BMJ Open

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Journal:	*BMJ Open*
Manuscript ID	bmjopen-2023-083603
Article Type:	Protocol
Date Submitted by the Author:	22-Dec-2023
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Keywords:	PALLIATIVE CARE, MEDICAL ETHICS, TRAUMA MANAGEMENT, Adult intensive & critical care < INTENSIVE & CRITICAL CARE

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Best Case/Worst Case-ICU: protocol for a multisite, stepped-wedge, randomized clinical trial of scenario planning for older adults with serious injury (improving communication in the trauma ICU)

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Word count: 3741
Tables: 2
Figures: 2
References: 34

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ABSTRACT

Introduction: Poor communication about serious injury in older adults can lead to treatment that is inconsistent with patient preferences, create conflict, and strain healthcare resources. We developed a communication intervention called Best Case/Worst Case-ICU that uses daily scenario planning, i.e., narrative description of plausible futures, to support prognostication and facilitate dialogue among patients, their families, and the trauma ICU team. This article describes a protocol for a multisite, randomized, stepped-wedge study to test the effectiveness of the intervention on the quality of communication in the ICU.

Methods and analysis: We will follow all patients aged 50 and older admitted to the trauma ICU for three or more days after serious injury at eight high volume Level 1 trauma centers. We aim to survey one family or "like family" member per eligible patient and clinicians providing care in the trauma ICU. Utilizing a stepped-wedge design, we will use permuted block randomization to assign the timing for each site to begin implementation of the intervention and routine use of the Best Case/Worst Case-ICU tool. We will use a linear mixed-effects model to test the effect of the tool on family-reported quality of communication (using the Quality of Communication (QOC) scale) as compared to usual care. Secondary outcomes include the effect of the tool on reducing clinician moral distress (using the Measure of Moral Distress for Healthcare Professionals (MMD-HP) scale) and patients' length of stay in the ICU.

Ethics and dissemination: Institutional Review Board (IRB) approval was granted at the University of Wisconsin (UW), and all study sites ceded review to the primary IRB. We plan to report results in peer-reviewed publications and national meetings.

Registration details: This study is funded by the National Institutes of Health (*R01AG078242*) and is registered at clinicaltrials.gov (*NCT05780918)*.

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Strengths and Limitations of this study:

- In this registry-enabled clinical trial, we will utilize the American College of Surgeons Trauma Quality Improvement Program (ACS TQIP) national registry to follow all eligible patients at eight high volume Level I trauma centers across the United States.
- We designed this study to minimize the potential for missing data and anticipate low rates of missingness because family surveys are collected at the time of enrollment and all trauma centers involved in this study report clinical data to the American College of Surgeons Trauma Quality Improvement Program (TQIP) for quality assurance and benchmarking.
- We have a strong implementation strategy, a fidelity-monitoring plan with weekly audit feedback, and the ability to verify adherence to the intervention.
- We will utilize a stepped wedge design, which allows us to test the intervention in a multilevel space, while minimizing the risk of contamination bias compared to a patient-level randomized design testing the same intervention.
- We will not link family surveys to individual patient outcomes, a study design compromise that reduces regulatory complexity but will limit our ability to interpret some study findings.

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INTRODUCTION

Background

Each year, half a million adults 50 years or above suffer injury from a fall or other traumatic event.[1, 2] Older adults fare far worse than younger patients with similar injuries due to chronic comorbid conditions and reduced physiologic reserve. As such, traumatic injury is often a pre-terminal event, with 20% in-hospital and 40% one-year mortality.[3] Treatment for traumatic injury frequently involves burdensome treatments (like invasive surgical procedures or prolonged life support) that may be inconsistent with patients' preferences and goals.[4-6] This disconnect between patients' priorities and treatments received can lead to conflict in the intensive care unit (ICU), specifically interpersonal conflict among clinicians (e.g., between nurses and surgeons) and with patients' loved ones (e.g., between surrogate decision makers and the trauma ICU team) during treatment discussions.[7, 8] Moreover, overtreatment at the end of life prolongs dying and contributes $44 billion annually in the United States to healthcare costs.[9] A communication intervention that facilitates the articulation of patient priorities could reduce unwanted invasive procedures and clarify patients' long-term goals, benefiting patients, loved ones, clinicians, and healthcare systems.[10]

