



TBI Research Overview

IN THE LAB,
ON THE
BATTLEFIELD



Rehabilitation in Traumatic Brain Injury

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Neurotrauma Research Portfolio Manager
Combat Casualty Care Research Program
and Joint Program Committee 6 (CCC)

US Army Medical Research and Materiel Command

January 15, 2013

The views expressed in this presentation are those of the author and do not reflect official policy or position of the Department of the Army, Department of Defense or the U.S. Government. I have no relevant financial relationships to disclose.





USAMRMC Mission and Vision

IN THE LAB,
ON THE
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MISSION



Provide medical knowledge and materiel lifecycle management to protect, treat and optimize warfighter health and performance across the full spectrum of operations.



VISION



We are the world's experts and leaders in the military relevant biomedical research and medical materiel communities, delivering the best medical solutions to enhance, protect, treat, and heal our warfighters.





USAMRMC Actual Personnel – 30 Sep 2011			
MILITARY	CIVILIAN	CONTRACTOR	TOTAL
1,085	2,692	2,870	6,647
16.32%	40.50%	43.18%	100.00%

USAMRMC Organization Chart

IN THE LAB,
ON THE
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Deputy Commander

Deputy Commander Special Staff

- Dir, Office of Small Business Programs
- Dir, Med Systems Office, ASAALT
- Dir, Office of Research Protections
- Dir, Plans, Programs, Analysis, & Eval
- Dir, Quality Management
- International Affairs Officer

Extramural Execution Mgmt

- Congressionally Directed Medical Research Programs (CDMRP)
- Telemedicine and Advanced Technology Research Center (TATRC)

- **Armed Forces Medical Examiner**
- National Mus of Health & Med

Command Sergeant Major

Commanding General

Commanding General Special Staff

- Inspector General
- Internal Review
- Principal Assistant Resp. for Contracting
- Staff Judge Advocate

Chief of Staff

Secretary of the General Staff

Chief of Staff Special Staff

- Dir, Materiel
- Dir, Surety, Safety, & Environment
- Equal Opportunity Advisor
- Protocol Officer
- Public Affairs Officer
- Enlisted Senior Career Counselor
- Staff Judge Advocate
- Strategic Partnerships Office

Deputy Chiefs of Staff

- DCS, Personnel (G1)
- DCS, Operations (G3)
- DCS, Logistics (G4)
- DCS, Info Mgmt / Info Tech (G6)
- DCS, Resource Management (G8)

Principal Assistant for Research and Technology

- Dir, Infectious Diseases Res Prog
- Dir, Combat Casualty Care Res Prog
- Dir, Military Operational Medicine Res Prog
- Dir, Clinical & Rehabilitative Medicine Res Prog
- Dir, Medical Training and Health Information Sciences
- Dir, CBRN Defense Medical Research Coordination Office
- Dir, Blast Injury Research Program Coordinating Office
 - Joint Trauma Anal & Prev of Inj in Cmbt (JTAPIC)

Principal Assistant for Acquisition

- Proj Mgr, Pharmaceutical Systems
- Proj Mgr, Medical Support Systems
- Proj Mgr, HIV Vaccine
- Proj Mgr, Armed Forces Inst of Regenerative Medicine
- Proj Mgr, Hyperbaric Oxygen
- Proj Mgr, Medical Devices
- Proj Mgr, Integrated Clinical Systems
- Proj Mgr, Helicopter Medevac Med Equip Pkg
- Proj Mgr, USAMRMC Enterprise IM/IT





USAMRMC - Collaborative by Nature & Necessity

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Defense Acquisition
Regulations Directorate

SUCCESSFUL LIFECYCLE MANAGEMENT COMMAND

INTEGRATION OF DOD AND FDA REGULATIONS



C·D·R·H

FDA

CDER

CBER

COLLABORATIVE COMMAND



NATIONAL
CANCER
INSTITUTE

CDC



Industry



ARMY
MEDICINE
CARING BEYOND THE CALL OF DUTY



USDA



International



Academia



Military vs. Civilian Biomedical R&D

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Area	Civilian Focus	USAMRMC Focus
General	<ul style="list-style-type: none"> Maintaining health 	<ul style="list-style-type: none"> Maintaining health <u>and</u> performance
Drivers	<ul style="list-style-type: none"> Civilian health demographics Market forces 	<ul style="list-style-type: none"> Military health threats Operational expediencies
Trauma	<ul style="list-style-type: none"> Septic shock Hospital-based care by physicians Rehabilitation 	<ul style="list-style-type: none"> Penetrating trauma and hemorrhagic shock Field care by self, buddy or medic Reducing medical logistics
Infectious Disease	<ul style="list-style-type: none"> Diseases endemic in CONUS Global pandemics 	<ul style="list-style-type: none"> Diseases endemic in OCONUS
Operational Medicine	<ul style="list-style-type: none"> Industrial occupational environments 	<ul style="list-style-type: none"> Extreme physical environments and workloads
MCBDP	<ul style="list-style-type: none"> Post exposure treatment Detect to treat 	<ul style="list-style-type: none"> Pre-exposure protection Emerging threats Diagnostics





Joint Program Committees Managing TBI Research

- JPC 5 – Military and Operational Medicine
 - mTBI with PTSD and mTBI with other co-morbidities
 - Prevention, protection
 - Cognitive readiness and rehabilitation
- JPC 6 – Combat Casualty Care
 - Management of spectrum of TBI
 - Point of injury to initial weeks in US Facility
- JPC 8 – Clinical and Rehab Medicine
 - US Military Treatment Facilities
 - Until returned to duty, medically boarded and/or transferred to VA care



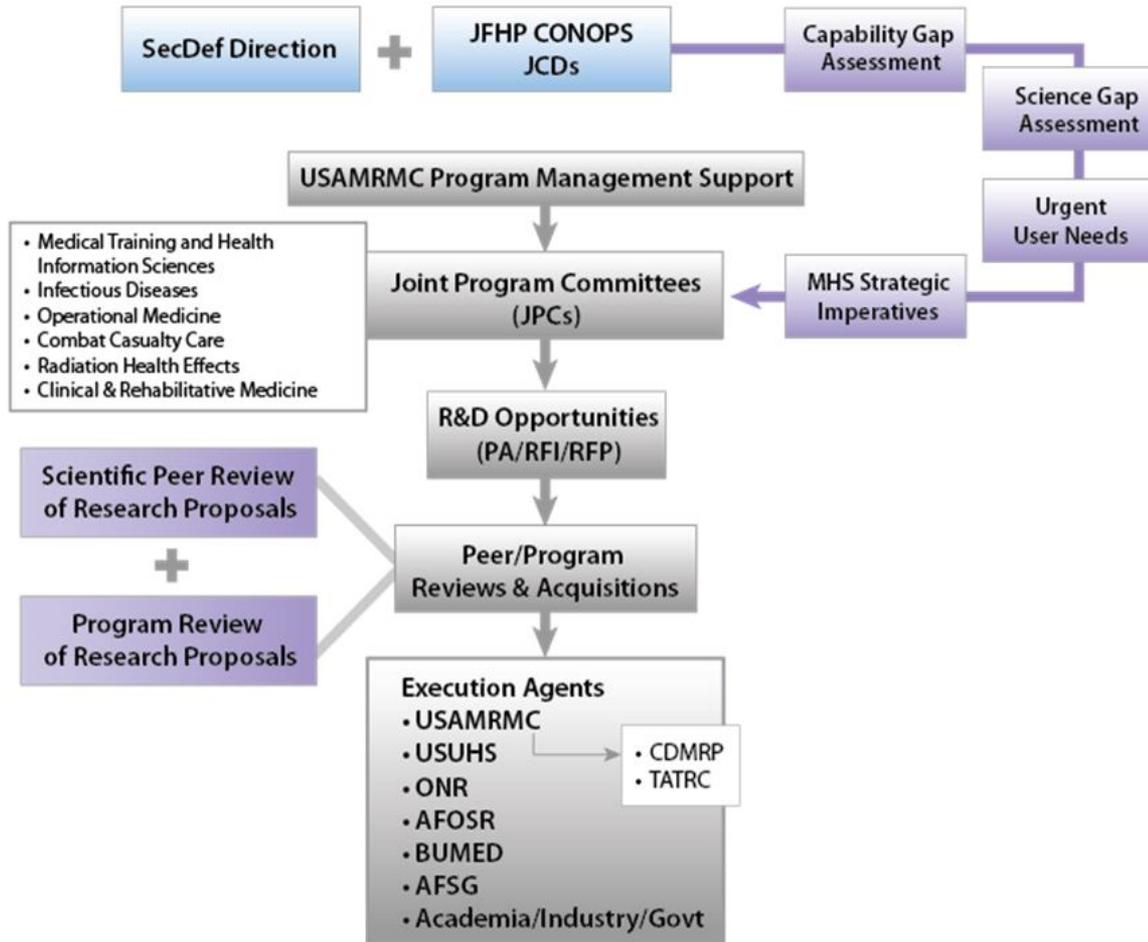


Defense Medical Research and Development Program

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Defense Medical Research and Development Program Process



JFHP CONOPS = Joint Force Health Protection Concept of Operations; JCD = Joint Capabilities Document
 MHS = Military Healthcare System

PA = Program Announcement
 RFI = Request for Information
 RFP = Request for Proposals

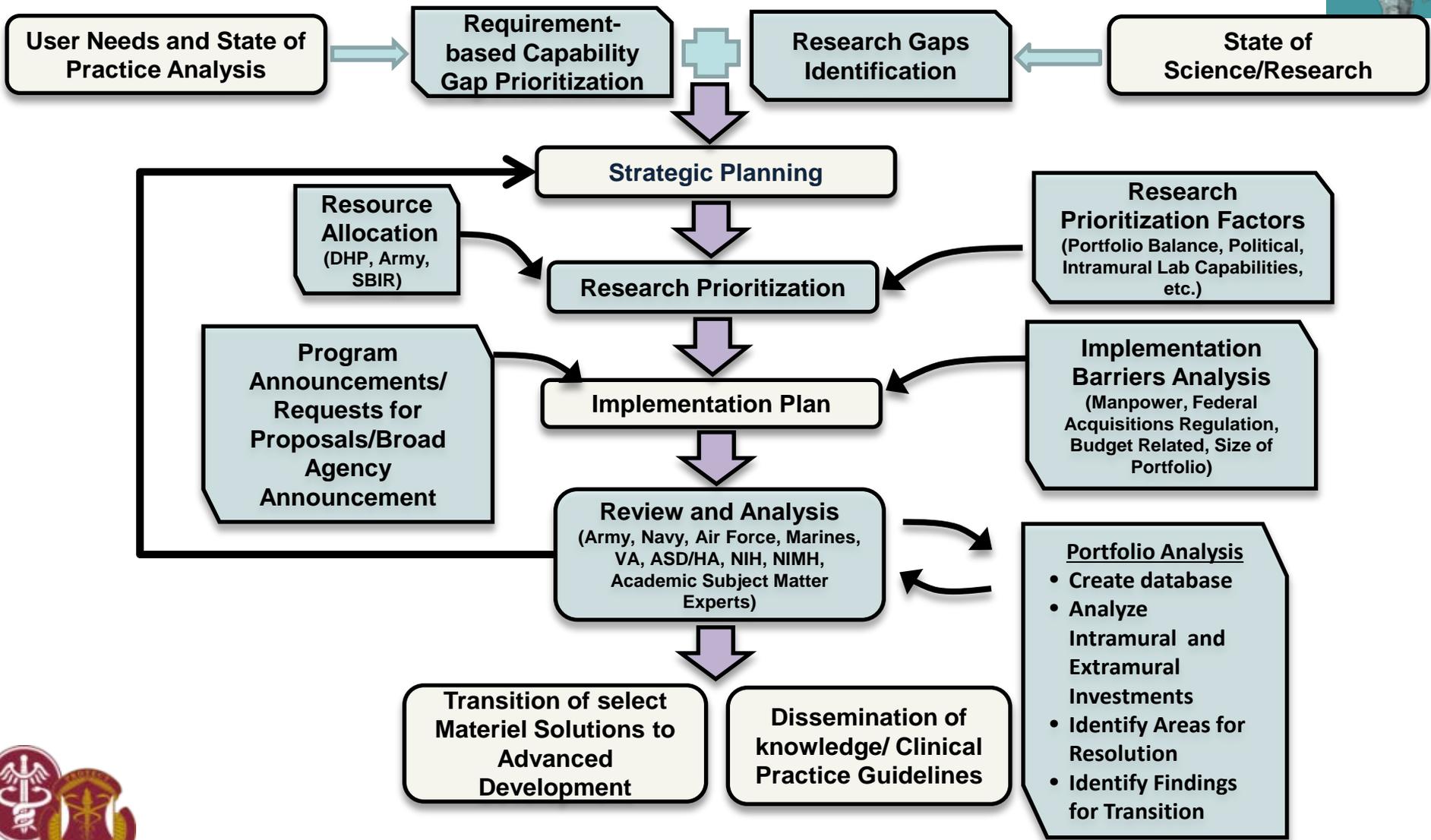
USAMRMC = US Army Medical Research and Development Command;
 USUHS = Uniformed Services University; ONR = Office of Naval Research; AFOSR = Air Force Office of Scientific Research; BUMED = Navy Bureau of Medicine and Surgery; AFSG = Air Force Surgeon Generals Office





