Trauma Survivors Outcomes & Support: Barriers, Challenges & Lessons Learned

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Trauma Survivors Outcomes & Support (TSOS)



TSOS Collaborative Team

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TSOS UH3 Overview

- Barriers/Challenges Scorecard
- Generalizable Lesson Learned (With an Eye to Pragmatic Trial Grant Review):

"What Constitutes the Requisite Elements of the **Approach** to the TSOS Trial?"

Barrier	Level of Difficulty					
	1	2	3	4	5	
Enrollment and engagement of patients/subjects			X			
Engagement of clinicians and Health Systems		X				
Data collection and merging datasets			X			
Regulatory issues (IRBs and consent)				X		
Stability of control intervention	X					
Implementing/Delivering Intervention Across Healthcare Organizations		X				



1 = little difficulty

Barrier	Level of Difficulty					
	1	2	3	4	5	
Enrollment and engagement of patients/subjects			X			
Engagement of clinicians and Health Systems		X				
Data collection and merging datasets			X			
Regulatory issues (IRBs and consent)				X		
Stability of control intervention	X					
Implementing/Delivering Intervention Across Healthcare Organizations		X				



1 = little difficulty

Study: UH3 Project: Trauma Survivors Outcomes

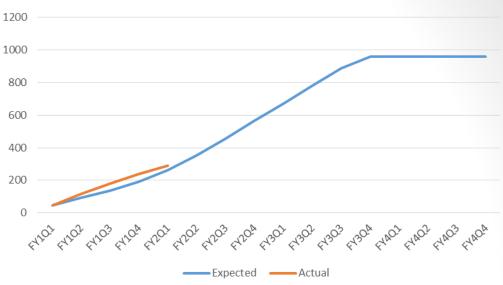
and Support

Principal Investigator: Douglas Zatzick, MD

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UH3 Award Date: August 2015

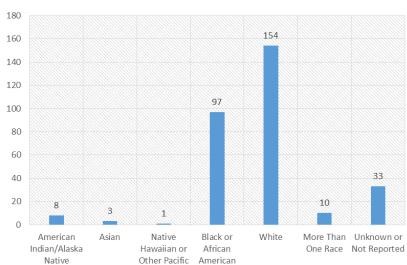




Ethnicity FY2Q1

■ Unknown/Not Reported Ethnicity





NH Collaboratory Rethinking Clinical Trials®

Not Hispanic or Latino Female Male Unknown Hispanic or Latino

Gender FY2Q1

Health Care Systems Research Collaboratory

Islander

Barrier	Level of Difficulty					
	1	2	3	4	5	
Enrollment and engagement of patients/subjects			X			
Engagement of clinicians and Health Systems		X				
Data collection and merging datasets			X			
Regulatory issues (IRBs and consent)				X		
Stability of control intervention	Χ					
Implementing/Delivering Intervention Across Healthcare Organizations		Х				



1 = little difficulty

Barriers, Challenges & Lessons Learned: Essential Elements of the TSOS Approach

<u>Challenges</u>

- 25 Site Regulatory Issues
- Multisite IT Harmonization

Barrier	Level of Difficulty					
	1	2	3	4	5	
Enrollment and engagement of patients/subjects			X			
Engagement of clinicians and Health Systems		X				
Data collection and merging datasets			X			
Regulatory issues (IRBs and consent)				X		
Stability of control intervention	X					
Implementing/Delivering Intervention Across Healthcare Organizations		X				



1 = little difficulty

Barriers, Challenges & Lessons Learned: Essential Elements of the TSOS Approach

Challenges

- 25 Site Regulatory Issues
- Multisite IT Harmonization

Strengths

- Intervention Development & Roll-out
- In-depth Understanding of Trauma Care System
 Practice Change

Trial Roll-out: Stepped Wedge Design Targets Practice Change by Beginning with Provider Feedback on Control Patients

Why TSOS? The Problem

Traumatic injury:

PTSD, depression, suicidal ideation High risk behaviors (e.g., alcohol) Traumatic brain injury, all common

Patients "sail off of a flat earth" after trauma center care



From Darnell & Zatzick TSOS Training Slide Set



Summary TSOS Lessons Learned

- Four Key Elements to TSOS Approach
 - 25 Site Regulatory Issues
 - Multisite IT Harmonization
 - Intervention Development & Roll-out
 - In-depth Understanding of Trauma Care System Practice Change
- For grant review: all elements could be considered essential requisites to pragmatic trial roll-out