Capability Gaps in Psychological Health/Traumatic Brain Injury Diagnosis, Treatment and Rehabilitation

US Army Medical Research and Materiel Command

19 April 2016

Panel Members

- Dr. Ron Hoover
  - Military Operational Medicine Research Program – Clinical and Psychological Health Program Manager
- Dr. Marcello Pilia, Panel Chair
  - Combat Casualty Care Program – Assistant Portfolio Manager
- Dr. Pamela Brown-Baer
  - Clinical and Rehabilitative Medicine Research Program – Sensory Systems Portfolio Manager
- Mr. Michael Husband
  - USAMMA –Project Manager Neurotrauma and Psychological Health

Purpose

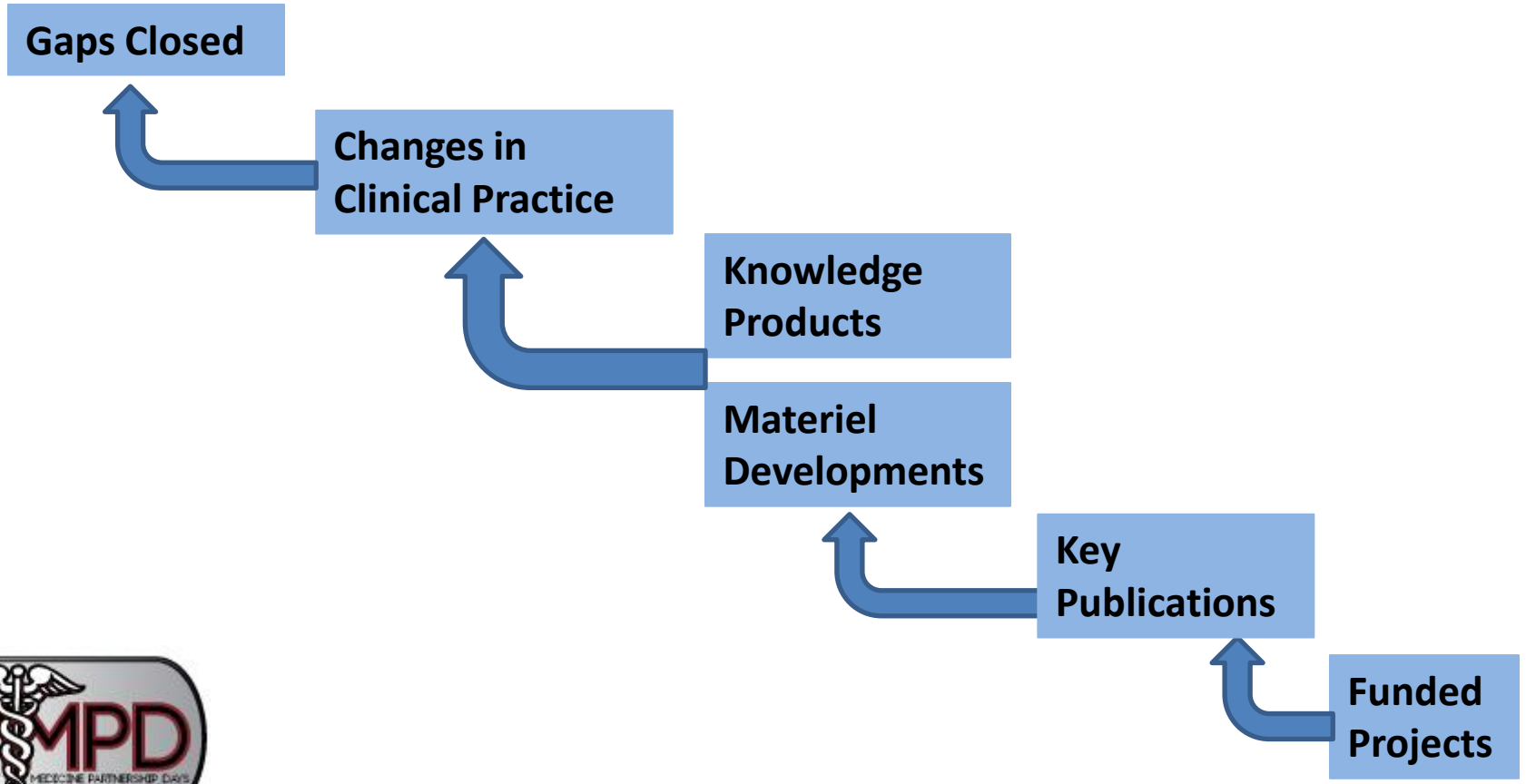
To increase understanding of Capability Gaps as they relate to Traumatic Brain Injury and Psychological Health Diagnosis, Treatment and Rehabilitation in our Wounded Warriors.