DoD Joint Program Committee Strategic Research Planning Process

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Mission

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To reduce the impact of injury and overall death rate resulting from battlefield wounds

Meet Demands on First Responders

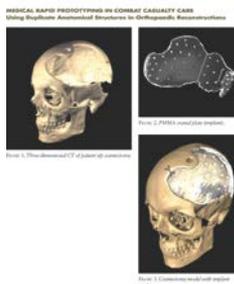
- Patient monitoring/assessment technologies
- Decision-assist algorithms/devices

Reduce the Number of Deaths on the Battlefield

- Damage control resuscitation
 - ✓ Clotting factors (TXA, fibrinogen, etc.)
 - ✓ Dried plasma, other blood products
 - ✓ Bleeding control devices/bandages
- Enhanced resuscitation fluids

Limit Brain Damage

- Biomarkers
- Screening & Diagnostic devices
- Neuroprotective drugs
- Neuroplasticity



Improve En Route Care

- Oxygen conservation
- Closed loop algorithms
- Lightweight modules
- "Virtual ICU"

Definitive Care of Combat Injuries

- Improved definitive care for orthopedic and maxillofacial injuries
- Improved wound/burn care
- Improved vascular surgery
- Treatments for lung injury due to smoke & blast

Reduce Morbidity and 'Died of Wounds' Rate

- Full physiologic life support
- Reduce complications from blood loss
- Maintain tissue viability

Clinical Trials

- Test advanced therapies and devices for use in Role 1 through early Role 4





Combat Casualty Care Key Focus Areas

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➤ Mortality

- **Non-compressible Hemorrhage**
 - Including Coagulopathy
- Compressible Hemorrhage
 - Extremity
 - Axilla/neck/groin
- Pneumothorax
- Airway Compromise
- Multisystem Organ Failure
- Sepsis (w/ JPC2)
- Deep Vein Thrombosis
- Other

➤ Morbidity

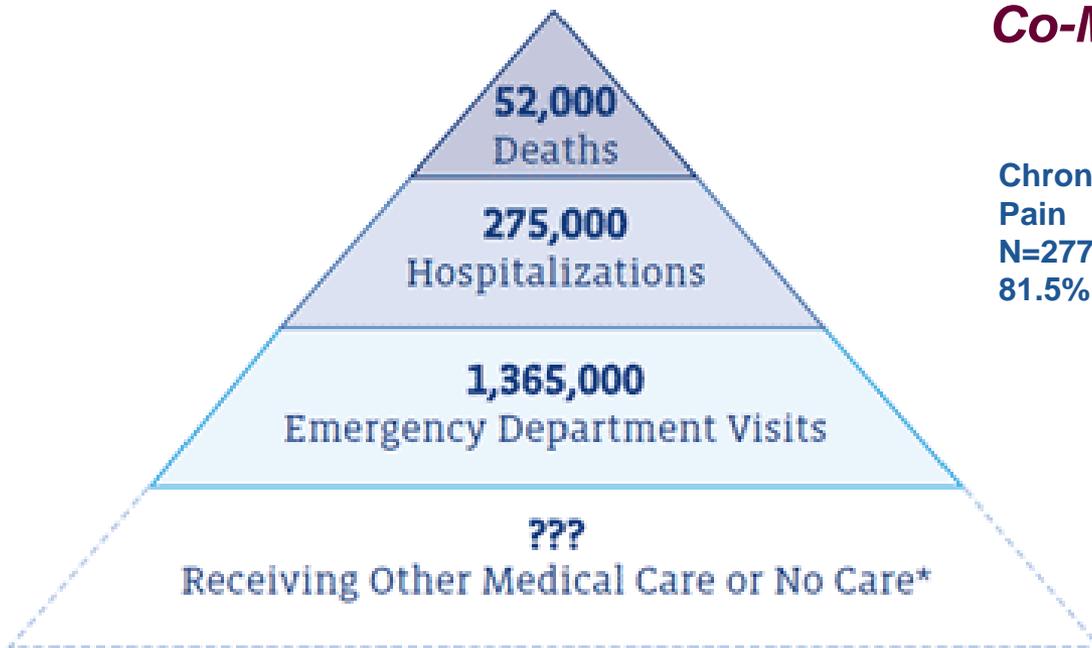
- **Traumatic Brain Injury**
 - Mild (w/ JPC5) to Severe
 - Massive Soft Tissue Injury
 - Orthopedic Trauma
 - Spine trauma
 - Spinal Cord Injury
 - Complex extremity
 - Burn
 - Craniofacial Injury
 - Pain (acute and chronic)
- } w/ JPC8
- Training (w/ JPC1)
 - Medic
 - Specialty Surgeon
 - Other Providers



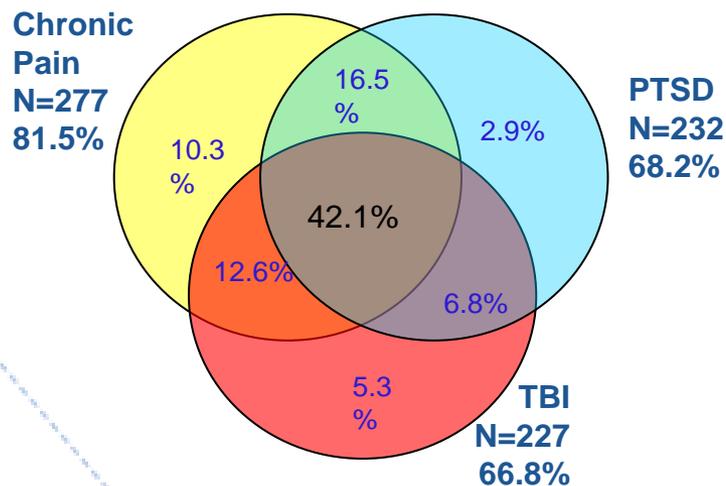


Traumatic Brain Injury

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Co-Morbidities Associated with mTBI and PTSD



- Sleep disorders
- Substance abuse
- Psychiatric illness
- Vestibular disorders
- Visual disorders
- Cognitive disorders

<http://www.cdc.gov/traumaticbraininjury/statistics.html>

Accessed 22 Feb 2012

Lew, et al: "Prevalence of Chronic Pain, Posttraumatic Stress Disorder, and Persistent Postconcussive Symptoms in OIF/OEF Veterans: Polytrauma Clinical Triad", Dept. of Veterans Affairs, Journal of Rehabilitative Research and Development, Vol. 46, No. 6, 2009, pp. 697-702, Fig. 1





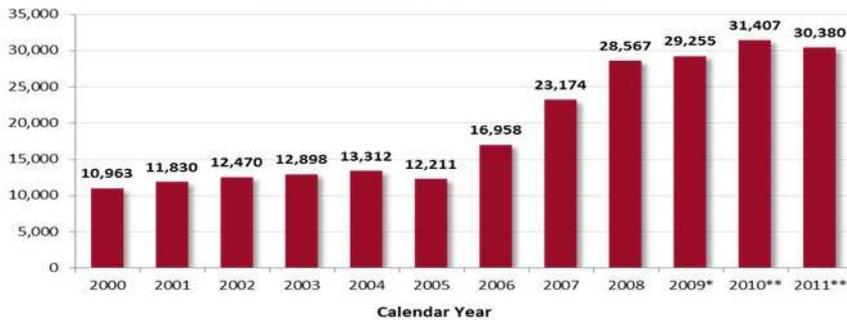
DoD-VA TBI definition and TBI threat

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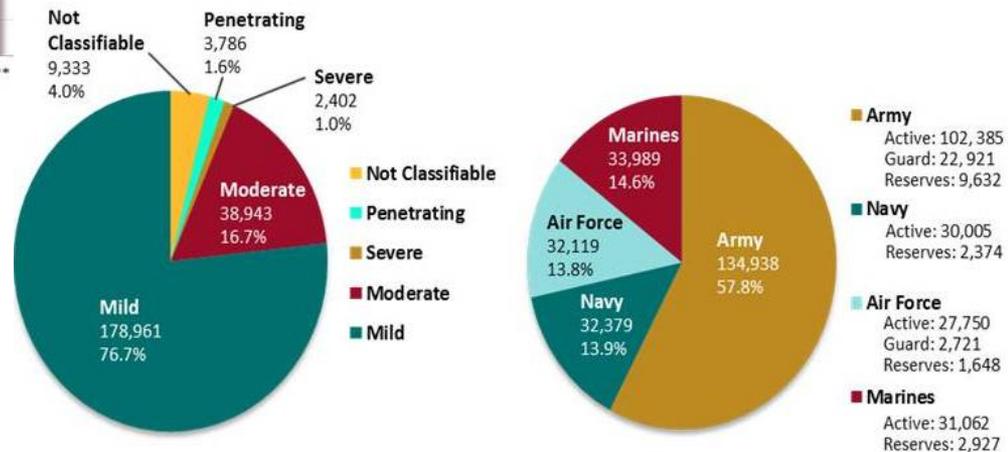


Mild	Moderate	Severe
Normal Structural Imaging	Normal or abnormal structural imaging	Normal or abnormal structural imaging
LOC = 0 – 30 minutes	LOC > 30 minutes and < 24 hours	LOC > 24 hours
AOC = a moment up to 24 hours	AOC > 24 hours Severity based on other criteria	AOC > 24 hours Severity based on other criteria
PTA = 0 – 1 day	PTA > 1 day and < 7 days	PTA > 7 days
GCS = 13 – 15	GCS = 9 – 12	GCS = 3 – 8
LOC = loss of consciousness, AOC = alteration of consciousness/mental state, PTA = post-traumatic amnesia, GCS = Glasgow Coma Scale		

