A Policy Relevant US Trauma Care System
Pragmatic Trial for PTSD and Comorbidity

(1UH2MH106338-01)

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Overview of Core Discussion

• UH2-UH3 Proposal
  - PTSD & MCC framework
    - Collaborative care “elements”
    - US trauma care systems & policy
• UH2 Milestones
  - Timeline
  - Current UH2-UH3 milestone progress
  - Potential barriers
  - Collaborative brainstorming of optimal UH2-UH3 milestone approaches
Other Discussion Points
(as time permits)

• Background: Prior DO-SBIS multisite alcohol screening and brief intervention pragmatic trial
• Prior nationwide PTSD & Comorbidity screening & intervention assessments
• Prior nationwide IT assessments
• Other implementation science considerations
• American College of Surgeons’ policy
Study Design

• Cluster randomized trial
• 24 US trauma centers
• 12 intervention sites receive training in PTSD & comorbidity
• Control sites care as usual
• 40 patients per site (960 patients total)
• Baseline pre-randomization evaluation
• 3, 6, 12 month follow-up
UH2-UH3 Hypotheses

- The intervention group when compared to the control group will demonstrate:
  - 1) ↓ PTSD symptoms
  - 2) ↓ Alcohol use problems
  - 3) Improved post-injury physical function
  - 4) Intervention will be equally effective among patients with and without traumatic brain injury
  - 5) Intervention will be equally effective among injury survivors with and without pre-existing chronic medical conditions
Background MCC Framework:
PTSD & Comorbidity Among Randomly Selected Emergency/Trauma Surgery Patients (N=878)

Zatzick et al JSAT 2012
PTSD & Comorbidity and the MCC Framework: Heterogeneity

- Mental health comorbidity: PTSD, depression, occult suicidal ideation, pain and somatic symptoms
- Substance abuse comorbidity: alcohol, stimulants, opiates, benzodiazepines, MJ
- Medical comorbidity: HTN, CAD, Diabetes, Pulmonary, Hepatic, Renal, Obesity, HIV, Epilepsy
- Injury: Traumatic Brain Injury (TBI)
PTSD & Comorbidity and the MCC Framework: Frequencies

- 63% ≥ 3 comorbidity
- 20%-40% high PTSD/depression
- 25% alcohol use problems
- 21% other substance use problems
- 40-50% Traumatic brain injury
- 50-60% ≥ 1 Chronic medical condition
Intervention Model: Stepped Measurement-Based Collaborative Care

Figure 2. Essential Elements of Trauma Center Screening & Intervention Targeting PTSD & Comorbidity

CARE MANAGEMENT INTERVENTION FOR PTSD & COMORBIDITY

I) Population-Based Screening for PTSD and Comorbidity
   A) Posttraumatic Concern Elicitation & Improvement
   B) CBT Elements Targeting
   C) Motivational Interview

II) Care-Management for PTSD and Comorbidity

III) Medication Consultation
   A) Primary Care
   B) Community Services

IV) Trauma Center Linkage
   A) Primary Care
   B) Community Services

IT Innovation: I) EMR Screening

II) Computerized Decision Support & Supervision

Improved Outcomes
1. Patient
2. Provider
3. Organization

Traumatic Event: Inpatient Surgical Hospitalization Outpatient Surgical Clinics Primary Care/Community Services
## Core Intervention Elements Targeting MCC After Injury