- Points
  - Research Programs
    - Military Operational Medicine
    - Combat Casualty Care
    - Clinical and Rehabilitative Medicine
  - Advanced Development
    - Neurotrauma & Psychological Health PMO

Capability Gap Closure

Methodology:

- Conduct a focused, data driven analysis to identify solutions and close gaps



Psychological Health

Dr. Ron Hoover, Clinical Psychologist

Military Operational Medicine Research Program

US Army Medical Research and Materiel Command

Gaps in Research

1. Psychological Health
   - *Resilience building: non-traditional methods that accelerate skill acquisition and use (targets: stress, depression, suicidal thinking)*
   - *Provider development /training tools for "best practices"*
2. Objective assessment tools for psychological disturbances
   - *Limitations of self-report*
   - *Could be used across different environments and for various psychological concerns (e.g., PTSD, suicidal Ideation, substance abuse, sleep/hyperarousal, persistent mood disturbances)*
   - *Portable, non-invasive, non-voluntary information source alerting leaders to fitness for duty concerns*
3. Automation of certain (bench) research activities
   - *Automated monitoring, recording, counting, coding, etc.(e.g., mouse vocalization classifications/counts measurement of behavioral indices)*

MOM Mission and Key Focus Areas

Develop effective medical countermeasures against operational stressors and to prevent physical and psychological injuries during training and operations in order to maximize the health, performance, and fitness of Service Members.

Science

INJURY

Injury Prevention and Reduction

THREATS

- Acoustic Trauma
- Blast Overpressure
- Blunt Head and Body Trauma
- Traumatic Brain Injury
- Face/Eye/Spinal Injury
- Musculoskeletal Injury
- Toxic Gas Inhalation
- Laser Eye Injury

PSYCH

Psychological Health and Resilience

THREATS

- PTSD/Other Anxiety Disorders
- Suicide Behavior
- Concussion (mTBI)
- Alcohol/Other Drug Use
- Co-occurring Mental Disorders
- Access/Retention in Behavioral Health Care
- Family Transitions and Well-being

PHYSIO

Physiological Health

THREATS

- Malnutrition
- Dehydration
- Sustained Fatiguing Work (Physical/Mental)
- Sleep Deficit & Circadian Desynchrony
- Distributed/Continuous Operations
- Dietary Supplements