TBI Diagnoses in U.S. Armed Forces



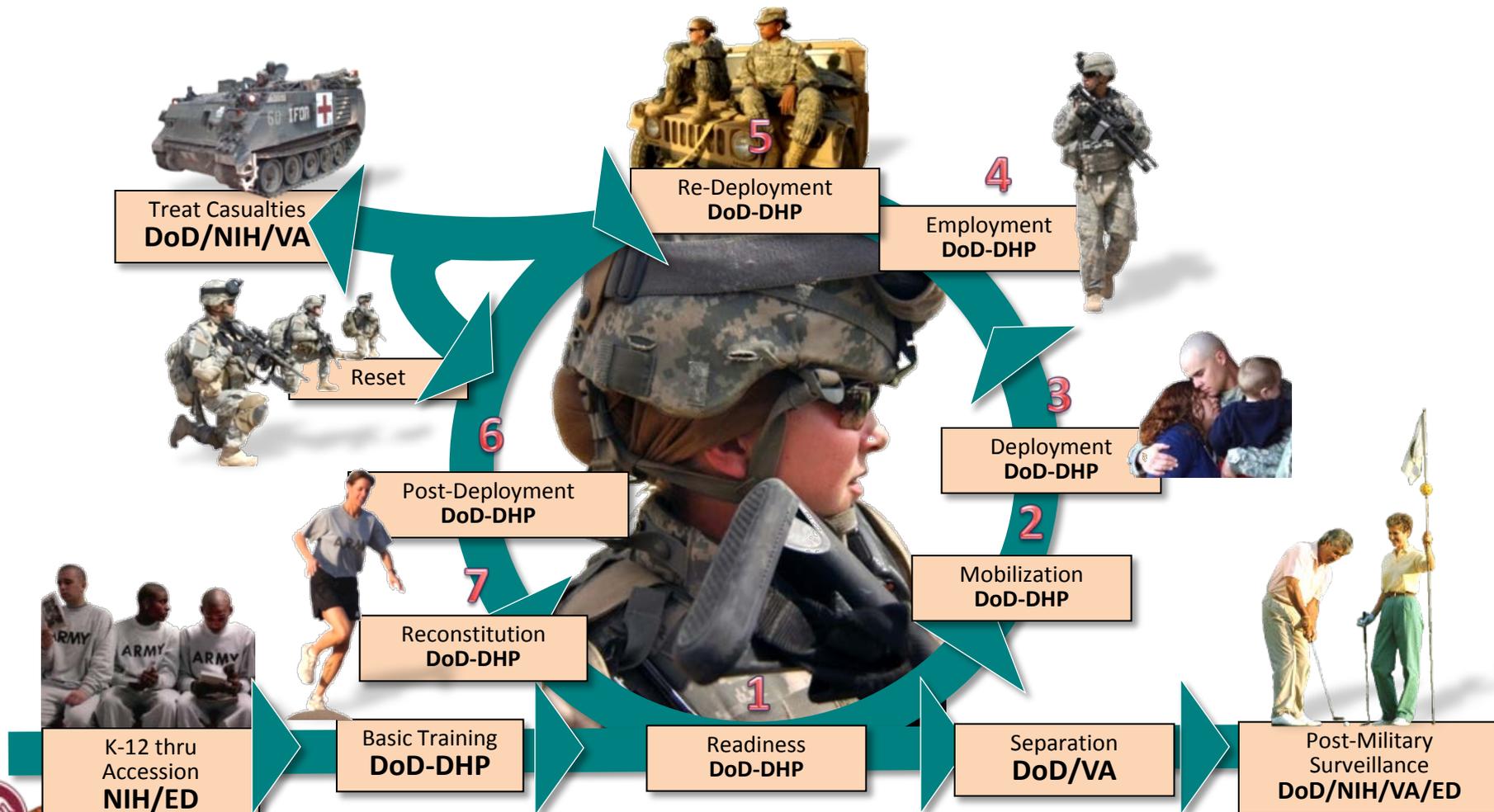
* 2000-2009 annual numbers updated as of 16 May 2011
 **2010 – 2011 annual numbers updated as of 10 Feb 2012





Joint Integrated Research Approach

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DEVELOPING AND MAINTAINING A FIT AND READY FORCE





Continuum of TBI Care Determines Research Approach

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RESEARCH NEEDS

Injury Prevention

Medical Standards for Protective Equipment

Objective Measure of Head Impact/Blast Exposure

Valid Criteria & Objective Servicemembers/Concussion Screening Tool

RDT&E: Combat Casualty Care

Portable Fieldable Diagnostic Device (In Theatre & Garrison)

Pharmaceutics & Surgical Technology

Psych Health and Related Symptoms

Recovery Timecourse & Rehabilitation

Valid RTD Standards & Measures of Rehabilitation

1. Basic Science & Epidemiology: 131 studies \$ 135,640K

2. TBI/Concussion Prevention/Education & Training

3. Possible TBI/Concussion from Impact or Blast

4. TBI/Concussion Screening (DoD Guidelines)

5. TBI/Concussion Assessment

6. TBI/Concussion Treatment

7. TBI/Concussion Recovery

8. Return to Duty

Return to Duty/Disability/Reclassification Assessment

Continuing Education and Reinforcement for Servicemembers, Leaders and Service Providers

Nutraceuticals, Standards for Helmets, Education/CPG's for Servicemembers, Leaders & Service Providers

Head Impact/Blast Injury Dosimeter (Fielding HMSS Gen 2 & DARPA Blast Gauge 2012)

Objective Assessments: Quantitative EEG (qEEG) and smooth pursuit eye tracking. BANDITS= biomarker assessment for neurotrauma diagnosis & improved triage system. (qEEG pivotal trial complete 2013, Build ruggedized prototype EYE-TRAC by end 2012, BANDITS Pivotal Trial Starting, FDA approval 2015)

Cognitive, Behavioral, Neurological and Diffusion Tensor Imaging (DTI), Magnetic Resonance Spectroscopy (MRS) and High Definition Fiber Tracking with advanced MRI (publication June 2012) (HDFT CY13)

Drugs, nutraceuticals and nutrition. Neuromodulation: Cranial Nerve Stimulation (Vagal nerve & Tongue stimulation) (Phase II clinical trial of NNZ-2566 for moderate-severe TBI started May 2010) (PoNS Study starting at Ft Campbell Sep 2012)

Rehabilitation: Measures/markers for rehabilitation assessment and for development of useful rehab approaches (complete on-going study by end 2014)

Improved, objective (and standardized) RTD assessments and guidelines (Advanced development; dissemination of findings end of 2012)

SOLUTIONS

(21 Dec 2012)



Current Assessment of mTBI/Concussion Research

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- Lack of a validated case definition of mTBI (still)
 - 41 definitions/guidelines identified by WHO ([J Rehabil Med. 2005 May;37\(3\):137-41](#))
 - Recent review by DoD-funded working group to develop concussion definition guidelines found that only 0.5% of literature identified was of MEDIUM quality and had inclusive case definitions and reported data at fixed time points relevant to one or more of the key questions they sought to address.
 - TBI is heterogeneous-saying that one has experienced a “mild TBI” is akin to saying one has experienced a “motor vehicle collision” – it is a category error ([J Trauma Acute Care Surg. 2012;73: S13YS23.](#))
- High frequency of exposure to blast related impact and non-impact (multiple exposures per warfighter)
- Co-morbidity with other Soldier behavioral health concerns (e.g. PTSD, depression, anxiety, suicidality, alcohol and drug abuse, risk taking behaviors, etc.)
- Multiple factors may complicate recovery from mTBI for soldiers wounded in theater ([Hoge, CW et al. Mild traumatic brain injury in US soldiers returning from Iraq. NEJM 2008; 358](#))
 - Risk of repeated head injuries
 - Misdiagnosis or under diagnosis





Six Ways to the Same GCS

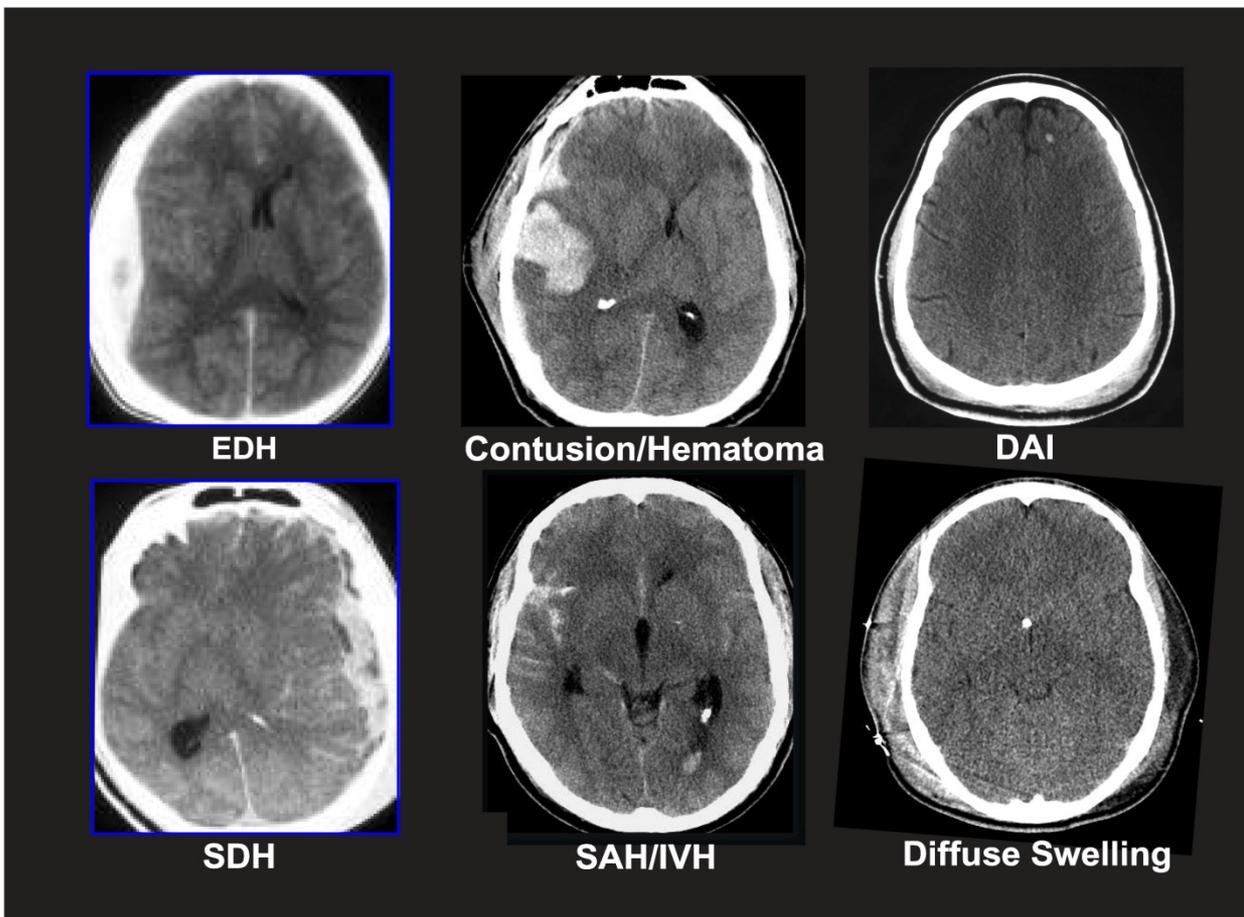


FIG. 1. Heterogeneity of severe traumatic brain injury (TBI). Computed tomography (CT) scans of six different patients with severe TBI, defined as a Glasgow Coma Scale score of <8, highlighting the significant heterogeneity of pathological findings. CT scans represent patients with epidural hematomas (EDH), contusions and parenchymal hematomas (Contusion/Hematoma), diffuse axonal injury (DAI), subdural hematoma (SDH), subarachnoid hemorrhage and intraventricular hemorrhage (SAH/IVH), and diffuse brain swelling (Diffuse Swelling).

