Toward National Trauma Care Practice Change for PTSD & Comorbidity: Lessons Learned from the TSOS Pragmatic Trial

Douglas Zatzick, MD
Professor Department of Psychiatry
University of Washington School of Medicine

&

Gregory J. Jurkovich, MD
Professor & Vice Chairman
Department of Surgery
University of California at Davis

Funded by Grant UH3 MH106338
Trauma Survivors Outcomes & Support (TSOS)

Trauma Surgery Policy Core
Gregory Jurkovich MD
Ron Maier MD
David Hoyt MD
Trauma Survivors Outcomes & Support (TSOS)

Collaborators
Doyanne Darnell PhD
Joan Russo PhD
Patrick Heagerty PhD
Lauren Whiteside MD MS
Jin Wang PhD
Lea Parker BA
Allison Engstrom BA
Erik Van Eaton MD
Larry Palinkas PhD
Overview

- TSOS trial updates
- Pragmatic trials & practice change
- Implementation science & practice change
- A decade of American College of Surgeons policy
- Current TSOS activities facilitating practice change
  - Recent TSOS Multiple Chronic Condition findings & “A National Trauma Care System Zero Preventable Deaths” policy discussion
  - TSOS intervention design elements
  - TSOS collaborative publication in the service of PTSD & comorbidity practice change
- Summary and future directions
TSOS Effectiveness-Implementation Hybrid Pragmatic Trial Framework

RE-AIM Evaluation Framework [35]

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

Robust Sustainable Implementation Systems [37-38]

Adoption

Effectiveness

Implementation

Maintenance

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

Clinical Trial

- Assessment of trauma center site adopter status
  - Innovators, laggards, other sites excluded

Effectiveness - Implementation Hybrid Pragmatic Trial

Stepped Wedge Cluster Randomized Trial

Control Recruitment Begins — Intervention Left On Promoting Sustainable Implementation

Diffusion of Innovations — Targets National Trauma Center Adoption

Policy

Time

ACS/COT Context

2011

May ACS/COT Policy Summit

2014

ACS/COT PTSD Practice Guideline

2019

Protocol Supported ACS/COT Policy Summit

TSOS Pragmatic Trial Update

- 25 US level I trauma center sites
- 516 Patients consented/screened
  - 305 patients randomized
  - 59% PTSD EHR screen in rate
- Stepped wedge intervention roll-out
  - 2/4 intervention waves trained
- 70-80% 3 & 6 mo. follow-up to date
TSOS Challenges, Strengths, and Lessons Learned

**Challenges**
25 site regulatory considerations
25 site information technology issues

**Strengths**
Intervention roll-out
Policy arm targeting practice change
Pragmatic Trials & Practice Change
Pragmatic Trials & Practice Change

• Ellenberg et al Data Monitoring Committees for Pragmatic Clinical Trials, Clinical Trials Oct 2015

• Discussion of trial futility:
  Why would a trial continue if results were unlikely to change practice?
Implementation Science & Practice Change

- Diffusion of Innovations (Rogers 1995)
- Variability in uptake of a new practice
  - Innovators
  - Early Adopters
  - Middle Adopters
  - Late Adopters
  - Laggards
US Trauma Centers (N ~ 1050)
US Trauma Center Adoption
US Trauma Center Adoption

- Innovator
US Trauma Center Adoption

- Innovator
- Early Adopter
US Trauma Center Adoption

- Innovator
- Early Adopter
- Middle Majority Adopter
US Trauma Center Adoption

- Innovator
- Early Adopter
- Middle Majority Adopter
- Late Adopter
US Trauma Center Adoption Curve

Percent of sites adopting

Time

Innovator

Early Adopter
US Trauma Center Adoption Curve

Percent of sites adopting

Time

Innovator

Early Adopter

Middle Majority Adopter
Disseminating Organizational Screening & Brief Interventions (DO-SBIS)

Evidence-based Interventions for Alcohol Problems in Trauma Centers
## DO-SBIS Trauma Center Adopter Categorization

