanding General will submit to the ASBREM. The EAB will be chaired by the USAMRMC Commanding General and will include representatives from U.S. Army Research, Development, and Engineering Command (RDECOM) (Co-chair), Biomedical & Human Systems Reliance Panels, USUHS, JIEDDO, MARCORSYSCOM, Army Materiel Command (AMC) G1/Command Surgeon, and U.S. Army Training and Doctrine Command. The PCO will serve as the coordinating office for all program management activities.

2. **Establish a Research Coordinating Cell.** Injured service members should be the beneficiaries of the best available medical care. They may voluntarily participate in approved ethical research that is of high value and carries potential benefits to their care. The PCO will establish a coordinating cell to manage requests from researchers for access to volunteers. These requests will be considered in terms of the importance of the research to improving the current care of wounded warriors, the suitability of alternate patient populations not involving wounded warriors, and the demands of the study on patients. After study data have been analyzed and key results reported, data will be made

available to other researchers according to a data sharing plan approved by the appropriate human use committees. This ensures efficient use of research data and maximizes potential benefits from the tests conducted. The PCO will also coordinate requests for access to other military study populations, including healthy Soldiers in deployment.

3. **Establish a Review Process for Medical Standards for Individual and Crew Blast Protection Systems.** Under the DoDD, the Assistant Secretary of Defense for Health Affairs (ASD/HA) is responsible for approving blast-related medical standards for the DoD. These medical standards include medically based performance standards for crew and personal protection systems and occupational exposure standards for weapon system occupational health risk assessments. The PCO will develop a process for critically assessing blast injury prediction models and tools and for recommending the best standards and assessment tools to ASD(HA) for approval as DoD medical standards.

4. **Establish a Blast Injury Research Website**. One of the most important components of any successful, coordinated program is the ability to easily share information. The PCO will develop a blast injury research website that will be the venue for sharing information across the DoD, other federal agencies, academia, and industry. This website will provide users with access to critically important historical information on blast bioeffects (e.g., what we have learned from decades of blast bioeffects research) and on information about ongoing and planned blast injury research projects. A password-protected program management portal will provide a venue for reporting progress for ongoing research projects, identifying program funding requirements, and soliciting research proposals that address specific knowledge gaps.

5. **Establish a Brain Injury Modeling Working Group**. One of the key knowledge gaps in the Blast Injury Research Program is determining if a link exists between primary blast (i.e., blast overpressure) exposure and mTBI. To address this gap, many researchers have developed advanced computational models of brain injury. Several of these models are highlighted in Chapter 4. Simulations produced by biomedically valid computational models may help to elucidate the precise mechanisms of brain injury that are critically important in the development of improved protection equipment, diagnostic tools, and treatments. As an extension of the current efforts and as biomedical data become available, outcome measures such as performance testing and other aspects of normal mental functioning will also be mapped to modes of injury. To coordinate brain injury modeling efforts and make the best use of computational modeling expertise and resources, the PCO will establish a brain injury modeling working group composed of subject matter experts from the DoD, other federal agencies, and academia. This working group will be charged with assessing the state of the art in computational modeling and evaluating the scientific quality and biomedical validity of available models.

Chapter 3
Consolidated Budget Presentation

A consolidated budget presentation for DoD biomedical research efforts and studies related to blast injury for the 2 fiscal years following the year of the report (FY08) is presented in **Table 3-1**. These figures do not include any additional congressional special interest appropriations.

Table 3-1 shows the consolidated fiscal budget for funded DoD biomedical research efforts and studies related to blast injury for FY08 through FY10 by program category. These fiscal values are consistent with the planning, programming, and budgeting guidance of the Department and reflect efforts included in the Program Objective Memorandum.

Table 3-1. Identified Funding by Fiscal Year and Program Management Category

Funded ($K)	Fiscal Year			
Program Category	FY08	FY09	FY10	Grand Total
Injury Prevention	22,204	21,348	19,458	63,010
Acute Treatment	66,684	81,135	69,916	217,735
Reset	6,900	6,900	7,800	21,600
Grand Total	95,788	109,383	97,174	302,345

Chapter 4
Key Accomplishments by Program Area

Injury Prevention

Computational Model Helps Elucidate Mechanisms of Blast-Induced Brain Injury

A team of medical researchers from the Massachusetts Institute of Technology (MIT), the MIT Institute for Soldier Nanotechnologies, the VA Medical Center Salisbury, Raytheon (Waltham, Massachusetts), Purdue University, and the Walter Reed Army Medical Center (WRAMC) have developed the Full-Head Model, the highest-resolution, anatomically correct mathematical model of the human head in existence. Simulations using this model may help researchers understand the complex mechanisms of blast-induced brain injury and develop improved protective equipment, diagnostic tools, and treatments. The developers published a paper on this model in a special edition of NeuroImage and presented the paper at the 4th Annual Congress of the International Brain Mapping & Interoperative Surgical Planning Society in 2007.

Study Sheds Light on the Possibility of Primary-Blast-Induced mTBI

Medical researchers at the Mental Illness Research, Education, and Clinical Center of the Veterans Integrated Service Network screened 66 veterans with blast-related brain injuries and identified a cohort who reported exposure only to primary blast forces (e.g., did not fall down and were not hit by anything) and who had symptoms at the time consistent with concussion. Data from this cohort may help researchers to fill a major knowledge gap in the Blast Injury Research Program by determining if there is a primary-blast-induced mTBI. This research has been published in the *Journal Neuropsychiatry Clinical Neuroscience* and presented at several lectures and conferences.

Dental Materials Research Helps Protect Soldiers from Blast-Related Face Injuries

Researchers from the U.S. Army Dental and Trauma Research Detachment (USADTRD) have partnered with the ARL and the NSRDEC to develop two prototype face masks to protect Soldiers from blast-related face injuries. The two prototype face masks were submitted as candidates for the U.S. Army Soldier Protection Demonstration held at Fort Benning, Georgia in the spring of 2007, where they competed favorably with 6 commercial face masks. The prototypes placed in the top 3 overall and in the top 4 for each individual evaluation category, including range of motion, communications, weapons firing, and close quarters combat.

Brain Injury Simulation Provides Insights to Protection Equipment Designs

Researchers from the Naval Medical Research Center (NMRC) have partnered with the Johns Hopkins University Applied Physics Laboratory to develop a mathematical simulation of blast-induced brain injury. The prototype Finite Element Model (FEM) is designed to precisely simulate the effects of the blast shock wave on the human head. Once validated, the FEM can be used by PPE developers to design improved head protection equipment such as combat helmets. This research has been published in peer-reviewed journals and presented at military symposia.

Animal Studies Show Delayed Lung Injuries from Blast Exposures

Researchers at the NMRC have conducted studies on the cognitive performance effects of acute and repeated blast overpressure exposure in rats. The study showed some short-term impairment depending on the orientation of the rats to the blast; however, an unexpected finding was significant lung hemorrhage 1 week after the exposure. This finding suggests that lung damage may be a "silent" injury from blast exposure. Findings will be published in 2008.

Study of Injuries Sustained in Blast Events during Operation Iraqi Freedom/Operation Enduring Freedom (OIF/OEF)

The NHRC examined head, neck, face, and extremity injury sustained in blast events during OIF/OEF. The results revealed that while the prevalence of extremity injury (71.6% of all battle casualties) has not changed from previous conflicts, the nature of the injuries has. This study reported that serious morbidity and death were most prevalent with lower extremity injuries (versus upper extremities) and that injuries to the vascular systems (rather than the orthopedic and muscle systems) were the most likely to result in adverse patient outcomes. The study also recognized that the head, neck, and face are increasingly vulnerable as a function of the current threat to U.S. operational forces and that current models for injury protection have not had their intended effect of reducing this trend. Findings were reported in the *Journal of Trauma*, a DoD Technical Report, and a presentation to the Blast and IED (improvised explosive device) Health Effects & Mitigation Conference. DoD PPE developers have used these data to emphasize engineering of lower extremity vascular tissue system protection.

Study of Blast-Induced TBI

The NHRC examined the complete range (mild to severe) of blast-induced TBI in a military population and found that a large number of TBI patients RTD from the far-forward areas without benefit of CT imaging or follow-up assessment (46% of documented TBI cases). This population was often subjected to additional blast-related events producing second and third mTBI during the same deployment. The study also identified a high-risk blast injury population that should be thoroughly screened for cognitive morbidity immediately upon post-deployment. Findings from the study will appear in the *Journal of Neurosurgery*, 2008 (in press). The study resulted in the establishment of a baseline epidemiological characterization of incidence, type, severity, and short-term outcomes that allows for the identification of risk factors and the development of appropriate mitigating tactical and clinical responses related to TBI.

Effects of Blast-Induced Injury on Subsequent Development of Adverse Mental Health Outcomes

The NHRC examined the effects of blast-induced injury on subsequent development of adverse mental health outcomes and found the degree of injury severity to be positively correlated with adverse mental health outcomes. The study showed an incidence of adverse mental health outcomes in 31.3% of those sustaining a battle injury. The results of this study were presented to the 2007 Stress Physiology Conference and in a DoD technical report. The results of this study are being used by DoD and VA mental health providers to more effectively identify target populations for mental health follow-up and to direct resources to those most likely to benefit from intervention.