The Best Case/Worst Case-ICU Tool

We developed a communication intervention called Best Case/Worst Case-ICU that uses scenario planning, i.e., narrative description of plausible futures, to support decision-making and facilitate dialogue among patients, their loved ones, and the trauma team. Typically, in accordance with standards for informed consent, clinicians present risks as discrete complications for isolated physiologic systems (e.g., a 50% chance of kidney failure) or the binary outcome of mortality (e.g., a 40% chance of survival).[11] Because this language does not describe how a patient might experience treatments or the expected downstream outcomes, such as predictable changes in functional status, prolonged recovery, or need for long-term care in a nursing home, patients and families may struggle to anticipate and

account for the consequences of serious injury and make treatment decisions accordingly. Scenario planning provides an alternative strategy for managing uncertainty that is in distinct contrast to emphasizing isolated risks or discrete treatment effects. Instead, scenario planning generates multiple plausible futures, prompting decision makers to consider causal relationships and visualize a range of outcomes based on sound analysis of the present.[12]

We designed the Best Case/Worst Case-ICU tool to help visualize uncertainty, illustrate the interplay between major events and prognosis, and describe how patients might experience the various treatments received along the course of care. By using a graphic aid to illustrate "what we are hoping for," "what we are worried about,"[13] and the evolution of the patient's story or clinical course over time, including setbacks and improvements, the tool aims to keep everyone (clinicians, patients, and loved ones) well-informed. The tool facilitates clinician delivery of critical prognostic information over the longitudinal course of care, allowing subsequent treatment decisions, e.g., additional operations or prolonged mechanical ventilation, to be made within the context of the patient's overall health status and goals. Ultimately, this tool alerts patients and families to the life-limiting nature of serious injury and provides valuable insight as they consider whether comfort-focused strategies might better support their care needs.

We designed the tool to fit the pace of busy trauma ICU rounds. The trauma team collaboratively completes the graphic aid during the summative systems-based review daily for each patient (Figure 1). With usual care, a clinician (typically a surgical resident) lists each physiologic system, i.e., neuro, cardiac, pulmonary, etc., or individual medical problems with an assessment and plan for each. When using the tool, they add "outlook", i.e., the best case scenario, at the end. While the attending physician or fellow generates this story, another team member records it on the graphic aid. The worst case scenario is modified as needed but does not typically require daily updating. The graphic aid is posted in

the patient's room, where loved ones and clinicians can use it to recall what to expect, visualize uncertainty, and see how things change over the patient's course of care.

The daily stories and the graphic aid provide support and perspective for everyone involved in the care of the patient. If the patient clinically improves, their loved ones are primed for the road to recovery. If the patient worsens, their loved ones will be prepared, and the gravity of the patient's illness will not come as a surprise. Important decisions, such as proceeding with an operation or continuing mechanical ventilation, can be made within the context of the patient's overall health trajectory. We hypothesize that this will lead to improved communication in the ICU, and patients will receive care that better aligns with their health goals. We also theorize this will reduce interpersonal ICU conflict that contributes to clinician burnout and moral distress.

METHODS AND ANALYSIS

Design and Setting

We will utilize a multisite, randomized, stepped-wedge design to test the effectiveness of the Best Case/Worst Case-ICU tool.[14] This 18-month study will be executed over six 3-month-long waves (Figure 2). In wave 1, all patients will receive usual care. With each subsequent wave, we will randomly select two sites to enter the implementation phase. Data collection will cease for sites during the implementation wave and the study implementation team will train clinicians to use the Best Case/Worst Case-ICU tool. After the implementation wave, the site will be in the intervention arm, and patients will receive care from a trauma team that routinely uses the Best Case/Worst Case-ICU tool.

We will conduct this study at eight high volume Level I trauma centers from across the United States (Table 1).

Table 1. Study sites with annual number of eligible patients based on 2019 ICU volume.

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Trauma Center	Location	Patients Meeting Study Eligibility Criteria	Stratification for Randomization
Harborview Medical Center (University of Washington)	Seattle, WA	702	Very High
University of Alabama at Birmingham	Birmingham, AL	615	Very High
Grady Memorial Hospital (Morehouse School of Medicine)	Atlanta, GA	583	Very High
Lehigh Valley Health Network	Allentown, PA	507	Very High
Rhode Island Hospital	Providence, RI	504	High
Shock Trauma (University of Maryland Medical Center)	Baltimore, MD	398	High
Froedtert Hospital (Medical College of Wisconsin)	Milwaukee, WI	321	High
UC Davis Medical Center	Sacramento, CA	289	High

Participants

Patients: We will follow all patients aged 50 and older admitted to the trauma ICU at study sites for three or more days after serious injury.

Family Members: For each patient who receives three or more days of ICU care provided primarily by the trauma ICU team, we will invite one family member or informally designated "like family" member or primary surrogate decision maker (hereafter family) to participate 5-7 days after admission. We will use medical records and nursing referrals to identify the person most frequently engaged in the patient's care. Family members must be at least 18-years-old, speak English or Spanish, and have decision-making capacity.[15] We will approach family members regardless of whether their loved one has been discharged from the ICU or is deceased.