Saatman, KE, et al. JOURNAL OF NEUROTRAUMA 25:719-738 (July 2008)





Current Assessment of Mild thru Severe Research

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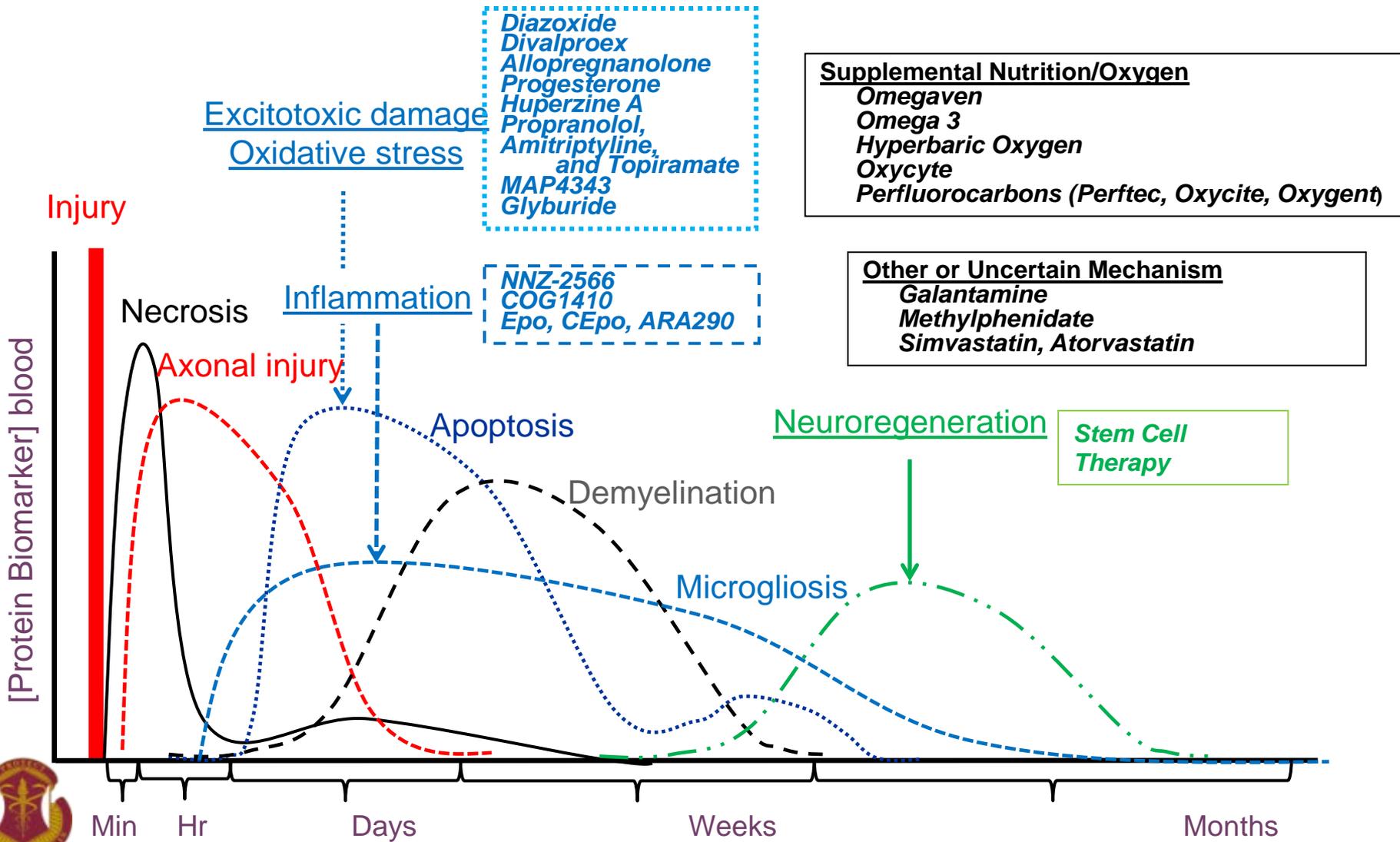
- Blast and impact TBI models require standardization
- Mild and repetitive mild TBI models require validation
- Blast effects may have a unique signature of injury, but it is very difficult to isolate primary blast wave components from rotational acceleration
- Screening/Assessment development has shown promise
 - Serum Biomarkers
 - Physiologic Assessments (quant EEG, Smooth Pursuit Eye Tracking, etc)
 - Imaging (Diffusion Tensor, High Definition Fiber Tractography, Positron Emission Tomography, functional MRI, MR Spectroscopy, etc)
 - Neuropsychological Assessment Tests (NPATs)
- While many therapies have appeared useful in pre-clinical models, they have not successfully translated to clinical use
 - Developed Federal Interagency TBI Research Informatics System with NINDS
 - Evaluating international comparative effectiveness research effort that in turn may help refine pre-clinical models
 - It may well be that past trials have failed simply because we do not have the capability to properly measure the effect of a given therapy in humans





Drug Target Mechanisms

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FITBIR Data Repository

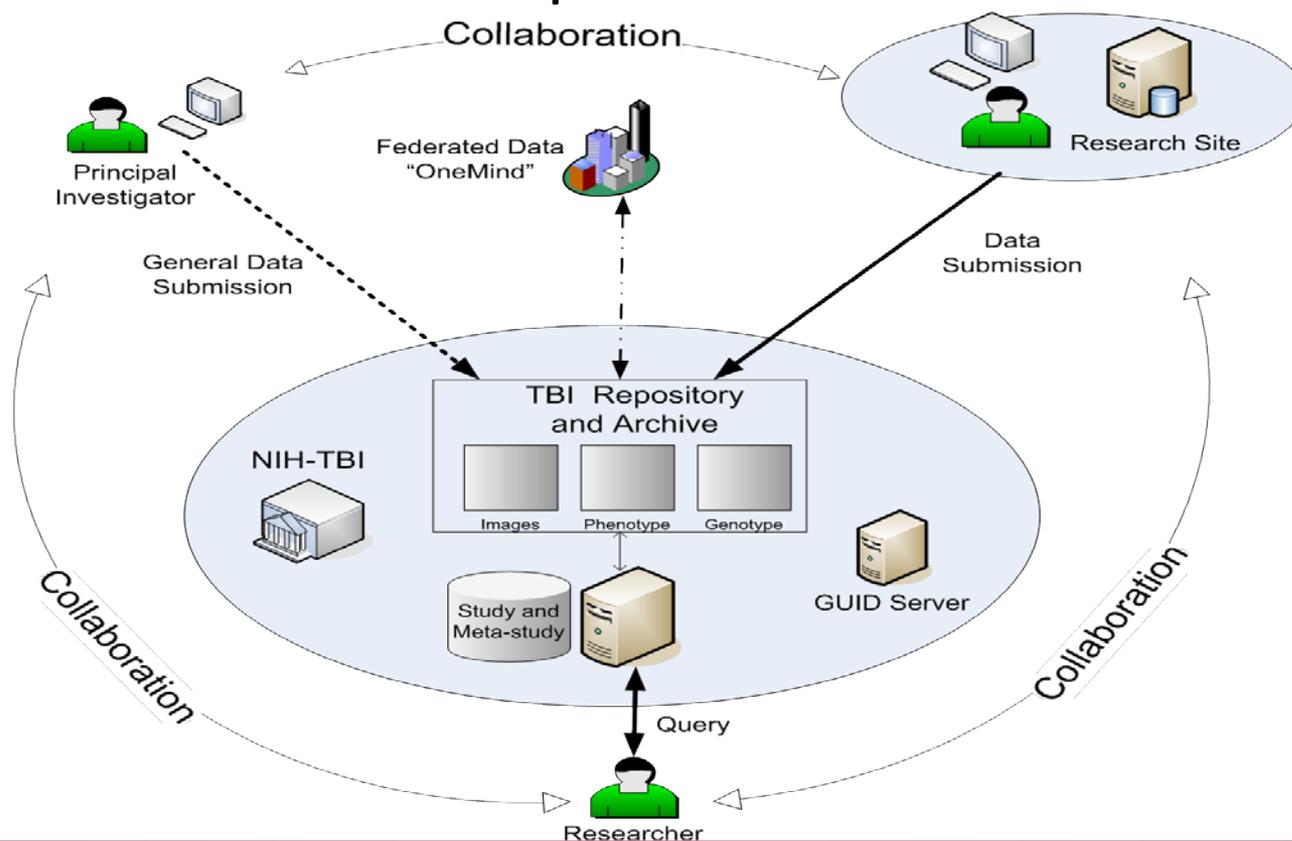
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Federal Interagency TBI Research

A collaboration between NIH and DOD to develop a biomedical informatics system to accelerate scientific discovery and treatment in Traumatic Brain Injury.

Database with multiple contributors and multiple accessors





Common Data Elements

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[Skip Navigation](#) [Project Overview](#) [Contact](#) [National Institutes of Health](#)



NINDS Common Data Elements

Harmonizing information. Streamlining research.

[Standards](#) | [Tools](#) | [Learn](#)

Streamline Your Neuroscience Clinical Research

using these content standards that enable clinical investigators to systematically collect, analyze, and share data across the research community.

The NINDS strongly encourages researchers who receive funding from the Institute to ensure their data collection is compatible with the common data elements (CDEs).

CDEs now available:

- [General \(CDEs that cross diseases\)](#)
- [Epilepsy](#) New!
- [Spinal Cord Injury](#)
- [Traumatic Brain Injury](#)

CDEs in development:

- [Stroke](#) - Public comments under review
- [Parkinson's Disease](#) - Final development
- Frontotemporal Dementia
- Huntington's Disease
- Amyotrophic Lateral Sclerosis
- Neuromuscular Disease
 - Congenital Muscular Dystrophy
 - Friedreich's Ataxia
- Headache



[Investigators and Research Teams – launch studies with CDEs:](#) The CDE Standards



[Data Managers and Programmers – incorporate the CDEs into your systems:](#) Use



[Discover how the CDE Project collaborates with others:](#) Learn more about the

<http://www.commondataelements.ninds.nih.gov/>





Rehabilitation after TBI

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- Much of what is used was developed in the stroke and SCI rehab arenas
 - Stroke is a focal, relatively homogeneous injury, TBI often diffuse
 - Providers tend to use what they were taught
 - Many approaches are un- or poorly validated (our Servicemembers deserve Evidence-Based approaches)
 - Definition of “recovered” is problematic especially for mTBI
 - Do we truly recover?
 - Outcome assessments are also a challenge
 - Many different assessments
 - Some can have coarse granularity(e.g. Glasgow Outcome Scale-Extended)





Rehabilitation after TBI

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- Assistive Technologies
 - Cueing/reminder systems
 - Touch screens
 - Assistive animals
 - Speech synthesizers
 - Special eyewear (prisms, patches, etc)
- Rehabilitation Technologies
 - Plasticity (nearly all can leverage computer-based/simulation/virtual reality technologies)
 - Physical Therapy (repetition)
 - Speech Therapy (swallowing)
 - Occupational Therapy
 - Vision Therapy
 - Neuromodulation
 - Cranial Nerve Stimulation (non-invasive and invasive)
 - Deep Brain Stimulation (invasive)





Cranial Nerve Non-Invasive Neuromodulation



PI: Dr Brett Logan, Blanchfield Army Community Hospital, Ft Campbell **Consultant:** Dr Yuri Danilov, TCNL, U. Wisc-Madison

Background

- CN-NINM has been demonstrated to create localized functional changes in brain activity levels, resulting in improved balance, posture, gait and limb movement control.

