



San Antonio
Polytrauma Clinical Research
Long-term outcomes and treatments

Carlos Jaramillo MD, PhD

San Antonio Polytrauma Research



OBJECTIVES

- How we built the San Antonio Polytrauma Research Program
- Clinical questions
- Types of studies and team science approach
- New directives
- Lessons learned

Iraq and Afghanistan



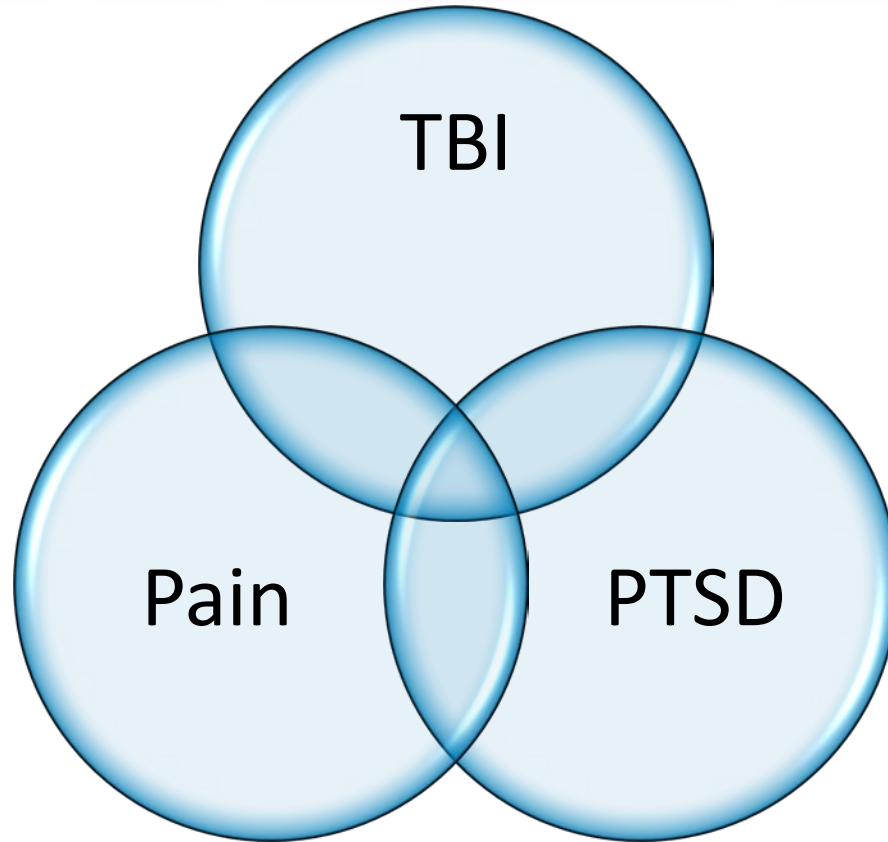
VETERANS HEALTH ADMINISTRATION

“Polytrauma occurs when a person experiences injuries to multiple body parts and organ systems...”



- Traumatic Brain Injury (TBI)
- Amputation
- Burns
- Spinal Cord Injury
- Auditory and visual damage
- Post-traumatic stress disorder (PTSD)
- Other medical conditions...

Polytrauma Clinical Triad



Clinical definitions, classifications of TBI severity



TABLE 1. TBI Severity Rating Scale

Severity	Glasgow Coma Scale Score	Duration of Loss of Consciousness	Duration of Posttraumatic Amnesia
Mild	13–15	<30 minutes and/or	<1 hour
Moderate	9–12	1–24 hours and/or	<24 hours
Severe	8 or less	>24 hours and/or	>24 hours