<table>
<thead>
<tr>
<th>Essential Element</th>
<th>Which of multiple (≥ 3) MCC Targeted</th>
<th>MCC strategic framework goals addressed*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population-based EMR PTSD &amp; comorbidity risk prediction</td>
<td>PTSD, depression, alcohol &amp; drug use problems, pain and somatic symptoms, &amp; chronic medical conditions after acute injury</td>
<td>Goal 1 Objective D, Implement and efficiently use health information technology; Automated screening efficiently identifies constellation of PTSD and comorbidity in injured populations</td>
</tr>
<tr>
<td>Care management with trauma center to primary care linkage</td>
<td>Coordination of acute injury mental health and pre-existing chronic medical condition care</td>
<td>Goal 2 Facilitate use of community based services and self-care management</td>
</tr>
<tr>
<td>Early post-injury medication history, reconciliation, and care coordination</td>
<td>PTSD, depression, pain, somatic symptom amplification &amp; TBI symptoms prevention, Chronic medical condition (e.g. HTN, CAD, Diabetes) reconciliation and coordination</td>
<td>Goal 1 Objective E Prevent occurrence of new chronic conditions and mitigate the consequences of existing conditions &amp; Goal 2 Objective C, Provide tools for medication management</td>
</tr>
<tr>
<td>Evidence-based MI embedded within care management</td>
<td>Targets alcohol and drug use problems and enhanced patient engagement</td>
<td>Goal 1 Objective E Prevent occurrence of new chronic conditions and mitigate the consequences of existing conditions</td>
</tr>
<tr>
<td>Evidence-based CBT embedded within care management</td>
<td>Targets PTSD, depression, pain, somatic symptom amplification and TBI sequelae. Also targets enhanced patient self-efficacy</td>
<td>Goal 1 Objective E Prevent occurrence of new chronic conditions and mitigate the consequences of existing conditions, &amp; Goal 2 Objective A Facilitate self-care management</td>
</tr>
<tr>
<td>Patient and caregiver-centered posttraumatic concern elicitation and improvement</td>
<td>Patient-centered concerns elicitation and improvement targets patient and family engagement in care of full MCC constellation</td>
<td>Goal 2 Optimize self-care management and coordinated use of services by patient and caregivers</td>
</tr>
<tr>
<td>Caseload supervision &amp; stepped measurement-based care implementation</td>
<td>PTSD, depression &amp; associated suicidal ideation, alcohol &amp; drug use problems, chronic medical conditions &amp; acute physical injury</td>
<td>Goal 3 Provide better information and education on treatment of MCCs to health-care workers</td>
</tr>
</tbody>
</table>

*All study elements address MCC Goal 4 Enhancing Research Knowledge on MCCs
Integration of Pragmatic Trial, Robust Implementation and Policy Conceptual Frameworks for US Trauma Care Systems

Figure 3. Integration of Large-Scale Pragmatic Trials, Robust Implementation, & Policy Relevance Conceptual Frameworks for Trauma Care Systems

Core Elements of Evidence-Based Program Targeting PTSD & Comorbidity After Injury
1) Population-based screening
2) Care management
   a) Posttraumatic concerns
   b) CBT & MI elements
3) Medication consultation targets PTSD & medical comorbidity
4) Trauma center to primary care and community linkage

Policy Relevant Large Scale Randomized Multisite Pragmatic Trial Targeting PTSD & Comorbidity

Interdisciplinary Research Team Working Synergistically With NIH HCS Research Collaboratory
1) Assessment of IT and methods guidance
2) Comprehensive application of RE-AIM framework
3) Dissemination & implementation costing, organizational behavior, & mixed methods

Fit

American College of Surgeons Policy Mandates and Practice Guidelines for US Trauma Care Systems
1) Population of US Level I trauma centers
2) 20 trauma centers optimally engaged in trial
3) Potential for policy targeting integration of IT capacity & procedures for screening and intervention for PTSD & comorbidity nationally

Derived from Glasgow and Chambers CTS 2012
UH2-UH3 Transition Milestones

1. Establish collaborative relationships and a scientific exchange: 7-2014
2. Implementation of Collaboratory approved policies and practices: 7-2014
3. Obtain IRB Approval: 10-2014
4. Finalized outcome assessments: 11-2014
5. Finalize incentives for participation with the American College of Surgeons: 12-2014
   - Research participation
   - Alcohol screening & brief intervention waiver
UH2-UH3 Transition Milestones

- 6. Develop detailed UH3 budget: 3-2015
- 7. Final revised 24 site statistical plan: 4-2015
- 8. Obtain final commitment from 24 sites: 5-2015
- 9. Decision support tool able to be used at 24 sites: 6-2015
- 10. UH2 Pilot
  - IRB approvals by 1-2015
  - Subject recruitment begins 2-2015
  - Recruitment ends 5-2015
  - Pilot complete 6-2015
# UH2 Milestone Timeline

