The Trauma Survivors Outcomes & Support (TSOS) Study: Data Sharing Considerations

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Data Sharing MCC UH3

• What is your current data sharing plan and do you foresee any obstacles?
• What information did the IRB require about how the data would be shared beyond the study in order to waive informed consent?
• How will you put the policy from the data sharing work group into practice in your study?
• What data you are planning to share from your project (individual-level data, group-level data, specific variables/outcomes, etc.)?
NIH Health Care Systems Research Collaboratory Data Sharing Considerations

• Maximize public health impact of NIH investment in demonstration projects
• Accelerate pace of learning in participating healthcare systems
• Increasing participation in research and learning by wide range of stakeholders
TSOS UH2-UH3 Data Sharing

• Goal to produce and disseminate information and resources that will facilitate the widespread implementation of screening and intervention procedures for PTSD and related comorbidity
• Share treatment manuals, reports/white papers, and data informing clinical/policy guidelines
• Intended to be widely disseminated throughout trauma centers and affiliated trauma care systems nationwide.
Collective Health Care System Knowledge Generation, Data Sharing, and Policy Guidelines Targeting PTSD & Comorbidity

- Knowledge generated by central TSOS study team in collaboration with 24 trauma center teams
- Knowledge generated feeds back to inform national trauma care system policy – all teams impacted
- Knowledge generation, data sharing and policy outcome hinges upon American College of Surgeons’ stakeholder partnership
American College of Surgeons’ Committee on Trauma

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

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

NIH Collaboratory
Rethinking Clinical Trials®
Health Care Systems Research Collaboratory
Data Sharing & American College of Surgeons’ Stakeholder Partnership

- 10 year science to trauma care system policy and practice partnership
- Study results directly inform trauma care system mandates and clinical practice guidelines
- Study team has ongoing advising role with College
Psychiatry, Psychology, and Posttraumatic Stress Disorder Intervention

The disciplines of psychology and psychiatry are important to the trauma center’s acute care and rehabilitation teams. Epidemiologic investigation at U.S. trauma centers demonstrates that approximately 20–40 percent of injured trauma survivors experience high levels of posttraumatic stress disorder (PTSD) and/or depressive symptoms during the year following injury. A series of investigations now demonstrate a strong relationship between the symptoms of PTSD, depression, and functional impairments after injury. In a nationwide U.S. study, PTSD and depression made an independent dose-related contribution to the inability to return to work within 12 months after injury hospitalization for 67 percent of individuals with one of the disorders and 78 percent of individuals with both disorders. Untreated PTSD and depression are also associated with increased health care and societal costs.

Early screening and referral for psychotherapy and pharmacologic treatment of PTSD and related co-morbid depression following injury have the potential to improve symptomatic and functional outcomes. 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.

**Supplemental Readings**


UH3 Data Sharing

- Final data set that includes patient, provider, and site level data shared
- Patients, sites, and providers identified only by study IDs
Privacy Considerations

• Patient level stigmatizing diagnoses
• Stigma and quality of care are issues for providers and sites
TSOS Data Sharing

- Study team accepts requests for data on case-by-case basis
- Requests in concert with study ACS/COT policy aims prioritized
- IRB approval required
TSOS Data Sharing Contextual Considerations

• Data requests current being taken from UH3 site investigators for prior pragmatic trial data
• American College of Surgeons’ requests for information on trauma center critical incident exposures and provider stress response symptoms
• Stepped wedge design sets up sites to be making queries about site specific study outcomes months before final composite data published