ENVIRO

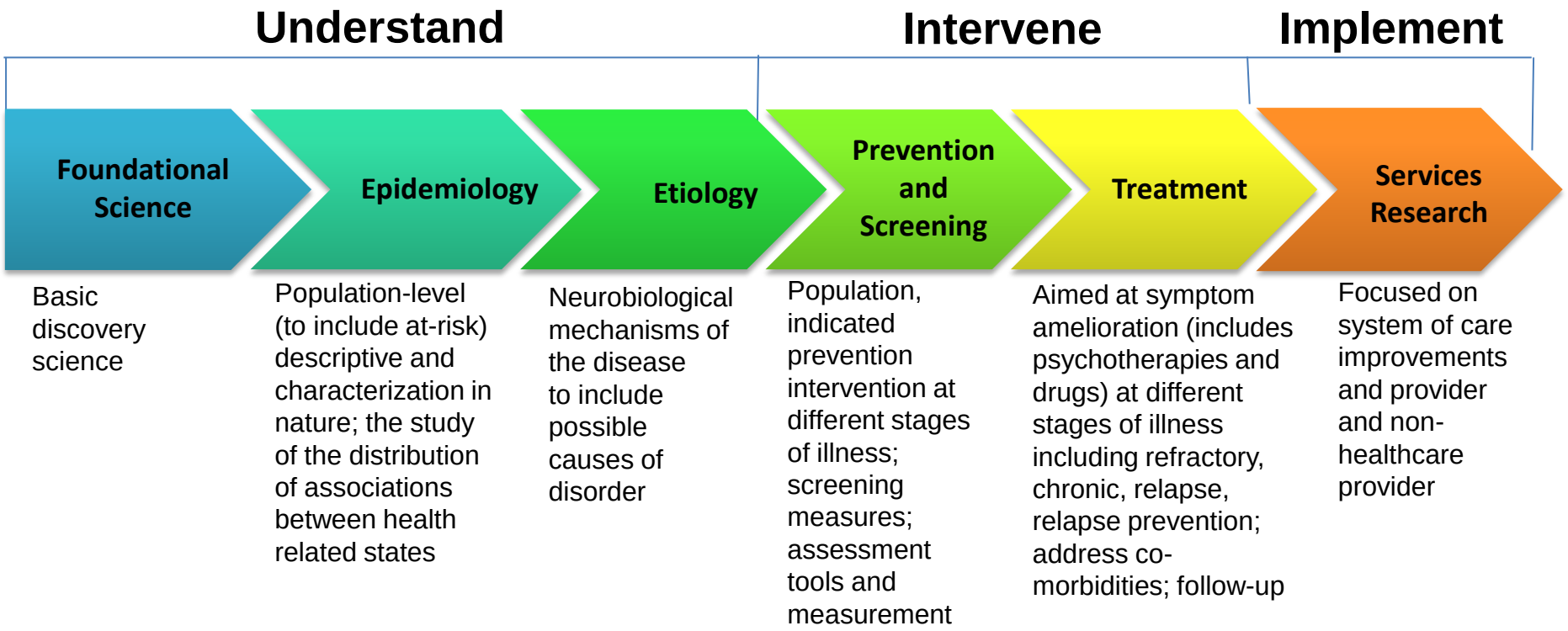
Environmental Health and Protection

THREATS

- Toxic Industrial Chemicals and Materials
- Dust and Air Pollution
- Altitude and Hypoxia
- Cold Stress
- Heat Stress
- Protective Equipment/ Clothing

Service Member and Family

Interagency Research Continuum



Traumatic Brain Injury

Dr. Marcello Pilia

Assistant Portfolio Manager

Combat Casualty Care Research Program

CCCRP Mission

Injury

I | II (6hrS | III (3 Days) | IV (until discharged)

Increasing Medical Capability

Mission: To reduce the mortality and morbidity resulting from injuries on the battlefield through the development of new life-saving strategies, new surgical techniques, biological and mechanical products, and the timely use of remote physiological monitoring.

