REHABILITATION OF MILD TRAUMATIC BRAIN INJURY IN OEF/OIF VETERANS: A MULTIDISCIPLINARY CHALLENGE

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VA HSR&D Cyber Seminar October 25, 2012

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Challenges of TBI Rehabilitation in OEF/OIF Veterans Outline

- The scope of the challenge: who is of particular concern for the VA in the coming years?
- Why does this cohort represent such a challenge?
- Considerations for treatment.
- Current treatment approaches at TRACTS for mTBI.

The Scope: mTBI

In the US military, TBI is the most common type of physical injury sustained by OEF/OIF service members, and EXPLOSION OR BLAST INJURY by explosive devices (improvised explosive devices, landmines, rockets, etc.) is the most common cause.

*Center for Disease Control & Prevention, 2010

mTBI

Criteria: must be >0 for one of the following:	**Grade I**	**Grade II**	**Grade III**
Loss of Consciousness (LOC)	None	<5 minutes	> 5 minutes
Post Traumatic Amnesia (PTA)	0-15 minutes	<24 hours but > 15 minutes	>24 hours
Alteration of Mental Status (AMS)	0-15 minutes	<24 hours but > 15 minutes	>24 hours

Developed based on Bailes & Cantu, 2001

Understanding the Complex Physical and Mental Health of OEF/OIF Veterans: TRACTS Core Assessment

Medical/Biological	Neuropsych Domains	Affective/Psychosocial	Blast & TBI	Neuroanatomy s/f MRI
Blood Chemistry	Simple & Divided Attention	PTSD CAPS & PCL-C	Boston Assessment TBI-Lifetime	Cortical Volume
Genetic	Information Processing Speed	DSM-IV AXIS I: SCID	Ohio State University TBI ID	Cortical Thickness
Neuro-steriod	Executive Function	Traumatic Life Events Questionnaire	Neurobehavioral Symptom Inventory	Diffusion Tensor
	Declarative & Procedural Memory	Deployment Risk & Resiliency Inventory		Resting State Networks
	Pre-morbid Function	Depression, Anxiety & Stress Scale-21		Functional Connectivity
	Perception	Pittsburg Sleep		
	Symptom Validity	McGill-Pain		
	Psychomotor Speed	ETOH, Nicotine		
		Sickness Impact Profile		

Demographics/Deployment Information
TRACTS Cohort (n=198)

Variable	Mean (SD)
Gender	87% male 13% female
Age	33.2 years (8.60) Range: 20-62
Ethnicity	White/Caucasian 68.2% Hispanic/Latino 15.7% American Indian 1.0% Asian 2.5% Black/African American 11.1%
Years of Education	13.91 (1.97) Range: 12-20
Estimate IQ	100.58 (11.70) Range: 66-123
Number of Deployments	1.37 (0.65)
Duration of Deployments (months)	14.72 (8.85)
Time since last Deployment (months)	33.15 (26.47)

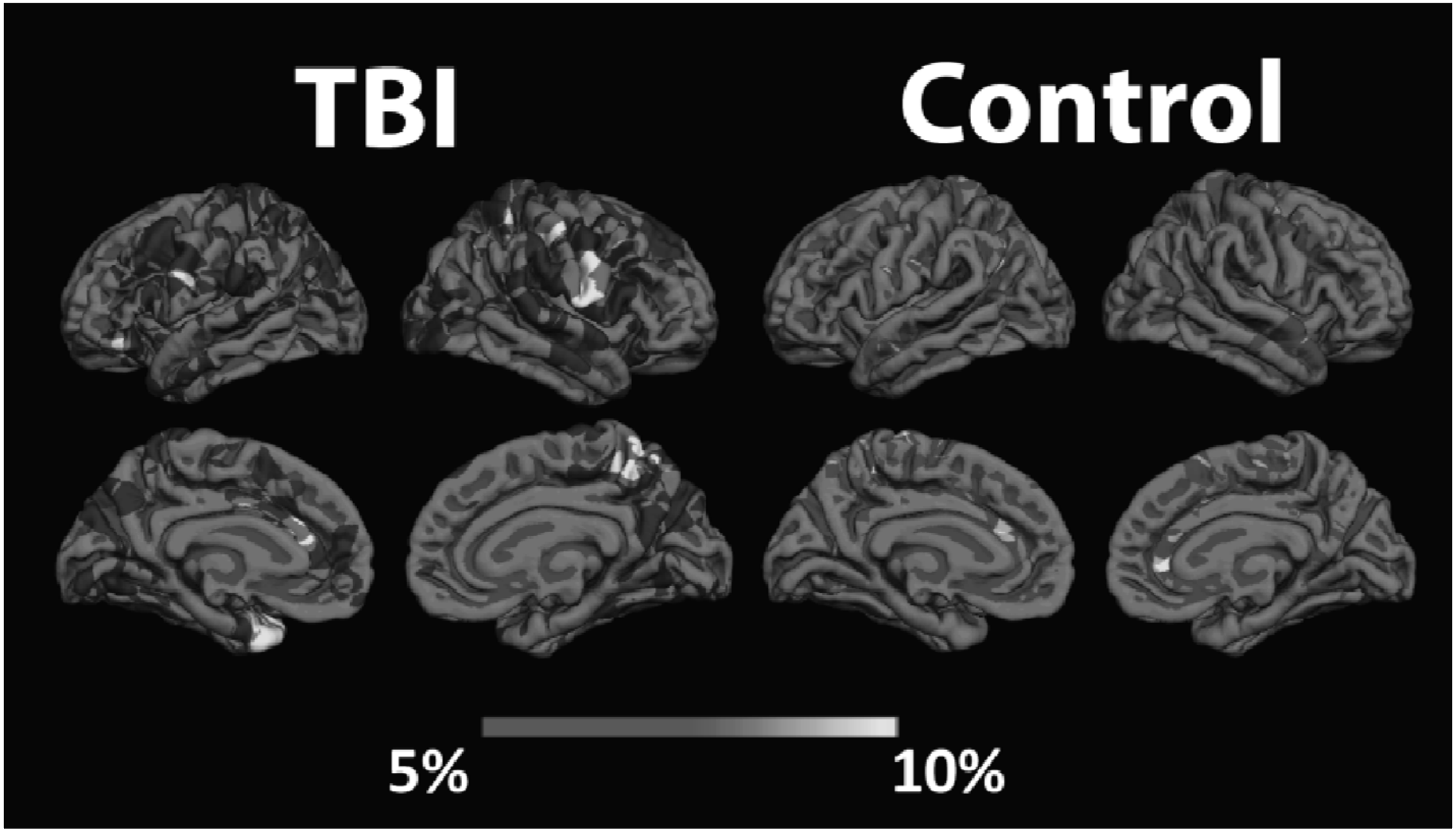
Why does this cohort represent such a challenge?

HETEROGENIETY !

Traumatic Brain Injury in OEF/OIF
Boston Assessment of TBI-Lifetime (BAT-L)

	Deployment Blast	**Military "Other"**	**Pre-Deployment**	**Post-Deployment**
Severe	0	0	2	0
Moderate	0	2	4	0
Mild	42 (21%) (6 with multiple)	52 (26%) (14 with multiple)	77 (39%) (27 with multiple)	14 (7%)
Stage 1	20	26	31	2
Stage 2	19	24	36	10
Stage 3	3	2	10	2

Heterogeneity of mTBI: Outlier Maps of Cortical Thinning

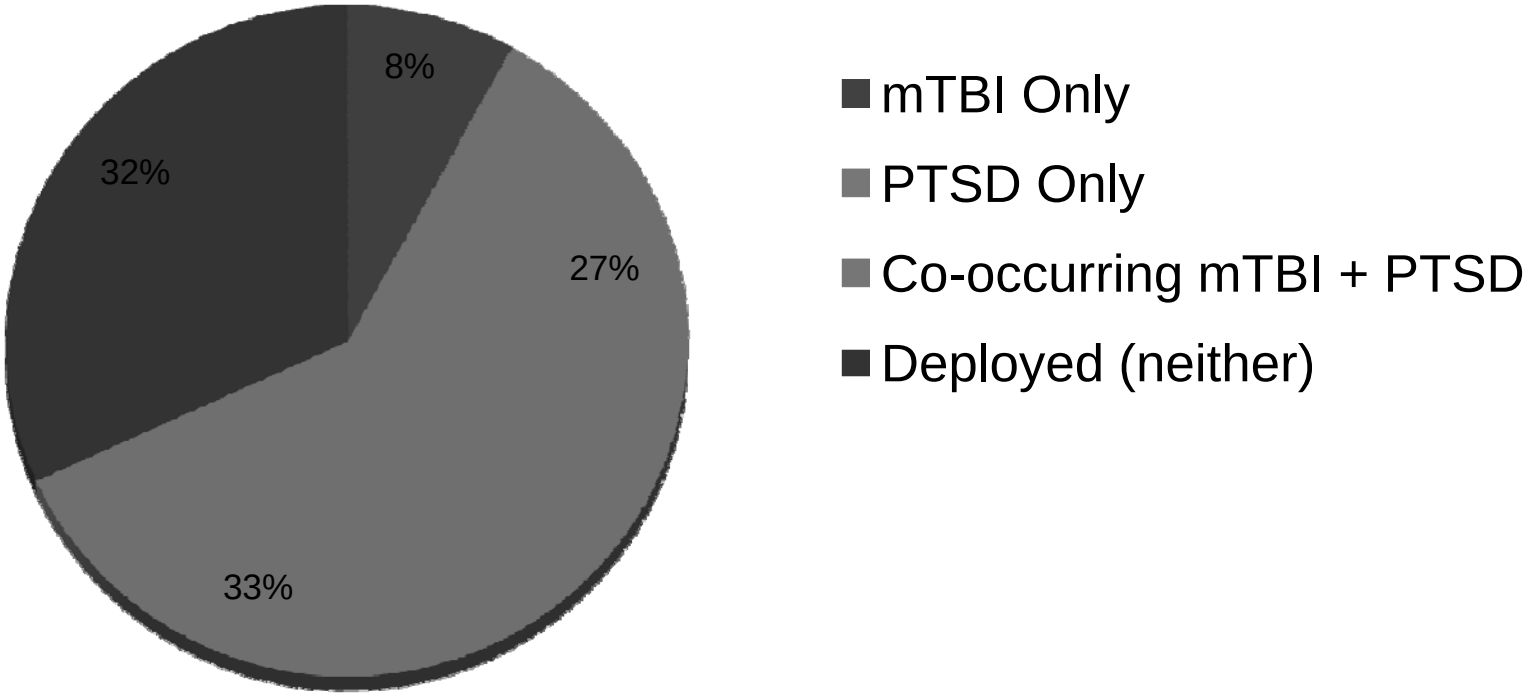


Simultaneity of Physical and Psychological Trauma in OEF/OIF

Post-Traumatic Stress Disorder
Clinician-Administered PTSD Scale (CAPS)

