The Trauma Survivors Outcomes & Support: UH2-UH3 Lessons Learned

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Lauren Whiteside (Emergency Medicine)
# TSOS Barriers Scorecard

<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>
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<tr>
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<td>Stability of control intervention</td>
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<tr>
<td>Implementing/Delivering Intervention Across Healthcare Organizations</td>
<td>Anticipated</td>
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1 = little difficulty
5 = extreme difficulty
TSOS UH3 Update

• Recruitment update and lessons learned
• Major challenge: Site variability/regulatory delays and stepped wedge design
• Anticipating site intervention implementation variability
Overview: TSOS Effectiveness-Implementation Hybrid Pragmatic Trial Framework

**RE-AIM Evaluation Framework [35]**

- **Adoption**
  - Assessment of trauma center site adoption status

- **Effectiveness**
  - Effectiveness – Implementation Hybrid Pragmatic Trial

- **Implementation**
  - Stepped Wedge Cluster Randomized Trial
  - Control Recruitment Begins → Intervention Left On Promoting Sustainable Implementation

- **Maintenance**
  - Diffusion of Innovations → Diffusion of Innovations → Targets National Trauma Center Adoption

**Clinical Trial Frameworks & Classic Theory [27, 36, 39-43]**

**Robust Sustainable Implementation Systems [37-38]**

- **Multiple Comorbid Conditions**
  - PTSD
  - Depression
  - Suicidal ideation
  - Alcohol use problems
  - Drug use problems
  - Traumatic brain injury
  - Chronic medical conditions

- **Critical Intervention Elements**
  - Care management
  - Motivational interviewing
  - Cognitive behavioral therapy elements
  - Medications
  - Primary care linkage

- **Barriers and implementation lessons learned from fielding of the trial**

- **American College of Surgeons policy summit targeting PTSD and comorbidity guidelines**


NIH Collaboratory: Rethinking Clinical Trials®

Health Care Systems Research Collaboratory
Overview: TSOS Effectiveness-Implementation

Hybrid Pragmatic Trial Framework


NIH Collaboratory: Rethinking Clinical Trials®
Overview: TSOS Effectiveness-Implementation
Hybrid Pragmatic Trial Framework


NIH Collaboratory
Rethinking Clinical Trials
Recruitment Update & Lessons Learned

• 20 sites ≥ 1 patient recruited
• 2 additional sites with automated recruitment workbook data transfer
• 2 sites regulatory delays: IRB re-review
TSOS EHR PTSD Screen Domains

- Female gender
- Non-White race/ethnicity
- Low income (insurance status as proxy)
- Intentional injury (e.g., assault, gunshot)
- ICU admit
- History of PTSD diagnosis
- History of other mental health diagnosis
- History of alcohol/drug use problems, positive BAC
- Tobacco use
- Prior inpatient admissions
Study: UH3 Project: Trauma Survivors Outcomes and Support

Principal Investigator: Douglas Zatzick, MD

NIH Grant Number: UH3 MH106338-02

UH3 Award Date: August 2015
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<tr>
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<th>Anticipated %</th>
<th>Actual %</th>
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<tr>
<td>Minority</td>
<td>21%</td>
<td>58%</td>
</tr>
<tr>
<td>Female</td>
<td>24%</td>
<td>58%</td>
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Major Challenge: Regulatory & Other Delays Contribute to Site Recruitment Variability

- Some sites rapid: Complete control recruitment all in one period
- Some sites delayed may not complete control recruitment before intervention switched on
- Scientific tension between stepped wedge design integrity & site implementation flexibility
- Initial solution
  - 4 minimum patients per period
  - 12 maximum patients per period
Additional Modifications to Address Site Start-up Variability

- 25\textsuperscript{th} site randomized from wait-list
- First period extended by 2 months
- High performance site(s) asked to recruit more control patients
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Emerging Scientific Issue for Effectiveness-Implementation Hybrid Pragmatic Trial Design

- Anticipating site variability in intervention implementation and related sustainable maintenance of screening and intervention procedures
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