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

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NIH Collaboratory *Rethinking Clinical Trials®*
Health Care Systems Research Collaboratory

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

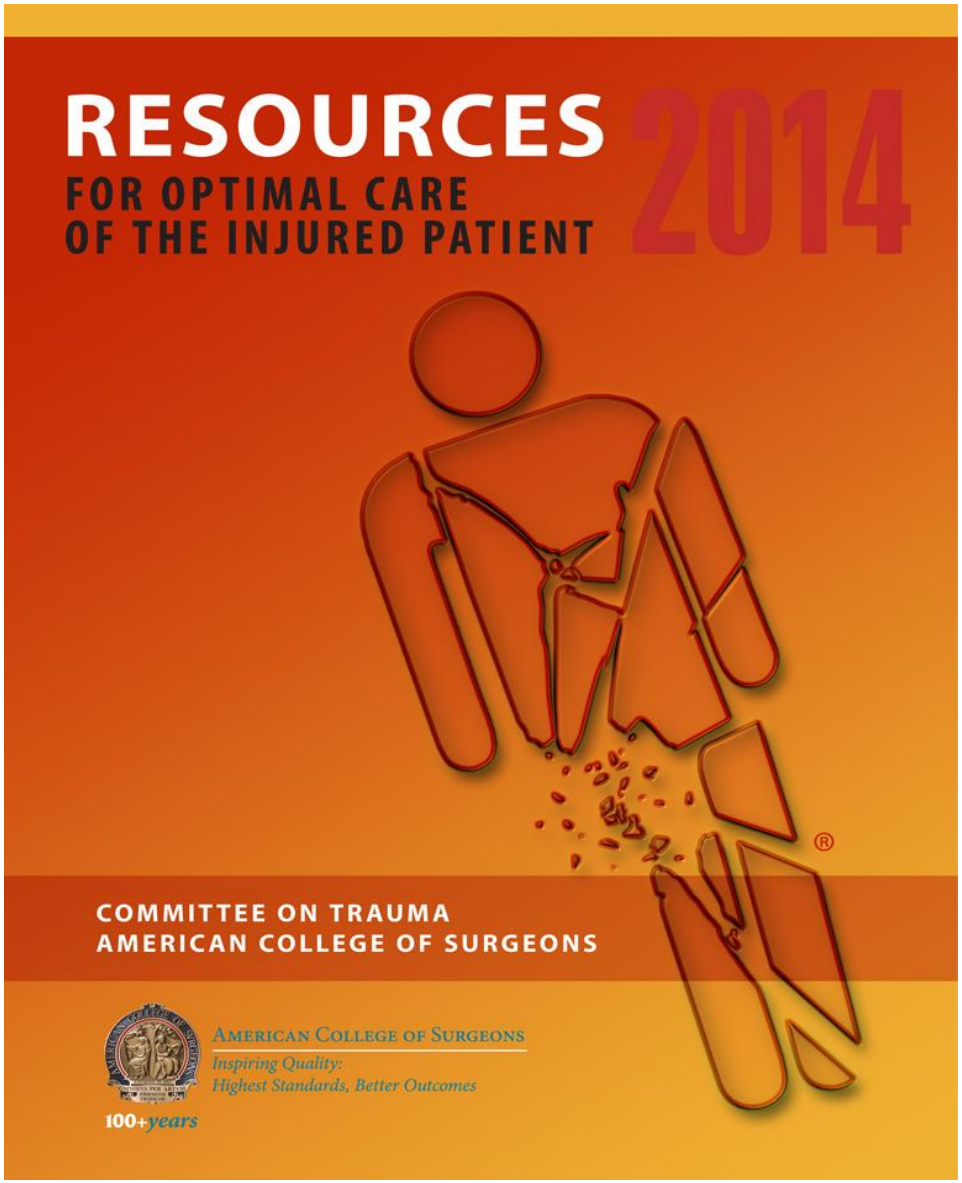
- Maximize public health impact of NIH investment in demonstration projects
- Accelerate pace of learning in participating healthcare systems
- Increasing participation in research and learning by wide range of stakeholders

