

Study Concept Proposal

Title: Trauma ICU Prevalence Project (TRIPP study)

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Sub-investigators: Multi-institutional participants

Background:

- The critically ill and injured population is projected to grow significantly over this decade [1], with the increasing demand for critical care services creating a 35% shortfall of intensivists hours by 2020, according to the Society of Critical Care Medicine [2]. In order to meet the needs of this population at both local and global levels, we need to understand the current epidemiology of ICU disease and injury, and current resource allocation for the demands of providing critical care. Gaining an understanding of the prevalence of certain conditions and healthcare resources in trauma ICUs (defined as the ICU that cares for the majority of the trauma patients needing intensive care in each participating hospital) may help focus clinical and research efforts toward areas of need. The model from which this study will be adapted is the EPIC II study from 2009 – *Extended Prevalence of Infection in Intensive Care* [3]. This study created a snapshot of infection in ICUs worldwide, illustrating how common infections were in ICUs and their associated risk of mortality.
- The study will be an observational, non-interventional, multicenter study done as a one-day prevalence study, to gain a broad overview of trends and conditions in the United States, and to allow comparison between regions.
- This study is important because it will demonstrate differences and commonalities in trauma critical care locally, regionally, and nationally. From a global health perspective, an understanding of this disease burden and how ICUs are structured will help identify deficiencies and where increased standardization is needed, but also will identify successes that can be modeled.

Objective:

- Primary objective: Provide a contemporary description of intensive care conditions, diagnoses, patterns, differences, and resource use for patients in trauma ICUs
- Secondary objective: Describe models of care delivery, surgical conditions, ICU bed allocation, and staffing structures for trauma patients in the USA and determine their association, if any, with morbidity and mortality.

Hypothesis:

- It is possible to identify disease prevalence and trends for trauma ICU patients on a broad scale
- Deficiencies and opportunities for improvement will be identified by comparing trauma ICU care on a national scale

Study design:

- Prospective, one-day point prevalence study, with a follow up at one month for discharge data
- A data collection website will be established for direct entry of de-identified data by each participating hospital
- Data points (see Data Collection sheet) will be obtained from chart review on the day of the study. Each participating hospital will receive a hospital identification number. Each patient enrolled will be numbered sequentially starting with #1. Patient's names and hospital record numbers will be kept at the local sites, but not entered into the study database.
- Due to the nature of the data requested, information must be collected on the participant subjects on the study day specifically.

Setting:

- ICUs at trauma centers, multi-institutional
- In the U.S., included hospitals will be trauma centers that have been designated by State agencies or the American College of Surgeons

Methodology:**Patients:**

- Inclusion Criteria:
 - i. adult trauma patients (≥ 15 years of age, as defined by the American College of Surgeons Committee on Trauma)
 - ii. primary admission diagnosis of traumatic injury;
 - iii. Non-trauma surgical patient (defined as having a surgical condition, operative or non-operative, that is the primary condition for which the patient is in ICU; if non-operative, the condition either has significant potential for needing surgery, or is primarily managed by a surgical team)
 - iv. location on day of study is in the ICU where the majority of trauma patients are treated in each particular hospital (the study ICU)
- Exclusion Criteria: children (< 15 years of age); prisoners.

Interventions:

- *None*

Study group:

- *Not applicable*

Control group:

- *Not applicable*

Randomization process (if applicable):

- *Not applicable*

Study end points:

- Data collection on the single study day and one-month follow up for discharge data

Proposed Duration of the Study:

- One day, with one follow up questionnaire

Statistical analysis to power the study:

- Descriptive analysis with reporting of continuous variables (mean/std dev or median/25th & 75th perc) and categorical variables (percentages). For comparisons, t-test, Kruskal-Wallis, chi-square, or Fisher's exact test will be used, as appropriate.

Budget:

- None

Feasibility: Very feasible; one day study with no database queries.

References:

[1] Duke EM. The Critical Care Workforce: A Study of the Supply and Demand for Critical Care Physicians. Health Resource and Service Administration. US Department of Health and Human Service. Washington DC. USA. 2008. 2006 Aug 22.

[2] <http://www.sccm.org/Communications/Pages/CriticalCareStats.aspx>

[3] Vincent JL, Rello J, Marshall J, Silva E, Anzueto A, Martin CD, Moreno R, Lipman J, Gomersall C, Sakr Y, Reinhart K; EPIC II Group of Investigators. International study of the prevalence and outcomes of infection in intensive care units. JAMA. 2009 Dec 2;302(21):2323-2329.