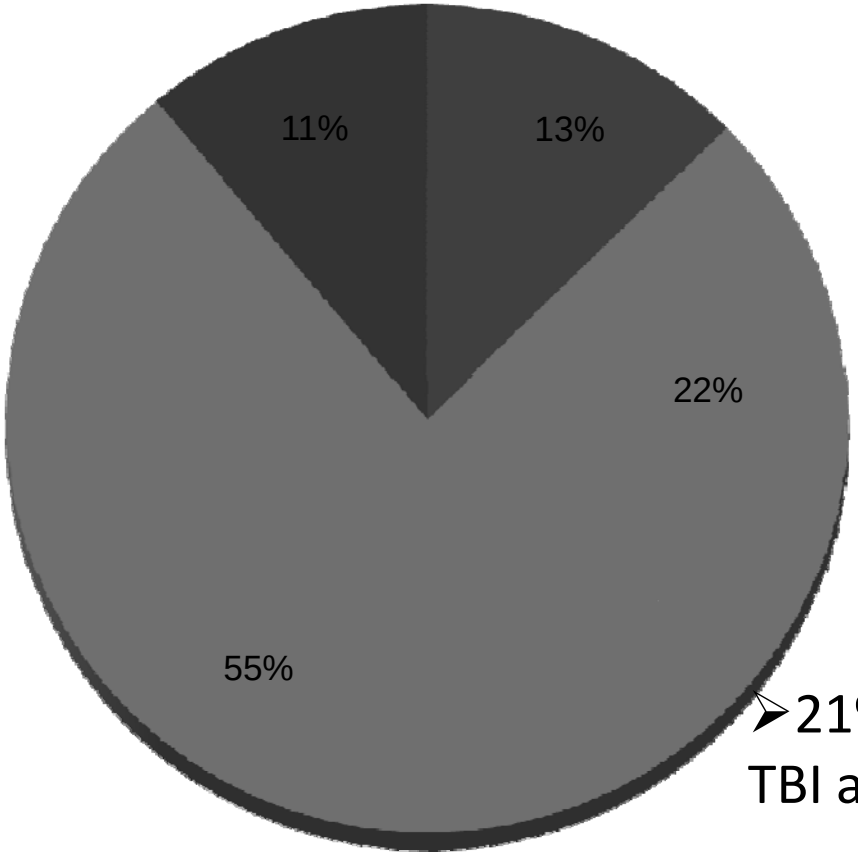
Current	Pre-Deployment	Post-Deployment
119 (60%)	35 (18%)	128 (65%)

Percentage of TRACTS Cohort (n=198) Military mTBI and Current PTSD



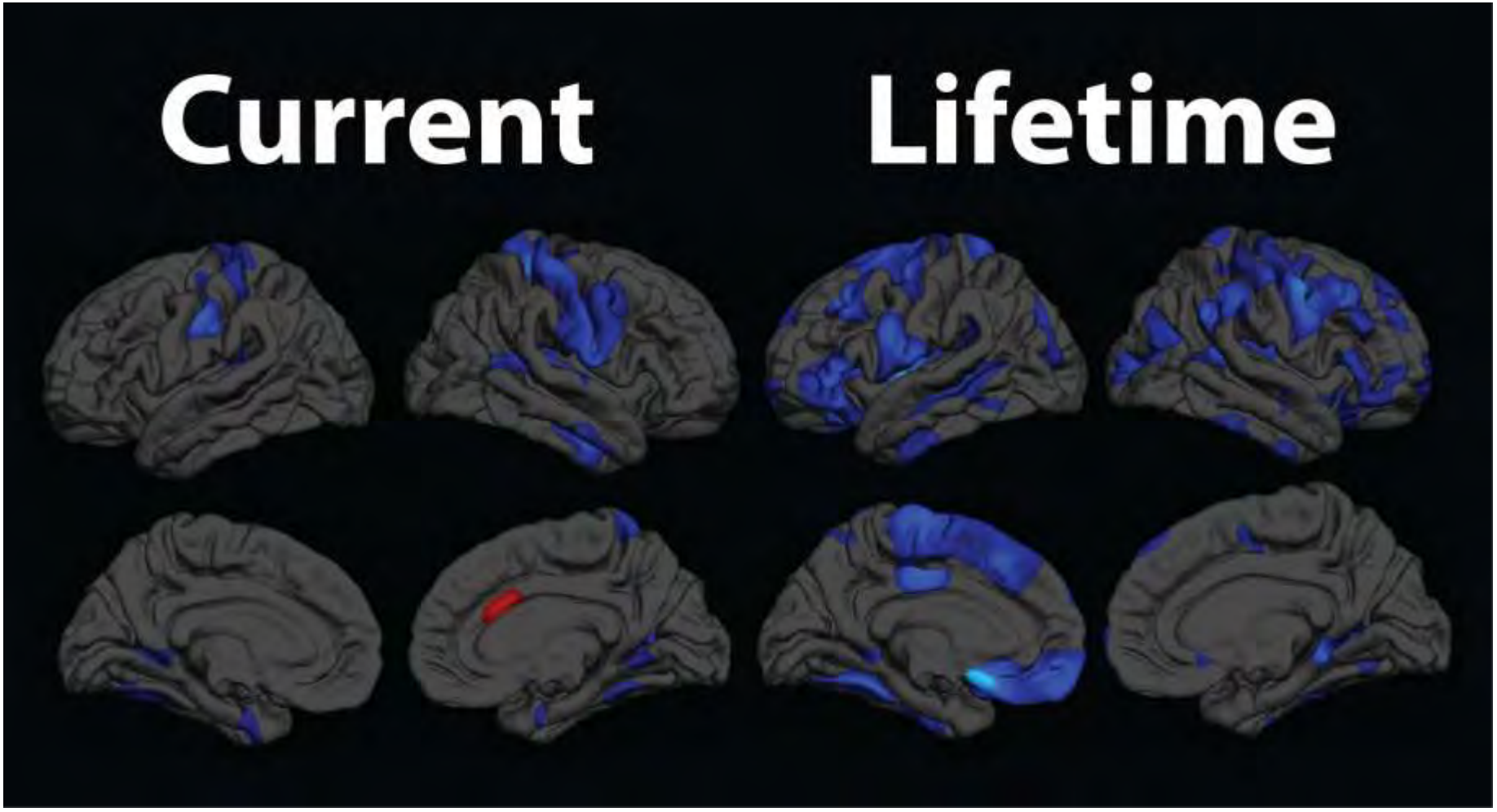
- Only 8% with uncomplicated mTBI
- 60% with PTSD; 33% with Co-occurring mTBI

Percentage of TRACTS Cohort (n=198) Lifetime Hx mTBI and Lifetime Hx PTSD

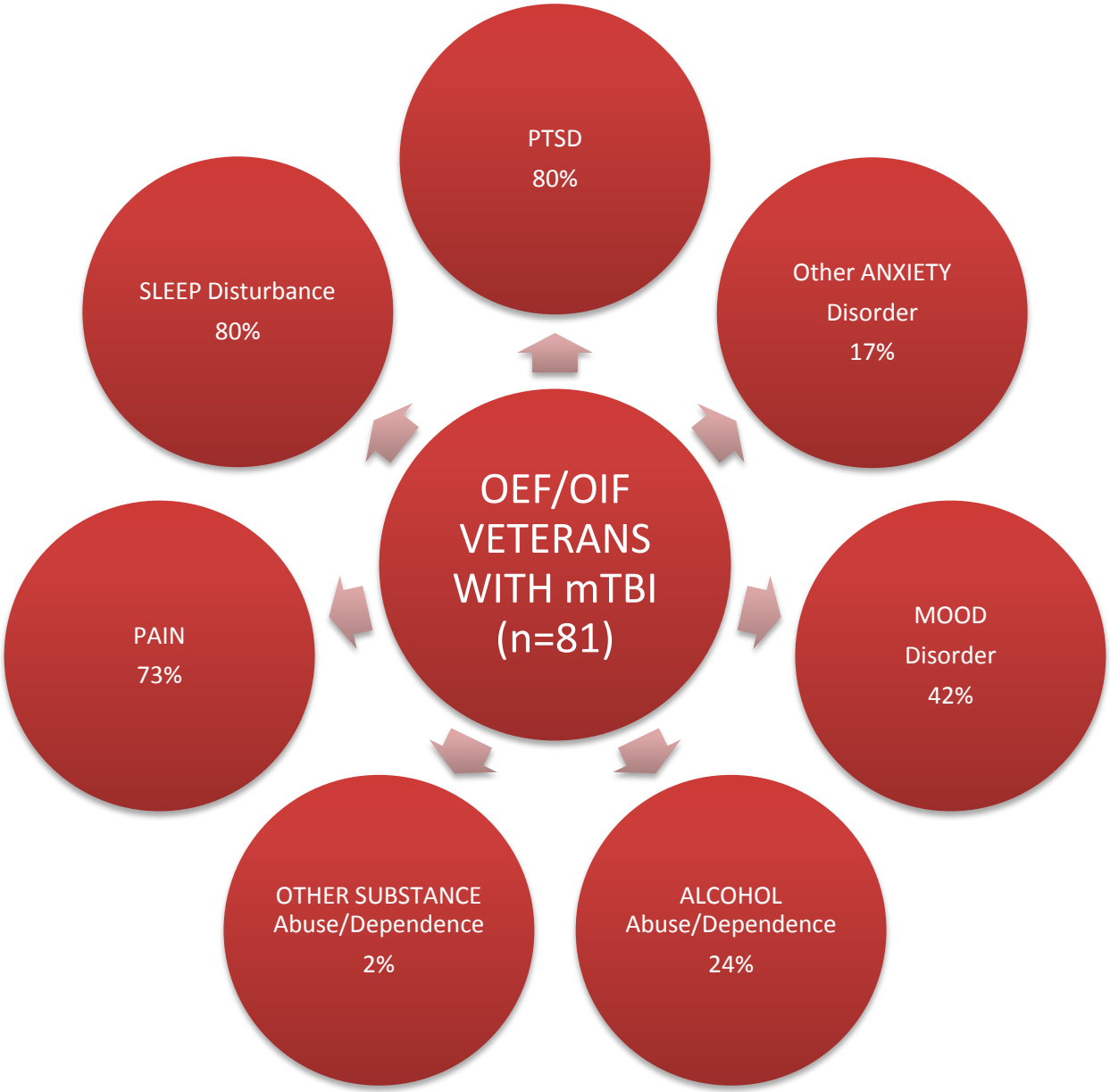


- 21% of "deployed controls" have lifetime history of TBI and/or PTSD
- 68% with lifetime history of TBI; 55% with co-occuring PTSD

Lifetime versus Current CAPS Score on Brain Structure



mTBI is a Poly-Morbid Condition



Number of Co-morbidities

Entire TRACTS sample

# of Co-morbidities (n=198):	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**3 or more**
# Service Members (%)	18 (9%)	34 (17%)	40 (20%)	37 (19%)	45 (23%)	20 (10%)	4 (2%)	106 (54%)

THOSE WITH mTBI

# of Co-morbidities (n=81):	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**3 or more**
# Service Members (%)	1 (1%)	12 (15%)	11 (14%)	20 (25%)	22 (27%)	14 (17%)	1 (1%)	57(70 %)