Antioxidant Supplements May Provide Protection Against Noise-Induced Hearing Loss

Researchers at the NHRC have teamed with Premier Micronutrient Corporation (Nashville, Tennessee) to study the effectiveness of a combination antioxidant, vitamin, and mineral supplement as a preventive measure for noise-induced hearing loss in U.S. Marines undergoing training. This special congressional interest program continues a decade of research by the Navy to identify dietary antioxidant supplements that may protect or restore noise-induced hearing loss.

Advanced Technology Offers Hearing Protection and Enhanced Communication

Researchers from the USAARL teamed with Communication and Ear Protection, Inc. (Enterprise, Alabama) under a Cooperative Research and Development Agreement to develop the Communication Enhancement and Protection System (CEPS). The CEPS is a hearing device designed to protect warfighters from impulse noise due to blast while maintaining normal ambient hearing and communication. The CEPS has been tested in the laboratory and in numerous field environments. One version of the CEPS is currently used by U.S. Army combat aircrew to allow them to maintain communication while outside the aircraft and still retain protection from impulse noise secondary to blast. The CEPS is being considered for combat fielding.

Medical Researchers Provide Solutions for Improved Protection from Blast-Related Eye Injuries

Protective Wrap Eyewear has proven to be extremely effective in preventing blast-related eye injuries; however, when used with prescription eyewear, service members may experience reduced visual acuity, ocular discomfort, and impaired distance judgments and locomotion. Medical researchers at the USAARL have solved this problem by developing the methodology, procedures, and tools required to modify prescription eyewear for use with Protective Wrap Eyewear. Implementation of this research has increased the number of service members who can use their Protective Wrap Eyewear, and it has prompted the Protective Wrap manufacturers to develop new designs to minimize the visual performance loss in future productions.

Biomedical Research Provides a Tool for Designing Improved Face and Eye Protection Equipment

Medical researchers at the USAARL have partnered with the Virginia Tech–Wake Forest University Center for Injury Biomechanics and Denton Vacuum (Moorestown, New Jersey) to develop a biofidelic tool that can predict blast-related fractures of facial bones and eye trauma. The tool is called the Facial and Ocular CountermeasUre Safety (FOCUS) headform. Face and eye protection equipment developers can use the FOCUS headform to design and test new protection equipment. The FOCUS headform research has been published in the peer-reviewed literature and presented at the 2007 DoD Force Health Protection Conference and the 2007 SAFE Association Conference.

Historical Blast Bioeffects Knowledge Solves a Current-Day Blast Injury Problem

The USAMRMC used existing blast bioeffects knowledge and biomedically valid injury prediction tools to assess the risk of blast-related injury to the F-35 Joint Strike Fighter (JSF) pilot during the JSF developmental testing. USAMRMC-sponsored researchers from L-3 Communications/Jaycor used the blast lung injury prediction tool (INJURY) to assess injury risks to the JSF pilot from the explosive release of the cockpit canopy during ejection. The assessment concluded that the risk of injury is minimal. These findings were documented in a technical report for the JSF Program Office and enabled the JSF acquisition program to proceed on schedule.

Medical Researchers Develop a Tool for Testing Individual Blast Protection Equipment

Scientists and engineers from L-3 Communications/Jaycor, working under contract to the USAMRMC, have partnered with the NSRDEC to develop a biomedically valid device for testing individual blast protection equipment, such as enhanced body armor. The tool, known as the Modified Blast Test Device (MBTD), builds upon nearly two decades of USAMRMC blast bioeffects research that led to the development of the blast lung injury prediction tool known as INJURY. The MBTD collects pressure data under the protection equipment during blast tests. The INJURY model uses the pressure data to predict the probability and severity of lung injury. The NSRDEC is currently using the MBTD to test concept blast protection equipment.

Medical Researchers Develop Improved Tools for Vehicle Crew Survivability Assessments

Scientists and engineers from L-3 Communications/Jaycor, working under contract to the USAMRMC, have developed and validated an improved device for predicting blast injuries to combat vehicle crewmen during congressionally mandated live-fire tests. The device known as the Advanced Blast Test Device (ABTD) is a lightweight, human-shaped device that records blast overpressure data in vehicle crew compartments during live-fire tests. Crew survivability assessors input the pressure data to the USAMRMC blast lung injury prediction model known as INJURY. INJURY predicts the probability and severity of blast-induced lung injury. This research project was conducted in collaboration with the survivability assessors at the ARL and the live-fire testers at the Aberdeen Test Center. The ABTD enables live-fire testers to collect accurate data on crew survival and to provide vehicle developers with the information they need to develop improved crew protection systems.

Adapting Existing Blast Injury Prediction Tools for New Applications

Scientists and engineers from L-3 Communications/Jaycor, working under contract to the USAMRMC, teamed with the NSRDEC to successfully demonstrate the validity of an existing blast lung injury prediction tool for predicting blast lethality. The existing tool, known as INJURY, was the culmination of nearly two decades of USAMRMC blast bioeffects research. INJURY predicts the probability and severity of blast-induced lung injury. The USAMRMC originally developed INJURY as a tool for assessing lung injury from low-level, occupational exposures to blast from high-powered weapon systems. The recent research demonstrated the validity of INJURY's predictions for high-level blast exposures. This research was published and presented at the Military Application of Blast Simulation Meeting. The NSRDEC is currently using the results of this research to select test conditions for assessing the effects of body armor on blast lethality.

Biomedical Research Provides Tools for Developing Improved Combat Helmets

A project sponsored by the Technical Support Working Group of the Combating Terrorism Technology Support Office (TSWG/CTTSO) has produced a headform designed for evaluating the blunt impact protection provided by combat helmets. The headform is designed to test behind armor blunt impact protection under ballistic, blast, and impact loading conditions. This project was a collaborative effort with the National Institute of Standards and Technology Office of Law Enforcement Standards (NIST OLES), the National Institute of Justice (NIJ), the Army Natick Soldier Systems Center, and Canada. The headform and test methodology have been provided to each of the participating organizations.

Preliminary Tests Lay the Groundwork for Assessing Health Risks from Repeated Blast Exposures

Preliminary tests were completed for a project sponsored by the TSWG/CTTSO to assess the neurological health risks to service members from repeated exposures to low-level blasts. The study participants are volunteer instructors from the U.S. Marine Corps Weapons Training Battalion (WTB) Dynamic Entry School ("Breachers"). The preliminary tests verified instrumentation requirements and provided preliminary data for the full-scale study that will begin in early FY08. This study is a collaborative effort between DARPA, Office of Naval Research (ONR), USAMRMC, and the WTB Dynamic Entry School.

Biomedical Research Provides Tools for Performance Testing Body Armor

A project sponsored by the TSWG/CTTSO has produced two devices ("rigs") for testing body armor penetration and blunt trauma performance. The penetration rig is a relatively inexpensive torso to enable armor to be tested to failure. The trauma rig is used to measure behind armor blunt trauma and the dynamic deflections during ballistic impact. This project was a collaborative effort between the NIST OLES, NIJ, Natick Soldier Systems Center, and Canada. Prototype rigs were provided to the participating organizations.

New Tool Captures Wounding Data to Guide Improvements in Body Armor Designs

A project sponsored by the TSWG/CTTSO has produced a software application that graphically illustrates wounding patterns based on combat trauma data. The application is known as Surface Wound Mapping (SWM) Software Suite. The current version contains data from more than 1,000 trauma cases and provides an integrated graphical display of wound density and injury severity with placement of PPE such as body armor on the body. The SWM application provides information that body armor developers can use to develop improved body armor. This project was a collaborative effort between SimQuest, the NHRC (U.S. Marine Combat Trauma Registry), the U.S. Army Institute of Surgical Research (USAISR) (Joint Theater Trauma Registry), and the Office of the Armed Forces Medical Examiner (Mortality Trauma Registry). The SWM software is currently widely distributed to military end users, including the ARL, ONR, NSRDEC, NHRC, USAISR, U.S. Army RDECOM, and the U.S. MARCORSYSCOM. Further refinement of the SWM software may be required after the project transfers to the JTAPIC Project in FY08.

Existing Biomedical Tools Evaluate Survivability of Personnel Inside an Entry-Control Point Structure

Applied Research Associates, under contract to the TSWG/CTTSO, teamed with the Israeli Ministry of Defense to evaluate the survivability of personnel inside an entry-control point tower (David Tower) exposed to vehicle-borne IED attack. The research team used an existing tool, the Hybrid III crash test dummy, to quantify the risk of injury from the blast shock wave. The results confirmed that the structure adequately protects its occupants from blast-related injuries.

Medical Research Provides Key Data to Support Baseline Neurological Assessments of Service Members

The DVBIC partnered with the University of Oklahoma, University of Colorado, and the National Rehabilitation Hospital, Washington, DC to establish military normative data for the ANAM test battery. Establishing military norms will facilitate predeployment cognitive testing of service members and allow the use of ANAM to detect cognitive problems that may be related to TBI, including blast-related injuries. The Tables of Norms are available on the University of Colorado website. Norms provided by DVBIC are embedded in the test instrument used for the predeployment testing of troops initiated by the Office of the Surgeon General.

