A Policy Relevant US Trauma Care System
Pragmatic Trial for PTSD & Comorbidity
(UH2 MH106338-01)

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Jeff Love (Project Coordination)
Trauma Survivors Outcomes & Support (TSOS): Overview

- Background: US Trauma Care Systems
- Background: PTSD & Comorbidity
- Background: Policy Relevance
- UH3 Study Design & Implementation
- Dissemination Plan
- Questions & Discussion
Background: US Trauma Health Care Systems
Background: Injury Events & Trauma Care Systems

• 30 million US injury visits annually
• 1.5-2.5 million injury admissions
• Over 1000 US trauma centers
• Level I trauma centers set standards nationally
US Trauma Care Systems: Care Coordination

Paramedic/Pre-Hospital

Emergency & Trauma Center

Primary Care and Community
US Trauma Care Systems: Unique Service Delivery Context

- “Open entry” of injured patients
  - Diverse health plans
  - No single administrative database
- Remarkable heterogeneity
  - Patient SES & ethnocultural diversity
  - Providers (MD, RN, MSW)
  - Information technology capacity
Background: Posttraumatic Stress Disorder (PTSD) & Comorbidity Multiple Chronic Condition Framework
PTSD & Other Mental Health/Substance Disorders Among Randomly Selected Harborview Emergency/Trauma Surgery Patients (N=878)

Zatzick Donovan Dunn Russo Wang Jurkovich et al JSAT 2012
PTSD & Comorbidity and the Multiple Chronic Condition Framework

• Mental health comorbidity: PTSD, depression and occult suicidal ideation (25-40%)
• Alcohol use problems (25%)
• Other substance use problems: Stimulants, opiates, benzodiazepines, MJ (20%)
• Chronic pain and somatic symptom amplification (10-20%)
• Traumatic Brain Injury (40-50%)
• Pre-injury chronic medical conditions (>50%)
# Chronic Medical Condition Heterogeneity Among Admitted Injury Survivors (N = 76,942)

<table>
<thead>
<tr>
<th>Condition/System</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>Hypertension</td>
<td>33%</td>
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<td>Heart Disease</td>
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<td>Pulmonary</td>
<td>16%</td>
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<tr>
<td>Diabetes</td>
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<tr>
<td>Renal</td>
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<tr>
<td>Hepatic</td>
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<tr>
<td>Obesity</td>
<td>5%</td>
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<tr>
<td>Neoplasm</td>
<td>4%</td>
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</table>
Background: Prior Collaborative Care Trials Successfully Targeting PTSD & Comorbidity

- ↓ Alcohol use & recurrent injury (Annals of Surgery 1999)
- ↓ Alcohol use - 20 trauma center sites (Addiction 2014)
- ↓ Injury risk/weapon carrying (JAMA Pediatrics 2014)
- ↓ PTSD symptoms & Alcohol use (JAMA Psychiatry 2004)
- ↓ PTSD symptoms with IT enhanced collaborative care (Under revision)
- ↓ PTSD symptoms & improved physical function (Annals of Surgery 2013)
RESEARCH METHODS & REPORTING

A guide to research partnerships for pragmatic clinical trials

Karin E Johnson research associate¹, Chris Tachibana scientific editor and writer¹, Gloria D Coronado senior investigator², Laura M Dember professor of medicine³, Russell E Glasgow associate director⁴, Susan S Huang associate professor and medical director of epidemiology and infection prevention⁵, Paul J Martin medical director⁶, Julie Richards project manager⁷, Gary Rosenthal professor⁷, Ed Septimus medical director infection prevention and epidemiology⁸, Gregory E Simon senior investigator¹, Leif Solberg associate medical director for care improvement research⁹, Jerry Suls senior scientist¹⁰, Ella Thompson project manager¹, Eric B Larson vice president for research¹

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Implementation Science: “Make It Happen” Research to Policy Partnership with The American College of Surgeons (Greenhalgh et al 2004, Milbank Quarterly)

Innovation in Service Organizations

“Let it happen” — “Help it happen” — “Make it happen”

Defining Features
- Unpredictable, unprogrammed, uncertain, emergent, adaptive, self-organizing
- Negotiated, influenced, enabled
- Scientific, orderly, planned, regulated, programmed, systems “properly managed”

Assumed Mechanism
- Natural, emergent
- Social
- Technical
- Managerial

Metaphor for Spread
- Emergence, adaptation
- Knowledge construction, making sense
- Diffusion
- Negotiation
- Knowledge Dissemination, Re-transfer
- Cascading, engineering