DoD Numbers for Traumatic Brain Injury Worldwide – Totals

2017

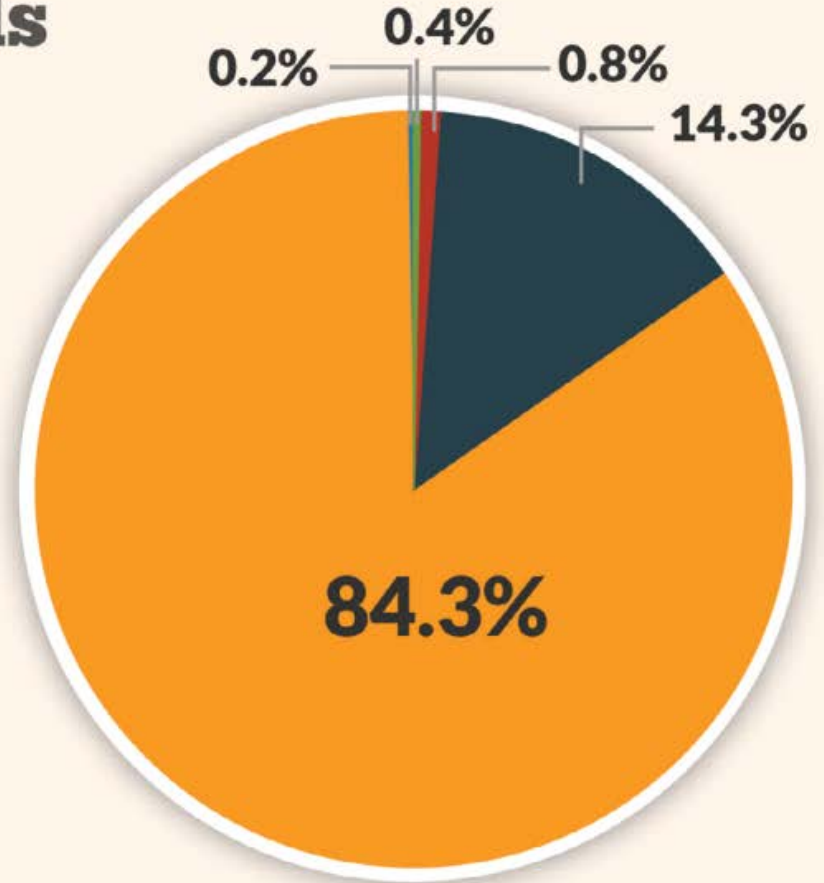
Penetrating	73
Severe	134
Moderate	2,559
Mild	15,042
Not Classifiable	33

Total - All Severities **17,841**

Source: Defense Medical Surveillance System (DMSS), Theater Medical Data Store (TMDS) provided by the Armed Forces Health Surveillance Center (AFHSB)

Prepared by the Defense and Veterans Brain Injury Center (DVBIC)

**Percentages do not add up to 100% due to rounding*



2017, as of June 21, 2018

Mild Traumatic Brain Injury (TBI)



Concussion: Definition

1. any period of loss of consciousness;
2. any loss of memory for events immediately before or after the accident;
3. any alteration in mental state at the time of the accident (eg, **feeling dazed, disoriented, or confused**); and
4. focal neurological deficit(s) that may or may not be transient; but where the severity of the injury does not exceed the following:
 - loss of consciousness of approximately 30 minutes or less;
 - after 30 minutes, an initial Glasgow Coma Scale (GCS) of 13–15; and
 - posttraumatic amnesia (PTA) not greater than 24 hours.

From American Congress of Rehabilitation Medicine (ACRM)

https://acrm.org/wp-content/uploads/pdf/TBIDef_English_10-10.pdf

VETERANS HEALTH ADMINISTRATION

Mild Traumatic Brain Injury (TBI)



Concussion: Definition

This definition includes:

1. the head being struck,
2. the head striking an object
3. the brain undergoing an acceleration/deceleration movement (ie, whiplash) without direct external trauma to the head.

OEF/OIF/OND Veterans



Complex, multifaceted problems...

Require the integration of two or more scientific/clinical approaches for solution