Clinicians: We will invite all clinicians providing care in the trauma ICU to participate in the intervention training. This includes ICU attendings (e.g., trauma surgeons), fellows, residents, advance practice

providers (APPs), bedside nurses and medical assistants, respiratory and physical therapists, social workers, pharmacists, and chaplains. We will exclude individuals who do not provide primary care in the trauma ICU, e.g., medical specialists.

Recruitment

In this registry-enabled study, all patient-level data will come from the American College of Surgeons Trauma Quality Improvement Program (ACS TQIP) national registry, which collects demographics and outcomes for all trauma patients at 850 participating centers according to the National Trauma Data Standards.[16] We will not directly recruit patients for this study. A research coordinator (RC) at each site will approach eligible family members in person or via telephone. Qualifying family members will receive a $20 incentive after a one-time survey completion.

We will send clinicians an anonymous link to an electronic survey via their hospital-based email address, with up to three additional email requests. To increase the response rate, RCs will request survey completion in person in the trauma ICU, during multiple shifts over the 4-week data collection period. Additionally, the site Principal Investigator (PI) will encourage completion of study procedures at ICU team meetings and through hospital-generated electronic notification systems (e.g., weekly email updates). Clinicians will receive a $5 incentive for each survey completed (up to $20 total). Attending surgeons and fellows will receive $100 for the completion of the 30-minute one-on-one training.

Randomization and Blinding

We will use permuted block randomization to assign the timing for each site to begin implementation of the intervention and routine use of the Best Case/Worst Case-ICU tool. Study sites will be stratified based on historic patient volume (i.e., very high or high) to increase the likelihood of a balanced distribution of participants across study arms. A study statistician will link treatment group assignment to patient and family member data using the patient's admission date.

Family members will be told the goal is to evaluate clinician-patient communication but will be blinded to the specific objectives of this study. Clinicians will not be blinded to treatment group. While we will inform all clinicians of the study goals, clinicians will not be told specific study outcomes or hypotheses. TQIP registrars will abstract data throughout the study, in a manner consistent with their normal work processes, without being informed on the status of interventional procedures. To decrease ascertainment bias, on-site research staff will not participate in intervention implementation and will adhere to a strict study script during interactions with clinicians and family members.

Intervention

Delivery of the intervention requires training trauma ICU teams how to use the Best Case/Worst Case-ICU tool. The intervention is considered quality improvement because its primary purpose is to integrate guideline recommended behaviors, e.g., timely communication with families/loved ones and emotional support as part of routine care in the ICU.[17, 18] Because the Best Case/Worst Case-ICU tool is intended for team-based clinician-family communication, the training program is tailored to the clinician's role on the trauma team.

We will invite all attending physicians and fellows who round in the trauma ICU to attend a 30-minute one-on-one instructional program followed by coaching, assessment, and additional training, as needed. Instruction for attendings and fellows will focus on translating clinical knowledge and prognostic information into the Best Case/Worst Case-ICU format. Key topics include daily scenario planning to tell a best case and worst case scenario, identifying major events that change the best case scenario, and completing the graphic aid, while also reviewing skills to support shared decision making for patients with serious illness. Attendings/fellows who do not achieve minimal competence (10 of 14 essential tool elements) on assessment will receive additional training until they reach competence.

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For resident trainees and APPs who are rotating in the ICU, we will host a 30 minute to 1 hour group session, which includes a 10-minute instructional video. This session focuses on teaching how to routinely complete the graphic aid on rounds with minimal disruption, specifically, how to include the patient's "outlook" and document the best case scenario. Using a hypothetical case, learners will practice completing the graphic aid and watch a standardized video reviewing the case. We will repeat this training on a regular basis to accommodate new residents brought into the ICU for clinical rotations. For general surgery residents, who often comprise a significant portion of resident trainees in the ICU, we will also offer an institution-wide one-time training.

We will provide education to bedside nurses and other clinical ICU staff during in-service meetings and other routine meetings as guided by on-site nurse managers. Our implementation team will describe the tool, answer questions, and reinforce the "this is what we are hoping for" and "this is what we are worried about" dialogue. To accommodate rotating 24/7 schedules, we will display educational posters and brochures directed toward communicating with nurses throughout the ICU, and include QR codes with links to instructional videos which detail how to use the tool and provide instructions on how to support family interactions with the graphic aid.

To accommodate staff turnover and attrition we will provide individual training for attending physicians and fellows who arrive at the institution after the implementation period using virtual one-on-one instruction. We will offer to train an on-site resource nurse champion for as needed nurse education at the discretion of the on-site nurse manager.