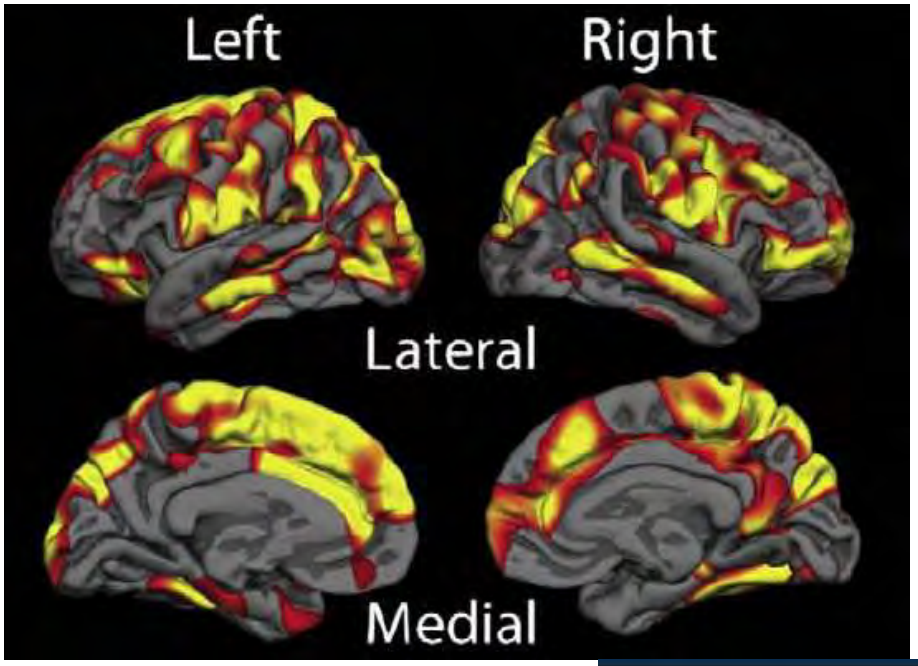
Biomedical Characteristics

Measure	TRACTS (n=198)	mTBI (n=81)	Normal
Mean Arterial Blood Pressure	89.83 ± 10.09	91.28 ± 9.48	70-110
Systolic Blood Pressure	116.86 ±12.75	118.16 ± 11.36	110-130
Diastolic Blood Pressure	76.32 ± 9.84	77.84 ± 9.50	75-85
Body Mass Index	28.60± 4.66	29.27 ± 4.76	18.5-24.9
Waist-Hip Ratio	.87 ± .08	.88 ± .09	≤.95 M/≤.80 F
Total Cholesterol	188.11 ± 37.29	191.93 ± 35.68	<200
LDL - Cholesterol	115.69 ± 33.72	118.35 ± 30.04	<100
HDL - Cholesterol	48.18± 12.71	48.06 ± 12.58	>60
Triglycerides	140.65 ± 121.21	146.14 ± 136.15	<150
Cardiac Homocysteine	10.55 ± 3.14	10.30 ± 2.26	<11.4
Glucose	86.13 ± 37.17	82.42 ± 12.04	65-99
Hemoglobin A1-C	5.45 ± .87	5.39 ± .27	<5.7
C-Reactive Protein	.24 ± .24	.26 ± .29	<.80

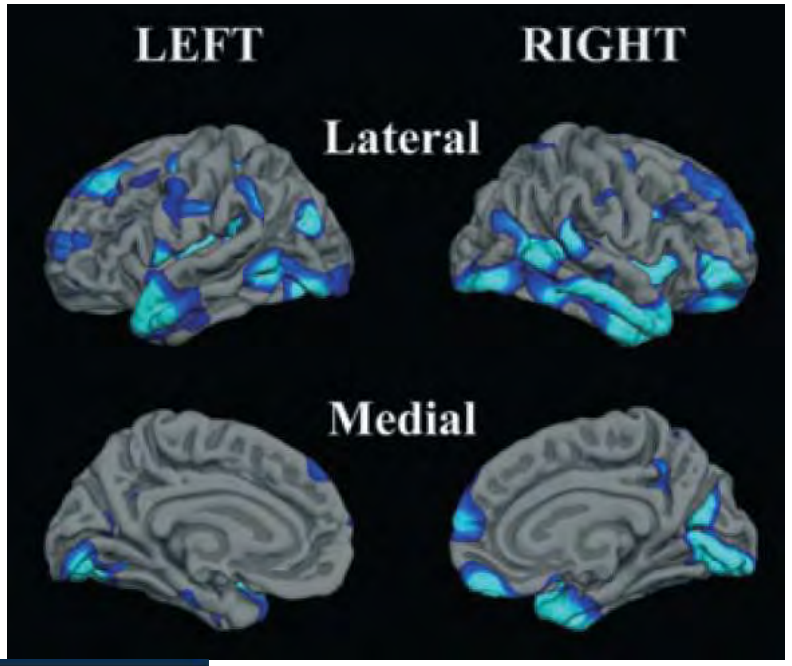
SO WHAT?

MANY OF THE CO-MORBID CONDITIONS SHARE THE SAME UNDERLYING NEURAL STRUCTURES AND SYSTEMS.

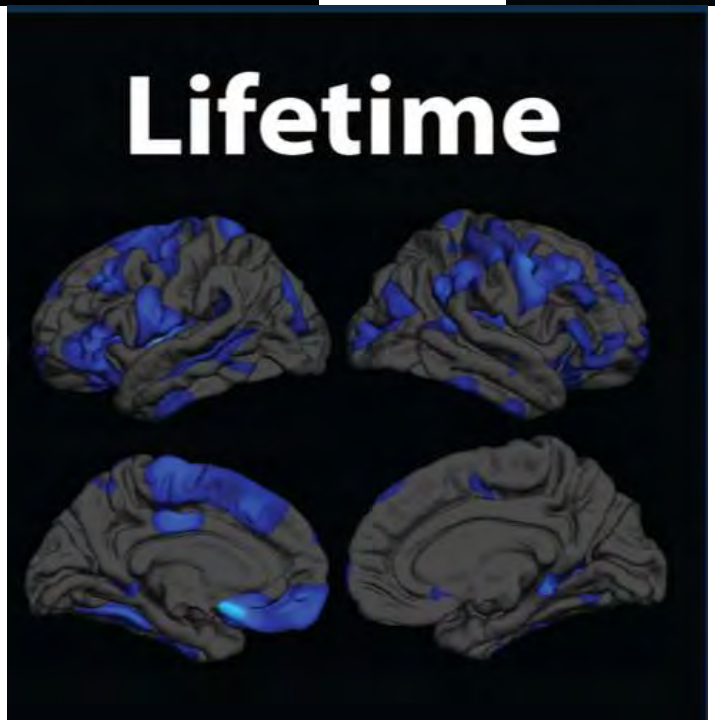
For example:



Cholesterol: Leritz et al. 2010



Alcohol: Fortier et al. 2011



PTSD: Salat et al. 2012

Not surprising….Shared Cognitive Dysfunction

Persistent mTBI	PTSD	Alcohol Abuse/Dependence	Cardiovascular Risk	Pain	Sleep
Memory	Memory	Memory	Memory	Memory	Memory
Attention/Concentration	Attention/Concentration	Attention/Concentration	Attention/Concentration	Attention/Concentration	Attention/Concentration
Executive Functions	Executive Functions	Executive Functions	Executive Functions	Executive Functions	Executive Functions
Headache		Headache		Headache	Headache
Fatigue	Fatigue	Fatigue	Fatigue	Fatigue	Fatigue
Hyperarousal	Hyperarousal				
Avoidance	Avoidance	Avoidance		Avoidance	Avoidance
Light Sensitivity				Light Sensitivity	Light Sensitivity
Insomnia	Insomnia	Insomnia		Insomnia	Insomnia
Depression	Depression	Depression	Depression	Depression	Depression
Irritability/Anger	Irritability/Anger	Irritability/Anger		Irritability/Anger	Irritability/Anger
Dizziness	Re-experiencing	Dizziness	Dizziness		Dizziness

Considerations Before Treatment to Maximize Potential Outcome

1. Blood work/physical to check for CVD risk factors out of range that could impact cognition and brain function (e.g., hypertension, cholesterolemia, liver function, etc.).

1. Full assessment of cognitive function to identify domains of decreased ability and identify strengths that can serve as a basis for rehabilitation.

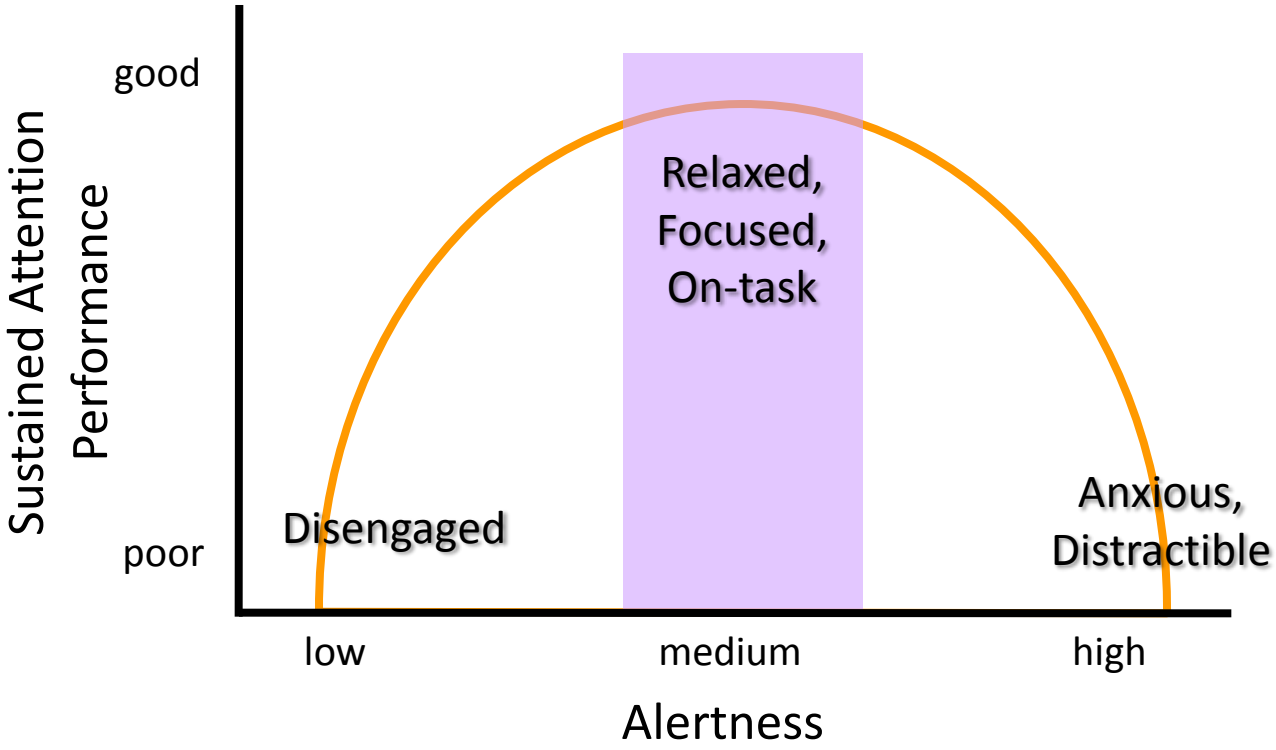
1. Control of substance abuse/dependence.

