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

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TSOS UH3 Overview

• Barriers Scorecard
• Progress & Barriers
• Generalizable Lessons Learned
# TSOS: Barriers Scorecard

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<thead>
<tr>
<th>Barrier</th>
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5 = extreme difficulty
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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

Total Active Subjects to Date

Study Quarters (from study start date)
- Expected
- Actual

Ethnicity Breakdown
- American Indian/Alaska Native
- Asian
- Black or African American
- More Than One Race
- Native Hawaiian or Other Pacific Islander
- Unknown or Not Reported
- White

Gender Breakdown
- Female
- Male
- Unknown or Not Reported

NIH Collaboratory
Rethinking Clinical Trials®
Health Care Systems Research Collaboratory
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