Following the above intervention training, an implementation liaison (e.g., a surgical resident or APP) at each site will continue to monitor and encourage routine use of the tool on rounds twice weekly to observe BC/WC-ICU in use and provide feedback or support for the rounding ICU team during the implementation phase.

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Adherence

An implementation liaison, who is separate from the research team that conducts surveys, will perform once-weekly audits comparing the number of study-qualified patients to the number who received daily communication using the Best Case/Worst Case-ICU tool, as assessed by graphic aid completion. The implementation liaison will retain a sample of de-identified graphic aids on digital record and note where each was posted in the ICU. The implementation team will use a scoring rubric to judge the completeness of each graphic aid and provide feedback to clinicians as needed. If we find that routine use of the intervention falls below 80% of eligible patients, we will deploy additional strategies to promote use. Specifically, we will follow up directly with individual trauma surgeons, perform twice-weekly audits, and distribute study-wide comparator reports to each site.

Control

Prior to implementation of the intervention at each site, all patients admitted to the trauma ICU will receive usual care, in accordance with the stepped-wedge study design. The pattern of usual care is well characterized,[11, 19-23] wherein clinician communication often focuses on isolated problems and treatment decisions, which can be disarticulated from the patient's overall health trajectory, prognosis, and long term functional or cognitive outcomes.

Data collection

TQIP registry: Patient-level data (i.e., demographics, clinical data, and patient outcomes, including ICU length of stay) are collected as part of the ACS TQIP trauma registry.[16] To promote quality care, participation in the TQIP registry is required for verification as a Level I trauma center and, independent of their participation in this study, each study site contracts trained registrars to abstract data elements for all patients admitted with traumatic injury. For this study, ACS TQIP will provide data, without direct patient identifiers, for each study-qualified patient admitted to the hospital during the study period. The

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ACS developed an incremental data collection platform (IDCP) for RCs to enter one additional variable not currently collected by TQIP (vital status at 6 months) and one data quality check (ICU length of stay). Seven to eight months after a patient's admission to the ICU, RCs will use the patient's Medical Record Number (MRN) and Trauma ID (provided by TQIP abstractors) to record this information into the ACS IDCP, where it will be linked to the TQIP database and the admission of interest. We will not link patient data to family member data collected by the study team.

Family Member Surveys: We will invite one family member per study-eligible patient to complete a one-time questionnaire administered 5-7 days after the patient's admission. The questionnaire consists of the Quality of Communication (QOC) survey,[24] the Receipt of Goal Concordant Care (GCC) survey,[25] and demographic questions about the family member and the patient.

Clinician Surveys: Three months prior to a site's implementation wave and again 12 months later, we will ask clinicians to complete the Measure of Moral Distress for Healthcare Professionals (MMD-HP) and Maslach Burnout Inventory (MBI) questionnaires.[26, 27] To reduce respondent burden, we will administer the two surveys two weeks apart, starting with the MMD-HP. We will also collect demographic information from clinicians including race/ethnicity, gender, role in the ICU, time in current position and time employed at the institution. Upon study completion, we will also ask trauma surgeons to complete the Practitioner Opinion Survey[28] to evaluate use of the intervention clinically.

The Qualtrics data collection platform (Version 2023, Qualtrics, Provo, UT, USA. https://www.qualtrics.com) will be used to store clinician and family survey data and voluntarily provided contact information. All study staff members who have access to identifiable subject information will be HIPAA and Human Subjects trained (e.g., CITI trained) prior to participating in study recruitment, enrollment, data collection and data analysis.

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Outcomes

Primary Outcome: We will compare family-reported QOC scores between treatment groups. The QOC instrument includes two subscales, the General QOC and the End-of-Life (EOL) QOC, wherein items not performed by the clinician receive a score of zero.[24] This allows us to discriminate between quality of communication attributable to satisfaction with the clinician, which often has high ceiling effects, and the quality of communication about prognosis and outcomes.

Key Secondary Outcomes: As a proximate measure of the effectiveness of the intervention on reducing ICU conflict, we will compare MMD-HP scores between treatment groups. The MMD-HP multiplies a clinician's reported frequency of experience and level of distress for situations specifically related to serious illness communication.[26] We will also compare treatment groups' scores on the MBI, which is recommended by the National Academy of Science and Medicine to measure clinician burnout.[29, 30]

To test the effectiveness of the intervention on patient outcomes we will compare the mean length of stay in the ICU, measured as the cumulative amount of time spent in the ICU post-injury, between treatment groups.

We outline additional secondary outcomes in table 2.