A Computational Model of Blast-Induced Brain Injury Leverages the Visible Human Project

The DVBIC teamed with WRAMC, Raytheon (Waltham, Massachusetts), and the MIT Institute for Soldier Nanotechnology to develop a computational model of blast-induced brain injury. The model leverages the National Library of Medicine's Visible Human Project that produced a complete, anatomically detailed, three-dimensional representation of the normal male and female human bodies. Simulations using this model may help researchers understand the complex mechanisms of blast-induced brain injury and develop improved protective equipment, diagnostic tools, and treatments. This research was included in a presentation on Computational Biology, Primary Blast Injury and the Central Nervous System at the 4th Annual World Congress of the International Brain Mapping and Inter-operative Surgical Planning Society. Two publications are currently in preparation: an invited review for *Future Neurology* and an invited submission for a special edition of *NeuroImage*.

Study Suggests a Link Between Head Injury and PTSD

The DVBIC partnered with Applied Research Associates, Inc. (Albuquerque, New Mexico) and the MIT to investigate head injury as a predictor of PTSD. Investigators studied the relationship between TBI and PTSD in survivors of the Oklahoma City Bombing. The results suggest that TBI was associated with subsequent development of PTSD. The knowledge gained from this study may be useful in identifying service members who may be at risk for developing PTSD. This study was submitted for publication in *Military Medicine*.

Existing Blast Injury Prediction Tools Support the Development of Individual Blast Protection Equipment

The NSRDEC teamed with Walter Reed Army Institute of Research (WRAIR), NMRC, the Naval Surface Warfare Center (Indian Head, Maryland), the ARL, and L-3 Communications/Jaycor (under contract to the USAMRMC) to develop and demonstrate an add-on body armor concept that provides protection against novel explosive weapons, such as thermobaric weapons, for personnel operating in enclosed environments, such as buildings and vehicles. This research combined large animal injury tests with a modified version of the USAMRMC blast lung injury prediction tool known as INJURY. The researchers developed and demonstrated an add-on protective concept that provided protection from blast lung injury at blast overpressure levels that produce a 25% lethal result for unprotected individuals. The findings from this research will support follow-on efforts in FY08 to develop integrated ballistic and blast protective materials and to develop a test device for evaluating blast-protective clothing and equipment.

Preliminary Research Suggests a Mechanism for Blast-Induced mTBI

DARPA teamed with WRAIR and NMRC to complete preliminary research to investigate possible mechanisms of blast-induced mTBI. The researchers exposed large animals to pure blast overpressure generated by a gas-driven shock tube. The exposed animals did not suffer mTBI. This research suggests that blast overpressure alone may not be the cause of blast-induced mTBI and that there may be other components in an actual explosion, such as heat, electromagnetic pulse, or toxic gases, that are responsible for causing mTBI. This research lays the ground work for DARPA's PREventing Violent Explosive Neurologic Trauma (PREVENT) research program that began at the end of FY07.

Collaborative Project Links Medical and Operational Data to Prevent Blast Injuries

The JIEDDO supported the development of the JTAPIC Project. This project was a collaborative effort among the military medical, intelligence, and protection equipment development communities that married trauma and operational data to support improvements in protection systems and tactics that prevent or mitigate blast-related injuries. The USAMRMC managed the project in collaboration with the Office of the Armed Forces Medical Examiner, U.S. Army Infantry Center and School, U.S. Army National Ground Intelligence Center, U.S. Army Program Executive Office Soldier, Project Manager Soldier Equipment, ARL, NHRC, MARCORSYSCOM, and the U.S. Air Force Office of the Surgeon General. Examples of JTAPIC Project accomplishments include the generation of near-real-time data that confirmed the presence of prominent threat weapons of interest to the intelligence community, the identification of potential vulnerabilities in operational procedures in theater, and the formulation of actionable information for combat vehicle developers that have led to the modification of vehicle equipment, such as seats designed to prevent or mitigate blast-related injuries.

Air Force Security Forces Squadron Evaluates Body Armor

U.S. Air Force personnel in Iraq evaluated a lighter weight, metal-infused ceramic plate for personnel flack vests developed by the Air Force Research Laboratory (AFRL) and Excera Materials Group (Columbus, Ohio). The study resulted in improvements to fit, comfort, and protection. The resulting technology exceeded current ballistic specifications.

Acute Treatment

BANDITS Enables Real-Time Monitoring of Patients with Mild to Severe TBI

Biomarkers that indicate the presence of TBI in animals and humans have been identified by researchers at WRAIR. In collaboration with Banyan Biomarkers, a private sector biotechnology firm, WRAIR has developed an automated system called BANDITS (Biomarker Assessment for Neurotrauma Diagnosis and Improved Triage System), which provides a clinical data acquisition and analysis platform providing continuous, real-time physiological data monitoring in patients with TBI. Preliminary results indicate that BANDITS can detect even mTBI. These discoveries have been presented at several conferences, including the Army Technology Applications for Combat Casualty Care (ATACCC) Conference National Neurotrauma Conference, and the Society for Neuroscience Conference, and resulted in the publication of three papers and six abstracts.

Brain Trauma and Neuroprotection Research Program Develops Brain Injury Model and Therapeutic Drug Candidate

Medical researchers at WRAIR have succeeded in developing the Penetrating Ballistic-Type Brain Injury model, a combat relevant model of penetrating brain injury that has been licensed to Stoelting, Inc. for worldwide distribution to the research community ensuring greater focus on military-relevant TBI research. Researchers at WRAIR have also completed preclinical trials of a novel therapeutic drug candidate (NNZ02566) and are proceeding to Phase 2 clinical trials in mild and severe TBI. This research was done in collaboration with Banyan Biomarkers, Neuren Pharmaceuticals, Stemnion LLC, and Theradigm, Inc. Research results have been widely shared with the military and the civilian research

community through presentations at conferences, including ATACCC, The Technical Cooperation Program (TTCP), and the annual U.S.-Israel Shoresh Conference and through publications and abstracts.

Silent Brain Seizures May Increase Morbidity and Mortality from TBI

Medical researchers at WRAIR have identified silent brain seizures as a factor that may increase the morbidity and mortality from TBI, uncovered the critical role of neuroinflammation in the acute response to TBI, and advanced the understanding of molecular and cellular changes specific to TBI. Research results have been widely shared with the military and the civilian research community through presentations at conferences, publications, and abstracts.

Blast Spinal Cord Injury Program Established as Joint Effort Between WRAMC and USUHS

The USUHS implemented the Blast Spinal Cord Injury (bSCI) Program in July 2007. The program received approval for clinical protocols to address the use of botulinum toxins in the treatment of blast-related spinal cord pain and has begun recruitment of patients with bSCI treated at WRAMC. This is joint effort between WRAMC and USUHS.

Initiation of Traumatic Injury Research Program at USUHS

Renovation of laboratory facilities has begun for the new Traumatic Injury Research Program in the Department of Military and Emergency Medicine at USUHS. Plans include construction of an electromagnetically shielded subject chamber. Aquinas, LLC (Milford, Connecticut) will be providing dynamic analysis of signals obtained during the research and University of Northern Colorado will provide event-related potential data from health control subjects. Investigators have published three papers on this research; one in *Cognitive Neurodynamics* and two included in the *Proceedings of the First International Conference on Cognitive Neurodynamics*.

Prototype Bandage Under Development to Control Hemorrhage and Improve Wound Healing

The USADTRD partnered with Cellphire, Inc. (Rockville, Maryland) to develop a prototype hemostatic agent using freeze-dried platelets that improves clotting time and clot strength and facilitates wound healing. Results were distributed in poster presentations at the Advance Trauma and Combat Casualty Care Meetings in 2006 and 2007 and at the Garmisch Conference in 2006.

New Clinical Practice Guidelines Developed by the DCR Program

The DCR program developed new clinical practice guidelines that have reduced mortality in patients with severe blast injuries. Guidelines are based on the evaluation of new hemostatic dressings and a multicenter evaluation of blood products in a swine model of hemorrhage and femur fracture relevant to blast injuries. Collaboration partners included the U.S. Army Medical Materiel Development Activity (USAMMDA); the U.S. Army Medical Department Center and School (USAMEDDCS), the ONR, the Oregon Health Sciences University, Harvard Medical School, TTCP, 29 civilian trauma centers within the United States, and Combat Support Hospitals in the theaters of operation. Knowledge gained was shared via 37 presentations at scientific and surgical conferences including the Shock Society, American Association for the Surgery of Trauma, Eastern Association for the Surgery of Trauma, Critical Care Medicine, ATACCC, Army Science Conference, TTCP-sponsored conferences at the USAISR, 48 publications in the scientific literature, including the *Journal of Trauma*, and in five technical reports.

New Technology to Detect and Quantify Diffuse Axonal Injury as an Indicator of TBI

The Telemedicine and Advanced Technology Research Center (TATRC) partnered with the University of Southern California to develop new technology to detect and quantify Diffuse Axonal Injury using Diffusion Tensor Imaging and conducted preliminary study to quantify abnormalities in TBI subjects. Their results were presented at the 4th Annual International Brain Mapping and Intraoperative Surgical Planning Symposium, September 2007. These findings contributed significantly to research on TBI and PTSD supported by the CDMRP.

