A Policy Relevant US Trauma Care System Pragmatic Trial for PTSD & Comorbidity: Trauma Survivors Outcomes & Support (TSOS)

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Overview: Lessons Learned

• Unique US Trauma Care System Context for MCC Pragmatic Trials
• UH3 Research Plan & Implementation
  - Dialogues with Collaboratory Cores
• Potential Barriers
• UH3 Dissemination/Sustainability
• Questions & Discussion
Lessons Learned - Unique Pragmatic Context: Trauma Care Systems Are Open Systems with Marked Patient Diversity & Health Care Delivery Heterogeneity
Lessons Learned MCC Heterogeneity: PTSD & Comorbidity and the Multiple Chronic Condition Framework

- Mental Health/ PTSD, depression, suicide (25-40%)
- Alcohol use problems (25%)
- Other substance use problems (20%)
- Chronic pain (10-20%)
- Traumatic Brain Injury (40-50%)
- Pre-injury chronic medical conditions (> 50%): HTN, Diabetes, CAD, Pulmonary, Liver, Neoplasm, Renal
- Evidence-based collaborative care interventions exist
Lessons Learned: The Importance of Stakeholder Partnerships in Pragmatic Trials

- Collaboratory Health Care Systems Core BMJ 2014
- American College of Surgeons’ Policy Partnership
- Implementation science “Make it Happen” approach to dissemination of pragmatic trial results
- Trauma care system pragmatic trial generalizability therefore includes:
  - Patients
  - Providers
  - Sites
PTSD screening & intervention best practice guideline recommendation
UH3 Research Plan: Aims & Hypotheses

Aims
1) Conduct pragmatic trial
2) Understand process of trial implementation
3) Disseminate results

Hypotheses
1) Intervention improves PTSD symptoms
2) Improved alcohol, depression & function
3) Explore intervention effect in patients with pre-injury chronic medical conditions
UH3 Study Design
Biostatistics Core Lessons Learned: Increased Numbers of Trauma Centers & Patients

- Cluster randomized trial
- Increase from 20 to 24 trauma centers
- 800 to 960 patients (40 patients/site)
TSOS US Level I Trauma Center Sites (N = 24)
UH3 Study Design

Biostatistics Core Lessons Learned: Proposed Stepped Wedge Cluster Randomized Design

- Stepped wedge design addresses site variability
- 24 sites randomized to 4 waves
- All sites recruit both control and intervention patients
- All sites begin recruiting controls
- Intervention “turned on” at each site
- Implementation advantage: all sites trained
- Design adds analytic complexity
Lessons Learned - Phenotypes Core: Data Quality Approaches for Trauma Centers with Heterogeneous EHR Capacity

- Reliance on phenotypes core materials
- 10 domain EHR screen identifies PTSD risk
- Patient reported outcome PTSD Checklist score ≥ 35 defines cohort
- EHR methods for sites that:
  - Standardizes data quality method
  - Overcomes gaps in automation ability
Phenotype Definition: PTSD Checklist \( \geq 35 \)

Automated Process Generates Cohort with EHR Data

Worklist Computes 10-domain PTSD Risk Screen

Worklist With Complete Data

EHR
Phenotype Definition:
PTSD Checklist $\geq 35$
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PTSD Checklist ≥ 35

Worklist Computes 10-domain PTSD Risk Screen

Addition of Non-EHR Data

Worklist With Complete Data

Data Quality: Training & Surveillance

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EHR Data Harmonization: Normalize to NTDS Dictionary

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EHR Data Harmonization: Normalize to NTDS Dictionary

Consent & Enter to TSOS Decision Support Tool

Data Quality: Training & Surveillance

Automated Process Generates EHR Worklist With Complete Data
Administer PTSD Checklist

Phenotype Definition: PTSD Checklist ≥ 35

Worklist Computes 10-domain PTSD Risk Screen

Phenotype Data Quality: Training & Surveillance

Addition of Non-EHR Data

Data Quality: Training & Surveillance

Worklist With Complete Data

Consent & Enter to TSOS Decision Support Tool

EHR Data Harmonization: Normalize to NTDS Dictionary

Addition of Non-EHR Data

Automated Process Generates Risk with EHR Data

EHR Data

Phenotype Data Quality: Training & Surveillance
Phenotype Definition: PTSD Checklist ≥ 35

Addition of Non-EHR Data

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Data Quality: Training & Surveillance

EHR or ADT Procedure Generates Daily Census

Addition of Non-EHR Data

Worklist With Complete Data

EHR Data Harmonization: Normalize to NTDS Dictionary

Consent & Enter to TSOS Decision Support Tool

Administer PTSD Checklist

EHR Data

Phenotype Data Quality: Training & Surveillance

Data Quality: Training & Surveillance

Training & Surveillance

Harmonization: Normalize to NTDS Dictionary

EHR or ADT Procedure Generates Daily Census

Phenotype Definition: PTSD Checklist ≥ 35
Administer PTSD Checklist

Phenotype Definition: PTSD Checklist ≥ 35

Data Quality: Training & Surveillance

Phenotype Data Quality: Training & Surveillance

EHR or ADT Procedure Generates Daily Census

Addition of Non-EHR Data

Worklist Computes 10-domain PTSD Risk Screen

EHR Data Harmonization: Normalize to NTDS Dictionary

Worklist With Incomplete Data

Manual Entry of Missing EHR Data

Consent & Enter to TSOS Decision Support Tool

Administer PTSD Checklist

Data Quality: Training & Surveillance

EHR Data Quality: Training & Surveillance

EHR or ADT Procedure Generates Daily Census

Addition of Non-EHR Data

Worklist With Complete Data

Consent & Enter to TSOS Decision Support Tool

Administer PTSD Checklist
Lessons Learned PRO Assessments at Baseline 3-, 6- & 12-months Post-injury: Targeted, Common & Harmonized

- PTSD (PTSD Checklist)
- Depression (PHQ-9)
- Alcohol use problem (AUDIT)
- Physical function (SF-36 PCS)
- Brief pain inventory (BPI)
Lessons Learned UH2 Pilot: Control Condition

- Enhanced usual trauma center care
- Nurse notification of patients with PTSD checklist ≥ 35
Stepped Collaborative Care Intervention: Decision Support Tool Supported Readily Implementable Elements

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

Step I:
- Medications – PTSD & Comorbidity

Step II:
- Behavioral Intervention: Motivational Interview & Cognitive Behavioral Therapy Elements

Step III:
- Specialty Referral

Step IV:
- Community Integration

Step V:
- Empathic Engagement – Care Coordination – Trauma Center – Outpatient – Primary Care Linkage
Regulatory/IRB Considerations & Potential Barriers

- Consolidated IRB structure
- WIRB approval March 2014
- 24 individual IRB submissions progressing
  - 8 approved
  - 12 under review
  - 4 to be submitted
- 19/24 sub-awards processed
- NIMH DSMB Review June 2015
- IRB modifications post-DSMB
- Delays possible with major protocol changes
Potential IT Barriers

- Participant site resource availability to create EHR queries
- Tool refinements required for expansion to 24 sites
Dissemination Year 5
American College of Surgeons
Policy Summit
PTSD
PTSD screening & intervention best practice guideline recommendation

PRO
PTSD Checklist Recommended
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

Principles for Revision
1. Continuous improvement
2. Incremental revision
3. Simplify where possible
4. Data driven
5. Move towards outcome

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
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