Table 2. Primary and secondary outcomes

Construct	Specific Measure	Type; range	Source	Timing
Family-reported Quality of Communication (QOC) ***primary study outcome***	The Quality of Communication questionnaire, including 6-item General communication subscale and 7-item end-of-life (EOL) communication subscale (20 items)	Continuous; 0-10	Family member survey	5-7 days after admission
Receipt of Goal Concordant Care (GCC)	The Goal Concordant Care survey 2 items: 1) preferences for care, 2) current receipt of care consistent with preferences	Binary; 1/0	Family member survey	5-7 days after admission
Moral Distress (MMD-HP)	MMD-HP measures the frequency and level of distress of clinician experiences, targeting situations specifically related to serious illness communication. (27 items)	Continuous; 0-432	Clinician survey	T0 & T1[a]

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Maslach Burnout Inventory (MBI)	MBI for Medical Personnel covers 3 areas: Emotional Exhaustion (EE), Depersonalization (DP), and low sense of Personal Accomplishment (PA) (22 items, only one version that all respondents will complete)	Continuous; EE: 0-54 DP: 0-30 PA: 0-48	Clinician survey	T0 & T1
ICU length of stay (LOS)	Total time measured in days patient spent receiving ICU care during admission for traumatic injury (not necessarily concurrent)	Continuous (log-transformed)	TQIP chart review	During hospitalization
Total ventilator days	Total time measured in days patient spent on a ventilator during admission for traumatic injury	Continuous	TQIP chart review	During hospitalization
Death	In hospital patient death	Time-to-event	TQIP chart review	During Hospitalization
	Patient 6-month mortality	Binary; 1/0	TQIP chart review	6 months
Withdrawal of Life-Supporting Treatment	Time between admission and withdrawal of life supporting treatment at the end of life	Time-to-event	TQIP chart review	During hospitalization
Practitioner Opinion Survey	Trauma surgeon's impressions of the communication tool (12 items)	Ordinal; 5-point Likert scale	Surgeon	Upon study Completion

[a]T0= 3 months before implementation, T1: 1 year after T0

Planned Analysis

Sample Size Calculation: Based on our primary hypothesis that family members in the intervention arm will be more likely to receive higher quality communication, we estimate the need for 1500 family-reported QOC surveys (750/group) to detect a difference of 0.40 in QOC scores. This detectable difference is consistent with other interventions designed to effectively improve serious illness communication and smaller differences are unlikely to be considered meaningful by clinicians, patients and families, and researchers. Our calculation assumes eight study sites, a 2-sided type 1 error rate of 0.05, a standard deviation of 1.92, and an intraclass correlation coefficient (ICC) of 0.001 based on preliminary data.[31] Based on these assumptions, we will have 80% power to detect a significant mean difference of 0.40. If we consider the upper limit of the 95% confidence interval for the ICC, i.e., ICC=0.02, the detectable difference increases to 0.48.

Primary outcomes analysis: Using an intent-to-treat analysis, we will use a linear mixed-effects model to test the effect of the tool on family-reported quality of communication as compared to usual care. The model will include a treatment indicator variable, a fixed effect for time (measured categorically by wave), and a random-intercept for site.[32]

Key secondary outcomes analysis: We will examine the effect of the intervention on key secondary outcomes in the context of linear mixed-effects models. Models examining clinician outcomes, i.e., MMD-HP and MBI scores, will include a post-study indicator variable and a random-intercept for site. For patient health outcomes, specifically ICU LOS, we will include a treatment indicator variable, as well as fixed effects for time, patient comorbidity and injury severity, and a random-intercept for site.

Exploratory analysis: Given the intricacies of examining ICU LOS when follow-up may be truncated due to patient death,[33] we will perform two exploratory analyses. First, we will examine ICU LOS among decedents only (i.e., those who died during their ICU hospitalization) using a linear mixed-effects model. Second, we will implement causal mediation analysis to determine if the effect that Best Case/Worst Case intervention has on ICU LOS is mediated by in-hospital mortality.

Missing data

Following the principles of the National Research Council (NRC) report, we designed this study to minimize the potential for missing data.[34] We expect missing outcomes will be minimal for QOC as it is collected in person or via telephone at the time of family member enrollment. We will handle missing data due to item non-response in a manner consistent with QOC scoring guidelines, i.e., we will impute unanswered survey questions with the respondent's median score for all answered questions within the subsection (general QOC or EOL QOC) if at least half the questions were answered.[24] We will require respondents to have subscale scores to receive an overall QOC score. We anticipate low rates of missing data for patient outcomes related to their trauma admission, since all participating trauma centers report this information to the TQIP registry for quality assurance purposes.

Patient and Public Involvement

Patients and members of the public were not involved in the design or conduct of the study. There is planned engagement of patients and family stakeholders via the Coalition for National Trauma Research (CNTR) and the Injury Research Engagement Panel for reporting and dissemination of this research.