1. Management of chronic pain and sleep disturbance.

TRACTS Rehabilitation Programs

- Cognitive Processing Therapy for co-occurring mTBI and PTSD (Ann Rasumusson, PI)
- Vocational Rehabilitation for OEF/OIF Veterans (Colleen Barber, PI)
- Cognitive Behavioral Therapy for Posttraumatic Headache for OEF/OIF veterans (John Otis, PI)
- Remediation of attentional dysfunction in mTBI and/or PTSD OEF/OIF veterans

Sustained Attention in TBI/PTSD

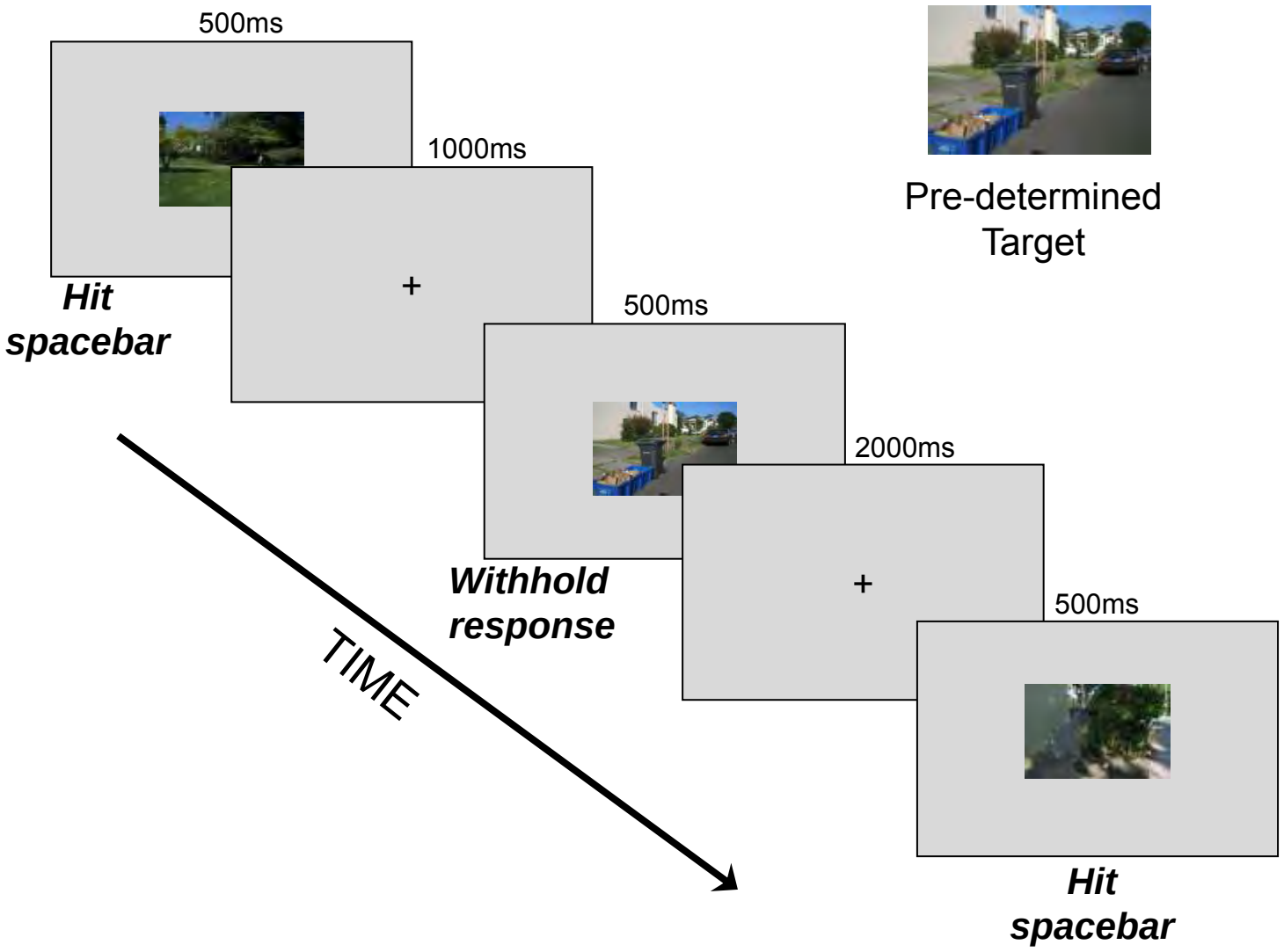


• TBI, PTSD, and deployment alone have been associated with increased distractibility and impaired sustaining attention

- Difficulty maintaining a focused and engaged state of attention

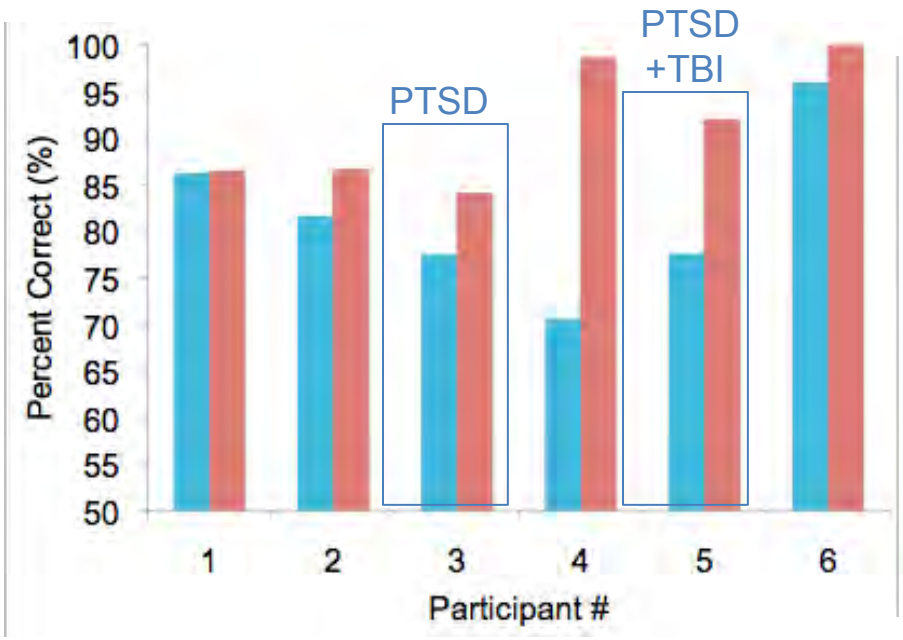
• Sustained attention deficits may underlie other deficits such as impulse control, decision-making, and emotion regulation

Sustained Attention Training (TAPAT)

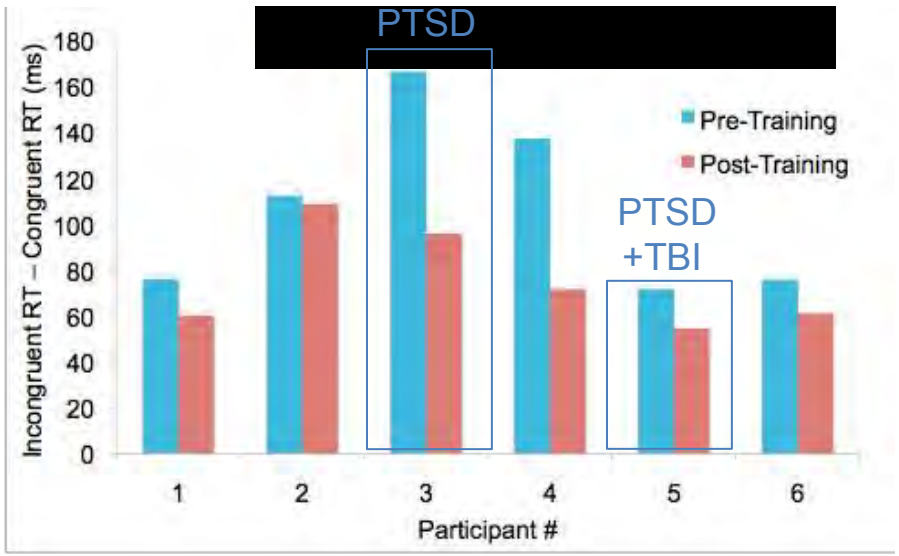


Sustained Attention Training: Pilot Results

Impulse Control



Distractibility (Conflict effect)



- All participants significantly improved at sustaining attention on the training task itself
- Participants also improved on impulse control and showed reduction in distractibility

Lessons Learned

- Cannot think of mTBI in OEF/OIF Veterans as something that can be treated in isolation of other prominent co-morbid conditions.
  - mTBI IN THIS COHORT RARELY EXISTS ALONE

- Very difficult cohort to engage and retain in modular therapies.

- Treatment compliance affected by ongoing factors such as pain, sleep disturbance and substance use/abuse.

Lessons Learned

- Critically important to consider cognitive, especially executive function deficits, as moderators of therapeutic processes (e.g., engagement and participation).

- Presence of cognitive deficits require flexible approaches to rehabilitation. Clinical materials and method of presentation should be tailored to fit the needs of the patient.

  Strict adherence to protocol may not be clinically beneficial.

Use a Patient-Centered Approach!!
ONE SIZE WILL NOT FIT ALL

US Department of Veterans Affairs

Telerehabilitation for Veterans with Combat Related Traumatic Brain Injury

Kris Siddharthan, PhD
James A Haley Veterans Hospital
Tampa, Fl

Award Number : W81XWH-08-2-0091
Award Dates: June, 2008 – June 2013

Background/rational

- OEF/OIF wounded > 35K
- Incidence of TBI /PTSD : 60%
- Long term rehabilitation
- VA resources limited
- Alternate modalities of care coordination
- Telerehabilitation

Objectives

1. Evaluate the efficacy of telerehab for care coordination.
2. Monitor physical and mental health outcomes.
3. Determine if telerehab is cost effective.
4. Capture patient satisfaction with telerehab for combat trauma.

Study Design

- 36 month design with a convenience sample of 75 OEF/OIF returnees.
- quantitative analysis of
  - Health outcomes, utilization, cost
- qualitative analysis of
  - veterans' perceptions of telerehab
  - Facilitators and barriers to implementing telerehabilitation

Inclusionary criterion

- Returnees from Iraq and Afghanistan with a clinical diagnosis of mild/moderate TBI.
- Use the James Haley Veterans Hospital as primary source of care
- Will benefit from the program
- Not institutionalized or psychotic.

Telerehab Intervention

- Full time interventionist (ARNP)
- MD's: primary care and specialists
- Psychologist
- Computer based
    - Internet: Secure VA server
    - Individual dialogues
    - Asynchronous chat
    - Text alerts

Telerehab intervention

Care coordination

a) Scheduling appointments

b) Pain management

c) Drug therapy

d) Substance abuse

e) Counseling

f) Behavior modification

Monitoring Health Status

- Activities of daily living
- Cognition
- Integration into society
- Psychosocial status
- Depression
- Musculoskeletal disorders
- Adverse events