<table>
<thead>
<tr>
<th>Category</th>
<th>Color</th>
<th>Surgeon Champion</th>
<th>Other Champion (eg RN)</th>
<th>NIH Funded Alcohol Research</th>
<th>FTE Allocation</th>
<th>Prior Training</th>
<th>Blood Alcohol Drawn</th>
<th>Responses to ACS Survey</th>
<th>ACS Survey Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Innovator</td>
<td></td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Mean of 4 items &lt;7</td>
<td>Yes</td>
</tr>
<tr>
<td>Early Majority</td>
<td></td>
<td>Yes/No</td>
<td>Yes/No</td>
<td>No</td>
<td>Yes/No</td>
<td>Yes</td>
<td>Yes</td>
<td>Mean of 4 items &gt;7</td>
<td>Yes</td>
</tr>
<tr>
<td>Middle Majority</td>
<td></td>
<td>Yes/No</td>
<td>Yes/No</td>
<td>No</td>
<td>Yes/No</td>
<td>No</td>
<td>Yes</td>
<td>Mean of 4 items &gt;7</td>
<td>Yes</td>
</tr>
<tr>
<td>Late Majority</td>
<td></td>
<td>Yes/No</td>
<td>Yes/No</td>
<td>No</td>
<td>Yes/No</td>
<td>No</td>
<td>Yes</td>
<td>No mean specified</td>
<td>Yes</td>
</tr>
<tr>
<td>Laggard</td>
<td></td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Mean of 4 items &lt;7</td>
<td>No</td>
</tr>
</tbody>
</table>
American College of Surgeons’ Committee on Trauma Policy Targeting Practice Change
American College of Surgeons’ Committee on Trauma Policy
American College of Surgeons’ Committee on Trauma

- 1976 1st Book
- 2006 “Green Book”
- 2014 “Orange Book”
American College of Surgeons’ Resources Guide Revision Process

- Criteria Published
- Time Period for Implementation by ACS Trauma Centers and VRC
- Criteria Operational Open for Stakeholder Comment 6 Months
- Criteria Review and Revision by COT 1 Year Time Period
- New Draft Criteria Open for Comment 3-6 Months
- Final Tuning by COT 6 Months

**Principles for Revision**
1. Continuous improvement
2. Incremental revision
3. Simplify where possible
4. Data driven
5. Move towards outcome
Two Decades of Orchestrated Clinical Trials & American College of Surgeons’ Policy

Single Site Alcohol Trials & Harborview Implements

ACS/COT Green Book Initial Alcohol Requirement

Multisite Alcohol RCT Single Site PTSD RCT

NIH ACS/COT Alcohol & PTSD Policy Summit

ACS/COT Gold Book Universal Alcohol Requirement & PTSD Guidelines

PCORI RCT

PCORI ACS/COT Policy Summit

UH3 Multisite PTSD RCT

NIH ACS/COT PTSD & Comorbidity Policy Summit

“Alcohol is such a significant associated factor and contributor to injury that it is vital that level I and level II trauma centers have a mechanism to identify patients who are problem drinkers.”

“In addition, level I centers must have the capability to provide an intervention for patients identified as problem drinkers.”
Disseminating Organizational Screening & Brief Interventions (DO-SBIS)

Evidence-based Interventions for Alcohol Problems in Trauma Centers
Alcohol Universal Screening & Intervention at Level I & II trauma centers
Two Decades of Orchestrated Clinical Trials & American College of Surgeons’ Policy

- 2000: Single Site Alcohol Trials & Harborview Implements
- 2006: ACS/COT Green Book Initial Alcohol Requirement
- 2011: NIH ACS/COT Alcohol & PTSD Policy Summit
- 2016: PCORI ACS/COT Policy Summit
- 2020: NIH ACS/COT PTSD & Comorbidity Policy Summit
PTSD screening & intervention best practice guideline recommendation
PTSD

“The incorporation of routine trauma center–based screening and intervention for PTSD and depression is an area that could benefit from the ongoing integration of emerging data and evolving expert opinion”.

2014
Patient-Centered Care

Three studies reviewed at ACS/COT Policy summit 9-23-16

Resource guide informational guideline recommendations under review by COT
Current TSOS Activities Targeting Practice Change
Current TSOS Activities Targeting Practice Change

- Recent TSOS multiple chronic condition research findings and “A National Trauma Care System Zero Preventable Deaths” policy discussion
- TSOS intervention design elements
- TSOS collaborative publication in the service of PTSD & comorbidity practice change
Primary focus on “resuscitation” deaths

TSOS study team advocating for greater focus on preventable deaths from mental health/substance use etiologies including suicide and unintentional overdose
Co-morbidity: PTSD, Depression/Suicidal Ideation, & Alcohol and Drug Use Problems Among Randomly Selected Trauma Surgery Inpatients (N=878)

- None: 21%
- PTSD & Substances: 79%

Zatzick, Donovan, Dunn, Russo, Wang, Jurkovich, Rivara, Whiteside, Ries & Gentilello JSAT 2012
Mental Health, Alcohol, Drug, Violence, Suicide & Chronic Medical Conditions in Trauma Patients: More is Worse

The Cumulative Burden of Mental, Substance Use, and General Medical Disorders and Rehospitalization and Mortality After an Injury

Douglas F. Zatzick, M.D., Ali Rowhani-Rahbar, M.D., Ph.D., Jin Wang, Ph.D., Joan Russo, Ph.D., Doyanne Darnell, Ph.D., Leah Ingraham, B.S., Lauren K. Whiteside, M.D., M.S., Roxanne Guiney, B.A., Margot Kelly Hedrick, Frederick P. Rivara, M.D., M.P.H.