https://ccc.amedd.army.mil

Neurotrauma Scope and Purpose

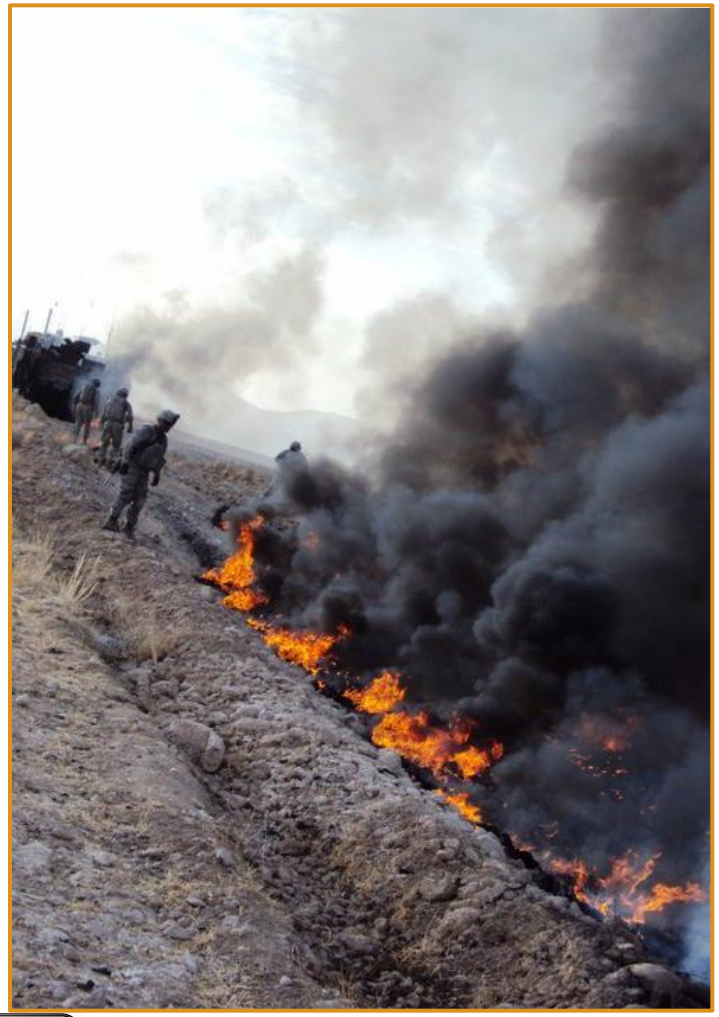
- **Scope**: The Neurotrauma program efforts are focused on closing military relevant gaps across a broad range of research areas to improve the prevention, diagnosis, management and treatment of traumatic brain injuries and related sequelae from point of injury through recovery.
- **Purpose**: Decrease morbidity and mortality from neurotrauma, mitigate secondary brain injury across all TBI severities and all echelons of care through requirements driven research, advance materiel and knowledge development to expand and develop new clinical guidelines, care algorithms, therapies, devices, and procedures that advance the decision-making capabilities of medical personnel, enabling earlier intervention and improve outcomes.