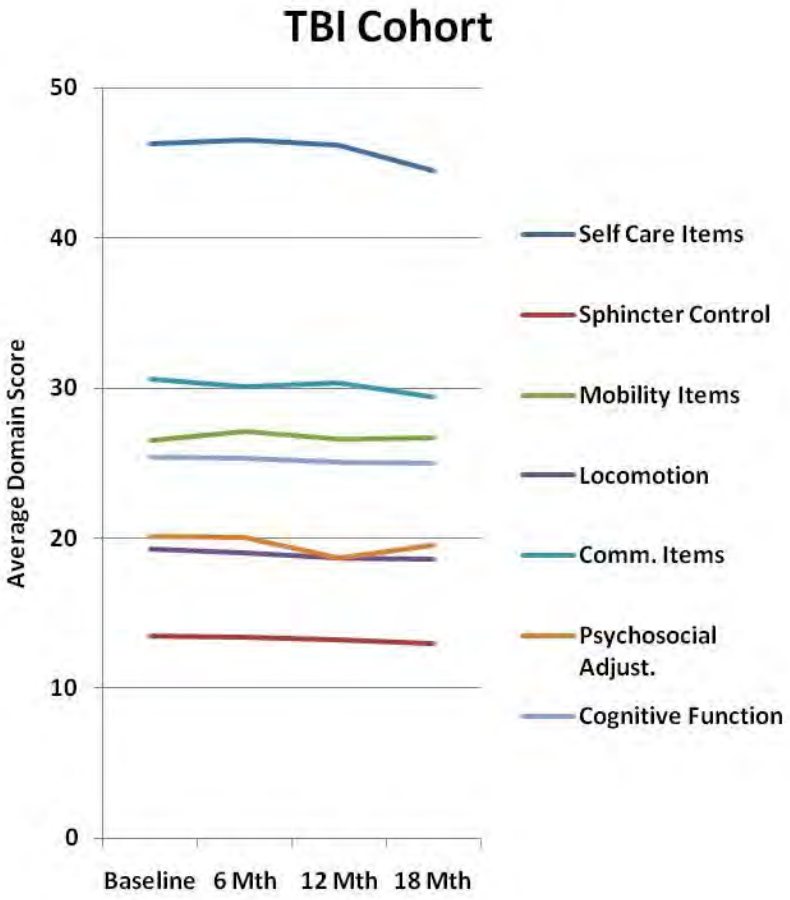
Instruments

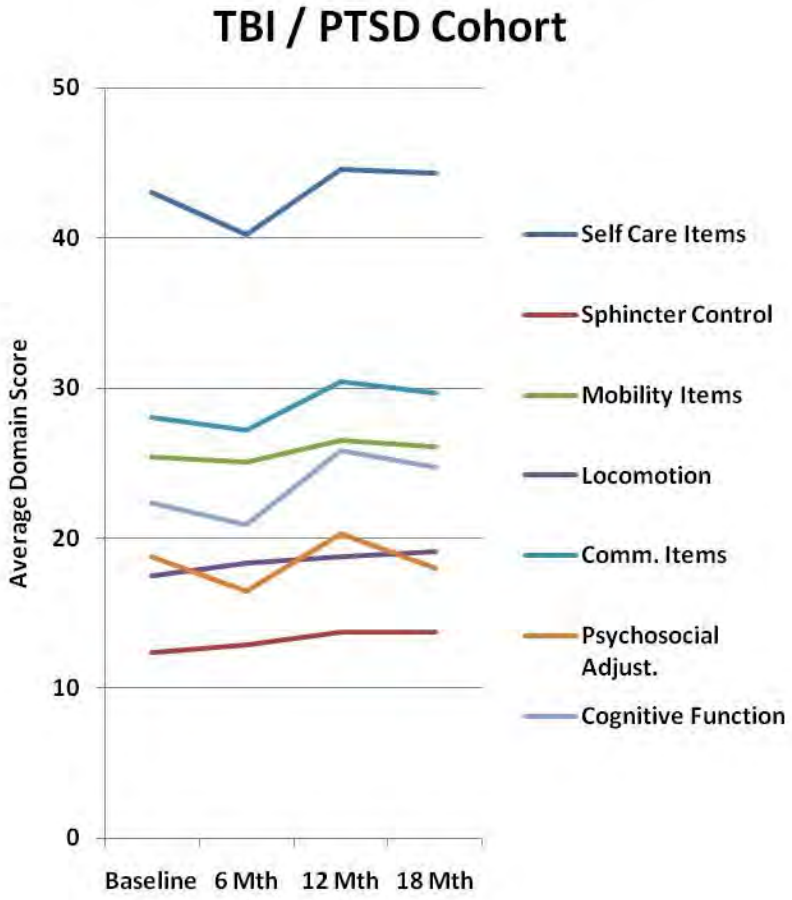
- Functional Independence Measures
- Craig Handicap Assessment and Reporting Technique (CHART)
- Patient Competency Rating Scale
- Beck Depression Inventory
- Modified PTSD Symptom Scale
- Alcohol Use Disorders Identification
- Medical Outcomes Social Support Survey

Veteran Demographics

N=75	TBI Cohort		TBI/PTSD Cohort	
Gender	**N**	**%**	**N**	**%**
Female	3	4.0%	0	0.0%
Male	58	77.3%	14	18.7%
Race/Ethnicity				
Black	4	5.3%	0	0.0%
Hispanic	15	20.0%	4	5.3%
Native Hawaiian	1	1.3%	1	1.3%
Unanswered	2	2.7%	1	1.3%
White	39	52.0%	8	10.7%
Age				
18-29	30	40.0%	3	4.0%
30-39	18	24.0%	3	4.0%
40-49	10	13.3%	6	8.0%
50+	3	4.0%	2	2.7%

Rehabilitation trajectories





Linear Latent growth curve models

- Dependent Variables: subscales
  - Craig Handicap Assessment and Reporting Technique
  - Patient Competency Rating Scale
  - FIM + FAM
- Adjusted for age, % service connected disability, marriage status, PTSD and interaction terms.

Results

- PTSD significant predictor in
  - CHART
    - Social integration
    - Mobility
    - Physical independence
  - FIM + FAM
    - Cognitive function
    - Communication items
    - Psychological adjustment
    - Mobility

Summary of Findings

- Physical Symptoms (locomotion, mobility) have stabilized
- Problem areas
  - Cognition (memory, problem solving)
  - Psychosocial adjustment (anger, emotional status)
  - Integrating into society
  - Suicidal tendencies

Conclusions

- Individualized treatment pathways needed.
- Alcohol and substance abuse complicates treatment.
- Fragmented care delays recovery.
- Veterans are appreciative of the program.

Transition to My HealtheVet

- Secure messaging (Veterans/caregivers)
- Provider Panel
  - Primary Care Physician
  - Clinical Psychologist
  - Neurologist
  - Social WorKer
  - Point of Contact (RN)

Questions ?

Controversies in the Use of HBO_2 for Symptomatic mTBI

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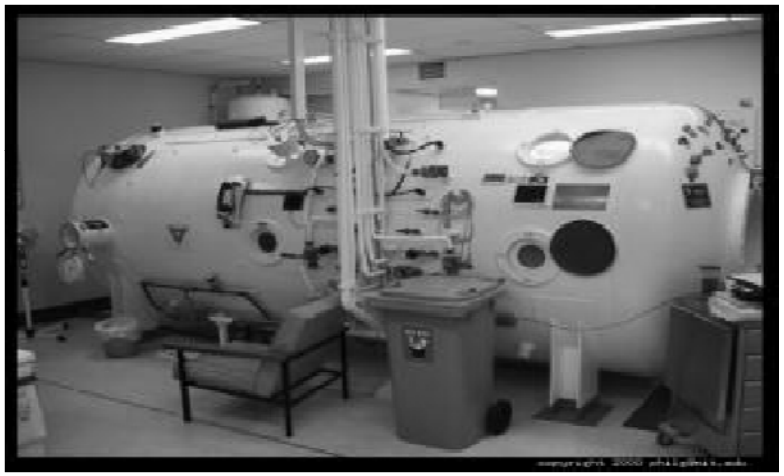
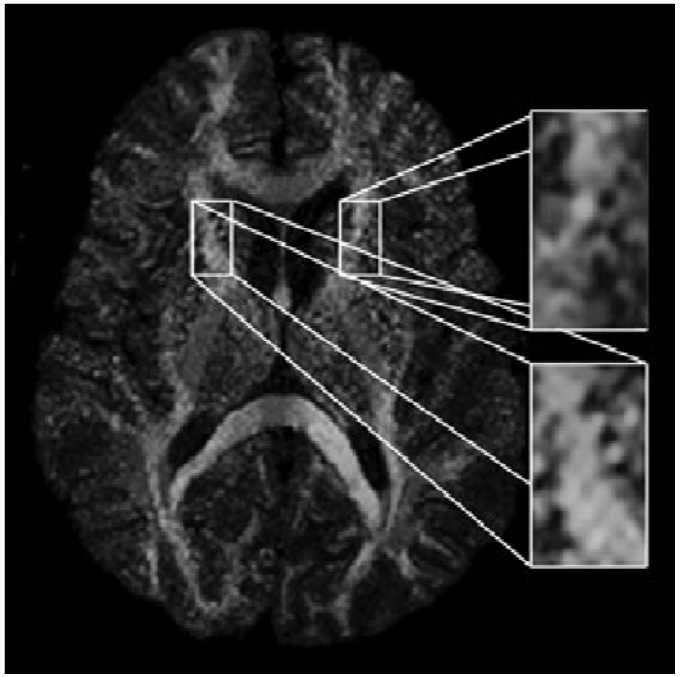
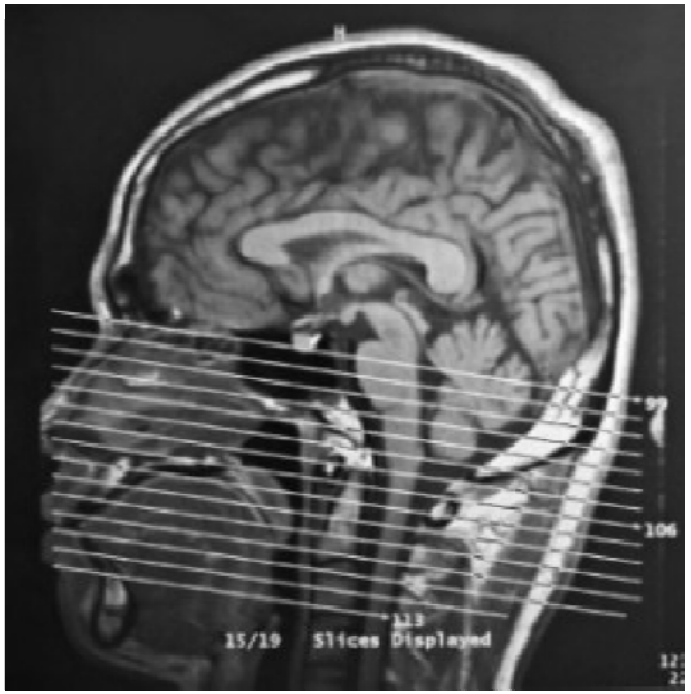
Topic Outline

- Why is DoD/VA studying HBOT for TBI ?
- Examining Theory – A Role for HBO_2 after TBI ?
- Applying HBO_2 to PCS – Trials & Tribulations



Why is DoD/VA studying HBOT for TBI ?





Why is DoD/VA studying HBOT for TBI ?

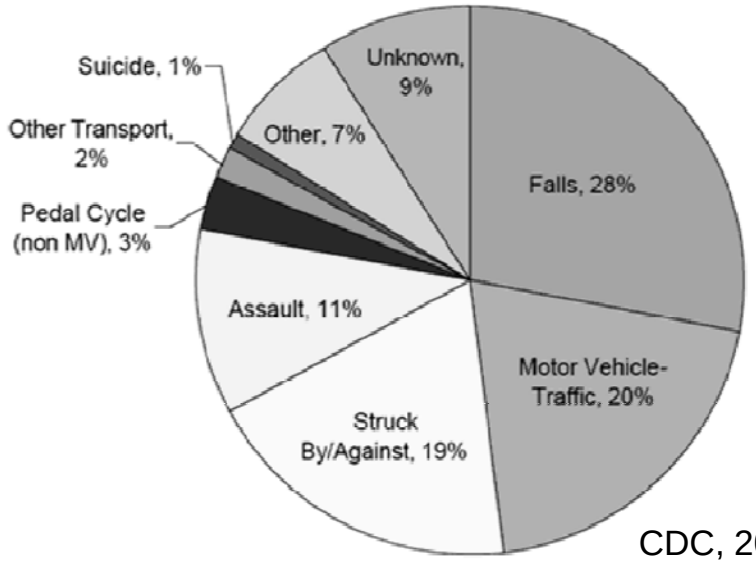
- Increasing incidence of TBI in Military and Veteran populations.
- Persistence of symptomatic mTBI after combat-related injuries.
- Pressures from VSO, Lobbyists, constituents.
- Pressures from Congress and DoD leadership

Why is DoD/VA studying HBOT for TBI ?