Approach

- The daily training regimen during the initial 2-week intensive phase will consist of two 90-minute 1-on-1 sessions with the trainer each day. Sessions comprised of 3 elements:
- **20-Minute Movement Training** (with PoNST™) Targeted training of body segments that typically move in synergistic adaptive patterns teaches the subject to develop isolated muscle control, joint mobility, relaxation, and strength. The goal of this training is to improve body awareness and re-train movements for improved neuromuscular control and mobility.
- **20 Minute Balance Training** (with PoNST™) The goal of balance training is to create body awareness, correct postural alignment, and improve balance by recalibrating proprioceptive, tactile and vestibular inputs. Initial balance training requires that the subject perform three progressively challenging 5-minute balance trials while using the PoNST™ device. The dimensions of the base of support and compliance of the seated or standing surface (sensory conditions) are varied to advance the challenge as appropriate.
- **20-Minute Cognitive/Memory/Attention Training** (with PoNST™) will be performed using a customized software program employing the Brain Fitness™ (Posit Science, San Francisco, CA), the HighIQPro Braintraining suite, or equivalent. The ability to sustain mental effort in purposeful, goal-directed activity will be continually monitored, and the training program progressed to maintain engagement and aid recovery in the identified functional deficits.



Pilot study in 40 mTBI cases at Ft Campbell Warrior Resiliency and Recovery Center. PoP: 1 Oct 2012 to 1 Apr 2013.

Analysis and Expected outcomes: Both individual (n=1) and cohort data set analysis will be conducted to identify both specific and generalizable effects of the intervention methods. We predict small but important changes after the first week of the In-Clinic intervention, and then progressive improvements in these scores in the successive weeks both In-Clinic and after training at home. We anticipate that subjects will begin to observe meaningful behavioral changes in both balance and gait, which hopefully will serve as a catalyst for continued effort and concomitant progress in these areas. In the latter phase of the study we also expect to observe functional transfer to other activities of daily living that contribute to improved quality of life and consequent mental health benefits, although we will not be formally measuring these outcomes in this pilot study.

Bach-y-Rita, P., Danilov, Y.P., Tyler, M.E., Grimm, R.J. (2005). "Late human brain plasticity: vestibular substitution with a tongue BrainPort human-machine interface." *Intellectica*, 1:40, pp 115-122. Association pour la Recherche Cognitive.



Cognitive/Motor Therapy Application Using Console-Based Videogame Platform (Blue Marble)

Flynn, Sheryl
Blue Marble Co.

OSD DHP SBIR 2009.1

1 Jul 2009 to 31 Oct 2014



Aims

- Complete Phase I/II development of a cost-effective intervention that induces the brain plasticity necessary for return to duty and/or a fulfilling civilian life

Approach

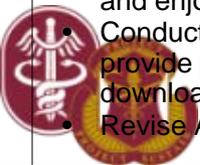
- Continue Phase I development of prototype version of game and assess/compare with neuropsychological tests using participants with TBI and subject matter experts
- Refine prototype as needed based on programming bugs/issues, visual issues, audio requirements, data storage, incorrect output, and enjoyment level and complete Alpha version
- Conduct an intervention with the alpha version of the game; provide participants with study packet including the game for download and detailed instructions
- Revise Alpha version and complete Beta 2 version of game

Deliverables

- A low-cost, video game-based intervention tool to train cognitive and sensorimotor domains in preparation for a service member's return to duty following mTBI

Status

- In Phase I, developed game storyboard and narrative, report on most appropriate technology for software version of game, the game design document, and basic interactive software demonstration of the core game mechanic
- Completed formal play-test of the rough prototype
- Currently completing phase II and moving to phase II-plus where a validation study will be executed



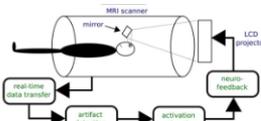
PI: Drs. Gabrieli, Van Boven Org: MIT, Geneva Foundation

Study Aim(s)

- Recruit 120 active service men and women with mTBI; 60 with and 60 without PTSD
- Characterize structural and functional brain patterns
- Assess the efficacy of real-time fMRI and/or computer-based cognitive training in reducing symptoms of mTBI
- Predict treatment response and outcomes for mTBI

Approach

The aim is to perform a randomized, double-blind clinical trial to determine the efficacy of realtime fmri training and/or cognitive training on improving executive function, memory, and attention of 120 soldiers diagnosed with a history of Mild Traumatic Brain Injury (mTBI) with or without comorbid PTSD. Every participant will undergo an 8-week training program with pre and post clinical, neuroimaging and behavioral assessment and four realtime fmri training sessions evenly spaced during the training.

mTBI?	+PTSD?		Cognitive training	Outcome Measures
	-PTSD?			
rtfMRI			+Feedback?	+Feedback?
			+Adaptive?	-Adaptive?
			-Feedback?	-Feedback?
			+Adaptive?	-Adaptive?

This clinical trial evaluates improvement in neuropsych measures as a result of cognitive training and realtime fMRI on active-duty personnel diagnosed with mTBI, with and without co-morbid PTSD.

Accomplishment: We have completed clinical trial protocol creation, IRB approval, acquisition of all neuropsychological tests and training materials for performing the realtime fMRI scans.

Timeline

Activities	CY	11	12	13	14
Protocol setup/IRB approval		█			
Recruitment, data acquisition			█	█	
Data analysis				█	
Finalize analysis and publications					█

Goals/Milestones

- CY11 Goal** – Protocol refinement and IRB approval
- IRB approval
 - Acquisition of neuropsychological battery
- CY12 Goals** – Instrumentation setup and data acquisition
- Create realtime fMRI setup for external use and image analysis workflow
 - Register trial and begin recruitment and data acquisition
- CY13 Goal** – Acquisition and analysis
- Continued data acquisition and analysis
- CY14 Goals** – Acquisition, analysis, publication
- Finalize data analysis
- Comments/Challenges/Issues/Concerns**
- None at this time

Neural Markers and Rehabilitation of Executive Functioning in Veterans with TBI and PTSD



PI: Elbogen

Org: University of North Carolina – Chapel Hill

Study/Product Aim(s)

The study involves a randomized clinical trial of an empirically-supported cognitive rehabilitation intervention that targets improved executive functioning, with the participation of N=100 veterans diagnosed with both TBI and PTSD (n=50 in experimental group and n=50 receiving usual care). The study aims to:

1. Use functional magnetic resonance imaging (fMRI) and electroencephalography (EEG) to evaluate changes in neural circuitry and neural activity associated with executive function as a result of cognitive rehabilitation intervention.
2. Evaluate neurocognitive and behavioral changes associated with a cognitive rehabilitation interventions among veterans with TBI/PTSD.
3. Assess the impact of cognitive changes on irritability/impulsivity and social/occupational functioning among veterans.

Approach

Experimental participants will be instructed to practice iPod touch applications that have shown to improve inhibitory control and self-monitoring behavior and also include an application to randomly cue participants to practice executive functioning skills whereas control participants will be instructed to practice iPod touch applications on visual memory. Family members in both groups will be trained as “mentors” to reinforce veterans’ use of the applications in everyday living environments. Components of the intervention will be administered via an iPod touch Interviews, neurocognitive testing, fMRIs, and EEGs will be conducted before and after the intervention period to evaluate the participant’s functioning.



Incorporating readily-available mobile technology into a cognitive rehabilitation intervention to target executive functioning



Conducting fMRIs and EEGs to link cognitive and behavioral effects of TBI/PTSD and cognitive rehabilitation to neural markers



Accomplishment: One year into the study we have successfully prepared and begun the clinical trial. In the 3 months since we began recruitment, we have enrolled and completed baseline data collection/intervention with 15 participants, exceeding our projected target.

Timeline

Activities	FY	11	12	13	14
Prepare for Clinical Trial (Complete)		█			
Conduct Baseline/Follow-up Data Collection			█	█	█
Implementation of Intervention			█	█	█
Data analysis and manuscript preparation					█

Goals/Milestones

FY11 Goal – Prepare for clinical trial

- Obtain study approval from UNC IRB and USAMRMC

FY12 Goals – Implement clinical trial

- Develop data collection system
- Train research personnel
- Begin recruitment, baseline data collection, and implementation of cognitive rehabilitation intervention

FY13 Goal – Communicate study progress/findings

- Begin follow-up data collection
- Present study progress at national conferences

FY14 Goals – Data analysis and production of deliverables

- Conduct statistical analysis
- Prepare manuscripts for publication

Comments/Challenges/Issues/Concerns

- We currently have no significant issues or concerns to report.

Enhanced Cognitive Rehabilitation to Treat Comorbid TBI and PTSD



PI: Amy Jak, Ph.D.

Org: Veterans Medical Research Foundation

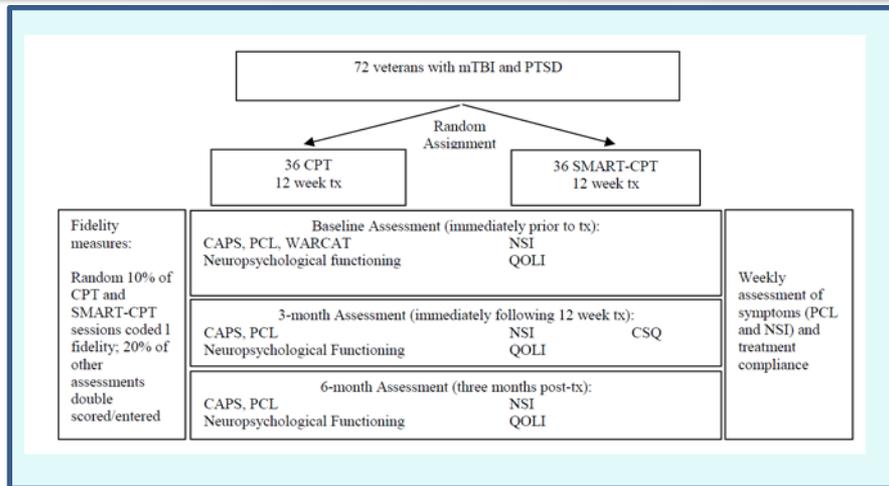
Study Aim(s)

Primary Aim 1: To investigate the efficacy of SMART-CPT in reducing emotional and neurobehavioral symptom severity in veterans with comorbid TBI and PTSD.

Primary Aim 2: To investigate the extent of cognitive changes in veterans with comorbid PTSD and TBI following treatment with SMART-CPT.

Approach

Randomized controlled treatment study to test a modification of Cognitive Processing Therapy (CPT) for PTSD in which CPT is interweaved with compensatory cognitive rehabilitation principles (CogSMART) to create a hybrid treatment, SMART-CPT. The study will enroll 72 veterans diagnosed with both PTSD and a history of mild to moderate TBI and randomize half to receive standard CPT and half to receive SMART-CPT for 12 weekly sessions. Veterans will also receive comprehensive symptom, mental health, and neuropsychological assessments at 3 timepoints during the study. The investigation seeks to improve treatment outcomes for combat-related psychological health and develop an evidence-based intervention for treatment of comorbid TBI and PTSD.