FIGURE 2. Different Conceptual and Theoretical Bases for the Spread of Innovation in Service Organizations
PTSD
PTSD screening & intervention best practice guideline recommendation
US Trauma Care System Pragmatic Trial Generalizability

- Patient
- Provider
- Site (Trauma Center)
UH3 Research Plan
Trauma Survivors Outcomes & Support (TSOS) UH3 Aims

1) Conduct pragmatic trial
2) Understand trial implementation
3) Dissemination of results through Amer. College of Surgeons’ policy
UH3 Study Design

- Cluster randomized trial
- 24 US trauma centers
- Stepped wedge design
- All sites begin recruiting controls
- Intervention “turned on” at each site
- 40 patients per site (960 patients total)
- Baseline PTSD & comorbidity assessment
- 3, 6 and 12 month follow-up interviews
UH2-UH3 Hypotheses: Aim 1

• The intervention group when compared to the control group will demonstrate:
  • 1) ↓ PTSD symptoms (primary hypothesis)
  • 2) ↓ Depressive symptoms
  • 3) ↓ Alcohol use problems
  • 4) Improved post-injury physical function
  • Exploration of intervention effects in patients with/without chronic medical conditions & TBI
  • Exploration of intervention effects on other conditions (e.g., chronic pain, drugs of abuse)
Trauma Center Site Selection Criteria

- Exclude child trauma centers (age < 18)
- RFA: No research network
- Not currently routinely screening or intervening for PTSD (Exclude “Innovators” < 10% of US sites)

- Availability of Champions:
  - Trauma surgery
  - PTSD intervention
  - Information technology
CONSORT: Trauma Center Recruitment

225 US Level I Trauma Centers Contacted

- Excluded 19 Children’s Hospitals
- 12 Prior Pragmatic Trial

89 Assessed for Participation

- 105 Declined Assessment
- 19 Declined After Assessment
- 13 Excluded PTSD Innovator
- 33 Waitlisted

24 Enrolled
TSOS US Level I Trauma Center Sites (N = 24)
Comparison of Trauma Centers Participating in the Trial with Those Not Participating

<table>
<thead>
<tr>
<th></th>
<th>TSOS (n = 24)</th>
<th>Others (n = 221)</th>
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<tbody>
<tr>
<td>US Region</td>
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<tr>
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<td>32.5%</td>
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<tr>
<td>South/SE</td>
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<tr>
<td>Northeast/East</td>
<td>16.0%</td>
<td>32.5%</td>
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<tr>
<td>West</td>
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<td>Central</td>
<td>16.0%</td>
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<tr>
<td>Rural</td>
<td>12.0%</td>
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<tr>
<td>Teaching hospital</td>
<td>92%</td>
<td>82%</td>
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<td>Population served</td>
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<td>Adult</td>
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<td>46.7%</td>
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<td>Adult &amp; pediatrics</td>
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<tr>
<td>Pediatrics</td>
<td>0.0%</td>
<td>11.7%</td>
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<td>Hospital beds (median)</td>
<td>559</td>
<td>533</td>
<td>0.43</td>
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</table>
Variability in TSOS Trauma Center Characteristics (N = 24)

• PTSD prevalence
  - Violent injury admissions
  - ICU

• Recruitment rates
  - Trauma center admit volume

• Follow-up rates
  - Substance use
  - Homelessness
Stepped Wedge Design

- Sites recruit control & intervention
- 24 sites randomized to 4 waves
- Begin with control recruitment
- Turn on intervention midway
**Stepped Wedge Cluster Randomized Design**

- **Patients Unexposed to intervention** (n = 480)
- **Patients Exposed to intervention** (n = 480)

Follow-up Period

Accrual period

Wave 1: n=8 - n=32

Wave 2: n=16 - n=24

Wave 3: n=24 - n=16

Wave 4: n=32 - n=8

6 centers/wave x 40 patients = 960 patients
Injury Admissions
Age ≥ 18

Medical Record
10 Domain PTSD Risk Screen

Exclude
Acute Psychiatric Prisoners
Non-English Speaking

Postpone
Cognitive Impairment

Exclude
< 3 PTSD Risk Factors

Consent
Administer PTSD Checklist

PTSD Checklist ≥ 35

Exclude
PTSD Checklist < 35

Cohort Definition
PTSD Checklist ≥ 35
The development of a population-based automated screening procedure for PTSD in acutely injured hospitalized trauma survivors

Joan Russo, Ph.D. a, Wayne Katon, M.D. a, Douglas Zatzick, M.D. a, b

a Department of Psychiatry and Behavioral Science, University of Washington School of Medicine, Seattle, WA 98104, USA
b Department of Psychiatry and Behavioral Sciences, Harborview Injury Prevention and Research Center, University of Washington School of Medicine, Seattle, WA 98104, USA

A B S T R A C T

Objective: This investigation aimed to advance posttraumatic stress disorder (PTSD) risk prediction among hospitalized injury survivors by developing a population-based automated screening tool derived from data elements available in the electronic medical record (EMR).