- Increasing incidence of TBI in Military and Veteran populations.

The Impact of TBI

- Civilian TBI experience
  - Most common cause of disability / death young people
  - 3.5 million TBIs annually
  - TBI disability in 2% US population; 50,000 deaths
  - 80% mild, 10% moderate, 10% severe
  - $56.3 billion/yr



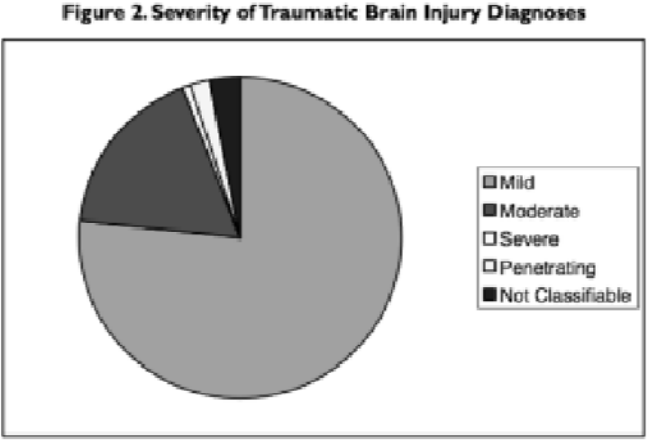
CDC, 2006

The Impact of TBI

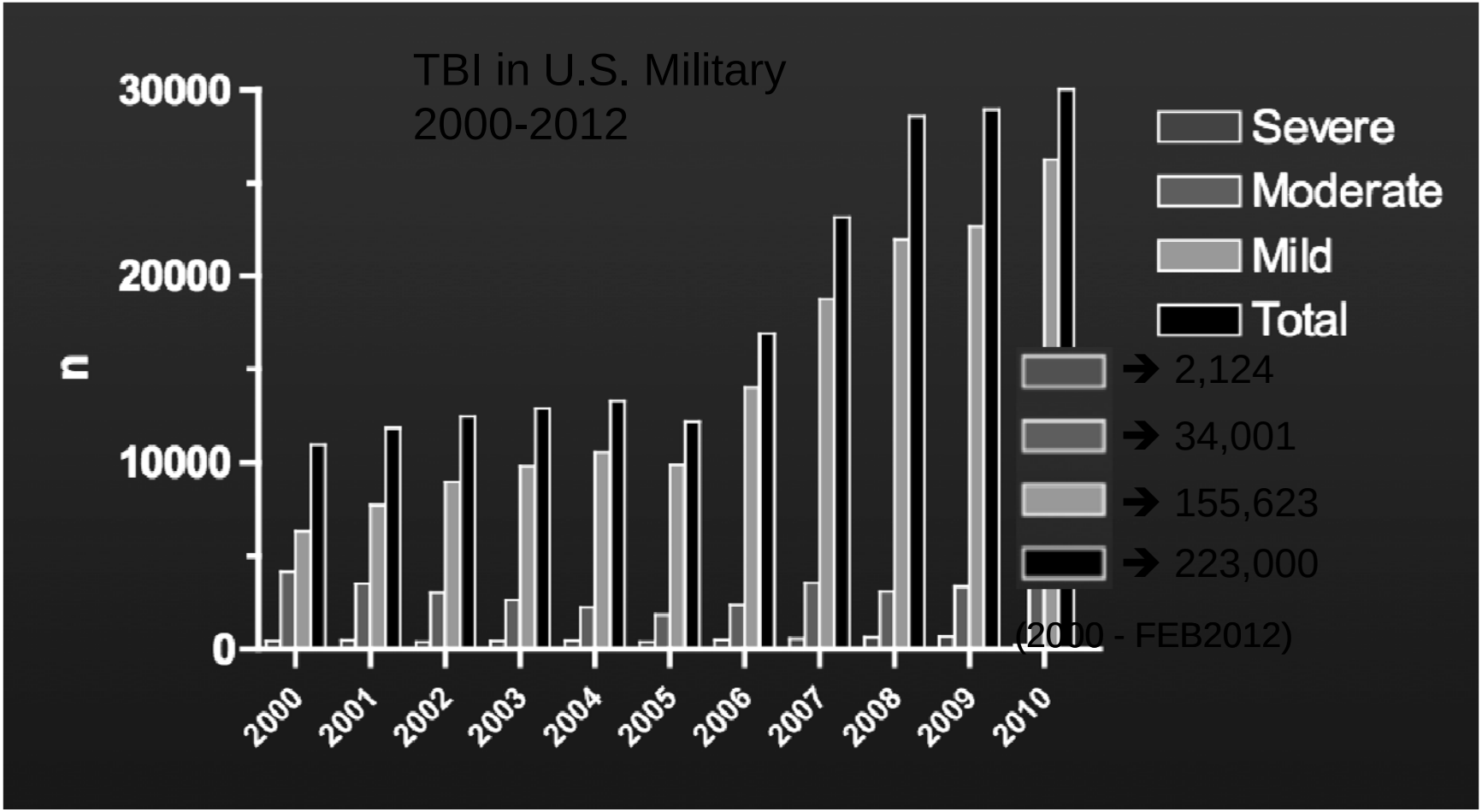
Mechanisms of Injury – Military Combat

The Impact of TBI

Mechanisms of Injury – Military non-Combat



The Impact of TBI



Iraq/Afghan Wars and TBI

- 15-23% of all deployed SMs have TBI or ~350,000[1]
  - >233,000 confirmed by DoD[2]
    - ~ 2,500 mod/severe

- 7-8% of all OEF/OIF SMs who have come to VA (750,000 or 55% of those eligible) have symptomatic mTBI[3]

- 73% of Vets with symptomatic mTBI also have mental health diagnosis (usually PTSD)[3]

[1]Congressional Budget Office
[2]www.dvbic.org/tbi-numbers.aspx
[3]www.queri.research.va.gov/ptbri/docs/vha-tbi-screening-eval.pdf

Costs of OEF/OIF TBI care in VA for FY2011

- PTSD alone = $ 8,300
- TBI alone = $11,700*
- TBI + PTSD = $13,800*
- Neither = $ 2,400
- Total = $2 billion of overall care

* excludes all inpatient rehabilitation costs

Source: Congressional Budget Office

Why is DoD/VA studying HBOT for TBI ?

- Persistence of symptomatic mTBI after combat-related injuries.

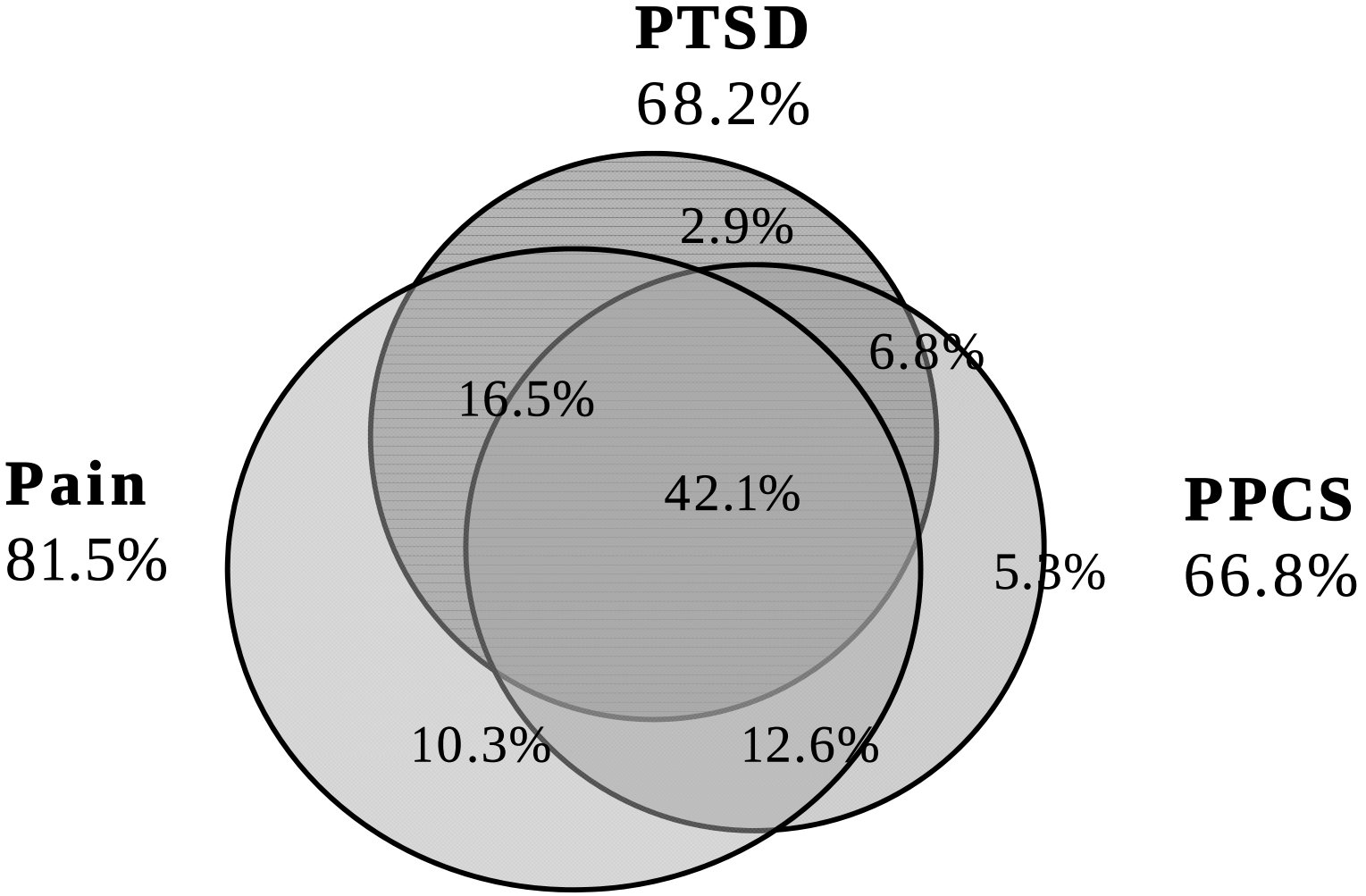
Persistent Symptoms after mTBI

Dizziness
Loss of Balance
Poor coordination
Headaches
Nausea
Visual disturbance
Light sensitivity
Hearing difficulty
Noise sensitivity
Body/extremity numbness
Altered taste or smell

Appetite change
Poor concentration
Forgetfulness
Difficulty making decisions
Slowed thinking
Fatigue
Insomnia
Feeling anxious
Feeling depressed
Easily irritated
Poor frustration tolerance