VA
HEALTH
CARE

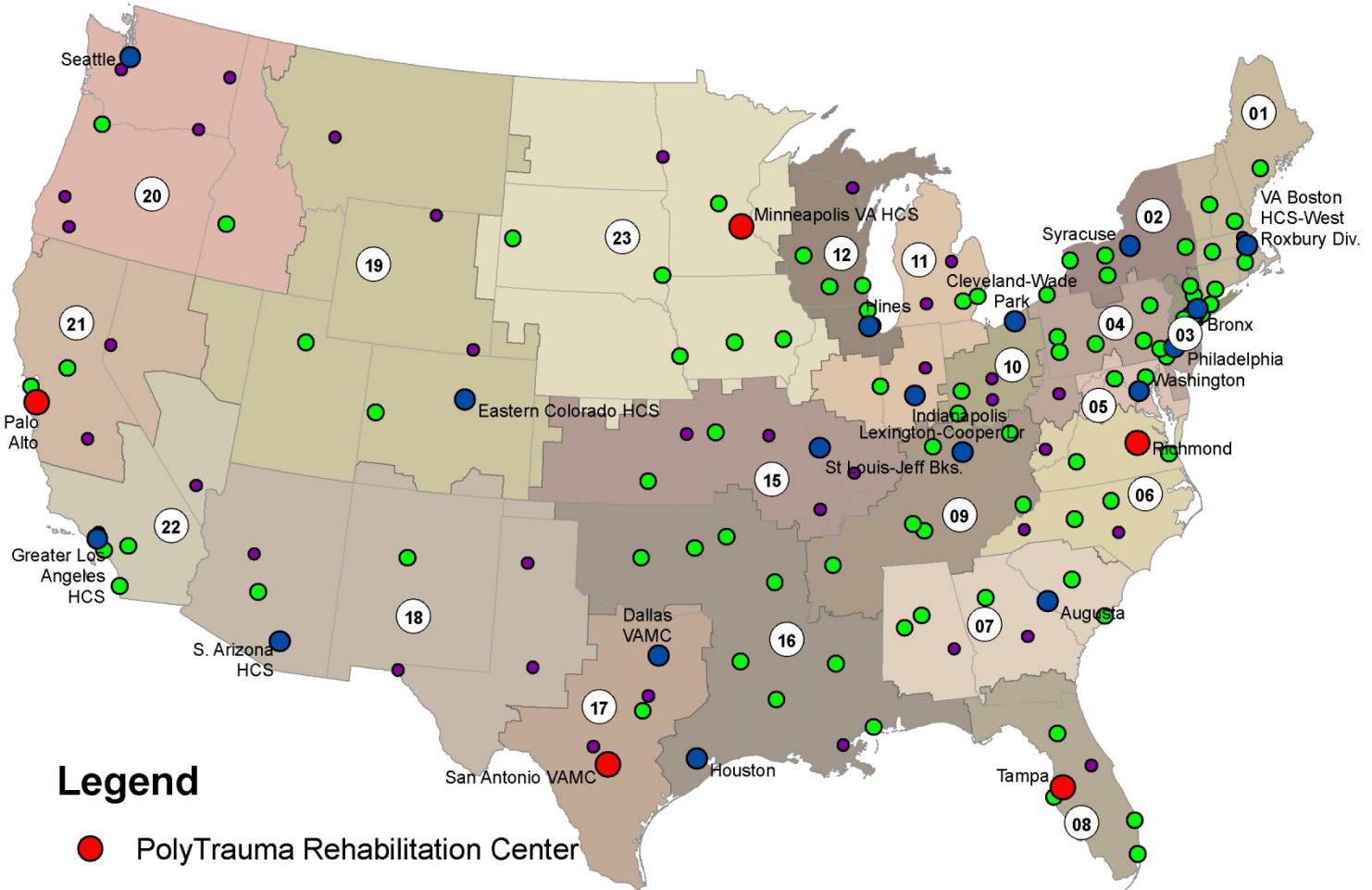
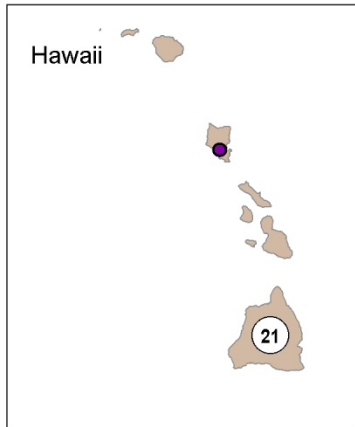
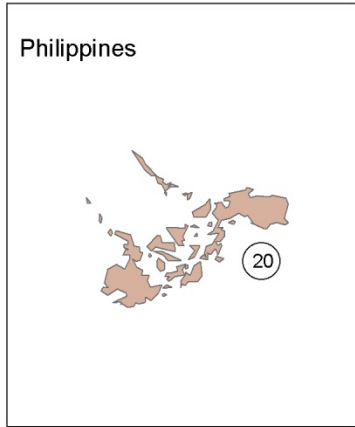
Defining
EXCELLENCE
in the 21st Century

VHA Polytrauma System of Care



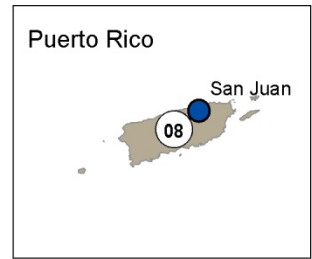
- **Level 1: Polytrauma Rehabilitation Centers (5)**
 - Regional referral centers for acute, comprehensive rehabilitation
 - Lead clinical care, research, education, program development
 - Tampa, Minneapolis, Richmond, Palo Alto, San Antonio
- **Level 2: Polytrauma Network Sites (23)**
 - Veteran Integrated Service Network referral sites for post-acute rehabilitation
- **Level 3: Polytrauma Support Clinic Teams (86; 2-8 per VISN)**
 - Interdisciplinary team follow-up and management of stable TBI/Polytrauma symptoms at local VA facilities
- **Level 4: Polytrauma Points of Contact (41 VA medical centers)**
 - Care coordination and referral to appropriate services