ETHICS AND DISSEMINATION

Ethical Review

This study presents minimal risks to participants. We will not obtain patient consent for randomization to treatment group or delivery of the intervention, or for data collection because the intervention qualifies as quality improvement, implementation occurs at the study-site level, and the TQIP quality registry collects all patient data regardless of study participation. We will not obtain consent for clinician training as the tool is considered quality improvement. We will obtain verbal consent for family member and clinician surveys at the time of survey completion and participants may withdraw at any time. Study participation will not affect the care a patient receives nor clinicians' professional standing. Institutional Review Board (IRB) approval was granted at the University of Wisconsin (UW), and study sites ceded review to the primary IRB. An independent Data Safety Monitoring Board (DSMB), representing a variety of backgrounds, including biostatistics and trauma care, will serve as the data and safety advisory group for all study sites. The DSMB met prior to study initiation, and will meet again after 12 months of family-member data collection and at the end of data collection. We will submit all reportable events to the DSMB and the primary IRB in accordance with their reporting guidelines. As this is a minimal risk study, there are no predefined stopping points due to futility, efficacy, or harms.

Relevance and Dissemination

Our intervention uses scenario planning to disrupt the clinical momentum that promotes passive accumulation and escalation of life-supporting treatments without active consideration of whether these treatments and their associated outcomes are consistent with the patient's overall health goals

and prognosis. If shown to be effective, our intervention could support improved patient centered outcomes for families, clinicians, and patients with serious illness in the ICU and reduce strain on ICU resources. We plan to publish study results in peer reviewed journals. Information about the intervention, including training materials, is available at https://patientpreferences.org/bcwc-icu/. A de-identified data set comprised of survey data, metadata, and analytic code will be made available through the National Archive of Computerized Data on Aging (NACDA), or comparable NIH-supported repository. Patient-level data collected by the TQIP registry is available upon request from the American College of Surgeons (ACS), who administer the TQIP program. Evidence of the effectiveness of the Best Case/Worst Case-ICU communication tool would support investment in clinician communication training, wide adoption by trauma centers, and provide new knowledge about how scenario planning can assist decision makers during serious illness.

Authors' Contributions: MLS is the principal investigator for this study. She developed the original study design and protocol with KK and BH, who provided input on study design, and the site principal investigators DS, CSC, JJ, KJB, KMO, MDC, PAC, RM, RG, RK, and SL. KB is the study manager. ABZ and MF developed the educational materials. LS, MLS, and BH drafted this manuscript. All authors reviewed and approved this manuscript.

Acknowledgments: We would like to thank the ACS and the Coalition for National Trauma Research (CNTR) for their collaboration. Specifically, we would like to acknowledge the support of Bhavin Patel (ACS) and Dr. Michelle Price (CNTR). We would also like to thank the Research Coordinators for their dedication.

Funding Statement: This work was supported by the National Institutes of Health grant number *R01AG078242*.

Competing Interests Statement: The authors declare no competing interests.

Figure 1. Example of the Best Case/Worst Case-ICU graphic aid. On each day of a patient's ICU stay, the trauma team uses a preprinted graphic aid to review major events from the previous 24 hours and describe the patient's overall health trajectory. On the graphic aid, each ICU day corresponds to a column, and the range of possible scenarios, i.e., stories describing how this new injury could play out over time, are designated on a vertical line. A star distinguishes the "best case scenario" and a box designates the "worst case scenario." Each day, the trauma team will record any new major events at the top of the column. The star is moved based on how a new event, like a diagnosis of pneumonia or an improvement in neurologic function after a stroke, changes the best case scenario. Over time, the placement of the star goes up or down depending on how these events change the patient's overall story.

Figure 2. Using a stepped-wedge design, we will conduct this study over six 3-month-long waves at eight high volume trauma centers. During the first wave, all patients will receive usual care. With each subsequent wave, two randomly selected sites will enter the implementation phase. Data collection will cease during implementation and the study implementation team will train clinicians to use the Best Case/Worst Case-ICU tool. Following the wave for implementation training, patients will receive care from a trauma team that routinely uses the Best Case/Worst Case-ICU tool.