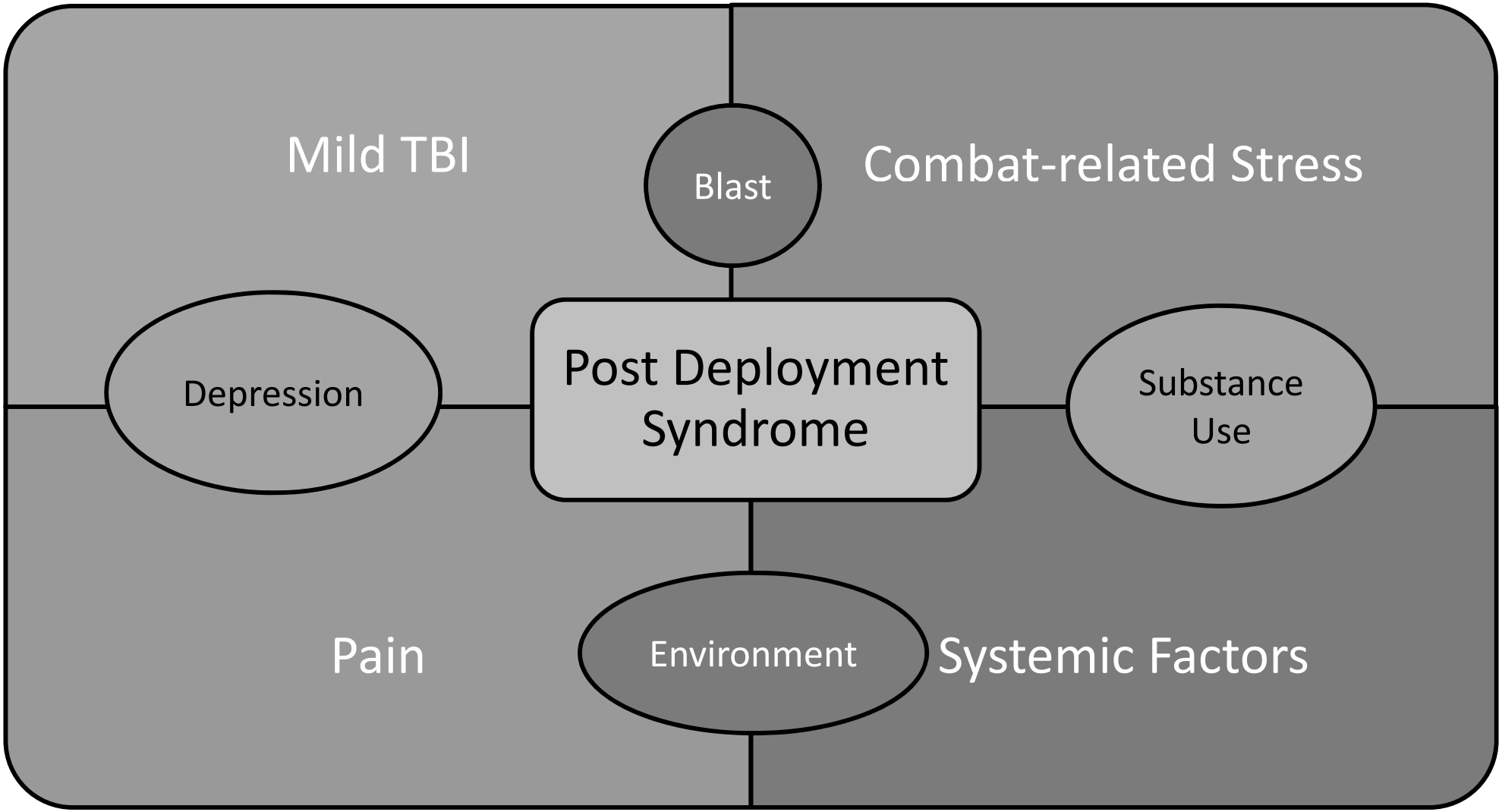
Cicerone: J Head Tr Rehabil 1995;10(3):1-17

Epidemiology: Overlap of PDS



Lew: *J Rehabil Res Dev* 2009;46(6)

PDS: A Complex Condition



Why is DoD/VA studying HBOT for TBI ?

- Societal Pressures for mTBI Treatments

Societal Pressures for mTBI Treatments

Belief that current TBI “treatments” are non-proven and non-scientific.

Concern for long-term effects of mTBI

- Less an issue of disabling impact of symptoms
- Strong focus on Chronic Traumatic Encephalopathy

Anecdotal reports of efficacy with HBOT.

Financial rewards.

Testimonials from patients.

Why is DoD/VA studying HBOT for TBI ?

Concern for troop readiness.

Concern for troop recruitment.

High profile of Congresswoman Gifford and others.

DoD and VA need to lead the way.

PCS Pathophysiology

The Cell's Perspective

Primary Insult Effects

- Direct Mechanical Damage at Time of Insult
- Respond to Preventive Measures

Secondary Insult Effects

- Delayed Non-Mechanical Effects
- Respond to Treatment Measures

PCS Pathophysiology
The Cell's Perspective

- Initial Stages of Injury
  - Direct Tissue Trauma
  - Impaired Blood Flow
    - CO_2 Responsiveness
    - Vasospasticity
    - Hyper / Hypoperfusion
  - Impaired Regulation Metabolism
    - Increased Cellular Work
    - Glucose / Lactate Imbalance

Examining Theory

A Role for HBO_2 in PCS?

Snake Oil

Science?

Examining Theory

Potential HBO_2 Applications to TBI

HBO_2 Mechanism	Acute TBI	Chronic TBI
Diffusion and Mechanical Compression	Not Applicable	Not Applicable
Modulation of Antibacterial Response	Not Applicable	Not Applicable
Correction of Cellular Hypoxia	Likely	Possible
Vasoconstriction	Likely	Unlikely
Reperfusion Injury Prophylaxis	Possible	Unlikely
Stimulation of Cellular Repair	Possible	Possible

Examining Theory

Proposed HBO_2 Effects on TBI

Bottom Line – Basic Science Still Lacking!

Controversies in the Use of HBO_2

Talking to the Animals

Systemic review of animal (rodent, cat, dog) research supports HBO_2 use in acute TBI

Acutely, HBO_2 significantly

- Reduces acute cerebral edema
- Reduces markers of cerebral inflammation
- Increases cerebral perfusion
- Enhances spatial learning / task

Shown also to enhance cognitive outcomes in chronic moderate-severe TBI

Controversies in the Use of HBO_2
Talking to the Animals

Caveats in examining animal literature

- HBO_2 treatment initiation
  - Animals usually begun minutes to 2 hours post injury
  - Humans usually 6+ hours to days post-injury
- No HBO_2 research in mTBI (acute or chronic)
- mTBI animal model lacking and PCS hard to understand in animal
- No direct translation of animal TBI work to humans

Controversies in the Use of HBO_2
The Human Research Experience

- Human Studies
  - Four Systematic Reviews
    - Included 23 publications (1972-2001)
    - Only four studies (382 subjects, 199 HBO_2 & 183 controls) met review criteria for scientific evaluation
    - Assessed acute, traumatic, moderate-severe TBI
    - Concluded current scientific evidence insufficient to prove effectiveness / ineffectiveness of HBO_2 for TBI
  - Two reviews and two trials published since 2001.

Controversies in the Use of HBO_2
The Human Research Experience

- Summary of acute human usage (in severe TBI):
  - One trial showed trend ($P \leq 0.08$) towards favorable outcome at 1.5 years post-injury.
  - Three trials showed a significant reduction (RR 0.69, 95%CI 0.54-0.88) in risk of dying (mortality) with 'numbers needed to treat' being 7.
  - No reduction in coma persistence or duration.
  - Enhanced mortality seem to be related to effects on ICP and pulmonary status

Controversies in the Use of HBO_2

The Human Research Experience

Summary of adverse events (186 patients in 4 studies) = 11.3%

- Three Seizures – 1.6%
- Fifteen Pulmonary Symptoms – 8%
- Two Otic Barotraumas – 1.1%

Controversies in the Use of HBO_2
The Human Research Experience

Caveats of Human Literature:

- Overall study quality assessed as low
- No sham therapy included
- Randomization inadequate
- Blinding not used
- Non-standard inclusion criteria across trials

No scientifically rigorous human research has been published in acute mild/moderate TBI or chronic TBI of any severity.

The Current Clinical Trials in the DoD and VA

- There are presently 4 DoD supported HBOT trials for persistent symptoms after mTBI.
  - Pilot study (HBOT vs Sham) completed
  - Pilot study (outcome measure validation) completed
  - Pilot study (HBOT [2 dose] vs Sham) underway – 60% completed
  - Definitive trial begun January 2012
- There is also 1 non-DoD open-label trial (Harch – LSU) underway
  - Non-randomized
  - No sham or control

Controversies in the Use of HBO_2

The Current Clinical Trials

International Hyperbaric Medical Foundation (15APR2010**) – Active / Recruiting**		
Study Name	Multicenter Observational Trial Hyperbaric Oxygen Therapy in Chronic Traumatic Brain Injury or Post-Traumatic Stress Disorder (NBIRR-1)	
PIs	Dr. James Wright & Dr. Paul Harch	
Sites	Multiple sites: currently 14 active, but number not specifically limited	
Inclusion Criteria	18-65 years old, mild – moderate TBI or PTSD, diagnosis by any prior evaluation, 20% performance decrement on ANAM / "reaction time"	
Study Design	Observational, Prospective, Unblinded, Self Control Cohort	N = 1000
Study Tests	Not Disclosed	
Protocol Groups	All subjects receive intervention (1.5 ATA oxygen, 60 minutes), Plan 40 sessions, but extend "as indicated" to 60 – 80 sessions	
Results	Improvements seen on all measures (function, neuropsych, SPECT)	