Capability Gaps Specific to TBI

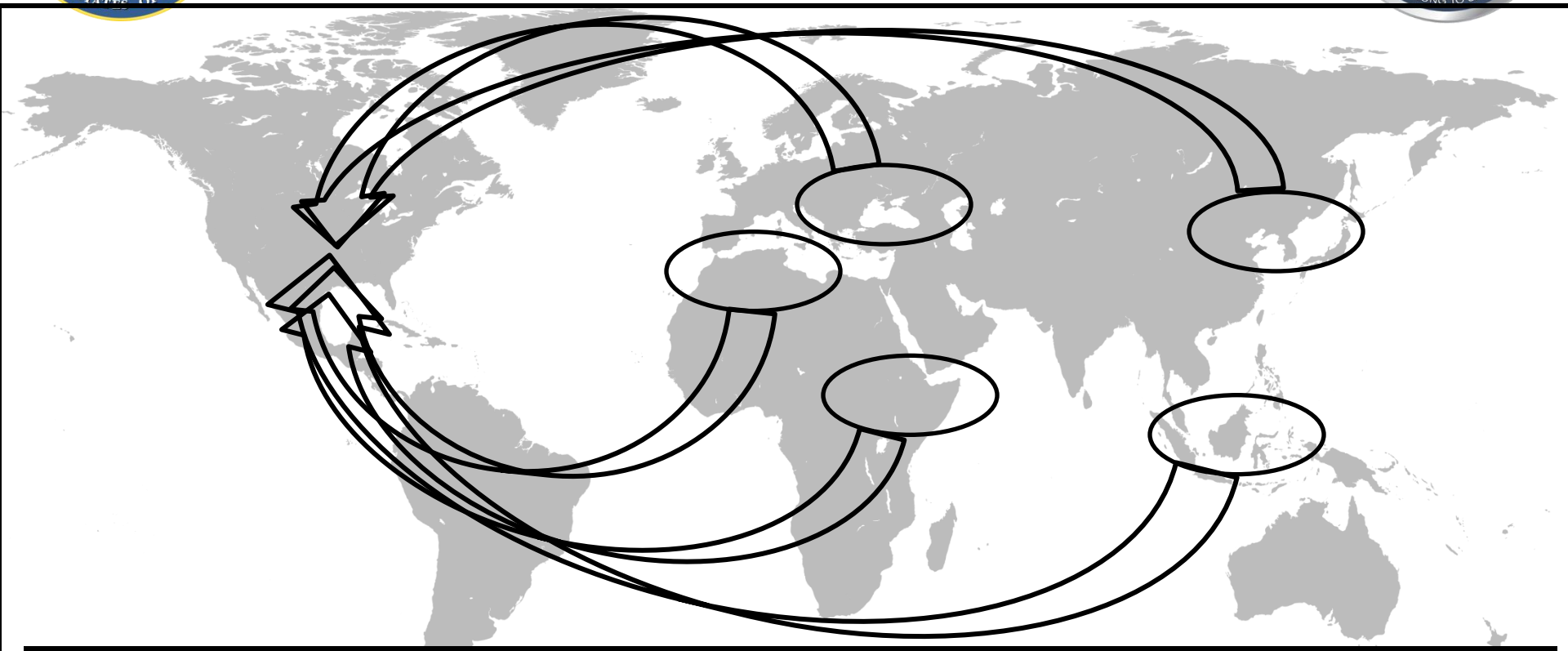
- Rapid identification of service members requiring higher level of care
  - Improve triage capabilities, decision making timeline for evacuation
- Rapid detection of mild TBI at point of need, acute and post-acute periods
  - Improve concussion diagnostic capabilities
- Epidemiology, Diagnosis, and natural history of TBI
  - Improve the understanding of factors that impact outcomes in SMs who have sustained a TBI (all severities)
- Enable monitoring of physiological parameters
  - Monitor, record and transmission of patient's' physiological status "seamless care and communication"
- Therapies to improve outcomes
  - Innovative interventions and/or devices to reduce secondary brain injuries, treat TBI-related neurodegenerative disease

TBI in the Era of OIF/OEF

Optimize survival and recovery



Look to Future Scenarios



- **"…without resource constraints, strategy would be unnecessary. Limited resources thus create the need for strategy. As resources become more constrained strategy becomes more important." – Todd Harrison**

End State (FY25-35)

- Outcomes of potentially survivable casualties are no longer limited by lack of early intervention, technology or knowledge shortfalls related to Neurotrauma.
  - Prehospital technologies are available to monitor, record, and transmit patient physiological parameters, allowing for earlier interventions potentially reducing incidence/severity of secondary injury
  - Effective, logistically supportable treatments and devices will be available for medics to stabilize and treat more severe TBIs starting at Role I and continuing through acute hospitalization
  - Next generation TBI treatments are available for prolonged prehospital management, up to 72 hours
  - Evidence-based treatments, therapies and knowledge products have led to the development of new and/or revised clinical practice guidelines for casualties with traumatic brain injury

Rehabilitation

Dr. Pamela Brown Baer

Sensory Systems Portfolio Manager

Clinical and Rehabilitative Medicine Research Program

US Army Medical Research and Materiel Command

Mission and Role of Care

Injury

Echelons of care

I	II (6hrs)	III (3 Days)	IV (until discharged)

Increasing Medical Capability

Mission: *To ethically and responsibly implement long-term strategies to develop knowledge and materiel products to reconstruct, rehabilitate, and provide definitive care for injured Service Members. The ultimate goal is to return the Service Member to duty and restore their quality of life.*

