**Study Title**: Trauma Institutional Priorities and Teams for Outcome Efficacy (TIPTOE)

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**Background and Rationale**

Trauma is the leading cause of death for individuals younger than age 45 and in 2017 was the third leading cause of death across all age groups in the U.S.13 The economic damage created through trauma amounted to $671 billion in the United States in 2013.1 Over the past several decades, multiple efforts, both national and international, have been undertaken to alleviate the burden of trauma, yet despite significant advances in clinical care, the number of deaths due to trauma continues to rise with a relative increase of 61% from 1980 to 2017.

In the U.S., the American College of Surgeons (ACS) has led multiple efforts to improve trauma care and patient outcomes. Beginning in 1987, The ACS started a verification system recommending a tiered system of trauma centers.14 Evaluating the results after trauma center participation has shown that hospitals participating in the trauma designation system have superior outcomes compared to non-trauma centers.15 When the ACS tiered system is examined in the context of patient outcomes, including mortality, we find a knowledge gap regarding to which extent organizational features impact clinical outcomes.

In the ACS tiered system, hospitals are designated with Levels 1-5, with the statement that “...clinical outcomes of severely injured patients are expected to be equivalent at Level 1 and 2 trauma centers....”14 It is expected that Level 1 and 2 trauma centers should have all of the necessary human resources (e.g. subspecialty physicians) and physical resources (physical plant and equipment) to care for the acutely injured patient.14 However, Level 1 trauma centers consistently demonstrate superior clinical outcomes compared to Level 2 trauma centers, suggesting that organizational features, such as the requirement for a surgeon- directed critical care service, at Level 1 organizations are leading to patient outcome differences since all the human resources (e.g. subspecialty physicians) are the same at Levels 1 and 2 trauma centers.16–20 These findings also align with previous literature supporting that institutional commitment, expressed through the organization of care, has an impact on outcomes of patients in intensive care units.5–7 However, the role of institutional commitment in trauma is currently under-researched, which amounts to an additional knowledge gap regarding the role institutional commitment plays with respect to trauma patient outcomes. Moreover, we do not know which organizational features of trauma care programs are indicative of institutional commitment.

With the 2014 edition of *Resources for the Optimal Care of the Injured Patient*, trauma centers are now required to participate in an improvement process that uses patient outcomes and quality of care as a benchmark.14 This requirement has been in the works since 2008 when the ACS established the Trauma Quality Improvement Program (TQIP) to build a process for trauma centers to measure and compare their risk-adjusted patient outcomes. TQIP is the most commonly used national benchmark and contains data for over 825 trauma centers.21 TQIP uses a mixed-models approach to risk adjustment, accounting for case-mix differences in demographics, medical comorbidities, and injury characteristics.22 TQIP does not provide risk adjustment at the Level of the trauma center but includes all Level 1 and 2 centers in a single category.22 Thus it is impossible to link specific organizational features to particular patient outcomes.

Previous studies have demonstrated significant variability in patient outcomes among Level 1 and 2 trauma centers.2–4,23 Additionally, depending on the type of injury examined there are outcome differences based on gender at these trauma centers.24,25 Yet, ACS Level 1 and 2 trauma centers all have organizational features that meet the minimum standard for accreditation.23 Further, beyond the standards themselves, how the particular attributes of trauma centers, and, on a larger scale, of regional trauma systems, contribute to optimal patient outcomes have not yet been identified or measured.26,27 Further support to the hypothesis that organizational features play an essential role in creating and maintaining the best patient outcomes in trauma care comes from results achieved by the Joint Trauma System of the U.S. Military. It has consistently demonstrated improved survival for those most severely injured and, as a single system, evaluates organizational features at the site of care delivery to optimize resources across the system while in the civilian population, trauma survival is decreasing.28

To further validate these assumptions, we conducted a study using the National Inpatient Sample, a Healthcare Utilization Project Database.29 We selected all patients with a traumatic injury and a long bone fracture to purposefully create a patient cohort that would have had multiple care teams (trauma, orthopedics, and anesthesia). We looked at the TQIP complication Acute Kidney Injury (AKI), and in this study of 68,540 patients we found that the incidence of AKI was 11.9%. Using logistic regression, the variables significantly associated with this outcome included the teaching status and profit status of the hospital. **Specifically, non- academic facilities and those facilities for profit had a higher risk of AKI.** The academic status of a facility is the main driver between Level 1 and Level 2 trauma centers.