VHA Polytrauma System of Care FY 2011



Legend

- PolyTrauma Rehabilitation Center
- Polytrauma Network Site
- Polytrauma Clinic Team
- Polytrauma Point Of Contact



VA Polytrauma Rehabilitation Centers



Richmond



Minneapolis



Tampa



Palo Alto



VA
HEALTH
CARE | Defining
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San Antonio

San Antonio PRC/STVHCS



VETERANS HEALTH ADMINISTRATION

San Antonio Polytrauma Center



2011: SA PRC opened

2012: Research Program - \$0

Dr. Carlos Jaramillo, MD, PhD

- Physical Medicine and Rehabilitation (PM&R)
- Basic research, geriatric rehabilitation, aging/longevity research – focus on the effect of aging on TBI
- 60% research/40% clinical

Dr. Blessen Eapen, MD

- PM&R/TBI Board Certified
- 100% clinical

San Antonio Polytrauma Center



Year one: 2012-2013

Partnership: Dr. Mary Jo Pugh – outcomes and epidemiology

Multiple grant applications

- pilot studies
- CDA
- Health Services/epidemiology
- Long-term outcomes clinical research
- Consortium projects
- Clinical interventions

Polytrauma Research Objectives



1. Understand the population: injuries, diagnoses, conditions, symptoms
2. Understand the clinical trajectories of these patients and long-term outcomes from these injuries/conditions
3. Understand the relative benefits of current interventions, medications, and treatment guidelines
4. Develop new clinical approaches that provide the most benefit and least harm

Clinical Case



- **35 y/o male**
- **Multiple deployments – OEF/OIF**
- **Referred to Polytrauma Network Site clinic for evaluation of possible history of TBI**
- **Headache, LBP, poor concentration**

Clinical Case



- 35 y/o male
- Multiple deployments – OEF/OIF
- Referred to Polytrauma Network Site clinic for evaluation of possible history of TBI
- HA, LBP, poor concentration
- **Served 10 years – combat engineer**
- **Not employed – considering school?**
- **Headaches; +photosensitivity**
- **LBP; 5 years**
- **Cognition: conversations, written text, grocery lists, medical appointments, medications**

Clinical Case



- Review of Systems

Fatigue

Dizziness

Insomnia

Nightmares

Photosensitivity

Tinnitus

Decreased appetite +/- nausea

Anxiety

Irritability – with occ aggressive outbursts

Neck pain

Clinical Case



TRAUMATIC BRAIN INJURY

Two combat related events with loss-of-consciousness of 1-5 minutes: one in 2010, and one in 2012.

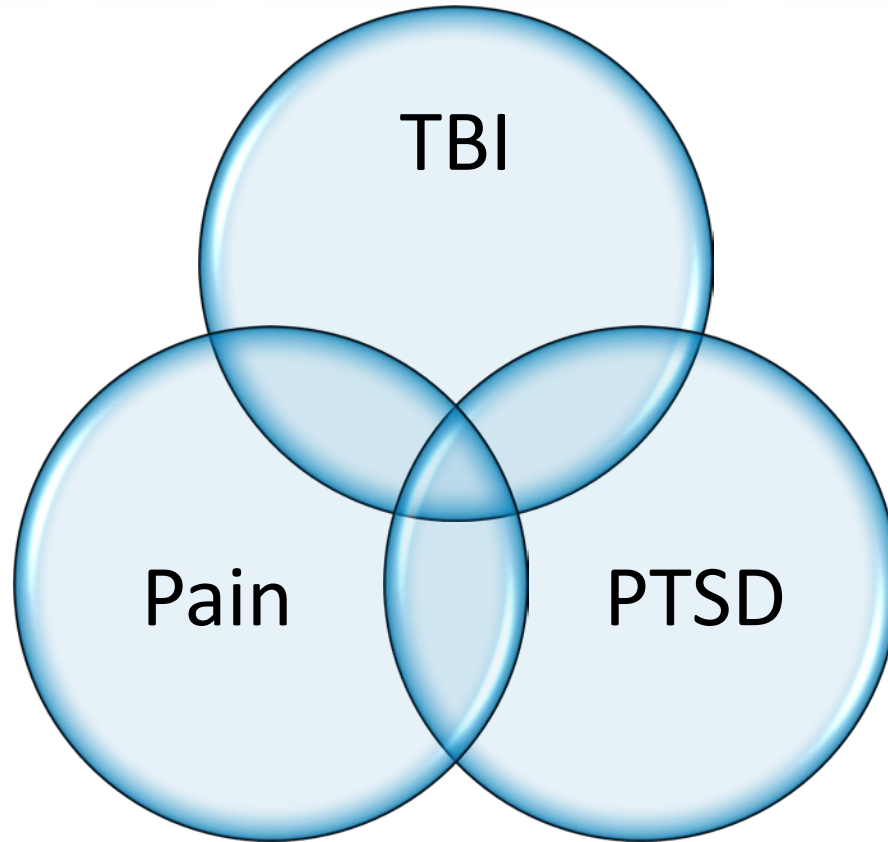
IEDs that resulted in casualties and the deaths of friends and colleagues.