Method: Potential EMR-derived PTSD risk factors with the greatest predictive utilities were identified for 878 randomly selected injured trauma survivors. Risk factors were assessed using logistic regression, sensitivity, specificity, predictive values and receiver operator characteristic (ROC) curve analyses.

Results: Ten EMR data elements contributed to the optimal PTSD risk prediction model including International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) PTSD diagnosis, other ICD-9-CM psychiatric diagnosis, other ICD-9-CM substance use disorder diagnosis or positive blood alcohol on admission, tobacco use, female gender, non-White ethnicity, uninsured, public or veteran insurance status, E-code identified intentional injury, intensive care unit admission and EMR documentation of any prior trauma center visits. The 10-item automated screen demonstrated good area under the ROC curve (0.72), sensitivity (0.71) and specificity (0.56).

Conclusions: Automated EMR screening can be used to efficiently and accurately triage injury survivors at risk for the development of PTSD. Automated EMR procedures could be combined with stepped care protocols to optimize the sustainable implementation of PTSD screening and intervention at trauma centers nationwide.
Cohort Definition: Patient Reported Outcome

- PTSD Checklist: 17 item DSM PTSD
- PTSD Checklist score ≥ 35 included
- All comorbidities included
Control Condition

- Usual trauma center care
- Infrequent PTSD intervention
- Poor trauma center to community linkage – fragmented care common
- Inconsistent attention to comorbidity
Evidenced-based Intervention: Stepped Collaborative Care (6 mo.)

- Combined disease management
  - Care management
  - Pharmacotherapy
  - Motivational interview & CBT elements

- Multidisciplinary teams
  - Care management (MSW, RN)
  - Mental health providers (e.g., PhD)
  - Medical & surgical providers (MD)
Stepped Collaborative Care: Readily Implementable Elements

Step I

Empathic Engagement – Care Coordination – Trauma Center – Outpatient – Primary Care Linkage
Stepped Collaborative Care: Readily Implementable Elements

Step I
- Empathic Engagement – Care Coordination
- Trauma Center – Outpatient – Primary Care Linkage

Step II
- Medications – PTSD & Comorbidity
Stepped Collaborative Care: Readily Implementable Elements

- **Empathic Engagement – Care Coordination**
- **Trauma Center – Outpatient – Primary Care Linkage**
- **Medications – PTSD & Comorbidity**
- **Behavioral Intervention: Motivational Interview & Cognitive Behavioral Therapy Elements**
Stepped Collaborative Care: Readily Implementable Elements

Step I: Empathic Engagement – Care Coordination – Trauma Center – Outpatient – Primary Care Linkage

Step II: Medications – PTSD & Comorbidity

Step III: Behavioral Intervention: Motivational Interview & Cognitive Behavioral Therapy Elements

Step IV: Specialty Referral
Stepped Collaborative Care: Readily Implementable Elements

Step I: Empathic Engagement – Care Coordination – Trauma Center – Outpatient – Primary Care Linkage

Step II: Medications – PTSD & Comorbidity

Step III: Behavioral Intervention: Motivational Interview & Cognitive Behavioral Therapy Elements

Step IV: Specialty Referral

Step V: Community Integration

Time
Intervention Training

- Front-line trauma providers
- 1 day on-site trauma center training
- Ongoing feedback and coaching using TSOS decision support tool
The Informatics Goal

- Leverage site IT capacity for trauma patient data extraction
The Informatics Goal

• Provide a real-time, workflow-integrated decision support tool
The Informatics Goal

• Align to existing methods for distributed research networking

Figure 1. Comprehensive Trauma Center Screening, Intervention & Quality Documentation for PTSD & Comorbidity

1) Institutional EMR & Administrative Databases – Real-time Extract
2) Computerized Decision Support for PTSD & Comorbidity: Workflow-integrated Screening & Intervention
3) Standardized Quality, Outcomes, & Research Outputs