**Hypothesis** *and/or* **Specific Aims***or* **Objectives**

**Hypothesis**

This leads to our **global hypothesis that the variability of organizational features in Level 1 and 2 trauma centers is a significant factor in the variability of patient outcomes across those trauma centers.** At this time, the correlation between organizational features and patient outcomes is not yet defined.2–4 This project aims to address two critical knowledge gaps a) a lack of understanding of how organizational features influence patient outcomes within Level 1 and 2 trauma centers and b) a lack of understanding of which organizational features of trauma systems are indicators of institutional commitment. In addition, we aim to provide actionable information to leadership, decision-makers, and stakeholders of Level 1 and 2 trauma centers, motivating changes of organizational characteristics that show empirical potential to impact patient outcomes positively.

**Primary objective**

**To determine the impact of organizational features of Level 1 trauma centers on patient outcomes.** We will use the CAFE questionnaire to collect data about organizational features (such as clinical, administrative, and operational resources) for the trauma programs of 230 Level 1 and Level 2 Trauma Centers. In addition, we will collect data from the Trauma Quality Improvement Program (TQIP) of all participating centers. All our data will be collected in the new TIPTOE database, re-using the architectural approach of the CAFÉ project, which allows us to employ Artificial Intelligence techniques to infer new knowledge. **To support our global hypothesis, we will use these data to test which organizational features are associated with patient outcomes, specifically patient mortality, length of stay, and major complications.**

**Secondary objectives**

**To assess which organizational features of trauma centers are indicative of institutional commitment**

We will use the data collected through the CAFÉ questionnaire to define which of the organizational features are indicative of institutional commitment using Latent Class analysis, allowing us to **represent the dependencies between organizational features and institutional commitment.** We will add this information to the TIPTOE database. This will allow automatic inferences on patterns of institutional commitment to represent, group and analyze factors indicative of institutional commitment using data collected during CAFE and the present project. This provides an additional source of knowledge guiding trauma center planning and decision-making.

**Study Design and Procedures (sometimes called “Methods”)**

This is a multi-center, prospective, observational, study of organizational features and trauma outcomes.

**Timeline**

This is a 16-week study with 3 phases: a 4-week start-up phase that includes limited up front configuration of the system to the local trauma system environment (e.g., inclusion of trauma team personnel, inclusion of trauma activation criteria, review of clinical practice guidelines, VPN configuration), and training; a 2-week run in phase; 8 weeks of data collection; and a 2-week analysis and reporting phase. Participating trauma centers will enter the data collection phase on a rolling basis, after the completion of the components of the preparation phase.

**Study Population**

We plan to open recruitment to all 190 Level 1 trauma centers and 263 Level 2 trauma centers. Based on our survey of Level 1 trauma centers, 87.2% of respondents agreed that participation in the proposed project would be desirable. However, using a conservative estimate, we expect that approximately 60% of level 1 centers and 40% of level 2 centers will participate in the current study. Therefore, the total number of centers we expect to enroll is approximately 230 levels 1 and 2 combined.

Inclusion Criteria

* Age >/= 18
* Meets criteria to be in the trauma registry

Exclusion Criteria

* Age < 18

**Risks and Benefits**

A risk to study participants is the potential for loss of confidentiality of study data.

Measures to protect the confidentiality of study data will be implemented as described in the Data Handling and Recordkeeping section below.

There will be no direct benefits to the study participants; however, knowledge gained from the study could potentially benefit patients in the future. The PI will review data periodically and ensure that the risk/benefit ratio remains as expected throughout the study.