Clinical Case



- VA and MTF - treatment guidelines for PTHA, PTSD, and pain. (9 CNS; 12 total)
- divalproex sodium and sumatriptan - headaches
- sertraline and buspirone – PTSD/anxiety
- quetiapine, zolpidem, and prazosin – sleep/nightmares
- gabapentin, cyclobenzaprine, and meloxicam - pain
- omeprazole - reflux
- sildenafil - erectile dysfunction.

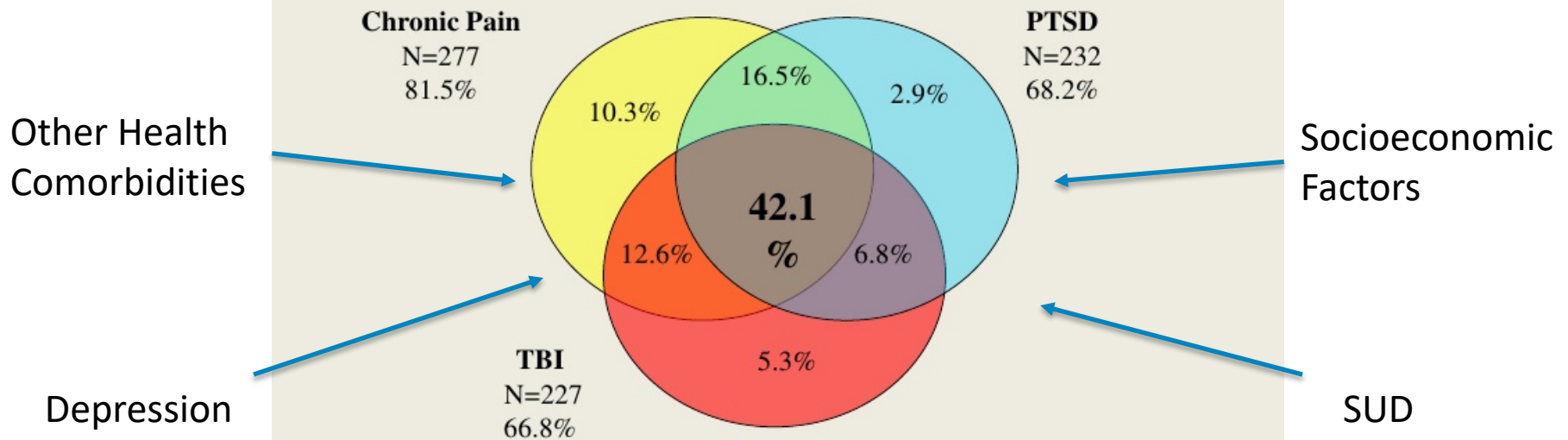
Polytrauma Clinical Triad



Polytrauma Clinical Trials: Population



Prevalence of Chronic Pain, PTSD and TBI in sample of 340 OEF/OIF veterans with polytrauma a



Lew, Otis, Tun et al., (2009). Prevalence of Chronic Pain, Post-traumatic Stress Disorder and Post-concussive Symptoms in OEF/OIF Veterans: The Polytrauma Clinical Triad. *JRRD*.

Slide 9

Mild TBI: Recovery Patterns

- The majority of patients with **sport-related** concussion recover within a 7- to 10-day period
- Approximately 10% of athletes have persistent signs and symptoms of concussion beyond 2 weeks.
- Cognitive dysfunctions typically resolve 3 months post-injury

mTBI: Post-concussive symptoms

Physical

- Headaches
- Neck pain
- Dizziness
- Photosensitivity
- Insomnia
- Fatigue

Cognitive

- Poor concentration
- Memory problem
- poor recall
- mental fatigue

Emotional

- Anxiety
- Depression
- Irritability

OEF/OIF/OND Veterans



Headaches

TINNITUS

Anxiety

Depression

Insomnia

Irritability

Dizziness/Vestibular

PHOTOSENSITIVITY

Neck pain

Fatigue

Low back pain

Memory dysfunction



Epidemiology and Outcomes Research



- Dr. Mary Jo Pugh, PhD
Secondary data analysis, big data analytics, retrospective studies, latent class/cluster analysis, machine based learning
 - Partnership on multiple grant submissions
 - Co-authors
 - Bridge and network building
 - Mentoring