Accomplishments: Regulatory approvals obtained/maintained; SMART-CPT treatment manual development completed; 9 Veterans enrolled since August 1, 2012, 8 in active treatment phase

Timeline

Activities	FY	12	13	14	15
Study Start Up					
Recruitment, Enrollment, Assessment, Treatment					
Ongoing recruitment, treatment, data entry					
Data Analysis, Dissemination of Results					

Goals/Milestones

FY12 Goal – Study Start Up

- Regulatory approvals obtained
- Study staff hired/trained

FY13 Goals – Recruitment, Enrollment, Treatment, and Assessment

- Ongoing recruitment
- Assessment/Treatment protocol (8 in active treatment phase)

FY14 Goal – Ongoing recruitment, treatment protocol, data entry

- Ongoing recruitment/enrollment/treatment protocol
- Data entry

FY15 Goals – Data Analysis, Presentation, Publication

- Data Analysis
- Dissemination of Results

Comments/Challenges/Issues/Concerns

Study proceeding as planned



Plasticity-Based Adaptive Cognitive Remediation (PACR) for OIF/OEF Veterans: A Randomized Controlled Trial

IN THE LAB,
ON THE
BATTLEFIELD



PI: Dr. Henry Mahncke

Org: Brain Plasticity, Inc

POP: 09/30/2011-10/29/2014

Study/Product Aim(s)

- Evaluate PACR's efficacy in patients with persistent post-concussive symptoms (PPCS) following mild traumatic brain injury (mTBI, including blast exposure).
- Evaluate the effect of PACR on generalized cognitive and functional performance
- Evaluate the endurance of effects following completion of PACR use
- Identify specific populations of treatment responders and non-responders

Approach

Team will employ a standard parallel arm, prospective, randomized, controlled, double-blind trial design of a treatment group using PACR vs. an active control group using computer games in 132 participants with PPCS following mTBI

Sites: Walter Reed National Military Medical Center, Tripler Army Medical Center, Boston Veterans Administration Medical Center, Veterans Administration Connecticut Healthcare System and Michael E. DeBakey Veterans Administration Medical Center

Goals/Milestones

FY12 Goals–

- Proposal completed and submitted to IRB

FY13 Goals–

- IRB approvals completed
- Initiate recruitment

FY14 Goals–

- Complete Enrollment and data collection
- Analyze data and submit report



Updated: 01/07/13

Brain Training to Enhance Frontal Lobe Reasoning in Soldiers with TBI

Award #: W81XWH-11-2-0194, Training to Enhance Reasoning



DMRDP

PI: Daniel C. Krawczyk, Ph.D.

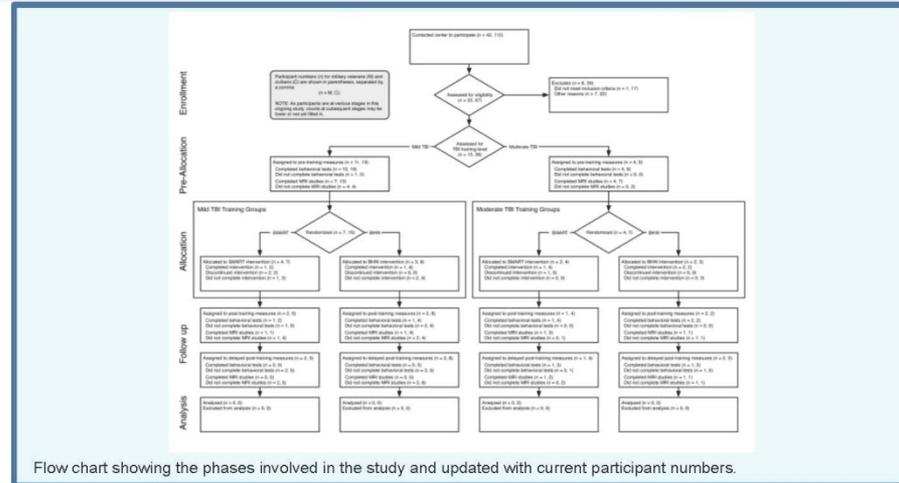
Org: The University of Texas at Dallas

Study/Product Aim(s)

- Examine the effects of Strategic Memory Advanced Reasoning Training (SMART) compared to a Brain Health Workshop (BHW) on cognition and real life outcomes in chronic traumatic brain injury (TBI).
- To examine brain changes as result of SMART versus BHW on functional Magnetic Resonance Imaging (fMRI) measures.
- To determine whether the effects of SMART versus BHW training are maintained at 3 months post-training.

Approach

We are evaluating a cognitive rehabilitation program, SMART, for improving attention, reasoning, and problem solving. We aim to determine whether individuals with chronic TBI benefit from SMART relative to a BHW control group. We use measures of cognition, real-life outcomes, and brain imaging (structural, functional, connectivity) to assess treatment efficacy. Comparisons are made prior to training, after training, and 3 months after the training in order to determine the effects of the training and how well improvements in cognition are maintained based on neuropsychological tests and brain imaging.



Flow chart showing the phases involved in the study and updated with current participant numbers.

Accomplishment: Initial results based on the first four training groups indicate that SMART training is significantly enhancing strategic memory and reasoning ability with added increases in working memory, inhibition, and life function scales.

Timeline

Activities	FY	11	12	13	14
Hire/train staff, obtain approvals,		█			
Enroll subjects, conduct training, testing, and imaging		█			
Data analysis for behavioral and imaging measures		█			
Report results in conference abstracts journal manuscripts		█			

Goals/Milestones

FY11 Goal – Obtain Approvals, hire/train staff, begin enrollment and experimental procedures

- Obtain Approvals from Institutional Review Boards & HRPO
- Hire/train staff relevant to conducting testing, training, imaging
- Commence enrollment in testing, training, imaging

FY12 Goals – Continue with enrollment of subjects and data collection

- Enroll participants in all phases of the study
- Present preliminary results at conferences and submit manuscripts

FY13 Goal – Continue with enrollment of subjects and data collection

- Complete Enrollment of subjects in all phases of the study
- Present preliminary results at conferences and submit manuscripts

FY14 Goals – Complete study

- Complete remaining outstanding phases of the study for all subjects
- Present results and submit journal manuscripts on full project results

Comments/Challenges/Issues/Concerns

- None at the present time.

Brain Training to Enhance Frontal Lobe Reasoning in Soldiers with TBI

Award #: W81XWH-11-2-0195, Training to Enhance Reasoning



DMRDP

PI: Sandra Bond Chapman, Ph.D.

Org: The University of Texas at Dallas

Study/Product Aim(s)

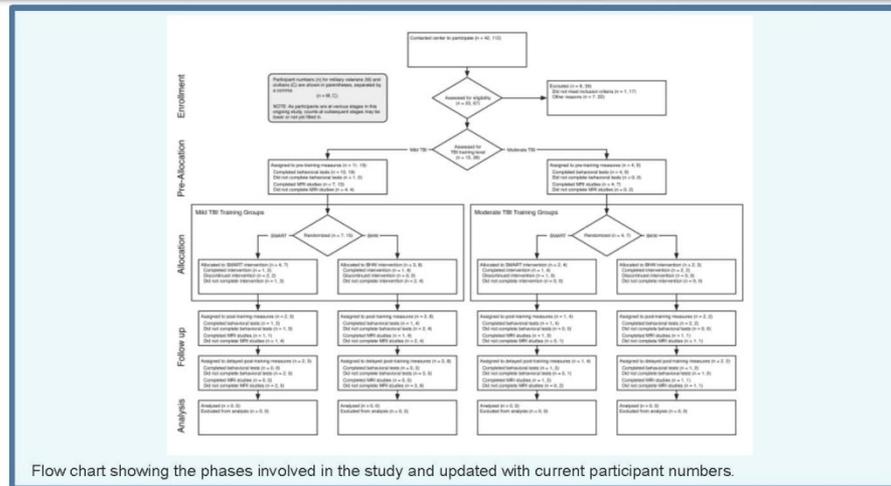
- Examine the effects of Strategic Memory Advanced Reasoning Training (SMART) compared to a Brain Health Workshop (BHW) on cognition and real life outcomes in chronic traumatic brain injury (TBI).
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Timeline

Activities	FY	11	12	13	14
Hire/train staff, obtain approvals,		█			
Enroll subjects, conduct training, testing, and imaging		█			
Data analysis for behavioral and imaging measures			█		
Report results in conference abstracts journal manuscripts			█		



Flow chart showing the phases involved in the study and updated with current participant numbers.

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FY14 Goals – Complete study

- Complete remaining outstanding phases of the study for all subjects
- Present results and submit journal manuscripts on full project results

Comments/Challenges/Issues/Concerns

- None at the present time.



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- Educational Materials
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"Concussions are treatable, the prognosis is good, and this course will get you started."
- CAPT J. L. Hancock, M.D., U.S. Navy

1 2 3 4 5

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Learn about traumatic brain injury (TBI), find help for your loved one and more.



Service Members & Veterans

Explore our resources, get answers to your FAQs, and watch service members tell their stories.



Medical Providers

Order important clinical tools, download DVBIC resources, or get expert advice.

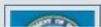
Crisis Intervention (24/7)

U.S. Department of Veterans Affairs (VA)

Suicide Prevention Hotline

1-800-273-8255

DoD Numbers for TBI



Worldwide numbers for

Featured Materials



Acute Concussion (mTBI)

brainline**military**
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Broken Brains





Study of Cognitive Rehabilitation Effectiveness (SCORE)

A randomized control treatment trial in a military population with mild TBI incurred during OEF/OIF deployment



PI: Douglas B. Cooper, PhD

Org: DVVIC

Study/Product Aim(s)

- Determine the effectiveness of cognitive rehabilitation in individuals with a history of mTBI.
- Determine which components of cognitive rehabilitation (or combination of components) are most effective.
- Determine which participant characteristics are associated with better treatment outcomes.

Approach

- The SCORE trial is a 6-week intervention with research evaluations at baseline, 3-, 6-, 12- and 18-weeks after initiation.
- Subjects are randomly assigned to one of four study arms, n=40 per group:
 1. Psychoeducational control
 2. Self-directed computerized cognitive rehabilitation
 3. Therapist-directed individualized cognitive rehabilitation
 4. Integrated interdisciplinary cognitive rehabilitation combined with cognitive-behavioral psychotherapy.



Accomplishment: Study enrollment began JUN 2011

Activities	FY	11	12	13	14
Obtain IRB approval		█			
Recruitment/Enrollment			████████████████████		
Follow-Up Data Collection			████████████████████		
Data Analysis, Write Papers				████████████████████	

Goals/Milestones

- FY11 Goal** – Initiation of trial and recruitment of subjects
- Hiring Staff-Coordinator and Research Associate March 15, 2011 and Research Psychometrist on May 2, 2011
 - Regulatory approval was received in APR 2011.
 - Completion/Regulatory Approval of Treatment Manuals on June 7, 2011
 - Recruitment started May 2011
 - First subject enrolled on July 7, 2011 with continuous enrollment to date
 - Database Implemented for Data Entry
- FY12 Goals** – Continued Recruitment of Subjects
- Continue participant enrollment
 - Interim Analysis of Data
- FY13 Goal – CY14 Goals**-Data Analysis
- Follow-up Data Collected
 - Final Data Analysis
 - Write papers and Dissemination

Imaging Support of Study of Cognitive Rehabilitation Effectiveness in Mild Traumatic Brain Injury (iSCORE)

PI: LTC Gerald York, M.D.

Org: DVBC

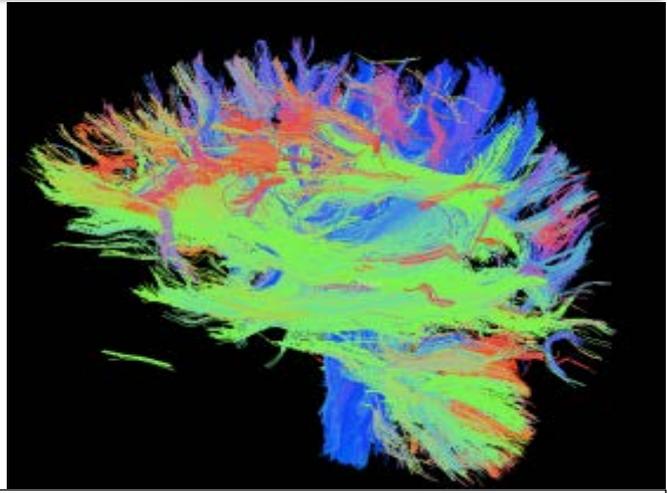
Study/Product Aim(s)

- Investigate longitudinal structural and functional imaging changes over time that correlate with outcome following a trial of cognitive rehabilitation
- Investigate the neural correlates of fatigue and misperception of effort as they relate to treatment outcome following mild TBI

Approach

Patients enrolled in SCORE!, (a cognitive rehabilitation study being conducted at BAMC) who agree to participate will be consented, enrolled and undergo MRI imaging, complete several behavioral measures a submaximal grip strength measurement and a cognitive task.

