Trauma Survivors Outcomes & Support (TSOS): Progress, Barriers & Lessons Learned

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Trauma Survivors Outcomes & Support (TSOS)

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TSOS UH3 Overview

- Barriers scorecard
- Progress toward study completion
- Generalizable lessons learned
<table>
<thead>
<tr>
<th>Barrier</th>
<th>Level of Difficulty</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enrollment and engagement of patients/subjects</td>
<td>X</td>
</tr>
<tr>
<td>Engagement of clinicians and Health Systems</td>
<td>X</td>
</tr>
<tr>
<td>Data collection and merging datasets</td>
<td>X</td>
</tr>
<tr>
<td>Regulatory issues (IRBs and consent)</td>
<td>X</td>
</tr>
<tr>
<td>Stability of control intervention</td>
<td>X</td>
</tr>
<tr>
<td>Implementing/Delivering Intervention Across Healthcare Organizations</td>
<td>X</td>
</tr>
</tbody>
</table>

1 = little difficulty  
5 = extreme difficulty
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 Progress

- Patient recruitment completed fall 2018
- Baseline data cleaned and analyzed
- 1027 Patients consented/screened
- 635 patients randomized
  - 370 Control
  - 265 Intervention
- Stepped wedge intervention ends spring 2019
- Follow-up ongoing
  - 80% 3 month follow-up
  - ~75% 12 month follow-up
TSOS Next Steps & Timeline

- Summer 2019 complete trauma registry data collection & cleaning
- Fall 2019 complete 12-month follow-up
- Fall & winter 2019-2020 data cleaning and analyses
- June 2020 American College of Surgeons’ policy summit
- Summer 2020 primary outcome paper submission
- 2021 data sharing begins
TSOS Lessons Learned

- Helpful to have a pragmatic approach to the monitoring of trial implementation processes
- Retrospectively, site staff and provider turnover was associated with major challenges during the study roll-out
- Going forward, the observation that some patients did not engage in the intervention may inform secondary hypotheses/analyses