



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

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Trauma Survivors Outcomes & Support (TSOS)



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TSOS UH3 Overview

- Barriers Scorecard
- Progress & Barriers
- Generalizable Lessons Learned

TSOS: Barriers Scorecard

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			

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TSOS Study Design

- 25 US trauma centers
- Stepped wedge cluster randomization
- All sites begin recruiting controls
- Intervention “turned on” at each site
- 40 patients per/site goal (960 pts. total)
- Patients provide informed consent
- Baseline PTSD & comorbidity assessment
- 3, 6 and 12 month follow-up interviews

TSOS Pragmatic Trial Update

- 935 Patients consented/screened
- 62.5% PTSD EHR screen in rate
- 585 patients randomized
 - 372 Control
 - 213 Intervention
- Stepped wedge intervention roll-out
 - 4/4 intervention waves trained
- 75-80% 3 & 6 mo. follow-up to date
- 70-75% 12 month follow-up

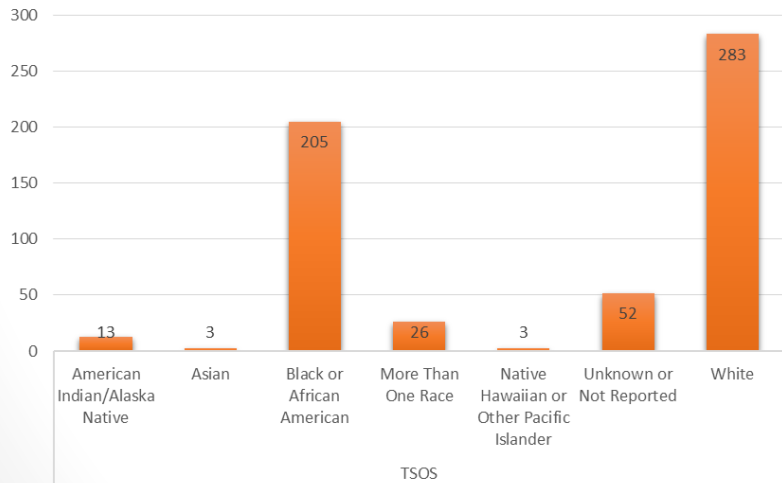
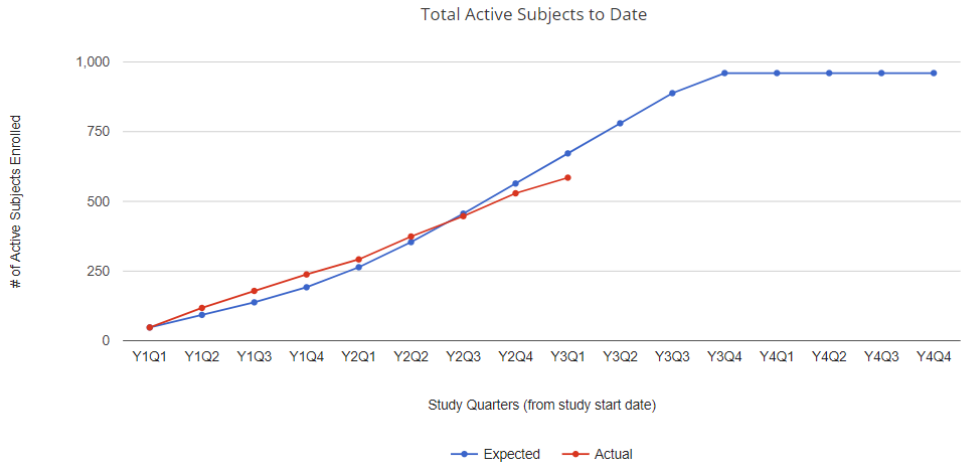
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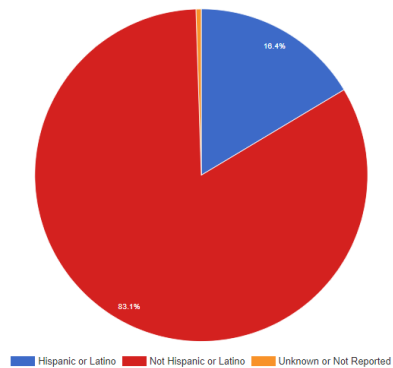
TSOS Pragmatic Trial Regulatory Tension: Generalizable Sites vs. Regulatory Expertise

- One site undergoes internal audit
- One site undergoes voluntary recruitment suspension by TSOS team
- One site cannot account for consented patient: Consent form review begins
- Review reveals an additional site with major informed consent procedure difficulties
- Recruitment at all sites suspended by DSMB
- Consent form review ongoing; 75% of patients properly consented supporting trial viability

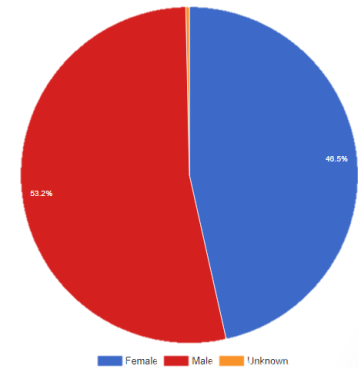
Study: UH3 Project: Trauma Survivors Outcomes and Support



Ethnicity Breakdown



Gender Breakdown



TSOS Next Steps & Timeline

- Work with DSMB to restart recruitment
- Continue to recruit intervention patients in final wave through 9/30/18
- Complete 12 month follow-up 9/30/19
- Obtain trauma registries, clean & analyze data
- American College of Surgeons' policy summit Spring 2020

Summary: TSOS Lessons Learned

- Carefully consider what pragmatic trial elements require more intensive site monitoring
- Understand implications of more intensive monitoring procedures for pragmatic trial costs