Development of a Stand-Alone Patient Simulator for Military Medic Training

The RDECOM Simulation & Training Technology Center developed, created, tested, and commercially produced SAPS (Stand-Alone Patient Simulator), the first physiologically accurate, wireless, rugged, field-capable, full-body patient simulator to train medics in ongoing exercises. SAPS is the primary test platform for prototype training injuries developed under The Severe Trauma Simulation Army Technology Objective (IV.MS.2007.1). Collaboration partners included USAMRMC, USAMEDDCS, PEO for Simulation, Training, and Instrumentation, Medical Education Technologies, Inc. (Sarasota, Florida), medical simulation training centers at Fort Lewis and Fort Campbell and the Navy Field Medical Service School, Camp Lejeune. Information on SAPS was presented at the Association of the United States Army (AUSA) Conference and the Interservice, Industry Training, Simulation, and Education Conference. Military validation and learning effectiveness studies are scheduled for 2008. Initial Operating Capability is scheduled at the Army Medical Simulation Training Centers in 2010.

Regional Anesthesia Simulator with Sensory Feedback Developed for Training Pain Management Specialists

Small Business Innovation Research (SBIR) partner Energid Technologies (Cambridge, Massachusetts) in collaboration with WRAMC developed a simulator for training pain management specialists. Using an innovative system to generate sensory feedback of needle insertion and injection of anesthetic, this simulator provides a nontethered training system that simulates more precisely the actual procedure. The simulator underwent project review by the DDR&E in November 2007. Information on the system was presented at two international meetings and in two publications. Upon completion of Phase 2 testing, the training system will be incorporated into the Regional Anesthesia Training Program at WRAMC.

Regional Anesthesia Simulator with Three-Dimensional Repositioning Capability Developed for Training Pain Management Specialists

SBIR partner Touch of Life Technologies (Aurora, Colorado) in collaboration with the National Library of Medicine and WRAMC developed a system to reposition the Virtual Human Male model in three-dimensional space to enable more anatomically correct placement of instruments used in training for specific anesthesia procedures. The system underwent project review by the DDR&E in November 2007. Upon completion of Phase 2 testing, the training system will be incorporated into the Regional Anesthesia Training Program at WRAMC.

Biomarkers in Blood Can Be Used to Identify and Manage TBI

Scientists at WRAIR in collaboration with Banyan Biomarkers (Alachua, Florida) have developed new drugs, termed theragnostics, that can be used to identify and manage TBI and tested these drugs in animal models. Results were shared in abstracts and poster presentations at national meetings including the ATACCC Meeting. Work is ongoing to develop these results into therapeutic and diagnostic products for treatment of TBI in humans.

Prototype Fractured-Femur Training System Creates Virtual Trauma in Virtual Patients

SBIR partners Touch of Life Technologies (Aurora, Colorado) and Simulation (Prior Lake, Minnesota) developed a prototype fractured femur virtual training system that provides a realistic "feel" using specially developed dual-haptics tactile devices. Information on the training system was presented at the Medicine Meets Virtual Reality Conference (January 2007) and the ATACCC Conference (August 2007). Prototypes are undergoing assessment testing to demonstrate training effectiveness before moving forward with commercial development.

Training Video Teaches Military Surgeons a New Procedure

SBIR partner Touch of Life Technologies (Aurora, Colorado) produced a training video for general surgeons on how to perform a fasciotomy to treat Compartment Syndrome. The video includes both cadaver-based procedures and actual fasciotomies filmed in Iraq. The video was produced in coordination with the American Academy of Orthopedic Surgeons, the Office of the Army Surgeon

General and military orthopedic and trauma surgeons. Presentations were made at the ATACCC Conference in August 2007. The training video has been approved for broad dissemination by the U.S. Army Office of the Surgeon General.

Animal Models Help Determine the Root Causes of Organ Damage After Blast Injury

The WRAIR determined (using animal models) that increased nitric oxide production causes cardiovascular abnormalities seen after blast injury. They also provided data suggesting that nitric oxide and iron are critical in the mediation of the inflammatory response that occurs after blast injury plus hemorrhage, leading to the failure of lung and other organ systems. These results were achieved in collaboration with the University of Pittsburgh, the University of Connecticut, and USAMRMC. Results were presented to the ATACCC Conference, the Society for Toxicology, the Society for Experimental Biology, and the Society of Free Radical Biology. The research resulted in four publications in peer-reviewed journals, one book chapter, and 19 abstracts. Understanding the basic mechanisms of tissue damage caused by blast injury makes possible the development of treatments and medications to reduce morbidity and mortality in combat.

Differences Found Between Blast-Induced and Other Forms of Brain Injury

Exploring the pathophysiological characterizations following primary blast injury, WRAIR discovered significant differences between blast-induced brain injury and other forms of TBI. They determined that protective vests not only reduced mortality and protected the lungs and heart but also significantly reduced brain injury, revealing a potential mitigation measure and leading to a better understanding of the nature of blast-induced brain injury. WRAIR was joined in this research by the University of Pittsburgh and the USUHS. The knowledge gained was presented at the ATACCC Conference (August 2007) and the 5th Annual Peter Safar Memorial Symposium. Results from this research will shape the experimental approaches used for the DARPA-funded PREVENT program and promising treatments from the animal experiments will be developed as clinical trials conducted jointly with USAMRMC and the collaborating trauma centers.

PREVENT Program Characterizes Neurotrauma from Explosive Blasts

The PREVENT program, centered at WRAIR, has assembled a world-class team of investigators to characterize nonpenetrating brain injuries from IED detonation, develop predictive models and test systems, and devise mitigation and treatment strategies. This multicenter research program funded by DARPA will involve extensive collaboration with investigators at the University of Pittsburgh, Harvard, Yale, USUHS, and Orthopedics Research Associates, Inc. (Fredericksburg, Virginia).

Animal Models of Tissue Trauma Plus Hemorrhage Test the Therapeutic Benefit of Treatments

The DCR Program at WRAIR has developed animal models for tissue trauma plus hemorrhage that allow investigators to test treatments targeted at improving survival, correcting metabolic and coagulation abnormalities, minimizing unwanted inflammatory responses, and reducing fluid requirements. In addition, metabolic and genetic markers indicating increased risk of dying from prolonged shock were identified. These multidisciplinary studies involved broad collaboration with many partners including USUHS, ONR, Republic of Korea Engineer and Scientist Exchange Program, The National Institute of Traumatology and Emergency Medicine (Budapest, Hungary), University of Colorado, Harvard, Kansas State University, University of Pennsylvania, and South Carolina University. Knowledge was shared through 16 presentations at scientific conferences, including ATACCC, Experimental Biology and Shock Society, and publication of 32 articles and abstracts in peer-reviewed journals including the *Journal of Applied Physiology*, and *Journal of Immunology and Shock*. Promising treatments will be subjected to clinical trials and those deemed safe and effective will be incorporated into DoD battlefield medicine guidelines.

Biomarkers for TBI

Preliminary results from the analysis of brain tissue, serum, and cerebrospinal fluid (CSF) in rats exposed to mild to moderate brain injury show a strong accumulation of MAP2 antibodies and SYT breakdown products in cortex. The ONR collaborated with researchers from the U.S. Army and the University of Florida to conduct the research and partnered with Banyan Biomarkers (Alachua, Florida) to develop the biomarker assays for serum and CSF. The study findings were presented at the ATACCC Conference and published in peer-reviewed journals. Results may lead to the development of a handheld device for rapid analysis of blood for biomarkers of TBI.

Freeze-Dried Plasma Found to Reverse Trauma-Induced Coagulopathy

The ONR collaborated with medical researchers from the USAISR and Oregon Health Science University to develop a clinically relevant large animal model of polytrauma and hemorrhagic shock. Investigators found that freeze-dried plasma, equal to the volume of shed blood, was the most effective method of reversing trauma-induced coagulopathy. Results of this study were presented at the ATACCC Conference and the 30th Annual Conference of Shock and were also published in peer-reviewed scientific journals. This provides additional data in support of the fielding of a freeze-dried plasma product currently in advanced development at USAMMDA.

Increased Pathology from Hemorrhage Noted in Presence of Head Trauma

The ONR partnered with medical researcher from the WRAIR, Hebrew University of Jerusalem, and the Medical College of Virginia to re-evaluate standard resuscitative therapies in an animal model of TBI combined with hemorrhagic shock. Preliminary results found an increase in pathology from hemorrhage in the presence of head trauma, possibly due to the extended time that the mean arterial pressure was below normal following injury. Findings from this study were presented at the ATACCC Conference and published in peer-reviewed journal articles. This knowledge product will be incorporated in Navy medical plans and policy.

A Novel Resuscitation Strategy Reduces Secondary Damage in TBI Patients

The ONR, in partnership with the University of Miami, investigated new therapeutic options for the management of cerebral perfusion pressure to reduce cerebral ischemia following TBI. Results in a clinically relevant model of brain injury and hemorrhagic shock indicated that early administration of supplemental arginine vasopressin rapidly corrected cerebral perfusion pressure, improved cerebrovascular compliance, and prevented circulatory collapse during fluid resuscitation. The program's findings were presented at the ATACCC Conference and published in peer-reviewed journals. The data obtained from this study supported Institutional Review Board approval for a human use clinical trial.