**Data Handling and Recordkeeping**

The Principal Investigator will carefully monitor study procedures to protect the safety of research subjects, the quality of the data and the integrity of the study. Data collected from the web portal will be stored on a secure server located within the United States. The research team will maintain an up-to-date list of authorized individuals who have access to the data. All data will be de-identified by removing any protected health information (see data sheet for full list of variables). A unique study identifier will be assigned to each participant to link their organizational and study data. The study team will use a secure, password-protected online data management system to enter, store, and manage the de-identified data that is HIPAA compliant. The web portal will be secured by HTTPS (HyperText Transfer Protocol Secure) encryption to ensure data security during transmission.

**TQIP data pull:** All ACS verified trauma centers are required to maintain a registry of all admitted trauma patients.14 This registry uses the National Trauma Data Standard for every variable. Most of these institutions participate in TQIP, which requires quarterly data submission. The data is submitted as an XML file, To facilitate compliance with the study, we will time our questionnaires with two of the quarterly submissions and collect synchronous data. As the TQIP participants are already preparing the data submission, we do not anticipate additional work for the centers submitting their data to the project. The trauma centers will submit to TQIP as normal and as part of that submission, TQIP validates every XML file for compliance. Once a file is deemed compliant, we will ask the participating trauma center to submit the same file through our web interface. This will ensure data consistency and minimize the burden on the trauma center.

We will use a website to collect data about organizational parameters of the participating trauma centers. The original CAFE trauma center questionnaire has a total of 109 parameters that are assessed. To minimize the workload for participants, we have restricted the number of CAFE questions to be imported to the TIPTOE questionnaire to 40 parameters. Each participating Level 1 trauma and level 2 trauma center will complete the questionnaire every 6 months for the duration of the project.

Data Retention:

The de-identified data collected from the web portal will be retained for a minimum of five years after the completion of the study. At the end of the retention period, the data will be destroyed in a manner that ensures the data cannot be reconstructed or accessed. The study team will ensure that the destruction of data complies with applicable regulations and institutional policies. The study team will document the destruction of data, including the date and method of destruction.

**Multisite Research**

This is a multisite observational study. The data collected from each site will be uploaded to a secure server, where it will be converted to a usable data format, analyzed for adherence to study protocol as submitted to the UAMS IRB.

**Data Analysis**

*Descriptive statistics.* We will calculate means and percentages for the trauma center outcomes, TIPTOE parameters, mechanism of injury (blunt vs. penetrating), severe brain injury, and geriatric admissions. Primary Analysis. The primary goal is to examine the relationships between the 40 TIPTOE parameters with trauma patient outcomes and identify the most influential predictors. More specifically, we will fit appropriate multivariable regression models to examine the relative impacts of these parameters on the trauma center patient outcomes. Initially, the analyses will be performed on the aggregate data from each trauma center. Given that the TIPTOE questionnaire will be completed every 6-months for the duration of the study, we will use separate linear mixed model for longitudinal data to allow for time- varying covariates to examine both the within-center and between-center effects. We will examine the relative importance of these variables based on the traditional inspection of standardized regression coefficients. Given that we are taking a conservative approach well-described in the literature, we will perform dominance analysis to determine the relative importance of the predictors. Dominance analysis examines the change in R2 resulting from the addition of a predictor to all possible subset regression models.

**Ethical Considerations**

This study will be conducted in accordance with all applicable government regulations and University of Arkansas for Medical Sciences research policies and procedures.  This protocol and any amendments will be submitted and approved by the IRB as required.

A waiver of the informed consent process is requested as this research involves no more than minimal risk to the subjects; a waiver will not adversely affect the rights and welfare of the subjects; and the research could not practicably be carried out without the waiver. The study involves protected health information (PHI) as described in this protocol. Plans to protect identifiers and to destroy identifiers as soon as practicable are described in the Data Handling and Recordkeeping section. The research cannot practicably be carried out without the HIPAA authorization because PHI must be accessed/used to complete the research.

**Dissemination of Data**

Results of this study may be used for presentations, posters, or publications. The publications will not contain any identifiable information that could be linked to a participant.

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