BEST CASE/WORST CASE-ICU PROTOCOL

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Best Case/Worst Case: ICU

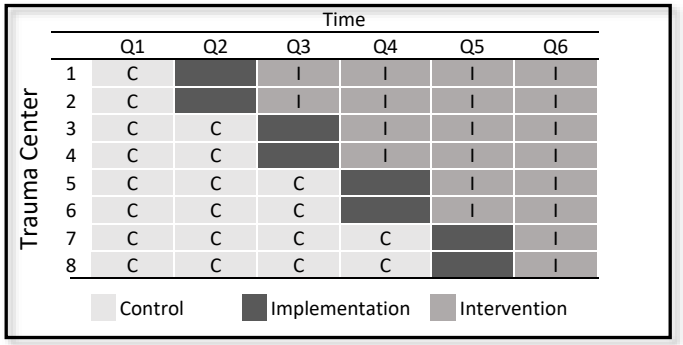
What things may look like going forward

Pt Initials: PJ

Room Number: 56

	Date: 1/3 Event: Car accident	Date: 1/4 Event: Ø	Date: 1/5 Event: stroke	Date: 1/6 Event: fevers	Date: 1/7 Event: Planned surgery
Hopes					
Range of What is Possible	**Best Case Scenario** -get breathing tube out in 1-2 days -hospital 1-2 wks -will need rehab 6-8 weeks -Return home, goes a bit slower, mostly like he was before	**Best Case Scenario**	**Best Case Scenario** -may need breathing tube longer -long time in SNF to recover, 8-12 weeks -return home, will need close support, mostly like he was before but slower	**Best Case Scenario** -a bit more time in ICU, but mostly the same	**Best Case Scenario** -Tracheostomy and feeding tube for 3-4 months until feeling better -expecting to get home but will need much help ~4-6 months
Worries	**Worst Case Scenario**	**Worst Case Scenario**	**Worst Case Scenario**	**Worst Case Scenario**	**Worst Case Scenario**

Worry he could die from this →



SPIRIT-Outcomes 2022 Checklist (for combined completion of SPIRIT 2013 and SPIRIT-Outcomes 2022 items)[a]

Section	Item No.	SPIRIT 2013 Item	SPIRIT-Outcomes 2022 item	Location Reported[b]
Administrative information				
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	-	
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	-	
	2b	All items from the World Health Organization Trial Registration Data Set	-	
Protocol version	3	Date and version identifier	-	
Funding	4	Sources and types of financial, material, and other support	-	
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	-	
	5b	Name and contact information for the trial sponsor	-	
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	-	
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	-	
Introduction				
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	-	
	6b	Explanation for choice of comparators	-	
Objectives	7	Specific objectives or hypotheses	-	

Section	Item No.	SPIRIT 2013 Item	SPIRIT-Outcomes 2022 item	Location Reported[b]
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	-	
Methods: Participants, interventions, and outcomes				
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	-	
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	-	
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered (for specific guidance see TIDieR checklist and guide)	-	
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	-	
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	-	
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	-	
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	-	

Section	Item No.	SPIRIT 2013 Item	SPIRIT-Outcomes 2022 item	Location Reported[b]
	12.1		Provide a rationale for the selection of the domain for the trial's primary outcome	
	12.2		If the analysis metric for the primary outcome represents within-participant change, define and justify the minimal important change in individuals	
	12.3		If the outcome data collected are continuous but will be analyzed as categorical (method of aggregation), specify the cutoff values to be used	
	12.4		If outcome assessments will be performed at several time points after randomization, state the time points that will be used for analysis	
	12.5		If a composite outcome is used, define all individual components of the composite outcome	
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	-	
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	-	
	14.1		Define and justify the target difference between treatment groups (eg, the minimal important difference)	
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	-	
Methods: Assignment of interventions (for controlled trials)				
Allocation:				
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	-	

Section	Item No.	SPIRIT 2013 Item	SPIRIT-Outcomes 2022 item	Location Reported[b]
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	-	
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	-	
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	-	
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	-	
Methods: Data collection, management, and analysis				
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	-	
	18a.1		Describe what is known about the responsiveness of the study instruments in a population similar to the study sample	
	18a.2		Describe who will assess the outcome (eg, nurse, parent)	
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	-	

Section	Item No.	SPIRIT 2013 Item	SPIRIT-Outcomes 2022 item	Location Reported[b]
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	-	
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	-	
	20a.1		Describe any planned methods to account for multiplicity in the analysis or interpretation of the primary and secondary outcomes (eg, coprimary outcomes, same outcome assessed at multiple time points, or subgroup analyses of an outcome)	
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	-	
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	-	
Methods: Monitoring				
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	-	
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	-	
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	-	

Section	Item No.	SPIRIT 2013 Item	SPIRIT-Outcomes 2022 item	Location Reported[b]
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	-	
Ethics and dissemination				
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	-	
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	-	
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	-	
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	-	
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	-	
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	-	
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	-	
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	-	
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	-	
	31b	Authorship eligibility guidelines and any intended use of professional writers	-	

Section	Item No.	SPIRIT 2013 Item	SPIRIT-Outcomes 2022 item	Location Reported[b]
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	-	
Appendices				
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	-	
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	-	

[a]It is strongly recommended that this checklist be read in conjunction with the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) Statement paper for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license and is reproduced with permission.
[b]Indicates page numbers and/or manuscript location: to be completed by authors.

