

Form "EAST Multicenter Study Proposal"

Details #10 (submitted 02/01/2023)

Please indicate if this is a...

New MCT proposal submission

If a revised proposal summarize the changes made to this proposal based on the feedback received:

Study Title

Mixed-Methods Analysis of Care Variation in Severe Traumatic Brain Injury

Primary Investigator:

Shayan Rakhit, MD

Institution that will be the primary site for the study:

Vanderbilt University Medical Center

Email of Primary Investigator:

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Co-PI/second point of contact for the study:

Mayur B. Patel, MD, MPH; Amelia W. Maiga, MD, MPH

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Are you a current member of EAST?

Yes

If you selected "No" above please identify a Sponsor that is an active EAST member:

Surgical and critical care decision making in severe traumatic brain injury (TBI) remains challenging due to a relative lack of high-quality evidence to guide management, despite the existence of well-known guidelines.

Use this area to briefly outline the burden of the problem to be examined.

In this context, significant variation exists in the care of severe TBI. Understanding reasons for this variation is an unmet scientific need. Reasons could include the lack of high-quality evidence, lack of specificity in existing guidelines, local resources, institutional culture, or other, yet unknown factors.

Briefly review what major published studies exist on the topic of the proposed project.

In 2002, Bulger et al examined variation in care, adherence to Brain Trauma Foundation guidelines, and outcomes (functional outcomes and mortality) across 34 academic trauma centers in the U.S., finding that a) considerable variation of care exists between centers and b) “aggressive” management resulted in lower mortality and no difference in functional outcomes. A 2011 meta-analysis by Lingsma et al also demonstrated substantial differences in outcomes between centers for patients enrolled in 10 randomized-controlled trials and 3 observational studies. Finally, van Essen et al conducted a survey investigating neurosurgical decision making in severe TBI of providers at 68 centers in Europe participating in the CENTER-TBI study in 2019, showing significant self-reported practice variation across centers. However, these studies were not able to rigorously examine the reasons for this care variation, even if care variation was related to variation in outcomes.

Use this area to briefly outline how this idea is innovative and it's anticipated impact.

Elucidating the causes of severe TBI care variation is a methodological challenge when approached with traditional quantitative health outcomes research methods due to the difficulty in measuring the factors associated with variation. However, qualitative methods allow investigators to gather open-ended data that, in combination with quantitative methods, could provide a rigorous platform to discover these causes.

Describe what & how the proposed MCT will add to the existing body of knowledge & literature.

We propose combining quantitative data (center level data and provider survey responses) and qualitative data (provider qualitative interviews) to conduct a mixed-methods analysis to improve our understanding of variations in care of severe TBI across the United States. To our knowledge, this would be the first study to utilize this methodology to understand care variation as well as significantly improving our understanding of both what and why variation in severe TBI exists.

Primary aim

Primary Aim: Qualitatively describe provider attitudes towards medical and surgical decision making in severe TBI at participating trauma centers.

Secondary Aim: Quantitatively

Secondary aims

a) survey trauma surgeon, neurosurgeon, and intensivist views at each center to learn what factors drive their decision making in severe TBI, including views on existing guidelines, local resources, and institutional culture

b) describe center level patient characteristics and outcomes, including severity of TBI, critical care and surgical intervention, palliative care provision, and mortality and neurologic outcomes.

Tertiary aim

Design

Retrospective

Primary aim and Secondary aim (a): trauma surgeons, neurosurgeons, and neurointensivists participating in care of severe TBI at level I trauma centers in the United States

Inclusion Criteria

Secondary aim (b): patients 18 years and older presenting with severe TBI, GCS less than or equal to 8

Exclusion Criteria

Patients who are pregnant and who are prisoners

This is a retrospective, mixed-methods, multi-center study.

Qualitative:

The PI research group will conduct in-depth interviews of a purposeful sample of providers of severe TBI care from each participating center.

