PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Best Case/Worst Case-ICU: protocol for a multisite, stepped-wedge, randomized clinical trial of scenario planning to improve communication in the ICU in US trauma centers for older adults with serious injury
AUTHORS	Stalter, Lily; Hanlon, Bret M.; Bushaw, Kyle; Kwekkeboom, Kristine L.; Zelenski, Amy; Fritz, Melanie; Buffington, Anne; Stein, DM; Cocanour, Christine S.; Robles, Anamaria; Jansen, Jan; Brasel, Karen; O'Connell, Kathleen; Cipolle, Mark; Ayoung-Chee, Patricia; Morris, Rachel; Gelbard, Rondi; Kozar, Rosemary; Lueckel, Stephanie; Schwarze, Margaret

VERSION 1 - REVIEW

REVIEWER NAME	Teaster, Pamela
REVIEWER AFFILIATION	Virginia Tech, Center for Gerontology (0555)
REVIEWER CONFLICT OF INTEREST	No competing interests.
DATE REVIEW RETURNED	08-Mar-2024

GENERAL COMMENTS	The protocols that the authors have put forth in the manuscript are extremely well-thought out and have the potential to contribute to better communication, decisions, and clinical outcomes for older adult patients in the trauma ICU. The following are minor suggestions to improve the manuscript. Specific comments to make to the authors: 1. Abstract: is it possible to indicate when you would be surveying the one family or like family member? 2. P. 5, What is the rationale for not linking family surveys to individual patient outcomes? 3. P. 8, This is merely a suggestion—would AI be useful to help you generate the scenarios? 4. P.9, Participants. It is very unlikely, but is it possible that you could include the patient in your study (plan for the extremely remote possibility)? 5. P. 11, please provide a sentence or so explanation about your decision to withhold the objectives of your study for the family member. 6. P. 12, line 43, How will you identify the resource nurse champion at each site? 7. P. 13, Adherence, line 17 and following, you mention that if "…routine use of the intervention falls below 80% of eligible patients, [you] will deploy additional strategies to promote use." Could you provide a little information about what might constitute these additional strategies? 8. P. 14, line 13, provide a sentence or so explanation about why you are not linking patient data to family member data.

	9. P. 17, line 9, spell out ICU Length of Stay the first time. 10. P. 19, line 2, is the intervention patient centered or also patient directed, meaning that the family member or surrogate decision maker (SDM) is acting as the patient would want, not necessarily as the SDM would want? Here, you are clarifying whether the decision maker is using a substituted judgment standard or a best interests standard.

REVIEWER NAME	Cook, Deborah
REVIEWER AFFILIATION	McMaster University
REVIEWER CONFLICT OF INTEREST	None
DATE REVIEW RETURNED	17-Mar-2024

GENERAL COMMENTS	This is a timely sensitive and rigorous trial. Thank you for this work.

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

Dr. Pamela Teaster, Virginia Tech

Comments to the Author:

The protocols that the authors have put forth in the manuscript are extremely well-thought out and have the potential to contribute to better communication, decisions, and clinical outcomes for older adult patients in the trauma ICU. The following are minor suggestions to improve the manuscript.

Thank you for your thoughtful review, it has helped us to improve our manuscript. We hope we have addressed all of your comments below.

Specific comments to make to the authors:

1. Abstract: is it possible to indicate when you would be surveying the one family or like family member?

Thank you for this suggestion. We have added this information to the abstract:

“We aim to survey one family or “like family” member per eligible patient 5-7 days following their loved ones’ admission and clinicians providing care in the trauma ICU.” – Abstract, Methods and analysis, line 3

2. P. 5, What is the rationale for not linking family surveys to individual patient outcomes?

Ideally, we would link family surveys to individual patient outcomes to explore and interpret study findings more thoroughly, and we acknowledge that it is a limitation of this study and that we have not elected to do so in order to preserve the protections granted to us for use of these data through minimization of Protected Health Information (PHI) collection. This was a study design compromise that significantly reduced the regulatory complexity of our study. To link the two distinct data sources, ACS TQIP data and family survey data, at the patient level would require identifiable patient information. Under our current methodology, ACS TQIP will provide us with patient-level data without

any direct patient identifiers and the family surveys will not include any PHI such as patient name or date of birth. This allows us to collect the minimal information necessary on patients and is an additional step we are taking to ensure their privacy. While we would have preferred to have all the data to inform our research question, we found in our pilot study that obtaining consent from trauma patients, and their families, for chart review, is a difficult endeavor and severely limits the study design due to poor feasibility. We have included a brief description of our rationale in our methods section:

"We will not link patient data to family member data collected by the study team, as neither the ACS TQIP provided data nor the family member data will contain Protected Health Information (PHI) (e.g., name, date of birth) that would allow us to link the two distinct data sources. The decision to not collect PHI not only safeguards patients' privacy, it also improves study feasibility as we have found obtaining consent from trauma patients difficult due to their critical condition." –Methods and analysis, Data collection, paragraph 1, line 12

3. P. 8, This is merely a suggestion—would AI be useful to help you generate the scenarios?

Thank you for this intriguing suggestion. With AIs increased use and continued improvements, using AI to generate scenarios may be a future path for this work. However, most of the information currently available to AI generators is likely probabilistic information attached to disarticulated risks, not the stories that are important for BCWC. Additionally, a clinician would still need to review the AI-generated scenarios. We designed the tool to fit into the busy pace of trauma ICU rounds with minimal disruption, and we feel that, at least for now, this is best achieved by having clinicians generate the scenarios.