Publications



14 peer review since 2014

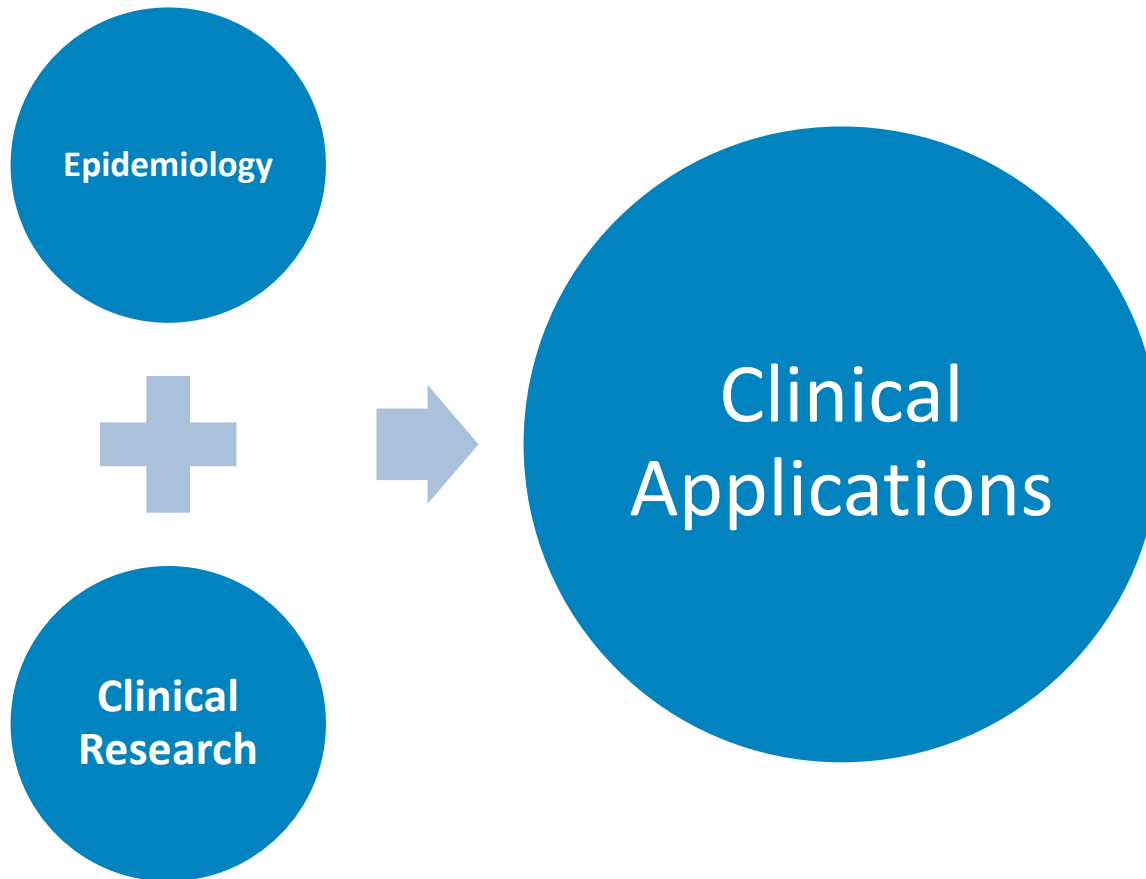
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- Faruqi SHA, Alaeddini A, **Jaramillo CA**, Potter JS, Pugh MJ. Mining patterns of comorbidity evolution in patients with multiple chronic conditions using unsupervised multi-level temporal Bayesian network. PLOS ONE. 2018 Jul 12;13(7): eCollection (2018)
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- Swan AA, Nelson JT, Swiger B, **Jaramillo CA**, Eapen BC, Packer M, Pugh MJ. Prevalence of hearing loss and tinnitus in Iraq and Afghanistan veterans: A Chronic Effects of Neurotrauma Consortium study. Hear Res. Jan 30. pii: [Epub ahead of print]. (2017)
- Pugh MJ, Finley EP, Wang CP, Copeland LA, **Jaramillo CA**, Swan AA, Elnitsky CA, Leykum LK, Mortensen EM, Eapen BA, Noel PH, Pugh JA; TRACC Research Team. A retrospective cohort study of comorbidity trajectories associated with traumatic brain injury in veterans of the Iraq and Afghanistan wars. Brain Inj. 30(12):1481-1490 (2016)