Quantitative:

Providers at each participating center will complete a survey, disseminated by site PIs. Each participating center will provide deidentified Trauma Quality Improvement Program (TQIP)-based center level data, collected by site PIs in conjunction with trauma program managers.

Please describe, completely but succinctly, how the project will be conducted.

Conduct of Study:

1) Qualitative interviews will be administered by PI research group via an electronic video meeting platform to a purposeful sample that will be identified in discussion with site PIs (sample may also include site PIs)

2)

a. Quantitative surveys will be administered and captured in a secure electronic database, disseminated by site PIs to all providers meeting inclusion criteria

b. Quantitative center-level deidentified data will be provided by querying TQIP and the medical record, in conjunction with site PIs, site Trauma Program Manager, and site trauma registrars and captured in a secure electronic database.

Primary Outcome

Primary aim: Provider in-depth interviews

Secondary aim (a): Provider survey answers

Secondary Outcome(s)

Secondary aim (b): Center-level TQIP variables (percentage for binary variables, mean for quantitative variables):

Select the variables to be collected & analyzed:

Baseline Participating Institution Information, Demographics, Baseline Clinical Characteristics, Hospital Course, Treatments & Interventions, Outcomes of Interest, Additional variables noted below:

Additional variables:

All available in TQIP: initial ED/hospital GCS; highest GCS; midline shift; anticoagulant therapy; bleeding disorder; cerebral monitor; decompressive craniectomy; age; race; ethnicity; sex; ICD-10 external cause code; Injury Severity Score; co-morbidities; blood product administration; hemorrhage control surgery; angiography for hemorrhage control; cardiac arrest; cerebrovascular accident

Primary aim: recorded video (Zoom) interview with transcript

Outline the data collection plan/tool succinctly

Secondary aim:

a. Individual provider survey into electronic data capture form

b. Center-level TQIP data into electronic data capture form

Has IRB approval been obtained at the primary site?

No

Is DUA required for participation in the study?

Yes

If applicable, list the primary contact (name/email) to contact to initiate & execute DUA:

Heather White (heather.white@vumc.org)

Identify the individuals that will primarily be responsible for data collection process:

PI, fellows, residents, medical students

Is there a primary statistician assigned to assist the PI w/design & data analysis?

Yes

If no, how was study design/power analysis determined/who will handle analysis once complete?

Primary aim:

Qualitative inductive grounded-theory coding with two coders to at least 85% agreement; initial coding with gerund and in vivo codes followed by focused coding to generate final categories; these then linked to general theory of factors impact provider decision making; using MAXQDA

Include detailed description of the data analysis plan:

Secondary aim:

a)For surveys: descriptive statistics of Likert responses, with variable clustering using Spearman's correlation except for variables in which all responses were unanimous; using R

b)For center-level data: descriptive statistics of center-level data, with means (continuous) and percentages (categorical); further analysis not required as this data is for framing survey and qualitative data; using R

Include Power Analysis: Not applicable

For providers: IRB approval will be obtained. All providers meeting inclusion criteria at a participating sites will be approached, provide informed consent, and complete the survey. In conjunction with site PIs, a purposeful sample of providers who have completed the survey will be approached, provide additional informed consent, and participate in an in-depth interview.

Please note what your enrollment procedure for this study entails:

For center-level data: Enrollment procedure is not applicable as data comes from TQIP. IRB exempt or expedited review as patient data already deidentified and aggregated in already existing quality improvement database (TQIP)

Outline consent procedures here, if applicable:

Providers will provide informed consent for both surveys and in-depth interviews

Please indicate what resources are available at the primary study institution:

Presence of a dedicated statistician, Research personnel ,Availability of data collectors

1. Alali AS, Fowler RA, Mainprize TG, Scales DC, Kiss A, de Mestral C, et al. Intracranial pressure monitoring in severe traumatic brain injury: results from the American College of Surgeons Trauma Quality Improvement Program. *J Neurotrauma*. 2013;30(20):1737-46. doi: 10.1089/neu.2012.2802