Discovery of a Mechanism of Pulmonary Damage from Blast Overpressure Leads to Improved Survival Rate in Animals

Investigators at NMRC have found that both blast overpressure and hyperbaric oxygen exposure increases the expression of heme oxygenase-1 and inducible nitric oxide synthetase in lungs of animals. Induction of heme oxygenase-1 expression in lungs by intraperitoneal injection of Hemin significantly improved the survival rate in animals exposed to blast overpressure. A technique to induce overexpression of heme oxygenase-1 in endothelial cells was developed using adenoviral-mediated gene transfers. Two papers on these results were published in the *Journal of Trauma*.

Automating the Control of Life-Support Devices Improves Clinical Outcomes

A Computer-Assisted Resuscitation Algorithm was developed and evaluated in a swine model of blast injury at WRAIR. Automating the control of life support was shown to provide effective and expedient restoration of blood pressure after hemorrhage. In addition, the limits of safe PEEP (positive end-expiratory pressure) administration during treatment for graded hemorrhage were determined. Collaborators at the ARL provided expertise in software development for this project. Results were presented at the ATACCC Conference in three oral presentations and three posters.

Extending Shelf Life of Stored Red Blood Cells

The Red Blood Cells, Extended Life (RBCXL) Program at USAMMDA has developed a red blood cell (RBC) collection and storage system using a new preservative that extends the current shelf-life of stored RBC from 6 to 8 weeks when tested in vitro. This would translate into a significant improvement of RBC shelf-life for combat operations in theater. In vivo testing of this system is under way to satisfy U.S. Food and Drug Administration requirements for approval and licensing. Collaborating partners in the development of RBCXL include the USAMRMC, Hemerus Medical, LLC (St. Paul, Minnesota), the Office of the Secretary of Defense (OSD) Technology Transition Initiative, and the Armed Services Blood Program. Research results were presented at the American Association of Blood Banks, the Biomedical Excellence for Safer Transfusion Working Group, the Armed Services Blood Program Workshop, in two publications in peer-reviewed journals and in the Annual Report to the U.S. Army Medical Research Acquisition Activity.

Blast-Safe Oxygen System Eliminates Risk of Secondary Explosion and Fire

USAMMDA partnered with SeQual Technologies (San Diego, California) and IGR Enterprises, Inc. (Cleveland, Ohio) to develop electrically powered oxygen generators to replace high-pressure oxygen cylinders used in life support of wounded warfighters, eliminating the risk of secondary explosions and fire from damaged cylinders. Blast-safe oxygen systems are being incorporated into current Mine-Resistant Ambush-Protected (MRAP) Ambulance purchases. More advanced blast-safe oxygen systems will be included in future medical MRAP and Future Combat Systems vehicles.

Conversion Kits Enable the Use of Combat Vehicles for Casualty Evacuation

USAMMDA, in collaboration with the AMEDDCS Directorate of Combat and Doctrine Development (DCDD), the Army Materiel Command Field Assistance in Science and Technology (AMC-FAST) Team in Iraq, U.S. Army Light Tactical Vehicle Program Management Office, and the Joint Program Office for MRAP Vehicles, has developed casualty evacuation Conversion Kits for armored combat vehicles for use on the battlefield when advanced medical evacuation (MEDEVAC) vehicles are not available. These kits are currently being used in combat operations, and availability has been widely disseminated among military and medical personnel.

Critical Shortage of Armored Ambulances in Current Operations Addressed

USAMMDA teamed with the AMEDDCS DCDD and the MARCORSYSCOM to design and develop armored ambulances for enhanced forward casualty care to mitigate the effects of blast on the battlefield. The coordinated effort was able to address this urgent need quickly and augmented the MRAP program by providing armored MEDEVAC vehicles significantly earlier than anticipated. BAE Systems (Santa Clara, California) was a key partner in the expedited design and development of the MRAP ambulances. USAMMDA collaborated with the AMC-FAST Team in Iraq, CENTCOM, MARCENT, and the AMC, medical and support units serving in Iraq and Afghanistan. The armored ground MEDEVAC vehicles will soon be deployed to the theater of combat providing critical, immediate lifesaving care that will improve the outcome for injured Soldiers on the battlefield today.

Clinical and Educational Systems to Improve the Screening and Treatment of TBI

DVBIC developed and implemented numerous clinical and educational systems to improve screening and treatment of combat-related TBI. Products include: Theater Clinical Practice Guidelines for mTBI, the Military Acute Concussive Evaluation (MACE) test battery, a system of TBI regional care coordination throughout the country, initiated 100% TBI screening program at Lakeland Regional Medical Center, a video teleconferencing system for case transitions from Military Treatment Facilities to the VA and a system for TBI e-consultation from theater. Information was distributed via an article published in the *Journal of Neurotrauma* and at the tri-service TBI Educational Symposium attended by more than 800 DoD providers. Theater Clinical Practice Guidelines have been included in the Pre-Deployment Medical Training curriculum in various Army and Air Force Army training courses.

Brain Injuries Sustained in the Afghanistan and Iraq Wars

DVBIC, in collaboration with WRAMC, summarized the extent of the problem with TBI in the current conflicts and has had a paper accepted for publication in the March 2008 issue of the *American Journal of Nursing* entitled *Traumatic Brain Injuries Sustained in the Afghanistan and Iraq Wars*. This manuscript, written specifically from a nursing perspective for a nursing audience, reviews published literature, current definitions, screening, and assessment by DVBIC and a (composite) case scenario and nursing implications.

TBI Screening Tool Permits Appropriate Referral of Returning Troops

DVBIC designed, modified, and implemented a TBI Screening Tool to assess more than 30,000 returning service members at large military bases. The instrument permitted appropriate referral of those with continuing symptoms to clinicians for evaluation and treatment. Collaborators at Fort Carson, Colorado and Fort Bragg, North Carolina assisted with the evaluation and adaptation of the tool, which has now been adopted by the VA for widespread use. A paper on the TBI Screening Tool was published in the November–December 2007 issue of the *Journal of Head Trauma Rehabilitation*. The Post-Deployment Health Assessment has adopted these screening questions, with minor modifications, to include in the larger screening tool of all service members with traumatic brain injuries, most blast-related, returning from OIF and OEF.

Clinical Practice Guidelines Initiated for Transfusions Using Thromboelastography

Medical research at the Air Force theater hospital (AFTH) led to guidelines for the transfusion of fresh whole blood (FHB) using thromboelastography (TEG) for the evaluation of life-threatening coagulopathy in injured warfighters. Data from AFTH TEG studies were presented at Canadian Trauma Symposium. The theater-wide use of the guidelines have led to better use of FHB and other scarce blood products in theater and fewer clinical blood product administration errors.

Temporary Vascular Shunts Extend Promise of Reducing War-Related Amputations

The AFTH in Iraq demonstrated that the use of temporary vascular shunts in battle injuries extends the promise to reducing war-related amputations. Temporary vascular shunts were used to maintain blood flow to severely injured extremities when arteries were severed. Shunted arteries demonstrated an early viability of 92%. Results of the practice were reported in the *Annals of Vascular Surgery*. Use of vascular shunts for temporary rescue of vascular function has become the standard of care.

Negative Pressure Wound Dressings System Reduces Wound Closure Time and Length of Hospital Stays

A study using negative pressure VAC (vacuum-assisted closure) wound dressings at the Air Force Medical Service theater hospital was associated with a 25% reduction in hospital stay, a 30% reduction in wound closure time, and a 0% wound complication rate. The study was a collaborative effort by the AFTH, CENTCOM, and Kinetic Concepts International (San Antonio, Texas). Results were published in the *Journal of Trauma-Injury Infection & Critical Care* and the *Journal of the American College of Surgery*. The wound VAC system is deployed to the theater of operations and is improving warfighter outcomes.

Reset

Military Amputee Intramural Research Program Assists Patients in Achieving the Highest Possible Level of Physical, Psychological, and Emotional Wellness

The Military Amputee Intramural Research Program was established as part of the overall U.S. Military Amputee Patient Care Program with a research management organization to support DoD's effort to assist patients in achieving the highest possible level of physical, psychological, and emotional wellness. The program is a collaboration of Brooke Army Medical Center and the Center for the Intrepid, WRAMC, and the Military Advanced Training Center, and the National Naval Medical Center. Results from this

program directly affect warfighter care and rehabilitation by helping physicians and therapists determine how to best treat blast injury victims The collaboration has generated presentations to the AUSA, Association of Military Surgeons of the United States, American Telemedicine Association, World Congress of the International Society of Orthotics and Prosthetics, and the Military Health System Annual Meeting.

Hearing Restored in Ototoxin and Noise-Exposed Animals

Sound Pharmaceuticals (Seattle, Washington) and the Naval Air Systems Command (NAVAIR) demonstrated for the first time the restoration of hearing using p27 short inhibitory ribonucleic acids (siRNAs) in ototoxin and noise-exposed animals. Results indicate that p27 antisense oligonucleotides (AON) and siRNA be injected directly into the inner ear of experimental animals to induce cell proliferation and regeneration. Also found that p27 siRNAs are 2.5 times better than p27 AON at inducing cell proliferation and regeneration. Results have been shared at various military symposia and in publications in peer-reviewed journals. Further research could lead to therapeutic agents to stimulate the regeneration of auditory cells and hairs cells in the deaf and hard-of-hearing.