Neuromusculoskeletal Rehabilitation

Pain Management

Regenerative Medicine

Sensory Systems

Clinical and Rehabilitative Medicine Research Program

NEUROMUSCULOSKELETAL INJURY REHABILITATION

Prosthetics, orthotics, spinal cord injury, and orthopedic injury rehabilitation

Conduct research and development to provide products and information solutions for diagnosis, treatment, and rehabilitation after neuromusculoskeletal injuries

PAIN MANAGEMENT (Battlefield, Acute, Chronic)

Management of pain ranging from the point of injury to chronic pain management

Conduct research and development to provide improved methods, drugs, and devices for the management of pain at all levels of care

REGENERATIVE MEDICINE AND TRANSPLANTS

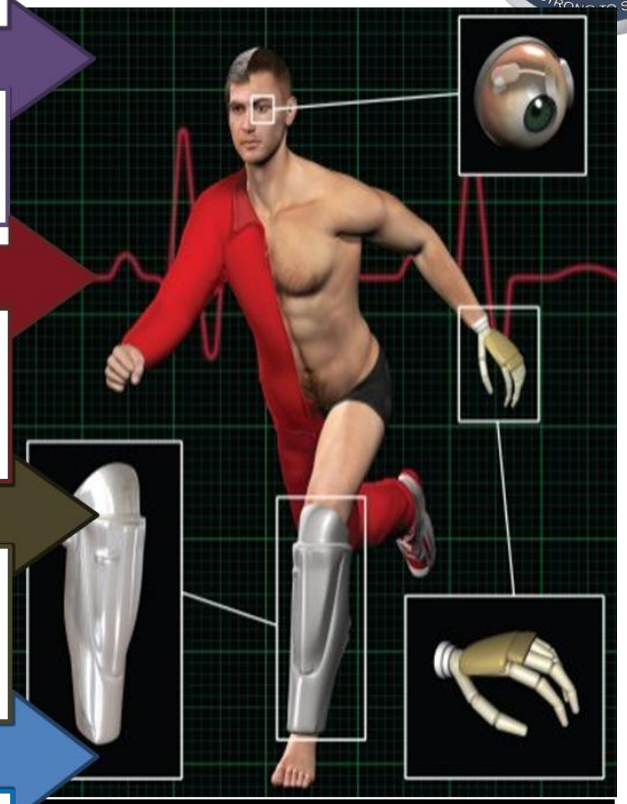
Extremity and craniomaxillofacial injuries, burns and scarless wound healing, Hand and face transplants, genitourinary lower abdominal reconstruction

Reconstruct or regenerate damaged or missing cells, tissues or organs to establish normal function

SENSORY SYSTEMS (Vision, Hearing, Balance)

Visual, auditory, and vestibular dysfunction associated with traumatic injury

Conduct research and development to provide treatments to restore and rehabilitate sensory system dysfunction



There are many strategies . . .
but only ONE goal.