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



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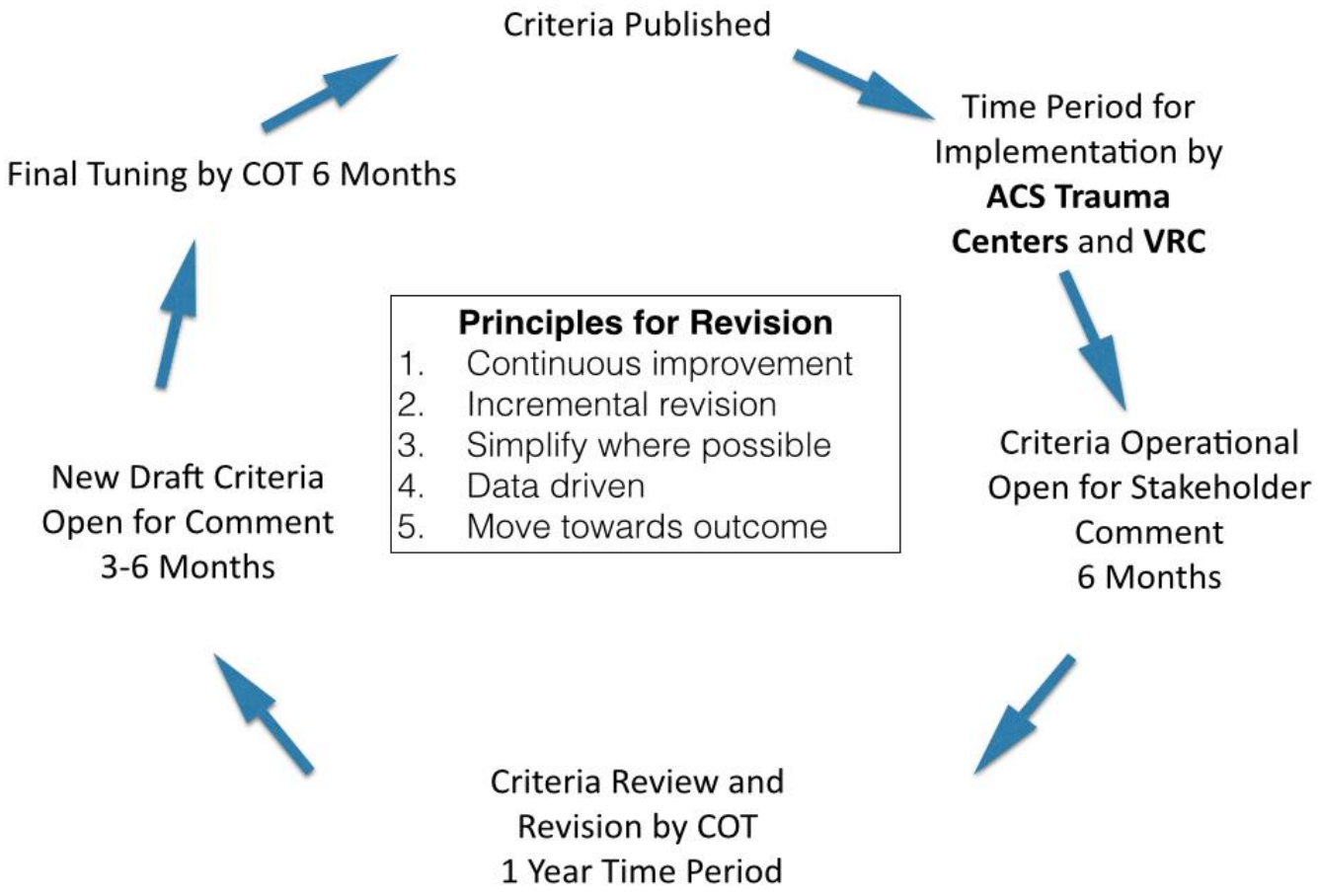
American College of Surgeons' Committee on Trauma

- 1976 1st Book
- 2006 "Green Book"
- 2014 "Orange Book"

American College of Surgeons' Resources Guide Revision Process



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

Resources Guide 2014 Chapter 12: PTSD & Co-morbidity

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.

Resource Guide Data Sharing End Product: An Evidence-base Supporting PTSD & Comorbidity Policy Recommendations

Supplemental Readings

Ehrlich PF, Brown JK, Drongowski R. Characterization of the drug-positive adolescent trauma population: should we, do we, and does it make a difference if we test? *J Pediatr Surg*. 2006;41(5):927-930.

Findley JK, Sanders KB, Groves JE. The role of psychiatry in the management of acute trauma surgery patients. *Prim Care Companion J Clin Psychiatry*. 2003;5(5):195-200.

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Mangram AJ, Shifflette VK, Mitchell CD, et al. The creation of a geriatric trauma unit "G-60." *Am Surg*. 2011;77(9):1144-1146.

Roberts JC, deRoon-Cassini TA, Brasel KJ. Posttraumatic stress disorder: a primer for trauma surgeons. *J Trauma*. 2010;69(1):231-237.

Shih RA, Schell TL, Hambarsoomian K, Belzberg H, Marshall GN. Prevalence of posttraumatic stress disorder and major depression after trauma center hospitalization. *J Trauma*. 2010;69(6):1560-1566.

Warren AM, Stucky K, Sherman JJ. Rehabilitation psychology's role in the Level I trauma center. *J Trauma Acute Care Surg*. 2013;74(5):1357-1362.

Zatzick D, Jurkovich G, Fan MY, et al. The association between posttraumatic stress and depressive symptoms, and functional outcomes in adolescents followed longitudinally after injury hospitalization. *Arch Pediatr Adolesc Med*. 2008;162(7):642-648.

Zatzick D, Jurkovich G, Rivara F, et al. A national US study of posttraumatic stress disorder, depression, and work and functional outcomes after injury hospitalization. *Ann Surg*. 2008;248(3):429-437.

Zatzick D, Roy-Byrne P, Russo J, et al. A randomized effectiveness trial of stepped collaborative care for acutely injured trauma survivors. *Arch Gen Psychiatry*. 2004;61(5):498-506.

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