Magnetic Fields Used to Deliver Therapeutic Compounds to the Inner Ear

BBMS, Ltd. (United Kingdom), Hyalose, LLC (Austin, Texas) and Do Coop Technologies (Or-Yehuda, Israel) collaborated with ONR to develop a system to deliver therapeutic compounds contained within biocompatible magnetic nanoparticles to ameliorate inner ear damage using external magnetic fields in an animal model. This system demonstrated for the first time quantified transport of nanoparticles to the inner ear. Results were presented at the ATACCC Conference and in peer-reviewed journals.

Oral Antioxidants Decrease Hearing Loss Across All Auditory Brain-Stem Response Frequencies

The University of Oklahoma Health Sciences Center, Sound Pharmaceuticals (Seattle, Washington), and NAVAIR collaborated to evaluate the efficacy of combined antioxidants on hearing recovery and protection of inner and outer hair cells in an animal model. They found that N-acetylcysteine and acetyl-L-carnitine each decreased hearing loss across all auditory brain-stem response frequencies. Their findings were presented to the ATACCC Conference and resulted in publications in peer-reviewed journals. Results may help optimize the oral treatment of acute acoustic trauma.

Procedure and Product That May Lengthen Amputated Fingers Made Available to a Military Clinic

The Regenerative Medicine Task Area characterized battlefield injuries, developed an animal model of large skeletal muscle loss, produced Clinical Practice Guidelines for initial wound care and developed resources to use adipose-derived mesenchymal stem cells as a therapy. This multicenter effort included Carnegie Mellon University, Georgia State University, University of Pittsburgh, University of California at San Francisco, University of Connecticut Health Center, University of Memphis, University of Texas at Austin, University of Texas Health Sciences Center, San Antonio, University of Texas at San Antonio, Vanderbilt University, Twin Star Medical (Minneapolis, Minnesota), Kinetic Concepts, Inc. (San Antonio, Texas), Luna Innovations, Inc. (Blacksburg, Virginia) and USAISR. Results were presented at the American Academy of Orthopedic Surgeons and the Orthopedic Trauma Association and in the *Bone and Joint Surgery Journal*, *Journal of Orthopedic Trauma*, *Journal of Trauma*, and the *Journal of the American College of Surgeons*. As a result of these efforts, a procedure and product that may lengthen amputated fingers have been made available at a military clinic. Developments are also currently being implemented by military surgeons and consultants to restore function to blast-injured limbs and faces.

State of the Science Symposia Series on Rehabilitation Research to Clinical Practice in Support of the Military Amputee Research Program

This 2006 symposium series disseminated state-of-the-art findings related to rehabilitative research and care for injuries experienced by Soldiers that often result in long-term medical rehabilitation. Topics

included advanced assistive devices, spinal cord injury, polytrauma, and sensory impairment. Participants included key leaders in medical rehabilitation from the Army and VA.

Spring Ankle with Regenerative Kinetics (SPARKy) Demonstrated

Military Amputee Research Program (MARP) partner Arizona State University developed and demonstrated the first-generation prototype of the SPARKy powered ankle prosthesis that supports linear walking on a treadmill with speeds ranging from 1 to 2 meters per second with smooth transitions between speeds.

Key Components Developed for Over-Ground Body-Weight Support System

The National Rehabilitation Hospital (Washington, DC), in partnership with MARP, developed key components (actuator selection and instrumentation of the rail system) for a new body-weight support system that will allow individuals with varying levels of walking ability to safely practice over-ground gait training.

Prosthetic Knee Suitable for Use in Extreme Situations

Otto Bock Health Care (Minneapolis, Minnesota), a MARP partner, developed a hardened microprocessor knee prosthesis (C-leg™) with enhanced durability, increased strength, longer battery life, field recharging features, and secure electronic function that is also serviceable and adjustable by the patient. The goal is a prosthetic knee suitable for use by amputees in a military environment.

Powered Foot and Ankle Prosthesis Could Enable Amputees to Perform Essential Mission Tasks

Medical researchers from MIT and Simbex, LLC (Lebanon, New Hampshire) partnered with MARP to develop a powered leg prosthesis that restores amputee balance, locomotory metabolism and speed, and a powered foot and ankle prosthesis that improves maneuverability and reduced metabolic cost. The powered foot and ankle prosthesis improves stability and speed to a degree that could potentially enable a warrior amputee to perform essential mission tasks.

Early Participation in Adaptive Sports and Sporting Events Benefits Both Physical and Social Aspects of Rehabilitation

Collaborative research between MARP and the Veterans Research Foundation of Pittsburgh, Human Engineering Research Laboratories, revealed that early participation in new adaptive sports and sporting events can increase the long-term benefits of a patient's rehabilitative process. Participation also increased the long-term benefits of socialization, community reintegration, health promotion, self-esteem, and functional independence. The study proved that the social aspects of these activities were just as beneficial in a patient's rehabilitation as the physical aspects.

Metabolic Response of Transtibial Amputees to Load Carriage Capabilities Less Impacted Than Injuries Suggest

Preliminary data from a MARP study on the biomechanical and metabolic analysis of amputees carrying military loads to meet RTD requirements indicate that, in terms of metabolic response, transtibial amputees may not be as greatly disadvantaged in load carriage capabilities as the extent of their injuries would suggest.

Mirror-Box Therapy Proves to Be an Effective Tool for the Treatment of Phantom Limb Pain in Military Amputees

MARP evaluated the efficacy of mirror-box and mental visualization treatments on phantom-limb pain. Ninety-three percent of subjects who used the mirror-box therapy reported significant improvements in phantom-limb pain. Worsening pain was reported by 50% of subjects treated with a covered mirror and 67% of subjects treated with mental visualization. MARP developed a mirror-box therapy based on these findings, as an effective and innovative tool for the treatment of phantom limb pain in military amputees.

Exploratory Study Links Amputation Level to Amputee's Gait and Function

An exploratory study by MARP on the effects of amputation level on transfemoral amputee function provided definitive evidence that transfemoral amputation length affects an amputee's gait and function. The study provides surgeons with evidence-based data to make operative decisions that improve the quality of life in the military amputee population.

Pilot Study Determines Neuromuscular Electrical Stimulation Decreases Phantom Limb Pain

Preliminary data from a MARP pilot study on neuromuscular electrical stimulation (NMES) in transtibial amputees indicated that NMES is an effective treatment method for decreasing phantom limb pain.

Chapter 5
Key Components of the Blast Injury Research Program

The Blast PCO was established to coordinate the large number of separate relevant efforts that can contribute solutions to the problems associated with blast threats. Within the DoD, medical research is conducted by the Army, Navy, Air Force, USHUS, and the DVBIC Center of Excellence. Funding for this research comes from each of the services, nonmedical research commands, DARPA, special congressional interest programs, notably $300M for TBI/PTSD in FY07 but also for military amputee research program and the DVBIC. Outside of the DoD, the VA is a key partner with similar efforts and needs. Other federal agencies, notably the NIH, have important related efforts. Various academic and industry centers around the country are also specialized in research relevant to the blast program focus. Several international efforts, including some foreign military medical research centers, have collaborative or contractual relationships with the DoD. Synchronization of the resources and capabilities of all of these programs has the potential to provide major advances. This chapter summarizes several key programs from some of these participants and funders.

FY07 PTSD/TBI Competitive Research Program

The PTSD/TBI Research Program is a Congressional Special Interest Medical Research Program administered by the USAMRMC Office of the CDMRP. This program was established to manage the $300M FY07 congressional special interest funding supplement directed to accelerate research on prevention, detection, diagnosis, and treatment of PTSD and TBI resulting from military operations. This includes research to benefit service members, their family members, veterans, retirees, and other beneficiaries of the Military Health System.

The CDMRP held stakeholders meetings on June 11–12, 2007 to assess the state of the science and research gaps in the areas of TBI and PTSD prevention, diagnosis, and treatment. Participants included representatives from the four Services, OSD(HA), VA, NIH, private industry, and academia. A vision setting meeting was held on June 13, 2007, immediately following the stakeholders meeting. The purpose of the vision setting meeting was to prioritize research gaps, establish goals and objectives, and develop an investment strategy. Participants in the vision setting meeting included representatives from the three Services, OSD(HA), USUHS, VA, and NIH.

The vision setting meeting produced the following investment strategy for the FY07 congressional appropriation of $300 million: (1) four intramural awards, $74M; (2) PTSD/TBI Clinical Consortium, $60M; (3) Advanced Technology-Therapeutic Development, $16M; (4) Investigator-Initiated Research, $10M; (5) Concept, $9M; (6) Multidisciplinary Research Consortium, $50M; (7) New Investigator, $6M; and (8) Center(s) of Excellence, $45M.

Research proposals submitted to the TBI/research program PTSD are reviewed according to the two-tier review model recommended by the National Academy of Sciences Institute of Medicine. The first tier is a scientific peer review of proposals against established criteria for determining scientific merit. The second tier is a programmatic review that compares submissions to military research needs and recommends proposals for funding based on scientific merit and overall program goals. Programmatic review of proposals is conducted by the Joint Program Integration Panel (JPIP). Panel members include representatives from the ASBREM Secretariat (Army, Navy, Air Force, the OSD (HA)); USUHS; DDR&E; the VA; the NIH; and clinical consultants from each of the Services. The Deputy Assistant Secretary of Defense Force Health Protection and Readiness (DASD(FHP&R)) approves all funding decisions for the PTSD/TBI Research Program.