White matter tractography of brain derived from Diffusion Tensor Imaging



Accomplishment: Protocol has received IRB approval. Participants are being recruited for enrollment.

Timeline and Cost

Activities	FY	10	11	12	13	14
Obtain IRB approval		█				
Scientific review completed			█			
Recruitment/Enrollment			█	█	█	█

Goals/Milestones

- FY10 Goals–**
- Proposal completed and submitted to IRB
- FY11 Goals–**
- Scientific review completed
 - IRB approval
 - Initiate recruitment
- FY12 Goal –**
- Complete Enrollment and data collection

Comments/Challenges/Issues/Concerns

IRB approval took longer than anticipated
 IOPI equipment was defective; had to re-order a part
 Currently enrolling patients



A Randomized Controlled Pilot Study of the Effectiveness and Feasibility of Novel Rehabilitation approaches for OIF and OEF Patients with Persistent Complaints of Cognitive Dysfunction Following TBI

PI: Louis M. French, Psy.D.

Location: WRAMC

Collaborating Institutions: N/A

Funding Source(s): CNRM

Aims

- Pilot study to determine the feasibility of a novel computer-based program to meet post-discharge needs for subjects complaining of deployment-related cognitive deficits.
- Feasibility will be demonstrated in terms of improvement in subjective complaints, performance on neuropsychological tests, and compliance and satisfaction with the computer program.

Approach

- A randomized, controlled study design to evaluate the efficacy of computer-based programs.
- Patients randomly assigned to one of two computer-based cognitive training programs or to a standard of care control group receiving cognitive speech-language or occupational therapy services at WRAMC.

Task	2009	2010	2011	2012
Regulatory Approval	[Green bar spanning 2009-2012]			
Participant Enrollment		[Yellow bar spanning 2010-2012]		
Data Analysis				[Grey bar in 2012]
Dissemination				[Grey bar in 2012]

Status

- Initial WR IRB Approval: March 3, 2010; CIRO/CRADA: July 13, 2010
- Continuing Review approved 24 September 2012.
- Total Enrollment: 38 of 174 (31 TBI, 7 non-TBI)
- Enrollment last quarter: 4

Deliverables/milestones in the last quarter

- “Outcomes from a Pilot Study using Computer-based Rehabilitative Tools in a Military Population” presented at the 17th Annual CyberPsychology & CyberTherapy Conference in Brussels, Belgium, September 2012; paper published in the Journal of CyberTherapy and Rehabilitation (Vol. 5, Issue 2, September 2012).
- In-service presentation to the Audiology/Speech research team on 23 August 2012.

Key Challenges

- Many of the patients that come through the BFC are not eligible for the research protocol because they do not fit the OIF/OEF inclusion criteria or they are excluded based on the exclusion criterion that they cannot have “multiple mTBIs within 2 years of their initial BFC appointment.”
- For eligible, consenting patients, holidays and leave interfere with daily computer session attendance, or the patient may be discharged from Walter Reed prior to completing the full 6 weeks of computer sessions.
- Potential participants are eager to try the computer programs and don't wish to be assigned to the standard of care control group.

Deliverables/milestones anticipated in the next year

- Recruitment at Ft. Belvoir expected to help study reach sample size (174).
- Begin running analyses on the pre and post data for prospective study.
- preliminary results reveal a trend towards improved self-reported cognitive and functional symptoms. Published Sullivan KW et al Stud Health Technol Inform. 2012;181:71-7. Q4 FY12



Using a Simulator to Enhance Cognitive Recovery After Mild Traumatic Brain Injury

PI: Melissa Amick, PhD

Location: VA Boston Healthcare System

Collaborating Institutions: N/A

Funding Source(s): VA RR&D

Aims

- To determine whether participants with a history of mild TBI and/or PTSD and self-reported driving difficulties perform more poorly than healthy controls on an assessment of driving abilities and to examine the association between cognitive and behavioral symptoms with driving abilities.

Approach

- 100 OEF/OIF veterans with a history of PTSD and/or mTBI and 50 age- and education matched control participants will complete: a simulated driving assessment, neuropsychological tasks, and questionnaires measuring psychological symptoms, driving history, and fatigue.
- Primary outcome measure is number of errors committed on the simulated driving assessment. Secondary outcome measures will include cognitive and behavioral variables.

Task	2009	2010	2011
Regulatory Approval	[Green bar spanning 2009 and 2010]		
Participant Enrollment	[Yellow bar spanning 2009, 2010, and 2011]		
Data Analysis		[Yellow bar spanning 2010 and 2011]	
Dissemination			[Grey bar in 2011]

Status

- Initial IRB Approval: VABHS local IRB approval 10/19/09
- Enrollment: 65 of 150

Deliverables/milestones in the last quarter

- Local IRB approval
- Approved amendment to broaden recruitment through collaboration with other local on-going studies of mTBI/PTSD
- Enrollment of first 50 participants with enrollment continuing
- Identification of driving simulator outcome measures
- Renewal submitted 6/2010 (scored, 31st %ile)
- Resubmission to RR&D, 12/2011
- Data presented at INS meeting 2/2011

Key Challenges

- **Challenge:** continued funding
- **Solution:** resubmission of grant
- **Challenge:** limited staff
- **Solution:** looking for funding to continue project

Deliverables/milestones anticipated in the next year

- Preliminary findings on the clinical utility of driving assessment submitted for presentation and scientific meetings and publication.

A Randomized, Controlled Trial of Interactive Metronome Technology for Remediation of Cognitive Difficulties Following Blast-Related TBI



PI: CDR Renee Pazdan, MD

Org: DVBC – Fort Carson

Study Aim(s)

- Determine whether the addition of Interactive Metronome (IM) training to treatment as usual (TAU) in patients with moderate to mild TBI due to blast results in greater improvements in attention and memory; better secondary outcomes such as postconcussion symptom status, vocational functioning, and quality of life; and improved normalization of electrocortical functioning, immediately and at 6 months.

Approach

- A randomized, controlled trial of 15 sessions of IM over 5 wks compared with 5 wks of TAU in those with mild to mod TBI due to blast.
- Patients randomized to IM training will complete 15 sessions over 5 wks
- Primary outcomes will include attention and memory functioning, measured prior to the start of treatment period, one week following the end of treatment period, and 6 months after treatment period.
- TAU patients will be offered IM after completing 6 month assessments.



Interim analyses indicate that IM treatment is associated with greater improvements in performance on neuropsychological tests compared to treatment as usual; evidence of brain plasticity and effect of building timing awareness and response-ability

Timeline

Activities	FY	09-10	11	12	13
Regulatory Approval		[Green bar spanning FY 09-10 to 13]			
Participant Enrollment			[Green bar spanning FY 11 to 13]		
Complete 7 week and 6 month Assessments for IM and TAU pts			[Green bar spanning FY 11 to 13]		
Post Follow up IM treatment delivery to TAU group members			[Green bar spanning FY 11 to 13]		
Data Analysis and Dissemination of Findings				[Green bar spanning FY 12 to 13]	

Goals/Milestones

FY10 Goals – Regulatory Approval and Initiation of Recruitment

- Recruitment of wave one; initiation of post treatment assessments

FY11 Goals –Participant Recruitment and Interim Analysis

- Participant recruitment, randomization and treatment delivery.
- Complete post-treatment and follow-up assessments
- Initiate interim analyses and report of initial (7 week) findings

FY12 Goals – Production readiness

- Complete enrollment, delivery of treatment
- Begin analysis of follow-up data and dissemination of findings

FY13 Goals

- Complete follow-up assessments
- Complete analyses and dissemination of findings

Comments/Challenges/Issues/Concerns

- Research staff no longer blinded to randomization; putting additional staff in place to recruit last 5 subjects
- Neuropsychological tests of memory and attention showed significant increases at 7 week testing in the IM group relative to those in the control group.



Traumatic Brain Injury Rehabilitation: A controlled, randomized multicenter study of interdisciplinary programs with adjuvant pharmacotherapy

PI: Larisa Kusar, M.D., Barbara Sigford, MD, PhD

Location: Minneapolis VA Health Care System

Collaborating Institutions: WRAMC, Richmond, Palo Alto and Tampa VA PRCs

Funding Source(s): DVHIP/DVBIC

Aims

• To integrate clinical research with care so as to enhance care both at present and in the future.” Specific objectives for Phase I include: (1) establishment of a national DoD/DVA TBI registry; (2) appropriate follow-up of DoD/DVA TBI patients; (3) standardized sequential evaluations of long-term outcome of TBI patients; (4) enhancement of care by integration with clinical research; (5) establishment of multicenter DoD/DVA network of hospitals for collaborative research. Phase II: (6) the prospective evaluation of TBI rehabilitation programs.

Approach

- Phase I, data will be collected and scored by professionals in the area being evaluated. Data will be collected at baseline, 6, 12 and 24 months. Evaluation is expected to take approximately 3 days.
- Phase II, patients will be assigned to one of two treatment protocols in a prospective, randomized fashion. Enrollments were completed in 6/2003. Enrolled patients were evaluated at baseline, 6, 12 and 24 months using the same data collection formats as Phase I with the addition of a measure of social pragmatics in the evaluation.

Status

- Initial IRB Approval: April 23,1993
- Enrollment: 142 of 190 (at this site) of which 98 were surrogate consents; 4 withdrew by self. Enrollment last quarter: 0
 - Two phase study Phase I: 76 enrollees, Phase II: 66 enrollees
- Study is closed to enrollment, Last subject enrolled/consented 2004
- Continuing Review submitted 6.6.2012 ; All approvals rec'd 10.2.2012
- Documentation of approval sent to Loretta Polite 10.3.2012

Deliverables/milestones to date

- Amendment to Phase I: 4.10.2007
- Amendment to Phase II: 6.29.2007
- Amendment to Phase II: 5.23.08
- Amendment 3.10.2009 re: location of data review to take place at WRAMC

Q4 FY12

Task	1993	1994-2004	2005-2011	2012	2013
Regulatory Approval	[Green bar]				
Participant Enrollment	[Green bar]				
Data Analysis			[Red bar]		
Dissemination					[Grey bar]

Key Challenges

- Ongoing applications for IRB annual review.
- Consulting with IRB for appropriate storage of materials for open study.
- Storage of Study Documentation
- DVBIC HQ scanning all documentation for management of archived records
- Per ORO, no original VA documents may be destroyed.

Deliverables/milestones anticipated in the next year

- Minneapolis data in process of review and entering into electronic database.

Results comparing cognitive-didactic and functional-experiential approaches to brain injury rehabilitation indicated improved but similar long-term global functional outcome. Participants in the cognitive treatment arm achieved better short-term functional cognitive performance than patients in the functional treatment arm.