3. P.9, Participants. It is very unlikely, but is it possible that you could include the patient in your study (plan for the extremely remote possibility)?

Given the critical condition of the patient population of interest, where all are severely injured and many are intubated, it is incredibly difficult to enroll study-eligible patients directly. We recognize that this limits our ability to fully understand the effect of the intervention on the patient's impressions of clinician communication. Since we anticipate very few patients will be able to complete the QOC survey themselves, we decided to survey only family or like-family members, whose cognitive abilities were (presumably) not impact by serious traumatic injury.

5. P. 11, please provide a sentence or so explanation about your decision to withhold the objectives of your study for the family member.

We have added our rationale to the text:

"Family members will be told the goal is to evaluate clinician-patient communication but will be blinded to the specific objectives (i.e., that we are testing a graphic aid communication tool) of this study, which may mitigate bias given the nature of our primary outcome.17, 18" – Methods and analysis, Randomization and blinding, paragraph 2, line 2

6. P. 12, line 43, How will you identify the resource nurse champion at each site?

The resource nurse champion will be identified by the on-site nurse manager. We have reworded our text to clarify:

“We will offer to train an on-site resource nurse champion, to be selected by the on-site nurse manager, for as needed nurse education at the discretion of the on-site nurse manager.” –Methods and analysis, Intervention, paragraph 5, line 3

7. P. 13, Adherence, line 17 and following, you mention that if “…routine use of the intervention falls below 80% of eligible patients, [you] will deploy additional strategies to promote use.” Could you provide a little information about what might constitute these additional strategies?

Thank you for this opportunity to clarify; we have expanded our description:

“Specifically, we will follow up directly with individual trauma surgeons to identify barriers, perform twice-weekly audits, and distribute study-wide comparator reports on adherence to each site. With the input of the site PI, we will determine site-specific strategies, such as incorporating pre-filled prompts to the graphic aid or providing improvement-based incentives, such as small rewards for high performance, e.g., cookies or other treats.” – Methods and analysis, Adherence, paragraph 1, line 8

8. P. 14, line 13, provide a sentence or so explanation about why you are not linking patient data to family member data.

To avoid collecting identifiable patient information and reduce regulatory complexity, we will not link patient member data to family member data collected by our team. We acknowledge that this is a limitation of this study. We have expanded on our description as follows:

“We will not link patient data to family member data collected by the study team, as neither the ACS TQIP provided data nor the family member data will contain Protected Health Information (e.g., name, date of birth) that would allow us to link the two distinct data sources. The decision to not collect PHI not only safeguards patients’ privacy, it also improves study feasibility as we have found obtaining consent from trauma patients difficult due to their critical condition.” –Methods and analysis, Data collection, paragraph 1, line 12

9. P. 17, line 9, spell out ICU Length of Stay the first time.

Thank you for catching this. We have included the acronym LOS the first time we mention ICU Length of stay:

“TQIP registry: Patient-level data (i.e., demographics, clinical data, and patient outcomes, including ICU length of stay (LOS))” – Methods and analysis, Data collection, paragraph 1, line 2

10. P. 19, line 2, is the intervention patient centered or also patient directed, meaning that the family member or surrogate decision maker (SDM) is acting as the patient would want, not necessarily as the SDM would want? Here, you are clarifying whether the decision maker is using a substituted judgment standard or a best interests standard.

We wholeheartedly agree that this is an important distinction. While our intervention has the potential to lead to improvements in patient directed care, our current study is not designed to test this, in part because this is quite a complex issue and measurement of patient versus surrogate priorities is fraught with hazard. As a secondary outcome, we will look at Receipt of Goal Concordant Care, which asks family members whether their loved one’s care was concordant with their knowledge of their

loved one's preferences (i.e., whether they (the patient) prefer a course of treatment that focuses on extending life as much as possible or they prefer a place that focuses on relieving pain and discomfort as much as possible). We will not survey patients regarding their preferences, for the reasons outlined above regarding the difficulty of enrolling patients in the trauma ICU. As such, we have only used the term "patient centered" in our text.

Reviewer: 2

Dr. Deborah Cook, McMaster University

Comments to the Author:

This is a timely sensitive and rigorous trial. Thank you for this work.

Thank you for your review.

References

1. White DB, Angus DC, Shields AM, Buddadhumaruk P, Pidro C, Paner C, Chaitin E, Chang CH, Pike F, Weissfeld L, Kahn JM, Darby JM, Kowinsky A, Martin S, Arnold RM; PARTNER Investigators. A Randomized Trial of a Family-Support Intervention in Intensive Care Units. N Engl J Med. 2018 Jun 21;378(25):2365-2375. doi: 10.1056/NEJMoa1802637. Epub 2018 May 23. PMID: 29791247.

2. Lincoln T, Shields A, Buddadhumaruk P, et al. Protocol for a randomised trial of an interprofessional team-delivered intervention to support surrogate decision-makers in ICUs. BMJ Open 2020;10:e033521. doi: 10.1136/bmjopen-2019-033521

3. Pronovost P, Needham D, Berenholtz S, Sinopoli D, Chu H, Cosgrove S, Sexton B, Hyzy R, Welsh R, Roth G, Bander J, Kepros J, Goeschel C. An intervention to decrease catheter-related bloodstream infections in the ICU. N Engl J Med. 2006 Dec 28;355(26):2725-32. doi: 10.1056/NEJMoa061115. Erratum in: N Engl J Med. 2007 Jun 21;356(25):2660. PMID: 17192537.