- Inpatient Admission
- Comprehensive Data Capture & Organization
- Supervised Screening & Intervention
- Data Standardization & Workflow Automation
- Quality, Outcomes, Research Data
The Informatics Challenge: Infrastructure Variability

A Nationwide Survey of Trauma Center Information Technology Leverage Capacity for Mental Health Comorbidity Screening

Erik G Van Eaton, MD, FACS, Douglas F Zatzick, MD, Thomas H Gallagher, Peter Tarczy-Hornoch, MD, FACMI, Frederick P Rivara, MD, MPH, David R Flum, MD, MPH, FACS, Roselyn Peterson, BA, Ronald V Maier, MD, FACS

BACKGROUND: Despite evidence that electronic medical record (EMR) information technology innovations can enhance the quality of trauma center care, few investigations have systematically assessed United States (US) trauma center EMR capacity, particularly for screening of mental health comorbidities.

STUDY DESIGN: Trauma programs at all US level I and II trauma centers were contacted and asked to complete a survey regarding health information technology (IT) and EMR capacity.

RESULTS: Three hundred ninety-one of 525 (74%) US level I and II trauma centers responded to the survey. More than 90% of trauma centers reported the ability to create custom patient tracking lists in their EMR. Forty-seven percent of centers were interested in automating a blood alcohol content screening process; only 14% reported successfully using their EMR to perform this task. Marked variation was observed across trauma center sites with regard to the types of EMR systems used as well as rates of adoption and turnover of EMR systems.

CONCLUSIONS: Most US level I and II trauma centers have installed EMR systems; however, marked heterogeneity exists with regard to EMR type, available features, and turnover. A minority of centers have leveraged their EMR for screening of mental health comorbidities among trauma inpatients. Greater attention to effective EMR use is warranted from trauma accreditation organizations. (J Am Coll Surg 2014;219:505–510. © 2014 by the American College of Surgeons)
Solution: Flexibility, and ...

Advanced Capacity
- Clinical Data Warehouse
- Query or Interface
- Local DRN Node
- Automation to:
  - Trauma Data Bank
  - Documentation
  - Distributed Research
- Frontline Provider
- Daily Worklist

Middle Majority
- EHR Data
- Query & Some Hand Entry
- Frontline Provider
- Daily Worklist
- TSOS Data Coord Center
  - Consented patients: granular data
  - Unconsented patients: population-level stats

Low Capacity
- EHR Data
- Hand Entry & Some Query
- Frontline Provider
- Daily Worklist
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<th>Basic Information</th>
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<td>Record/Patient Status</td>
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</tr>
<tr>
<td>First Name</td>
<td>Jane</td>
</tr>
<tr>
<td>Last Name</td>
<td>Doe</td>
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<td>Middle Name</td>
<td>A</td>
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<td>Alias</td>
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<td>Birth Date</td>
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<td>Exclusions Prior To Approach</td>
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... Structure

**TSOS DECISION SUPPORT TOOL**

### Intervention Care Management Note

- **Patient:** Jana Doe
- **Status:** Active
- **Date:** 2/29/2013
- **Total Time Spent:** 30
- **Mode:** In Person
- **Patient Location:** Hospital/Bedside
- **Note:** Initial interview with patient

### Patient Concerns

- **Time Spent (minutes):** 30

**Concerns**

- **Concern:** Physical Health
- **Elicited?** ✓
- **Addressed?** ✓

**Note:** Patient in severe pain, “I'm afraid I will never walk again after the assault”. Surgical inpatient team contacted regarding pain control. Will follow patient's progress.
Blinded Assessments 3-, 6- & 12-months Post-injury: Patient Reported Outcomes

- PTSD (PTSD Checklist)
- Depression (PHQ-9)
- Alcohol use problem (AUDIT)
- Physical function (SF-36 PCS)
- Anticipated 75-80% 12-month f/u
Analyses

• Intervention vs. Control Comparisons
  - PTSD (Primary)
  - Alcohol
  - Depression
  - Physical function
  - Pre-injury Medical Conditions (ICD)
  - Traumatic brain injury (ICD)

• Health economic assessment

• RE-AIM assessment of implementation and sustainability
Dissemination
Year 5
American
College of
Surgeons
Policy Summit
PTSD screening & intervention best practice guideline recommendation
PTSD screening & intervention best practice guideline recommendation

Patient Reported Outcome 17 item PTSD Checklist Recommended
Next Steps
“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.”
Questions & Discussion