2. Biersteker HA, Andriessen TM, Horn J, Franschman G, van der Naalt J, Hoedemaekers CW, et al. Factors influencing intracranial pressure monitoring guideline compliance and outcome after severe traumatic brain injury. *Crit Care Med*. 2012;40(6):1914-22. doi: 10.1097/CCM.0b013e3182474bde

3. Bulger EM, Nathens AB, Rivara FP, Moore M, MacKenzie EJ, Jurkovich GJ. Management of severe head injury: institutional variations in care and effect on outcome. *Crit Care Med*. 2002;30(8):1870-6. doi: 10.1097/00003246-200208000-00033

4. Clifton GL, Choi SC, Miller ER, Levin HS, Smith KR, Jr., Muizelaar JP, et al. Intercenter variance in clinical trials of head trauma--experience of the National Acute Brain Injury Study: Hypothermia. *J Neurosurg*. 2001;95(5):751-5. doi: 10.3171/jns.2001.95.5.0751

**Include a brief listing of
key references:**

5. Curry LA, Krumholz HM, O'Cathain A, Plano Clark VL, Cherlin E, Bradley EH. Mixed methods in biomedical and health services research. *Circ Cardiovasc Qual Outcomes*. 2013;6(1):119-23. doi: 10.1161/CIRCOUTCOMES.112.967885

6. Delaney LD, Thumma J, Howard R, Solano Q, Fry B, Dimick JB, et al. Surgeon Variation in the Application of Robotic Technique for Abdominal Hernia Repair: A Mixed-Methods Study. *Journal of Surgical Research*. 2022;279:52-61. doi: 10.1016/j.jss.2022.05.008

7. Holtrop JS, Potworowski G, Green LA, Feters M. Analysis of Novel Care Management Programs in Primary Care: An Example of Mixed Methods in Health Services Research. *Journal of Mixed Methods Research*. 2019;13(1):85-112. <https://doi.org/10.1177/15586898166686>

8. Koliass AG, Scotton WJ, Belli A, King AT, Brennan PM, Bulters DO, et al. Surgical management of acute subdural haematomas: current practice patterns in the United Kingdom and the Republic of Ireland. *Br J Neurosurg*. 2013;27(3):330-3. doi: 10.3109/02688697.2013.779365

9.Lingsma HF, Roozenbeek B, Li B, Lu J, Weir J, Butcher I, et al. Large between-center differences in outcome after moderate and severe traumatic brain injury in the international mission on prognosis and clinical trial design in traumatic brain injury (IMPACT) study. *Neurosurgery*. 2011;68(3):601-7; discussion 7-8. doi: 10.1227/NEU.0b013e318209333b

10.O'Cathain A, Knowles E, Turner J, Maheswaran R, Goodacre S, Hirst E, et al. Health Services and Delivery Research. Explaining variation in emergency admissions: a mixed-methods study of emergency and urgent care systems. Southampton (UK): NIHR Journals Library. DOI: 10.3310/hsdr02480

11.Rayan N, Barnes S, Fleming N, Kudyakov R, Ballard D, Gentilello LM, et al. Barriers to compliance with evidence-based care in trauma. *J Trauma Acute Care Surg*. 2012;72(3):585-92; discussion 92-3. doi: 10.1097/TA.0b013e318243da4d

12.Suwanabol PA, Reichstein AC, Suzer-Gurtekin ZT, Forman J, Silveira MJ, Mody L, et al. Surgeons' Perceived Barriers to Palliative and End-of-Life Care: A Mixed Methods Study of a Surgical Society. *J Palliat Med*. 2018;21(6):780-8. doi: 10.1089/jpm.2017.0470

13.van Essen TA, den Boogert HF, Crossen MC, de Ruyter GCW, Haitsma I, Polinder S, et al. Variation in neurosurgical management of traumatic brain injury: a survey in 68 centers participating in the CENTER-TBI study. *Acta Neurochir (Wien)*. 2019;161(3):435-49. doi: 10.1007/s00701-018-3761-z