LTC Teresa L. Brininger, Director, CRMRP
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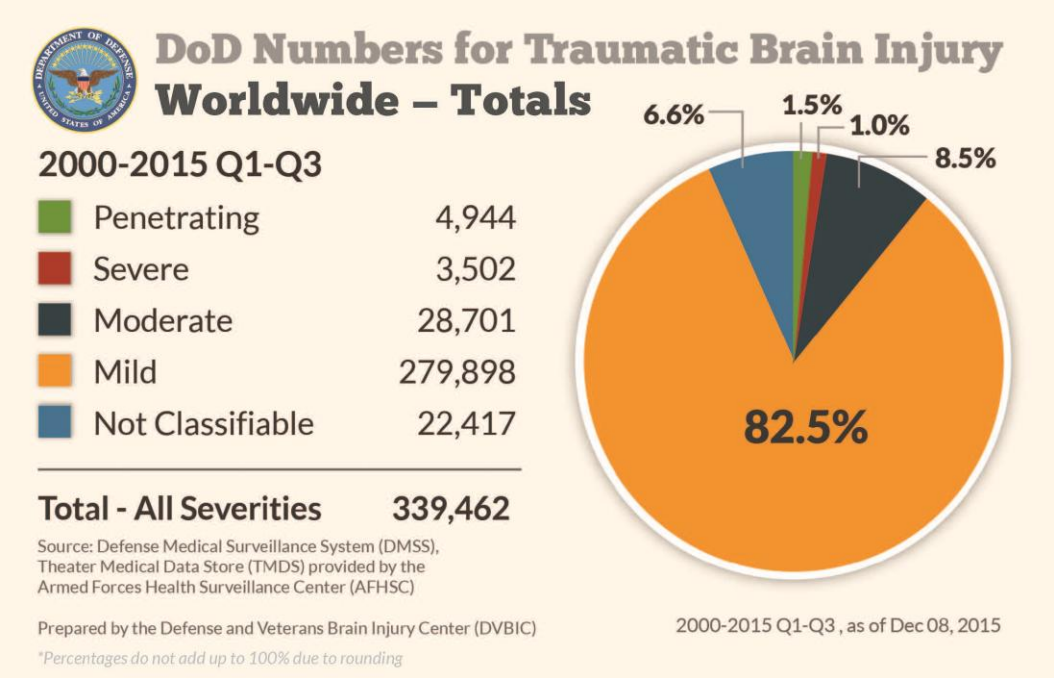
Traumatic Brain Injury and Sensory Systems



- Service members exposed to blast with resultant traumatic brain injury commonly report symptoms including dizziness and imbalance (Terrio et al., *J Head Trauma Rehabil*, 2009).
- Balance disorders secondary to traumatic brain injury have become increasingly common among service members, affecting an estimated 17% of soldiers deployed to Iraq and Afghanistan (Gottshall K et al., *Journal of Neurologic Physical Therapy*, 2010).

Capability Gaps Specific to Traumatic Brain Injury

1. Vision
   - *Inadequate understanding of the epidemiology, etiology, and treatments of vision and multi-sensory dysfunction associated with traumatic brain injury (TBI)*

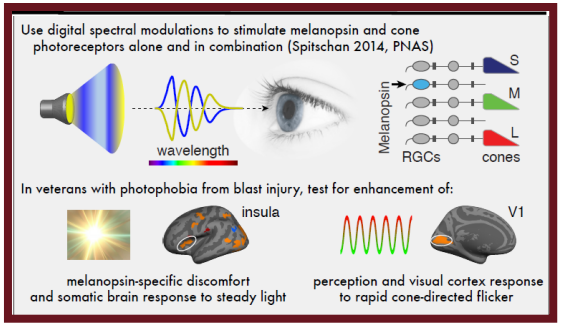
2. Hearing
   - *Inadequate understanding of the epidemiology, etiology, and treatments of hearing and multi-sensory dysfunction associated with traumatic brain injury (TBI)*

3. Balance
   - *Inadequate understanding of the epidemiology, etiology, and treatments of balance and multi-sensory dysfunction associated with traumatic brain injury (TBI)*

4. Pain Management and Neuromusculoskeletal (NMS) Injury
   - *Better chronic pain management strategies for primary care providers*
   - *Optimal treatment strategies for patients with TBI and NMS*

Sensory System Research

1. Understanding Sensory Co-Morbidity
   - *Characterizing Photo-phobia*
   - *Developing potential treatments*
2. Diagnosis
   - *Sensorimotor Assessment and Rehabilitation Apparatus*
   - *Diagnose multisensory impairment*
3. Treatment and Rehabilitation
   - *Balance Assessment and Rehabilitation*
   - *Audio biofeedback (AFB) balance rehabilitation program*



End State (FY25-35)

- Neurotrauma rehabilitation outcomes are no longer limited by lack of early intervention, technology or knowledge shortfalls.
  - Point of injury care ensures optimal outcomes of neurotrauma rehabilitation
  - Patient-specific treatment algorithms provide personalized-medicine rehabilitation strategies
  - Interdisciplinary strategies employed offer patient-centric care to maximize outcomes
  - Evidence-based treatments, therapies and knowledge products have led to the development of new and/or revised clinical practice guidelines for casualties with traumatic brain injury
  - Service members reintegrate with highest quality of life outcome

