Form "EAST Multicenter Study Proposal" Details #12 (submitted 02/01/2023)

Please indicate if this is

New MCT proposal submission

a...

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

Quantifying the shortage of trauma and acute care surgeons in the United States: An EAST **Study Title**

Multicenter Trial

Primary Investigator: Patrick Murphy

Institution that will be the

Medical College of Wisconsin primary site for the

study:

Email of Primary

Investigator:

pmurphy@mcw.edu

Co-PI/second point of

contact for the study:

Marc de Moya

Email of Co-PI/second

point of contact for the

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study:

Are you a current

member of EAST?

Yes

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

EAST member:

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

Trauma and emergency general surgery patients account for nearly 20% of all admissions to hospitals in the USA accounting for \$85 billion dollars or 25% of all inpatient costs. Over the last 20 years there has been a paradigm shift in the care for these patients across the USA in a recognition of the physiologic complexity and demand. Previously no dedicated systems or infrastructure was dedicated to providing 24/7 emergency surgery services leaving the care of these patients fractured and inconsistent. Now, Acute Care Surgery (ACS) models covering emergency general surgery, trauma and surgical intensive care units are being adopted across the country. The services are tasked with caring for sicker and more complex patients compared to the past and to their elective surgery counterparts. The surgeons who run these services, acute care surgeons, are also increasingly assuming responsibility for night and weekend call. The American Association for Medical Colleges projects there will be a shortfall of up to 120,000 physicians by 2032, including an almost 25,000 shortage in the surgical subspecialties. There is also evidence of a deficit of acute care surgeons. The ratio of acute care surgeons to population has plateaued in the U.S., and there is a large degree of geographic variability in the number of acute care surgeons. Together, this is generating a shortfall that has direct impact on patient care. There is a critical need to create a stable ACS workforce to ensure that the needs of acute care surgery patients are met. Recent work has attempted to define a 'reasonable' clinical workload for acute care surgeons, approximately 26 weeks of service per year and 4-5 in-house call per night, or approximately 204 'shifts' per year. However, our previous work identified a discrepancy of 4 weeks between the current workload of acute care surgeons and a 'reasonable' workload. Prior studies were survey based and relied on self-reported data. Further, beyond overall annual workload, prior studies have not determined the optimal ratio of patient census to individual surgeons for acute care surgery and trauma service lines. The current recommendation for intensive care unit staffing is 14 patients per physician on average per day. There is a critical knowledge gap regarding the number of surgeons required to reasonably and safely staff a division of acute care surgery. Our central hypothesis is that all divisions of acute care surgery, when considering reasonable workload, suffer from a shortage of surgeons to varying degrees. Further, we hypothesise that trauma patients cared for at institutions who experience a critical staff shortage may have worse outcomes. By better understanding the shortage of surgeons our results will inform our longterm goal of creating a sustainable ACS workforce to ensure high-quality patient care.

Murphy PB, Coleman J, Karam B, Morris RS, Figueroa J, de Moya M. A national study defining 1.0 full-time employment in trauma and acute care surgery. J Trauma Acute Care Surg. 2022 Apr 1;92(4):648-655. doi: 10.1097/TA.000000000003504. PMID: 34936589.

Ward NS, Afessa B, Kleinpell R, Tisherman S, Ries M, Howell M, Halpern N, Kahn J; Members of Society of Critical Care Medicine Taskforce on ICU Staffing. Intensivist/patient ratios in closed ICUs: a statement from the Society of Critical Care Medicine Taskforce on ICU Staffing. Crit Care Med. 2013 Feb;41(2):638-45. doi: 10.1097/CCM.0b013e3182741478. PMID: 23263586.

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

Knowlton LM, Minei J, Tennakoon L, Davis KA, Doucet J, Bernard A, Haider A, Scherer LRT 3rd, Spain DA, Staudenmayer KL. The economic footprint of acute care surgery in the United States: Implications for systems development. J Trauma Acute Care Surg. 2019 Apr;86(4):609-616. doi: 10.1097/TA.0000000000002181. PMID: 30589750; PMCID: PMC6433481.