Application of Instructional Technology Software as a Cognitive and Vocational Rehabilitation Tool Post-TBI



PI: Tina Trudel, PhD

Org: DVBIC – Charlottesville, VA

Study/Product Aim(s)

- To assess the effectiveness of computerized instructional tools as an adjunct to standard community integrated brain injury rehabilitation.
- To examine service members' experiences and satisfaction utilizing computerized intervention tools.
- To inform participant instructional tool selection to maximize potential benefit.

Approach

- Service members with TBI will be recruited through DVBIC Charlottesville.
- Participants will be randomly assigned to either an unstructured interactive computer activity with clinician interface or to the identified instructional modules with clinician interface, as an adjunct to the existing rehab program.
- Pre and post assessments and program outcomes (including functional and vocational) will be assessed and analyzed for both groups.
- Participants will be interviewed regarding feedback, perceived benefit and satisfaction with the intervention.



Photo credit: Master Sgt. John Nimmo, Sr.

Timeline and Cost

Activities	FY	11	12	13
Development of software		■	■	
Participant enrollment			■	■
Intervention/interviews			■	■
Data analysis and dissemination				■

Updated: 28OCT2012

Goals/Milestones

FY11 Goals

- Recommended content modifications sent to software programmers.
- Grant applications submitted by ISI in order to fund software enhancements per recommendations
- Finalize software upgrades/enhancements

FY12 Goals

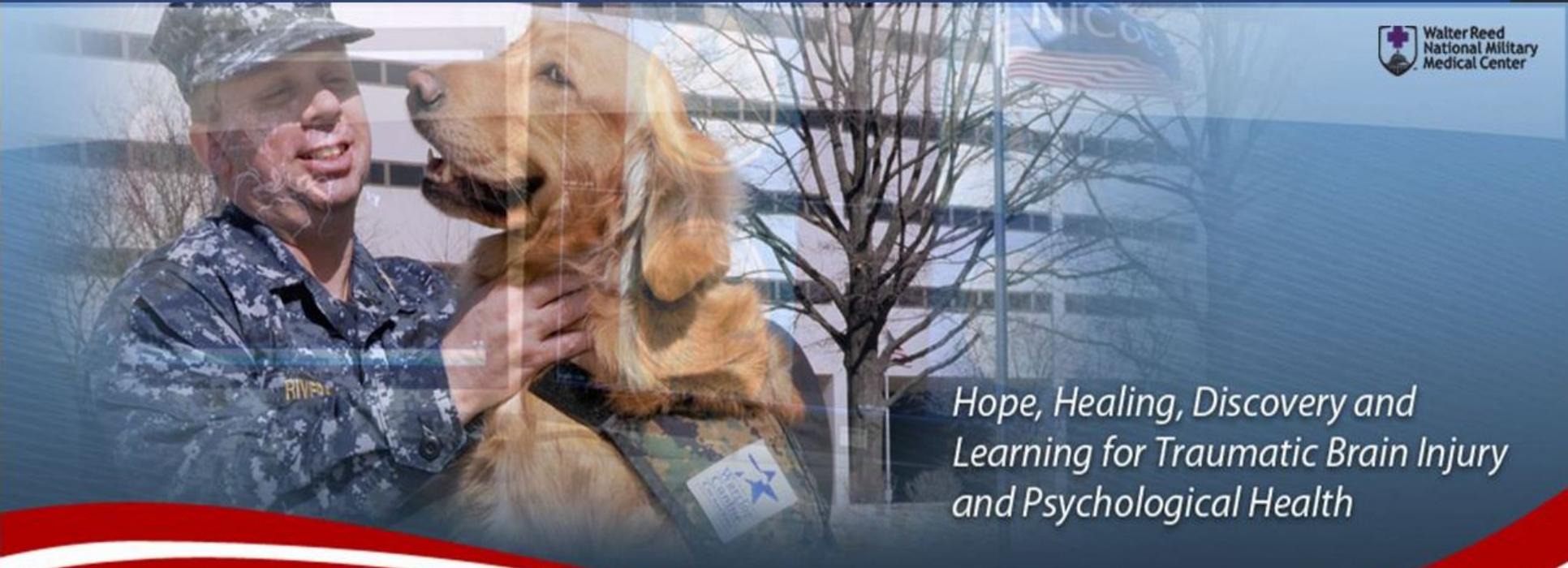
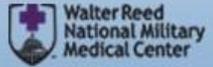
- Secure funding to finalize software upgrades/enhancements
- Train staff on software utilization
- Initiate subject recruitment and implementation of intervention

FY13 Goals

- Analyze data and disseminate results

Comments/Challenges/Issues/Concerns

- Securing adequate sample size.
- Software development/upgrading taking longer than anticipated



*Hope, Healing, Discovery and
Learning for Traumatic Brain Injury
and Psychological Health*

Assessing the impact of mTBI on multisensory integration while maneuvering on foot

Designate: TBI + Hearing + Vestibular

PI: Brungart, Douglas

Org: Walter Reed NMMC/ National Intrepid CoE

Problem, Hypothesis and Military Relevance

Problem: TBI is known to produce substantial deficits in auditory, visual, and vestibular processing, however the impacts it has on multisensory integration are not well known.

Military Relevance: This effort will directly attack one of the most critical issues regarding the re-deployment of soldiers with TBI: the ability to move, shoot, and communicate on the battlefield.

Technical Approach: This study will take an aurally-aided visual search paradigm that has been shown to be effective for assessing audio-visual integration in stationary environments and a well established auditory and auditory-visual speech recognition task and put them to a moving platform that will greatly increase the sensory load and simulate dismounted combat operations.



Proposed Solution

Objective: Evaluate auditory-vestibular-visual interaction in normal and TBI participants with an aurally-aided visual search task and a speech recognition task with relevance to dismounted military operations.

Description of Effort: We will modify the CAREN simulator at the National Intrepid Center of Excellence to include a spatialized speaker array. This will allow us to conduct true multisensory integration tasks.

Benefits of Proposed Technology: By incorporating multimodal tasks that test the most difficult multisensory environments involved in dismounted patrolling, we expect to: 1) Enhance our ability to diagnose multisensory problems in TBI patients; 2) Inform fitness-for-duty standards; and 3) Examine potential methods for rehabilitating TBI-related sensory deficits.

Activities	FY	13	14	15
Phase 1: Implement spatial sound array in CAREN				
Phase 2: Establish baseline search times for visual, auditory and aurally aided tasks for normal and TBI participants				
Phase 3: Develop a model of visual search time for normal participants with degraded vision and audition. Evaluate auditory-visual speech perception in dynamic multisource environments.				



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Center for the Study of Neuroscience and Regenerative Medicine

Description of Flash



- Diagnostics & Imaging
- Biomarkers
- Neuroprotection & Modeling
- Neuroregeneration
- Neuroplasticity
- Rehabilitation & Evaluation

Project Title: Pilot Study to Assess the Application of Haptic Technology to Functional Improvement in Persons with Mild and Moderate Traumatic Brain Injury

Principal Investigator: Leighton Chan, M.D., M.P.H.

ABSTRACT

Traumatic Brain Injury is a complex condition that is not completely understood. Our laboratory is working towards determining the feasibility of haptic technologies to assess and treat a population of individuals who have mild to moderate TBI. We are using the haptic along with a computer system to create challenging and engaging virtual environments and extract objective measures concerning their orientation, motor, and cognitive skills. We have performed a pilot study using college students and showed that they were highly engaged, and that objective measures could be extracted. These measures showed that fine motor learning occurred over a course of three trials in the virtual environment. We have since expanded our virtual environments to include a gun disassembly task, sandwich making task, and a letter spelling task which has similarities to Scrabble. We have also programmed two spatial orientation tasks, a maze that can be navigated from two viewpoints, within or above, and a network of corridors that is navigated only from within.

We have received feedback from Brain Injury Services, Inc., an organization that provides services to persons with TBI. The group came to the lab to provide insight on how to improve our physical and virtual environments. We have a protocol in place for which we will be collecting data from these TBI patients and others recruited through the CNRM Recruitment Core. We will be looking at the ability of the virtual environments to engage and challenge the individuals as well as determining objective measures for analysis. We will also be comparing outcomes from the virtual environment to those from classic measures, including the Purdue Pegboard and Wolf Motor Function Test.

Project Title: Effects of Rapid Reciprocal Exercise vs. Light Therapy in TBI
Principal Investigator: Diane L. Damiano, Ph.D.

ABSTRACT

Objectives:

We will: 1) compare performance of healthy volunteers and ambulatory adults with traumatic brain injury (TBI) on a range of motor, neurobehavioral and brain imaging outcomes; and 2) evaluate effects of rapid, reciprocal arm and leg exercise with an elliptical trainer on high-level motor coordination and balance, and neurobehavioral and cognitive functioning in persons with TBI. Outcomes will be compared to those from a novel intervention for improving mood and cognition, Bright Light Therapy (BLT). Brain connectivity and changes in connectivity in response to interventions will be quantified. We hypothesize even highly functional adults with TBI will have poorer scores on all measures than controls; exercise will lead to significant improvements in motor performance and balance compared to BLT; and neurobehavioral and cognitive function will improve with both interventions. We further hypothesize that improvements in cortical connectivity and representation will relate directly to functional ones.

Study Population:

80 adults (50 with TBI) will be recruited so that 20 with TBI and 20 healthy volunteers complete the study. Only the TBI group will receive intervention.

Design:

Healthy controls will have a single assessment that includes motor, neuropsychological and brain imaging tests. Participants with TBI will perform both interventions: 3 months of fast elliptical training or Bright Light Therapy in randomized order with a four-week washout period between them. Assessments will occur at 0, 3, 4, and 7 months. The exercise device will be an elliptical trainer that exercises the legs and arms with the emphasis on maintaining a fast speed. Mild resistance will be provided initially and progressively increased once speed is optimized. An in-home light box will be used for the other intervention. Each intervention will be performed in the home 5 days per week for 30 minutes, over 12 weeks.

Outcome Measures:

Performance on complex motor & balance tasks will be assessed with 3D motion capture & EMG, the Smart Balance Measurement System and the High Level Mobility Assessment Tool (Hi-MAT). Primary outcomes are Hi-MAT score reaction time during balance testing and the Hamilton Rating Scale for Depression (Ham-D). Secondary outcomes will include walking speed and device cadence, PTSD Checklist (PCL-17), and relevant portions of the Automated Neuropsychological Assessment Metrics (ANAM) battery, among others. Cortical connectivity will be quantified using resting state functional connectivity magnetic resonance imaging (MRI) and Diffusion Tensor Imaging (DTI), which evaluates white matter tracts. Cortical activation patterns will be quantified with fMRI.



Conclusions

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- In the military healthcare system, we focus on TBI rehabilitation in a relatively short-term window (approx 1 year) as by that time it is typically clear whether or not the Service Member should be retained on active duty
 - More severely injured SM's move to the VA Polytrauma Network
- We support cognitive rehabilitation research efforts within both DoD and VA as well as in academia and industry
 - Issues such as clinical definitions, evolving understanding of the natural history and pathobiology of TBI, and evolving understanding of the need for accurate and specific outcome measures currently drive our research process.
 - We will be developing a more detailed strategic plan for cognitive rehab in CY 13 based upon lessons learned in this and other TBI research arenas.
- Cognitive rehabilitation in “mild” TBI will remain a challenge to assess because of the heterogeneity of the injury and its co-morbidities as well as the huge number of confounding variables introduced in the outpatient setting. Large, well designed and controlled studies will be necessary.
- Our understanding of neuroplasticity continues to improve and gives us a sense of optimism as we move forward.
 - Improving capabilities of functional imaging and neurophysiological assessment technologies will help us develop a better understanding of how these interventions work and how they can be improved.





Questions?

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Research is to see what everybody else has seen, and to think what nobody else has thought.

- Albert Szent-Gyorgyi