Neurotrauma & Psychological Health PMO

Mr Michael Husband

Project Manager Neurotrauma and Psychological Health

United States Army Medical Materiel Development Activity

Innovative Therapeutic Strategies

Development efforts for an FDA approved acute Drug Treatment for Traumatic Brain Injury (TBI)

- Currently have 1 funded effort in Phase 2 clinical trial for the acute treatment of moderate-severe TBI (IV formulation) and mild TBI (oral formulation)

Gaps

- Need promising candidates in the pipeline (Phase 1, Pre-Clinical)
- Other delivery methods (Intranasal?)
- Alternative strategies (hypothermia, cellular therapies, more?)
  - Hypothermia: Currently have SBIR for selective brain cooling
  - Cellular therapies: Phase 2 in severe TBI for bone marrow stem cells
- Mild TBI treatment to prevent Post-Concussive Syndrome

Laboratory Assay for TBI

Description:

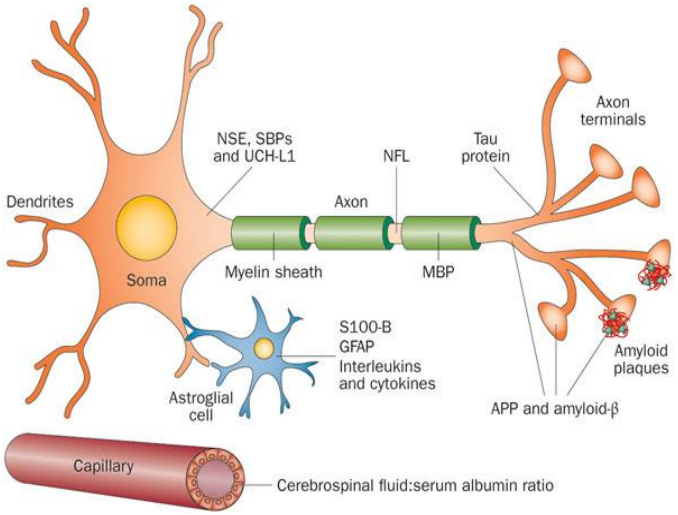
- Biomarker (GFAP and UCH-L1) assay for determining exposure to TBI
  - Benchtop Device (Increment I)
  - Point of Care Device (Increment II)

Limitations:

- Inadequacy of current gold standard
- Level of detection may not produce notable difference between CT-/CT+
- Assay time

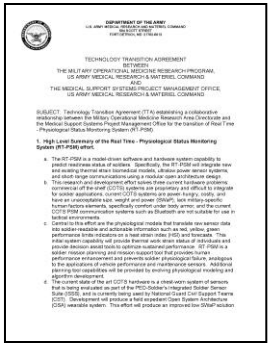
Needed from Industry:

- Research on additional Biomarkers
- Improved assay design
  - Indication for TBI diagnosis, prognosis, response to therapy, need for neurosurgical intervention
  - Disposable handheld system
  - Longer reagent shelf life



Tools for Successful Transitions

- Begin with the end in mind
  - Know your requirement
  - "Good enough" now is better than perfect later
  - Avoid losing focus on what's really important
  - Know your target → Avoid the allure of "bright, shiny objects"
- Integrate early → Many disciplines are on the critical path to product fielding
- Know what the FDA may be thinking → Reviewers see more potential products in a month than most scientists do in a career
- Technology Transition Agreements (TTAs) → ensures critical thinking & commitments when putting pen to paper



MMPD
MILITARY MEDICINE PARTNERSHIP DAYS

Questions?

For additional questions after the conclusion of the conference, send an email message to usarmy.detrick.medcom-usamrmc.mbx.mmpd@mail.mil