Jenkins PC, Painter S, Bell TM, Kline JA, Zarzaur BL. The conference effect: National surgery meetings are associated with increased mortality at trauma centers without American College of Surgeons verification. PLoS One. 2019 Mar 26;14(3):e0214020. doi: 10.1371/journal.pone.0214020. PMID: 30913224; PMCID: PMC6435237.

Brown CVR, Joseph BA, Davis K, Jurkovich GJ. Modifiable factors to improve work-life balance for trauma surgeons. J Trauma Acute Care Surg. 2021 Jan 1;90(1):122-128. doi: 10.1097/TA.0000000000002910. PMID: 32925572.

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

This will be the first multi-center study to quantitatively capture the clinical work performed by trauma and acute care surgeons, investigate the shortage of surgeons and explore the impact on patient care. Further, safe patient-to-provider ratios have not been established and are nuanced. Including a qualitative portion to the study will be hypothesis generating.

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

The MCT will add to the existing body of literature by applying our current understanding of 'reasonable' clinical workload to real-world practice. It will further expand on the perception of safe staffing and provider-to-patient ratios for acute care surgery and trauma service lines.

Primary aim

Estimate the shortage of full-time trauma and acute care surgeons at Level I and Level II trauma centers in the USA.

Secondary aims

Explore perspectives of surgeons on safe provider-to-patient ratios for trauma, acute care surgery and surgical intensive care.

Tertiary aim

Compare trauma outcomes between critically short-staffed trauma and acute care surgery divisions and non-critically short-staffed in an exploratory analysis.

Design

Retrospective

Inclusion Criteria

Level 1 and Level 2 trauma centers in the United States

Exclusion Criteria

Inability to provide acute all service line schedules for 2022

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

Purposeful sampling will be used to recruit and enroll Divisions of Trauma/Acute Care Surgery at Level I and Level II trauma centers across the United States. The head of each Division will provide the clinical schedule for calendar year 2022 of all services and clinical work performed by their staff. The assigned full-time equivalent of each staff will also be collected from the Division head. A brief video-interview will confirm the clinical demand, service line design and the annual number of 'shifts' required annually to cover all clinical demands of the Division. A shift is defined as 10, 12 or 14 hours depending on the Division's design of service lines, weekend and overnight responsibilities. Follow-up survey and semistructured qualitative interviews will be performed to explore safe provider-to-patient staffing.

Primary Outcome

The primary outcome for aim one will be to quantify the clinical FTE shortage, on average, across a purposeful sample of Level I and Level II trauma centers in the United States.

Secondary Outcome(s)

Secondary outcomes include both qualitative outcomes (factors influencing provider-topatient ratios) and quantitative outcomes such as the range of provider-to-patient ratios and the relationship between the degree of clinical FTE shortage and trauma patient outcomes, morbidity, mortality and length of stay via local trauma registries.

collected & analyzed:

Select the variables to be Baseline Participating Institution Information, Baseline Clinical Characteristics, Outcomes of Interest, Additional variables noted below:

Additional variables:

Number of surgeons who contribute to covering acute care surgery, trauma, surgical intensive care and other clinical activities required by the Division of Trauma and Acute Care Surgery such as elective surgery and clinic. The clinical full-time equivalent assigned to each provider.

Outline the data collection plan/tool succinctly

Data will be collected in three ways. First, annual clinical schedules for included Divisions of Trauma and Acute Care Surgery will be collected for the calendar year 2022 from participating institutions. These will be reviewed with the Division Chief of each division in a 1-hour video conference to clarify the number of shifts required to cover the clinical demand annually. Next, surgeons at each included institution will be asked to complete a 10 question, electronic survey on their perspective on safe provider to patient ratios for surgeons. Scenarios of clinical coverage with varied support (advanced practice providers and residents) will be provided and participants will answer questions about safe staffing ratios. One surgeon from each institution will be asked to complete a 30-minute virtual interview to explore the nuances of provider-to-patient ratios and considerations for safe staffing. The number of surgeons and assigned clinical FTE will be collected. Finally, included institutions will provide their overall trauma volume and risk-adjusted trauma outcomes including morbidity and mortality as reported to the Trauma Quality Improvement Program.