Objective: Each year in the United States, 1.5–2.5 million individuals require hospitalization for an injury. Multiple mental, substance use, and chronic general medical disorders are endemic among injury survivors with and without traumatic brain injury (TBI), yet few studies have assessed the association between the cumulative burden of these conditions and health care outcomes. This study of patients hospitalized for an injury assessed associations between comorbid mental, substance use, and general medical disorders, TBI, and violent events or suicide attempts and the postinjury outcomes of recurrent hospitalization and death.

Methods: Recurrent hospitalization and all-cause mortality were examined in this population–based retrospective cohort study. A total of 76,942 patients hospitalized for an injury in Washington State during 2006–2007 were followed for five years. ICD-9-CM codes identified conditions prior to or at the index injury admission. Index admissions related to injuries from firearms, assaultive violence, suicide attempts, and overdoses were identified through E-codes.

Results: Adjusted regression analyses demonstrated a significant, dose-response relationship between an increasing cumulative burden of disorders and an increasing risk of recurrent hospitalization (four or more conditions, relative risk=3.89, 95% confidence interval [CI]=3.66–4.14). Adjusted Cox proportional hazard regression demonstrated a similar relationship between increasing cumulative burden of disorders and all-cause mortality (four or more conditions, hazard ratio=5.33, CI=4.71–6.04).

Conclusions: Increasing cumulative burden of disorders was associated with greater postinjury risk of recurrent hospitalization and death. Orchestrated investigative and policy efforts could introduce screening and intervention procedures that target this spectrum of comorbidity.

Psychiatric Services in Advance (doi: 10.1176/appi.ps.201600311)
Washington State Trauma Care System (N = 76,942)

• Retrospective cohort study
• 76,942 injury admits 2006-2007
• ICD comorbidity & E-Codes assessed
  - Mental Health Diagnosis
  - Alcohol Diagnosis
  - Drug Diagnosis
  - Chronic medical Diagnosis
  - Suicide admission
  - Gun violence admission
• 5 year outcomes
  - Recurrent hospital admissions
  - All cause mortality
Washington State Trauma Care System (N = 76,942)

- 29% Mental health DX
- 25% Alcohol DX
- 21% Drug DX
- 62% Chronic medical DX
- 14% Suicide/overdose admission
- 4% Gunshot/assault admission
Comorbidity Cumulative Burden: All Cause Mortality Dose-Response

• \( \uparrow \) Mortality with \( \uparrow \) Disorders

<table>
<thead>
<tr>
<th>Group</th>
<th>HR</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥4 Disorders</td>
<td>5.3</td>
<td>4.7, 6.0</td>
</tr>
<tr>
<td>3 Disorders</td>
<td>3.8</td>
<td>3.4, 4.3</td>
</tr>
<tr>
<td>2 Disorders</td>
<td>3.5</td>
<td>3.1, 3.9</td>
</tr>
<tr>
<td>1 Disorder</td>
<td>2.5</td>
<td>2.2, 2.8</td>
</tr>
<tr>
<td>0 Disorders</td>
<td>---</td>
<td></td>
</tr>
</tbody>
</table>
TSOS Intervention Design Nudges Trauma Center Practice Change

- Stepped wedge design begins each site as control
- When intervention “turned on” control patient cases reviewed
Why *Trauma Survivors Outcomes & Support* (TSOS)?

The problem

Traumatic injury
- PTSD, depression, suicidal ideation
- High risk behaviors (e.g., alcohol)
- Traumatic brain injury
- Chronic medical conditions common

Patients “sail off of a flat earth”

From Darnell & Zatzick TSOS Training Slide Set
TSOS Publications & Data Sharing Also Aim to “Nudge” Practice Change
PTSD Chapter References

Supplemental Readings


TSOS Publications & Data Sharing Also Aim to “Nudge” Practice Change

• Collaborative publication is an essential goal of the TSOS trial
• TSOS data sharing in the service of PTSD & comorbidity practice change
Summary

• Key element of pragmatic trials is the targeting of practice change
• Implementation science frameworks useful
• TSOS has incorporated up-front multiple design features targeting practice change
  - Longstanding policy dialogue
  - Stepped wedge intervention roll-out
  - Collaborative publication & data sharing