Controversies in the Use of HBO_2

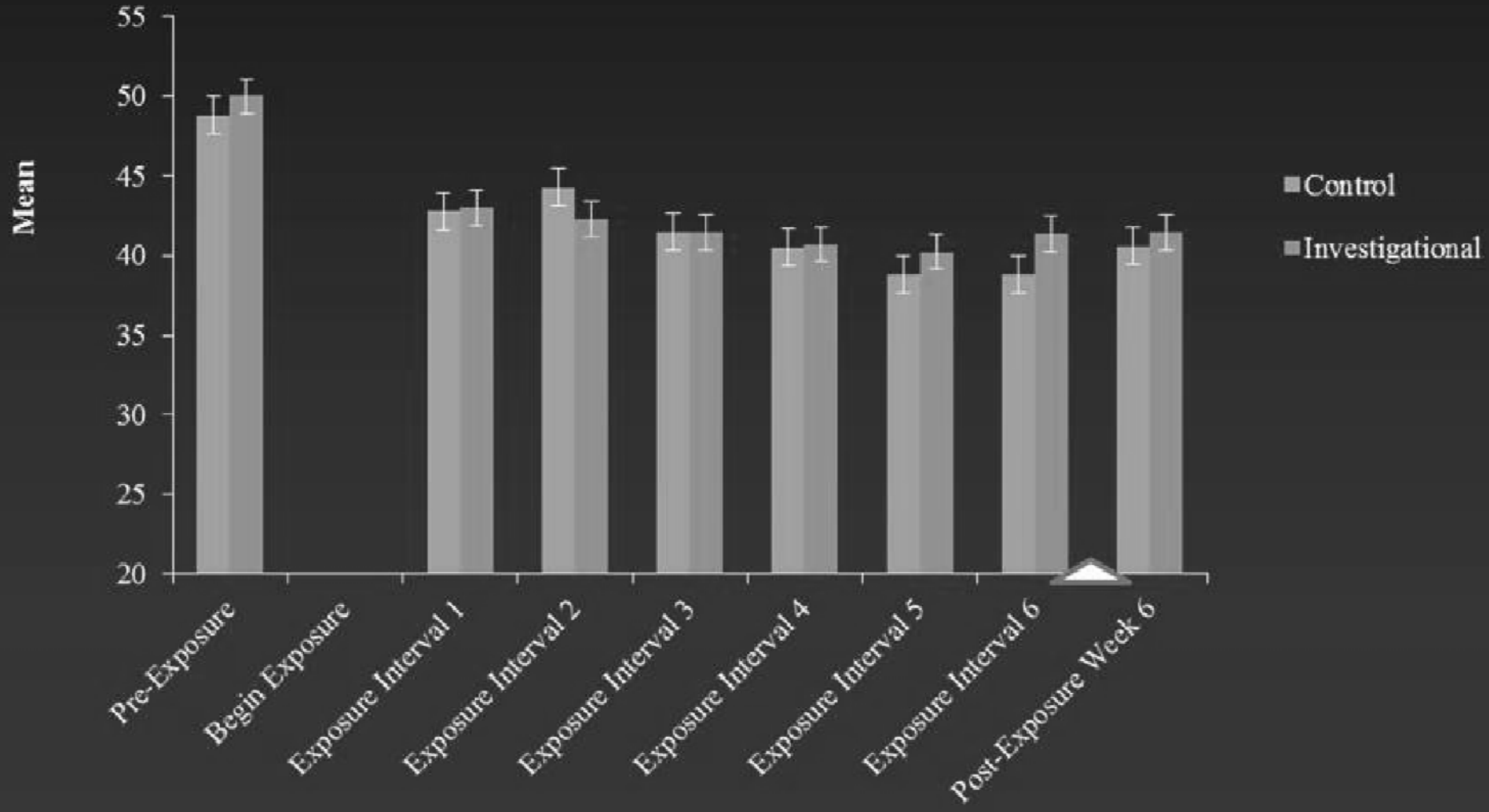
The Current Clinical Trials

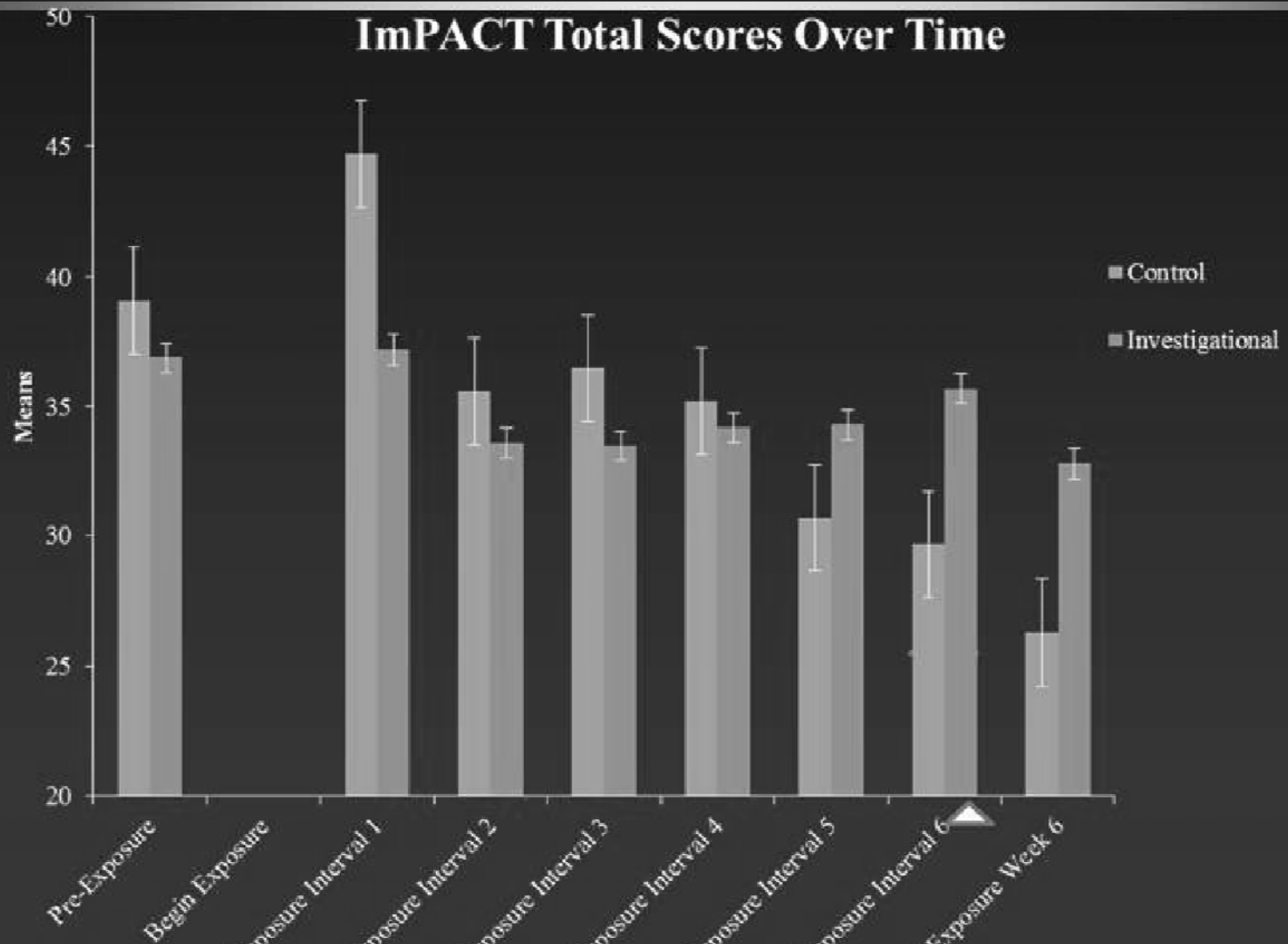
Intermountain Health Care, Inc. (27JAN2009**) – Completed**		
Study Name	Hyperbaric Oxygen Therapy in Chronic Stable Brain Injury (HYBOBI)	
PIs	Dr. Lin Weaver & Susan Churchill, APRN-NP	
Sites	LDS Hospital, Salt Lake City, Utah	
Inclusion Criteria	18-80 years old, chronic, stable, mild brain injury sequelae (secondary to stroke, anoxia or trauma), confirmed by questionnaires / testing	
Study Design	Observational, Prospective, Unblinded, Self-Control Cohort	N = 60
Study Tests	Neuropsychological testing, functional measures, health-related quality of life measures, and neurological examination, subjects own controls.	
Protocol Groups	All subjects receive intervention (1.5 ATA oxygen, 60 minutes “door to door”), 60 total sessions	
Findings	No significant effects of HBOT. Subjects tolerated sessions. Measurement tools tolerated and reproducible.	

Controversies in the Use of HBO_2
The Current Clinical Trials

US Air Force Trial (17DEC2008**) – Completed**		
Study Name	Treatment of Moderate to Mild Cognitive Dysfunction Caused by Traumatic Brain Injury (TBI) with Hyperbaric Oxygen Therapy (HBOT)	
PIs	Col Robert Michaelson, Maj Gerald York, Col (ret) George Wolf	
Sites	San Antonio Military Medical Center, San Antonio, Tx	
Inclusion Criteria	19-60 years old, mild – moderate TBI, researcher confirmed diagnosis, stable status and medications	
Study Design	Randomized, Prospective, Sham Controlled, Single Blind	N = 50
Study Tests	ImPACT, ANAM, TOVA, PCL-M, fMRI, Biomarkers	
Protocol Groups	Sham – 1.3 ATA Air (3 x 30 min, w / 10 min air breaks), 30 Exposures HBO2 – 2.4 ATA Oxygen (3 x 30 min, w / 10 min air breaks), 30 Exp.	
Findings	Significant improvement in both groups on ImPACT and PCL measures, but no b/n group differences.	

PCL Composite Scores Over Time




ImPACT Total Scores Over Time
Means
50
45
40
35
30
25
20
Control
Investigational
Pre-Exposure
Begin Exposure
Exposure Interval 1
Exposure Interval 2
Exposure Interval 3
Exposure Interval 4
Exposure Interval 5
Exposure Interval 6
Post-Exposure Week 6

Controversies in the Use of HBO_2

The Current Clinical Trials

VCU - VA - US Navy Trial (06OCT2010**) – Active / Recruiting**		
Study Name	Hyperbaric Oxygen Therapy (HBO2T) for Post-Concussive Symptoms (PSC) After Mild Traumatic Brain Injury (mTBI)	
PIs	Dr. David Cifu, CAPT Brett Hart, Dr. William Walker	
Sites	Hunter Holmes McGuire VA Medical Center, Richmond, VA – Testing Naval Operational Medicine Institute, Pensacola, FL – HBO_2 Exposure	
Inclusion Criteria	19-60 years old, chronic, stable, mTBI, researcher confirmed by questionnaires / testing	
Study Design	Randomized, Prospective, Double Blind, Sham Controlled	N = 60/20
Study Tests	9 Symptom Assess, 12 Neuropsych, Computerized Posture, Eye Track	
Protocol Groups	Group A: 2.0 ATA (100% O_2 - 2.0 ATA Equivalent), 40 Sessions, 60 min Group B: 2.0 ATA (75% O_2 - 1.5 ATA Equivalent), 40 Sessions, 60 min Group C: 2.0 ATA (10.5% O_2- 1.0 ATA Equivalent), 40 Sessions, 60 min	

Controversies in the Use of HBO_2

The Current Clinical Trials

US Army MRMC Trial (24FEB2011**) – Active / Recruiting**		
Study Name	A Pilot Phase II Study of Hyperbaric Oxygen for Persistent Post-Concussive Symptoms after Mild Traumatic Brain Injury (HOPPS)	
PIs	Col Scott Miller, Dr. Lin Weaver, Susan Churchill, Dr. David Cifu	
Sites	Naval Hospital Camp Pendleton, CA - Portable Chamber Evans Army Hospital , Ft. Carson, CO - Portable Chamber Eisenhower Army Med. Center, Fort Gordon, GA - Fixed Chamber	
Inclusion Criteria	18-65 years old, Cohort 1 – PTSD, Cohort 2 – chronic, stable, mTBI , researcher confirmed by questionnaires / testing	
Study Design	Randomized, Prospective, ± Single Blind, Sham Controlled	N = 96/24
Study Tests	RPQ, NSI, 19 Others Secondary, Dynavision, 6-Minute Walk Test	
Protocol Groups	Cohort 1(a): PTSD, No Intervention, Local Care Cohort 2(b): mTBI, No Intervention, Local Care Cohort 2(c): mTBI, Active (1.5 ATA Oxygen, 60 min), 40 Sessions Cohort 2(d): mTBI, Sham Control (1.2 ATA Air, 60 min), 40 Sessions	

Controversies in the Use of HBO_2

HBO_2 for PCS – Concluding the Story

- Mild TBI is in the spotlight.
- Increasing rumors that mTBIs are more malignant than previously believed.
- Increasing rumors that treatments for symptoms associated with mTBI are ineffective.
- Increasing rumors that HBOT may offer answer .

Controversies in the Use of HBO_2

HBO_2 for PCS – Concluding the Story

- Management of symptomatic TBI is not aimed at being "curative"
  - Symptomatic Treatment
  - Reassurance
- HBO_2 (or at least pressurization or other sham) may have a role in treatment.
- Multiple HBOT trials ongoing.
- HBOT is not appropriate for TBI treatment based on current research evidence.

HBOT for symptomatic mTBI
Pass (on) the Gas (for now?)

Questions?