The first of three JPIP programmatic review meetings was held on December 17–18, 2007. During this meeting, the JPIP reviewed research proposals submitted under the PTSD and TBI Concept Award,

Intramural PTSD and TBI Advanced Technology-Therapeutic Development Award, and Intramural PTSD and TBI Investigator-Initiated Research Award mechanisms. These program announcement award decisions were accelerated because of the constraints of the specific awards. Concept awards were limited to modest efforts not requiring new human use approval, ensuring that these can be quickly initiated. These projects explore novel and potentially important ideas, for which preliminary data may not be available and provide an opportunity to rapidly explore key research gaps that may be addressed through follow-on research. The other award topics evaluated in this first review meeting involved projects that were led by intramural (DoD or VA) laboratories where the FY07 funding must be executed before September 30, 2008. These could be accelerated because they are built only on existing relevant intramural research efforts and were simultaneously processed through internal federal scientific review and human/animal use reviews. The JPIP made funding recommendations for the program that were forwarded to the DASD(FHP&R) for approval on December 21, 2007, and are now in the contracting award process. The JPIP will review proposals for the remaining award mechanisms during meetings in January and March 2008.

Armed Forces Institute of Regenerative Medicine

The USAMRMC is in the process of setting up a new institute dedicated to the treatment of battlefield injuries through the use of regenerative medicine. It is envisioned that the Armed Forces Institute of Regenerative Medicine (AFIRM) will be a virtual organization consisting of multiple universities working in conjunction with the USAISR under the framework of a 5-year cooperative agreement. Current funding is: Army RDT&E: $5M/year, Navy RDT&E $1M/year, NIH $0.5M/year, FY07 Supplemental for Burns, Orthopedic, and Trauma $10M spread out over 5 years. This gives a total budget of $8.5M/year. The VA and DARPA were approached but did not provide funds.

OIF and OEF have resulted in more than 4,300 U.S. military fatalities and more than 30,000 injuries. Treatment of combat-related injury and trauma is particularly complex. While advances in body armor have greatly improved torso (vital organ) protection, thereby increasing survivability, those who survive often have more serious injuries than in past military conflicts. Conventional weapons and the destructive force of IEDs ravage face, neck, head and limbs, causing massive trauma and tissue loss. Approximately 6% of those wounded in Iraq have required amputations.

Regenerative medicine, which has achieved success in the regeneration of human tissues and organs for repair or replacement, represents great potential for treating military personnel with debilitating, disfiguring, and disabling extremity injuries. Regenerative medicine uses bioengineering techniques to prompt the body to regenerate cells and tissues, often using the patient's own cells combined with degradable biomaterials. Technologies for engineering tissues are developing rapidly, with the ultimate goal of delivering advanced therapies, such as whole organs and engineered fingers and limbs, as safely and efficiently as possible.

The institute will be financed with basic research through exploratory development funds and will be expected to make major advances in the ability to understand and control the cellular response in wound repair and organ/tissue regeneration as well as designing and engineering new biomaterial scaffolds to guide the regeneration process. It is expected that this institute will be able to translate some of its technologies into patients within the 5-year period.

The Program Announcement (PA) was released in August and seven proposals were received on October 18, 2007. A Technical Review Board was convened and pared these down to two finalists who gave oral presentations to the Technical Review Board on December 5, 2007. A final selection was made by a Programmatic Review Board on December 14, 2007. The Board praised both proposals and found them both nearly equal in merit. The White House inquired about the AFIRM as a potential announcement to be made in the State of the Union Address. At the White House's request, DoD programmed $8.5M/year extra to USAMRMC to fund the second candidate. The winners should be announced in January 2008.

Defense Center of Excellence for Psychological Health and TBI

The Deputy Secretary of Defense directed the establishment of the DCoE for PH and TBI by November 30, 2007. The DCoE will be a collaborative program integrating military prevention and protection, family and community outreach, and support, clinical care, and research expertise from across the federal and private sectors. It will lead DoD in establishing quality standards and program excellence for psychological health and traumatic brain injuries.

The current DVBIC, a longstanding program of surveillance, assessment, treatment, education, and research in matters of TBI will integrate as a component of the DCoE. Also, DVBIC will maintain its nation-wide, hospital-based network of DoD and VA clinical and research sites.

In addition to the expertise in TBI, the DCoE will be staffed with experts in psychological health. The DCoE will conduct research and establish programs and education addressing mental, emotional, and behavioral functioning as well as enhancing resilience and psychological fitness. The Center for Deployment Psychology will also integrate its staff and functions as a component of the DCoE.

The DCoE will develop a national collaborative network to coordinate existing medical, academic, research, and advocacy assets within the Services, VA, and Health and Human Services (HHS), other federal, state, and local agencies, as well as academic institutions.

The integration of programs among government and civilian communities, measured outcomes of clinical programs, research, telehealth initiatives, and advanced medical technology, will result in unprecedented expertise in evidence-based programs to optimize psychological health and rehabilitate traumatic brain injuries.

A new facility will be constructed for the core activities of the DCoE. That facility will be called the National Intrepid Center of Excellence and proposed plans for its specific location are under development.

The Director of the DCoE is Colonel (Promotable) Loree Sutton, USA, who reports to the ASD(HA). A three-phase organizational plan began with selection of a senior staff and commencement of operations immediately, with full operations at the permanent location in 2009.

The DCoE will be an interdisciplinary directorate under the TRICARE Management Activity. The military Services have been requested to provide nominees to fill principal Director positions.

Military Amputee Research Program

Ongoing combat operations have produced a surge from 3% to 6% in complex combat injuries involving amputations of major limbs. The Military Amputee Patient Care Program headquartered at WRAMC provides a center of expertise for state-of-the-art treatment, the rehabilitation of military amputee patients to the highest level of physical function, and a return to active duty if possible. To support this program, the MARP was formed at the WRAMC, and now also includes an organized research core at the Center for the Intrepid at Brooke Army Medical Center (BAMC). MARP funding started with an FY04 Congressional Special Interest appropriation and continued through FY05, FY06, and FY07 but not in FY08. The program has identified five areas of prosthetic/amputee-related research focus:

- Prosthetic technology
- Rehabilitation strategies
- Clinical management
- Epidemiological studies
- Database development and management

The MARP accepts proposals from internal WRAMC, BAMC, and DoD researchers and external non-DoD researchers from academic and private sectors. The goal of the intramural program is to support

research that will optimize patient recovery after traumatic limb loss. Most patients want to return to their active lifestyles after recovery and continue to engage in activities such as running. Current prosthetic technologies are limited in this regard. With such a large group of young military personnel utilizing prosthetic devices, there is both a great need and an opportunity to conduct research that will lead to the development of more functional and comfortable prosthetic technologies and improved rehabilitative training strategies. Research areas include comparison studies of various technologies and rehabilitation methods. A good prosthetic fit is critical to patient satisfaction. Researchers are thus investigating various types of socket designs and suspension systems. Other studies examine the differences in a patient's functional performance when comparing the utility of mechanical versus electronically controlled prosthetic systems.

The program is managed by TATRC as part of a larger program with a growing portfolio of projects aimed at providing advanced prosthetics, orthotics, and other assistive devices, treatments, and interventions for patients with major limb amputations, fractures, and other orthopaedic-related injuries. There is significant overlap and collaboration between this portfolio and areas of research including neural prosthetics, TBI, spinal cord injury, tissue generation, and robotics.

Current projects include:

- Powered and Regenerative Kinetics Prostheses
- Advanced Socket Design
- Comfortable and Dynamic Sensing Socket
- Osseointegration Infection Prevention
- Over-Ground Body-Weight Support Gait Training System
- Limb Trauma Outcomes
- Quality of Life Surveys
- Orthotic and Prosthetic Education

The TATRC Advanced Prosthetics and Human Performance portfolio provides funding and management oversight for congressionally sponsored projects as well as management oversight for portfolio-related SBIR and Small Business Technology Transfer research. Additionally, TATRC provides funding and management oversight to the U.S. MARP that funds research at the WRAMC Military Amputee Training Center, and the Center for the Intrepid at the Brooke Army Medical Center. TATRC cooperates with the DARPA on the Revolutionizing Prosthetics program and also with the VA on various portfolio-related research efforts.

Preventing Violent Explosive Neurologic Trauma

Previous efforts to understand brain injuries that result from nonkinetic explosive effects have focused on a single explanation—blast overpressure. However, IED-induced injuries in Iraq do not fit this hypothesis. Evidence indicates that traumatic brain injuries unique to exposure to blast exist absent of typical overpressure injuries (damage to gas-filled organs such as the bowel and lungs). The PREVENT Program seeks to protect our warfighters from TBI resulting from such explosions.

The initial phase of the program will comprehensively evaluate the physics of interaction between an IED blast and the neurological system and determine which component(s) are causally associated with neurologic injury. Specific goals include:

- Addressing the mechanisms of explosive blast injury at the molecular as well as the macroscopic scales including, but not limited to, cellular, tissue level, organ level, and organ system level
- Characterizing the injury over the pathophysiological evolution ranging from primary injury resulting directly from the insult, to the consequent secondary pathophysiological cascade, extending beyond biogenic responses into psychogenic outcomes

- Isolating the spectrum of physical mechanisms in explosion environments and determining their coupled effects on the central nervous system

The second phase of the program will focus on prevention of injury and guide the development of passive and active mitigation strategies, the engineering and development of personal protective armor, and therapeutic interventions for those injured. The program also will develop test systems and predictive models. These models will characterize blast exposure to optimize treatment paradigms, explosive blast mitigation, and protective strategies.