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<td>2. Collaboratory policy acceptance</td>
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<td>3. Centralized IRB approval</td>
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<td>4. Finalized outcome assessments</td>
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<td>5. Surgical College incentives final</td>
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<td>6. UH3 budget developed</td>
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<td>9. Decision support tool deployed</td>
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<td>10. Pilot at 2 non-UH3 sites</td>
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<td>B. Recruitment begins</td>
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<td>D. Pilot complete</td>
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</table>
UH2-UH3 Milestones Progress: Site Recruitment

- Broad criteria
- Approach derived from DO-SBIS
- Inclusion: 3 Champions
  - Trauma surgery
  - PTSD recruitment/intervention
  - Information technology
- Exclusion: Well developed PTSD screening/intervention capacity
UH2-UH3 Milestones Progress: Site Recruitment

- 2 UH2 pilot sites identified and feasibility discussions have begun
- 24 UH3 sites required
  - 14 sites meet criteria & progressing
  - 12 sites in-depth discussions
- Ongoing contact nationally
Potential Barriers: IRB Approvals

• Centralized versus local IRB
• Tradeoffs: Centralized – potential loss of excellent sites
• Tradeoffs: Local – delays with modifications
• Brainstorming feasible solutions
Potential Barriers: Site Payments

- Direct payment to trauma service
- Subcontract (more lengthy process)
Potential Barriers: Scale Consensus

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<tr>
<th>Study Measure</th>
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<td>ICD TBI severity</td>
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<td>ICD Chronic Medical Conditions</td>
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<td>EMR &amp; Self-reported demographics</td>
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<td>Consciousness/Glasgow Coma Scale</td>
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<td>PTSD (PTSD Checklist DSM-IV &amp; DSM-5)</td>
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<td>Depression (PHQ-9)</td>
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<td>Postconcussive/Somatic Sympt. (NSCOT)</td>
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<td>Reactions to Research Participation (RRPQ)</td>
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<td>EMR/Trauma Registry Utilization Data</td>
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</table>

Ongoing - Automated Data
Potential Barriers: Power, Sample Size & Other Statistical Issues

• Spring 2014 discussions with D. Murray
  - Power considerations increases site N from 20 to 24
  - P. Heagerty joins team oversees UH2-UH3 transition statistical planning
Thank You!
We look forward to ongoing brainstorming
Other Topics (as time permits)
Comprehensive Acute Care Medical IT Approach for PTSD & Comorbidity Targeting Real Time Work-flow Integration of Clinical Care

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

Van Eaton, Zatzick, Gallagher, Tarczy-Hornoch, Rivara, Flum, Peterson & Maier
Accepted for Publication Journal of the American College of Surgeons’
IT Milestones & Goals

• Decision support tool can be deployed to 24 sites (Mandatory)
• EMR PTSD evaluation options
  - Automated
  - Manual
The development of a population-based automated screening procedure for PTSD in acutely injured hospitalized trauma survivors

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ABSTRACT
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 utility were identified for PTSD. Next, relevant risk factors were assessed using logistic regression, sensitivity, specificity, predictive values and receiver operator characteristic (ROC) curve analyses.

Results: The 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 diagnosis, positive blood alcohol on admission, influenza use, female gender, non-White ethnicity, uninsured, public or veteran insurance status, 9-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 (0.67) and specificity (0.86).

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.