Publications continued



- Collett GA, Song K, **Jaramillo CA**, Potter JS, Finley EP, et al. Prevalence of Central Nervous System Polypharmacy and Associations with Overdose and Suicide-Related Behaviors in Iraq and Afghanistan War Veterans in VA Care 2010–2011. *Drugs - real world outcomes*. January 08; :1-8 (2016).
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- Pugh MJ, **Jaramillo CA**, Leung KW, Faverio P, Fleming N, Mortensen EM, Amuan ME, Wang CP, Eapen BC, Restrepo M, Morris MJ. Increasing prevalence of chronic lung disease in veterans of the wars in Iraq and Afghanistan. *Military Medicine*. May; 181 (5): 476-481(2016)
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- SPugh MJ, Orman JA, **Jaramillo CA**, Salinsky MC, Eapen BC, Towne AR, Amuan ME, Roman G, McNamee SD, Kent TA, McMillan KK, Hamid H, Grafman JH. The Prevalence of Epilepsy and Association with Traumatic Brain Injury in Veterans of the Afghanistan and Iraq Wars. *Journal of Head Trauma Rehabilitation*, 1, April (2014).

Polytrauma Clinical Research Program



Funded Projects 2013



- Chronic Effects of Neurotrauma Consortium
Study Site: Longitudinal Study
- Consortium to Alleviate PTSD Study Site: PTHA
RCT
- TRACC: Identifying and Validating Complex
Comorbidity Clusters in OEF-OIF Veterans



Multi-center collaborative (VA, DoD, Private, Academic): links basic, translational, clinical neuroscience research.

David X. Cifu, MD: Principle Investigator and CENC Director, Virginia Commonwealth University, VA.

- Fill knowledge gaps – basic science of mild TBI
- Determine effects on late-life outcomes and neurodegeneration
- Identify individuals most susceptible to effects
- Identify the most effective treatment strategies

www.cenc.rti.org



Observational Study on Late Neurologic Effects of OEF/OIF/OND Combat: Study 1

- 5- year longitudinal: observational cohort study
- Multi-site: Richmond VA, Tampa FL, Houston TX, San Antonio TX, Fort Belvoir VA, Portland OR
- Study Chair: William Walker, MD; Virginia Commonwealth University
- Characterize the late effects of mild TBI, assess the influence and interaction of potential risk factors for early dementia.



Observational Study on Late Neurologic Effects of OEF/OIF/OND Combat: Study 1

- Late effects of mild TBI, risk factors for early dementia.
- 880 mild TBI; 220 no TBI
- Patient reported outcomes + cognitive/neurologic function
- Serum biomarkers: USUHS
- Neuroimaging

San Antonio: \$1,326,194

www.cenc.rti.org



2019 – 2024: LIMBIC

Observational Study on Late Neurologic Effects of OEF/OIF/OND Combat:
Study 1

- Late effects of mild TBI, risk factors for early dementia.
- 880 mild TBI; 220 no TBI
- Patient reported outcomes + cognitive/neurologic function
- Serum biomarkers: USUHS
- Neuroimaging
- Integration with other long-term studies

San Antonio: \$1,326,194

www.cenc.rti.org



Epidemiology of mTBI: Aim 3

(Mary Jo Pugh, PhD)

The Nexus of Mild TBI and Trajectories of Persistent Comorbidity in Warfighters with Mild TBI

Data: 2002-2016

DoD Trauma Registry

DoD Diagnoses, Type of Care, Medications Prescribed

VA Diagnoses, Type of Care, Medications Prescribed

CAP/STRONG STAR





DoD, VA approve \$45 million to fund the Consortium to Alleviate PTSD

Award to be managed by the UT Health Science Center San Antonio and the VA National Center for PTSD, leaders of the national PTSD research consortium

SAN ANTONIO (Aug. 12, 2013) — In an unprecedented show of support for our nation's wounded warriors, the U.S. Department of Defense and the U.S. Department of Veterans Affairs have agreed to provide approximately \$45 million over five years for post-traumatic stress disorder (PTSD) research to advance PTSD diagnosis, prevention and treatment for service members and veterans. The University of Texas Health Science Center at San Antonio and the VA National Center for PTSD lead the consortium, announced over the weekend by the White House and DoD and VA officials.

The Consortium to Alleviate PTSD (CAP) will provide an array of cutting-edge clinical treatment trials and biological studies for active military and veterans with PTSD and related conditions, said CAP Consortium Director Alan L. Peterson, Ph.D., professor of psychiatry in the School of Medicine at the UT Health Science Center San Antonio. The consortium's initiatives will include efforts to learn more about the biology/physiology of PTSD development and treatment response to inform diagnosis, prediction of disease outcome, and new or improved treatment methods.