Appendix A
Acronyms

AFTH	Air Force Theater Hospital
AMC	U.S. Army Materiel Command
ANAM	Automated Neuropsychological Assessment Metrics
AON	Anti-sense Oligonucleotides
ARL	U.S. Army Research Lab
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
ATACCC	Army Technology Applications for Combat Casualty Care
AUSA	Association of the United States Army
CDMRP	Congressionally Directed Medical Research Programs
CEPS	Communication Enhancement and Protection System
CSF	Cerebrospinal Fluid
CTTSO	Combating Terrorism Technology Support Office
DARPA	Defense Advanced Research Projects Agency
DASD(FHP&R)	Deputy Assistant Secretary of Defense Force Health Protection and Readiness
DCDD	Directorate of Combat and Doctrine Development
DCR	Damage Control Resuscitation
DCoE	Defense Centers of Excellence
DDR&E	Director of Defense Research and Engineering
DoD	Department of Defense
DoDD	Department of Defense Directive
DVBIC	Defense and Veterans Brain Injury Center
EA	Executive Agent
EAB	Executive Advisory Board
FAST	Field Assistance in Science and Technology
FEM	Finite Element Model
FHB	Fresh Whole Blood
FOCUS	Facial and Ocular Countermeasure Safety
FY	Fiscal Year
HMMWV	High Mobility Multipurpose Wheeled Vehicles
IED	Improvised Explosive Device
IIPT	Integrating Integrated Product Teams
JHU/APL	Johns Hopkins University Applied Physics Lab
JIEDDO	Joint Improvised Explosive Device Defeat Organization
JLTV	Joint Lightweight Tactical Vehicle
JPIP	Joint Program Integration Panel
JSF	Joint Strike Fighter
JTAPIC	Joint Trauma Analysis and Prevention of Injury in Combat
MACE	Military Acute Concussive Evaluation
MARCORSYSCOM	Marine Corps Systems Command
MEDEVAC	Medical Evacuation
MIT	Massachusetts Institute of Technology
MRAP	Mine-Resistant Ambush Protected
mTBI	Mild Traumatic Brain Injury
NDAA	National Defense Authorization Act
NAVAIR	Naval Air Systems Command
NHRC	Naval Health Research Center

NIH	National Institutes of Health
NIJ	National Institute of Justice
NIST	National Institute of Standards and Technology
NMES	Neuro-Muscular Electrical Stimulation
NMRC	Naval Medical Research Center
NSRDEC	U.S. Army Natick Soldier Research, Development, and Engineering Center
OEF	Operation Enduring Freedom
OIF	Operation Iraqi Freedom
OLES	Office of Law Enforcement Standards
ONR	Office of Naval Research
OSD	Office of the Secretary of Defense
PCO	Program Coordinating Office
PEEP	Positive End-Expiratory Pressure
PH	Psychological Health
PMs	Program Managers
PPE	Personal Protective Equipment
PREVENT	Preventing Violent Explosive Neurological Trauma
PTSD	Post-traumatic Stress Disorder
RBC	Red Blood Cells
RBCXL	Red Blood Cells, Extended Life
RDECOM	U.S. Army Research, Development, and Engineering Command
RTD	Return-To-Duty
SBIR	Small Business Innovation Research
SCI	Spinal Cord Injury
SECARMY	Secretary of the Army
siRNA	Short Inhibitory Ribonucleic Acid
SWM	Surface Wound Mapping
TATRC	U.S. Army Telemedicine and Advanced Technology Research Center
TBI	Traumatic Brain Injury
TEG	Thromboelastography
TSWG	Technical Support Working Group
TTCP	The Technical Cooperation Program
USAARL	U.S. Army Aeromedical Research Laboratory
USAF	U.S. Air Force
USAISR	U.S. Army Institute of Surgical Research
USAMEDCOM	U.S. Army Medical Command
USAMEDDCS	U.S. Army Medical Department Center and School
USAMMDA	U.S. Army Medical Materiel Development Activity
USAMRMC	U.S. Army Medical Research and Materiel Command
USUHS	Uniformed Services University of the Health Sciences
VA	Department of Veterans Affairs
VAC	Vacuum-Assisted Closure
WRAIR	Walter Reed Army Institute of Research
WRAMC	Walter Reed Army Medical Center
WTB	Weapons Training Battalion

Appendix B
Crosswalk Between Required Information and the FY 2007 Annual Report

The following table shows the crosswalk between the required information from Section 256 of the National Defense Authorization Act (NDAA) for FY 2006, Public Law 109-163 and the FY2007 Annual Report.

Required Information from Section 256 of the NDAA for FY 2006, Public Law 109-163	Crosswalk with FY 2007 Annual Report
1. A description of the activities undertaken under this section during the 2 years preceding the report to improve the prevention, mitigation, and treatment of blast injuries.	• Chapter 1, pages 1-2—1-3: **Key Program Accomplishments** section summarizes key program accomplishments during the preceding 2 years. • Chapter 2, pages 2-1—2-3: **Blast Injury Research Program Coordinating Office (PCO) Accomplishments** section lists key Blast PCO accomplishments during the preceding 2 years. • Chapter 4, pages 4-1—4-15: **Key Accomplishments by Program Area** describes specific accomplishments during the preceding 2 years in each of the three major program areas of the Blast Injury Research Program. • Chapter 5, pages 5-1—5-5: **Key Components of the Blast Injury Research Program** describes the significant activities of five major blast injury research programs during the preceding 2 years. These programs are the FY07 PTSD/TBI Competitive Research Program, the Armed Forces Institute of Regenerative Medicine, the Defense Center of Excellence for Psychological Health and TBI, the Military Amputee Research Program, and the DARPA Preventing Violent Explosive Neurologic Trauma (PREVENT) program.
2. A consolidated budget presentation for DoD biomedical research efforts and studies related to blast injury for the 2 fiscal years (FY) following the year of the report.	• Chapter 3, page 3-1: **Consolidated Budget Presentation** shows the consolidated budget for research efforts and studies related to blast injury for FY08-FY10.

Required Information from Section 256 of the NDAA for FY 2006, Public Law 109-163	Crosswalk with FY 2007 Annual Report
3. A description of any gaps in the capabilities of the Department and any plans to address such gaps within biomedical research related to blast injury, blast injury diagnostic and treatment programs, and blast injury tracking and monitoring activities.	• Chapter 1, pages 1-1—1-2: **Key Program Features** and **Key Research Topics** sections describe major capability and knowledge gaps, and research focus areas that will address the gaps. • Chapter 2, page 2-2: **Program Funding Requirements** section describes the FY10-15 programmed funding request for research projects that address recognized capability and knowledge gaps. • Chapter 2, pages 2-3—2-4: **Blast PCO Major Objectives** section describes five specific Blast PCO program management process objectives focused on addressing recognized capability and knowledge gaps.
4. A description of collaboration, if any, with other departments and agencies of the federal government and with other countries during the 2 years preceding the report in efforts for the prevention, mitigation, and treatment of blast injuries.	• Chapter 4, pages 4-1—4-15: **Key Accomplishments by Program Area** describes specific accomplishments during the preceding 2 years in each of the three major program areas of the Blast Injury Research Program. Each accomplishment description identifies the primary performers and collaborators. Collaborators cited in this section include DoD organizations, federal agencies, other countries, academia, and industry.
5. A description of any efforts during the 2 years preceding the report to disseminate findings on the diagnosis and treatment of blast injuries through civilian and military research and medical communities.	• Chapter 4, pages 4-1—4-15: **Key Accomplishments by Program Area** describes specific accomplishments during the preceding 2 years in each of the three major program areas of the Blast Injury Research Program. Each accomplishment description identifies the dissemination of information from the research effort. Examples include the presentation of research findings at workshops and conferences, and the publication of research findings in technical reports and in the open scientific literature.
6. A description of the status of efforts during the 2 years preceding the report to incorporate blast injury effects data into appropriate programs of the DoD and into the development of comprehensive force protection systems that are effective in confronting blast, ballistic, and fire threats.	• Chapter 4, pages 4-1—4-15: **Key Accomplishments by Program Area** describes specific accomplishments during the preceding 2 years in each of the three major program areas of the Blast Injury Research Program. Each accomplishment description identifies the incorporation of research findings and products into DoD programs and into force protection systems. Examples include the incorporation of research findings into materiel development programs, into follow-on research efforts and into blast injury prevention, mitigation, and treatment practices and policy.

Appendix C
Taxonomy of Injuries from Explosive Devices

- *Primary.* Blast overpressure injury resulting in direct tissue damage from the shock wave coupling into the body.
- *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.).
- *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.
- *Quaternary.* Other "explosive products" effects—heat (radiant and convective) and toxic toxidromes from fuel, metals, etc. - causing burn and inhalation injury.
- *Quinary.* Clinical consequences of "post detonation environmental contaminants" including bacteria (deliberate and commensal, with or without sepsis), radiation (dirty bombs), and tissue reactions to fuel and metals.

Source: DoDD 6025.21E, Medical Research for Prevention, Mitigation, and Treatment of Blast Injuries, July 5, 2006