Published by Elsevier Inc.
Computerized Decision Support for PTSD & Comorbidity
(Derived from “CORES” Van Eaton et al 2005)
IT Architecture

Trauma Survivors Outcomes and Support Study (TSOS)

Technical Architecture Diagram

University of Washington School of Medicine

Site 1: Harborview Medical Center

Site 2: Other Site

External Site 24

Study Team

Patient List

Study Team

Patient List

Study Team

Patient List

Patient Data

Clinical Communication

Patient Data

Clinical Communication

Internet Information Services (IIS)

ASCM User Authentication

TSOS Website

PROD

DEV

TEST

STAGE

=200MB

=100MB

=100MB

=100MB

DB

DB

DB

DB

VM

VM

VM

VM

Study Supervisor

Clinical Applications

Amaliza

its-am-data DB

Patient List

Amaliza Affiliated Developer

VM

SQL
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 diffusion, construction, making sense
- Negotiation, knowledge dissemination, re-transfer, cascading, engineering

Figure 2. Different Conceptual and Theoretical Bases for the Spread of Innovation in Service Organizations
# Implementation Science/RE-AIM Outcome Framework

<table>
<thead>
<tr>
<th>UH2-UH3 Phase</th>
<th>Patient, Provider or Site Assessment</th>
<th>N</th>
<th>How Assessed</th>
<th>Measures/Assessment</th>
<th>RE-AIM Domain/Level</th>
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<tbody>
<tr>
<td>UH2</td>
<td>Site Recruitment</td>
<td>20</td>
<td>CONSORT</td>
<td>Characteristics of 20 sites versus all other US sites</td>
<td>Reach Site</td>
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<td>UH2</td>
<td>Trauma Surgeon Provider</td>
<td>20-40</td>
<td>Phone</td>
<td>Middle adopter status interview assessment</td>
<td>Adoption Site/Provider</td>
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<td>UH2</td>
<td>Care Manager Champion</td>
<td>20-40</td>
<td>Phone</td>
<td>Middle status interview assessment</td>
<td>Adoption Site/Provider</td>
</tr>
<tr>
<td>UH2</td>
<td>Medication Champion</td>
<td>20-40</td>
<td>Phone</td>
<td>Middle adopter status interview assessment</td>
<td>Adoption Site/Provider</td>
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<tr>
<td>UH2</td>
<td>IT Expertise</td>
<td>20-40</td>
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<tr>
<td>UH2-UH3</td>
<td>Trauma Center Providers</td>
<td>10*20</td>
<td>Web</td>
<td>Organizational change, culture, &amp; climate surveys</td>
<td>Implementation Provider</td>
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<tr>
<td>UH3</td>
<td>Intervention Champion</td>
<td>20</td>
<td>Web</td>
<td>Weekly recruitment log activity</td>
<td>Implement. Provider/Site</td>
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<td>UH3</td>
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<td>Provid. logs</td>
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<td>PTSD, &amp; comorbidity, gender &amp; ethnicity subgroups</td>
<td>Effectiveness, Patient</td>
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<td>EMR, trauma registry self-report, cost &amp; work, logs</td>
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<td>≥ 6 months follow-up after intervention complete</td>
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<td>Semi-structured key informant interviews</td>
<td>Implement/Maintenance</td>
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<td>Questionnaire</td>
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American College of Surgeons Partnership: Orchestration of Pragmatic Trials & Policy

Single-site Alcohol RCTs and Harborview Implementation → ACS Policy Summit → ACS Policy Mandate for Alcohol → NIH Funding → Multisite Alcohol RCT & Nationwide Implementation
“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
Orchestration of Pragmatic Trials & ACS Policy: PTSD

Single-Site Pragmatic Trials and Harborview Implementation

ACS Policy Summit

ACS Clinical Best Practice Guideline for PTSD

TIME

2001

2011
PTSD screening & intervention best practice guideline recommendation
Disseminating Organizational Screening & Brief Interventions (DO-SBIS)

Evidence-based Interventions for Alcohol Problems in Trauma Centers
DO-SBIS RCT

- 20 Middle Majority sites randomized
- 10 sites receive organizational intervention and SBI training
- 10 Control sites
- 878 patients
- 76% 6 month follow-up
- 72% 12 month follow-up
DO-SBIS Multisite RCT

204 Level I Trauma Centers
Readiness Assessment

138 Middle Majority Centers
In-Depth Provider Readiness Assessment

Select 20 Middle Majority

Randomize

10 Intervention Trauma Centers

10 Control Trauma Centers

Exclude 66 Laggards, Innovators

Exclude 118 Middle Majority
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<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>
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