STRONG STAR
South Texas Research Organizational Network Guiding Studies on Trauma And Resilience
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CAP: Randomized Clinical Trial of Cognitive-Behavioral Therapy for Posttraumatic Headache

Principal Investigator: Donald McGeary, PhD

Aim: Evaluate the effectiveness of a manualized behavioral health intervention for posttraumatic headache in Iraq and Afghanistan war veterans with co-occurring symptoms of posttraumatic stress.

More than 100,000 military service members and veterans



PI: Donald McGeary, PhD
University of Texas Health
Science Center at San Antonio

Study Sites:

South Texas Veterans Health Care System (STVHCS), Polytrauma Rehabilitation Center, San Antonio;
University of Texas Health Science Center at San Antonio (UT Health San Antonio)

Alan Peterson, PhD – CAP overall PI

Don McGeary PhD – Study PI

Carlos Jaramillo MD, PhD – Site PI

Posttraumatic Headache: 5- year clinical trial



Consortium to Alleviate PTSD: Alan Peterson, PhD: Don McGeary PhD – Study PI

Carlos Jaramillo MD, PhD – Site PI

- 3 arm Randomized Control Trial: Cognitive behavioral therapy PTHA
- Outcomes including headache symptoms, PTSD, PCS
- Serum biomarkers
- 200 participants
- **\$3,074,337 five years**

FORT-A



(Don McGeary PhD; Carlos Jaramillo MD, PhD)

- Functional Orthopedic Rehabilitation Treatment— with mindfulness and Acceptance and Commitment therapy.
- 5 year clinical trial-NIH NCAM
- Establishing Efficacy of a Functional Restoration-Based CAM Pain Management Program in a Combat Injured Veterans Population
- A randomized clinical trial of an interdisciplinary program with a strong CAM component (the FORT-A Program) to address chronic pain management and persistent opioid use in a sample of 130 OEF/OIF/OND Veterans with polymorbid chronic musculoskeletal pain

Polytrauma Clinical Trials: FORT A



- NCCIH: R01 AT008422-01
- **Project Title:** Establishing efficacy of a functional-restoration-based CAM pain management program
- **\$2,782,957 for five years**



TBI Model Systems



Justin O'Rourke PhD – PI

Carlos Jaramillo MD, PhD – Medical Director

- Longitudinal Observational Study
 - Civilians and Veterans with TBI
 - Primarily Mild to Severe TBI
 - Parallel to Civilian TBIMS (16 centers)

TRACC: Identifying and Validating Complex Comorbidity Clusters in OEF-OIF Veterans



Mary Jo Pugh, PhD

- Big Data analytics
- Epidemiology
- LCA – clusters
- Predictive modeling

Polytrauma Clinical Trials

- DoD - CDMRP
- **Project Title:** Implementation of a Brief Cognitive Rehabilitation Intervention to Enhance Efficiency of Service Delivery for Service Members and Veterans with mTBI: Core-SCORE

\$1,417,456 for three years



Current Funding



- Core-SCORE: \$1,471,456
- IMAP – TBI Model Systems: \$53,535 annually
- Pain Collaboratory – Chronic pain in Primary Care: \$7,351,951 (6 years)
- CENC/LIMBIC - \$1,326,194
- Epidemiology of Epilepsy - \$1,198,195 (4 years)
- FORT A - \$2,782,957 (5 years)
- PTHA - \$3,074,337 (5 years with extension year)

Collaborators

- Dr. Blessen Eapen, MD
 - Dr. Mary Jo Pugh, PhD
 - CENC/LIMBIC
 - Dr. David X. Cifu, MD
 - Dr. William Walker, MD
 - Dr. Lisa Wilde, PhD
 - Dr. David Tate, PhD
 - TBI Model Systems
 - Dr. Risa Richardson, PhD
 - Dr. Justin O'Rourke, PhD
 - Consortium to Alleviate PTSD – STRONG STAR
 - Dr. Don McGeary, PhD
 - Dr. Cindy McGeary, PhD
 - Dr. Alan Peterson, PhD
 - Dr. Donald Royall, MD
- Defense Veterans Brain Injury Center
- Dr. Doug Cooper, PhD

San Antonio Polytrauma Research



LESSONS LEARNED

- Grant submission!
- Team Science, collaborations, strategic partnership: Grant evaluation – strength of the team!
 - Formalized by grant funding and academic interests
 - Choosing collaborators and projects
- Growth management
 - Too fast? Too slow?
- Follow up studies
- Financial and human resources management
 - part-time employees
 - sharing employees with collaborators
 - long-term finance planning
 - employee turnover
 - incentive based pay
- Staying flexible and relevant