Has IRB approval been obtained at the primary site?

No

Is DUA required for participation in the study?

No

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

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

PI, research fellows, research coordinator

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

No

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

The PI has experience in both quantitative and qualitative methodology and will perform the final analysis for each aim.

Include detailed description of the data analysis plan:

A median and interquartile range will be calculated for the primary outcome of deficit of FTE for the sample population and for each of the 5 geographic areas in the United States that were purposefully sampled. A mixed deductive and inductive thematic analysis will be used for the qualitative semi-structured interviews. Survey responses will be summarized using descriptive statistics without comparison. Finally, an exploratory analysis will be undertaken to compare critically short-staffed divisions, defined as =25% of shifts above available clinical FTEs will to non-critically short-staffed divisions. Parametric testing will be used to compared normally distributed data while non-parametric testing will be used to compare non-normally distributed data. A weighted analysis will be performed for the morbidity and mortality outcomes based on demographic and injury risk-adjustment.

Include Power Analysis:

Purposeful sampling will be used to recruit at least 3 institutions from each of the Northeast, Southwest, West, Southeast and Midwest. Based on our own institutions' clinical demand and current FTEs, our Division is 4 clinical FTEs short to meet clinical demand and maintain 204 shifts / year per 1.0 clinical FTE. Based on a standard deviation of 1.5 FTEs and a normal distribution we require 19 institutions. For the qualitative portion of the study and considering the relatively heterogeneity of the sample (Level I and Level II trauma centers), 9 to 17 surgeons will be required to reach thematic saturation.

Please note what your enrollment procedure for this study entails:

Enrolment entails approaching the PI regarding eligibility. Eligible centers will email 2022 clinical schedules for conversion into annual shifts. A 1-hr video interview will be arranged between the Division Head to establish clinical demand and assigned FTEs of each Division staff. A follow-up survey will be sent to Division surgeons requesting participation in the survey regarding patient-to-provider staffing and an opportunity to participate in a qualitative interview.

Outline consent procedures here, if applicable:

Consent will be obtained from each Division Head of enrolled institutions and from each surgeon who wishes to participate in the survey/semi-structured interview.

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

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

Knowlton, L. M. et al. The economic footprint of acute care surgery in the United States: Implications for systems development. in Journal of Trauma and Acute Care Surgery vol. 86 609–614

Brown, C. V. R., Joseph, B. A., Davis, K. & Jurkovich, G. J. Modifiable factors to improve work-life balance for trauma surgeons. in Journal of Trauma and Acute Care Surgery vol. 90 122–128

Murphy PB, Coleman J, Karam B, Morris RS, Figueroa J, de Moya M. A national study defining 1.0 full-time employment in trauma and acute care surgery. J Trauma Acute Care Surg. 2022 Apr 1;92(4):648-655

Include a brief listing of key references:

Ward NS, Afessa B, Kleinpell R, Tisherman S, Ries M, Howell M, Halpern N, Kahn J; Members of Society of Critical Care Medicine Taskforce on ICU Staffing. Intensivist/patient ratios in closed ICUs: a statement from the Society of Critical Care Medicine Taskforce on ICU Staffing. Crit Care Med. 2013 Feb;41(2):638-45

Elkbuli, A. et al. The Shortage of Trauma Surgeons in the US. American Surgeon 88, 280–288

Jenkins PC, Painter S, Bell TM, Kline JA, Zarzaur BL. The conference effect: National surgery meetings are associated with increased mortality at trauma centers without American College of Surgeons verification. PLoS One. 2019 Mar 26;14(3):e0214020

Hennink, M. & Kaiser, B. N. Sample sizes for saturation in qualitative research: A systematic review of empirical tests. Social Science and Medicine 292, (2022).