BMJ Open

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

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2023-083603.R1
Article Type:	Protocol
Date Submitted by the Author:	24-May-2024
Complete List of Authors:	Stalter, Lily; University of Wisconsin-Madison, Department of Surgery Hanlon, Bret M.; University of Wisconsin-Madison, Department of Surgery; University of Wisconsin-Madison, Department of Biostatistics & Medical Informatics Bushaw, Kyle; University of Wisconsin-Madison, Department of Surgery Kwekkeboom, Kristine L.; University of Wisconsin-Madison, School of Nursing Zelenski, Amy ; University of Wisconsin-Madison, Department of Medicine Fritz, Melanie; University of Wisconsin-Madison, Department of Surgery Buffington, Anne; University of Wisconsin-Madison, Department of Surgery Stein, DM; University of Maryland School of Medicine, Shock Trauma Center Cocanour, Christine S. ; University of California Davis, Department of Surgery Robles, Anamaria; University of California Davis, Department of Surgery Jansen, Jan; University of Alabama at Birmingham, Department of Surgery Brasel, Karen; Oregon Health and Science University, School of Medicine O'Connell, Kathleen; University of Washington, Department of Medicine Cipolle, Mark; Lehigh Valley Health Network, Division of Trauma-Surgical Critical Care Ayoung-Chee, Patricia; Morehouse School of Medicine, Department of Surgery, Morehouse School of Medicine Morris, Rachel ; Medical College of Wisconsin, Department of Surgery, Division of Trauma and Acute Care Surgery Gelbard, Rondi; The University of Alabama at Birmingham, Department of Surgery Kozar, Rosemary; University of Maryland School of Medicine, Shock Trauma Center Lueckel, Stephanie; Brown University, Division of Acute Care Surgery and Surgical Critical Care Schwarze, Margaret; University of Wisconsin Madison, Department of Surgery
Primary Subject Heading:	Communication

Secondary Subject Heading:	Intensive care
Keywords:	PALLIATIVE CARE, MEDICAL ETHICS, TRAUMA MANAGEMENT, Adult intensive & critical care < INTENSIVE & CRITICAL CARE, Clinical Trial

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

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Word count: 3999
Tables: 2
Figures: 2
References: 39

ABSTRACT

Introduction: Poor communication about serious injury in older adults can lead to treatment that is inconsistent with patient preferences, create conflict, and strain healthcare resources. We developed a communication intervention called Best Case/Worst Case-ICU that uses daily scenario planning, i.e., narrative description of plausible futures, to support prognostication and facilitate dialogue among patients, their families, and the trauma ICU team. This article describes a protocol for a multisite, randomized, stepped-wedge study to test the effectiveness of the intervention on the quality of communication in the ICU.

Methods and analysis: We will follow all patients aged 50 and older admitted to the trauma ICU for three or more days after serious injury at eight high volume Level 1 trauma centers. 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. Utilizing a stepped-wedge design, we will use permuted block randomization to assign the timing for each site to begin implementation of the intervention and routine use of the Best Case/Worst Case-ICU tool. We will use a linear mixed-effects model to test the effect of the tool on family-reported quality of communication (using the Quality of Communication (QOC) scale) as compared to usual care. Secondary outcomes include the effect of the tool on reducing clinician moral distress (using the Measure of Moral Distress for Healthcare Professionals (MMD-HP) scale) and patients' length of stay in the ICU.

Ethics and dissemination: Institutional Review Board (IRB) approval was granted at the University of Wisconsin (UW), and all study sites ceded review to the primary IRB. We plan to report results in peer-reviewed publications and national meetings.

Registration details: This study is funded by the National Institutes of Health (*R01AG078242*) and is registered at clinicaltrials.gov (*NCT05780918)*.

Strengths and Limitations of this study:

- In this registry-enabled clinical trial, we will utilize the American College of Surgeons Trauma Quality Improvement Program (ACS TQIP) national registry to follow all eligible patients at eight high volume Level I trauma centers across the United States.
- We designed this study to minimize the potential for missing data and anticipate low rates of missingness because family surveys are collected at the time of enrollment and all trauma centers involved in this study report clinical data to the American College of Surgeons Trauma Quality Improvement Program (TQIP) for quality assurance and benchmarking.
- We have a strong implementation strategy, a fidelity-monitoring plan with weekly audit feedback, and the ability to verify adherence to the intervention.
- We will utilize a stepped wedge design, which allows us to test the intervention in a multilevel space, while minimizing the risk of contamination bias compared to a patient-level randomized design testing the same intervention.
- We will not survey patients nor link family surveys to individual patient outcomes, this study design compromise improves study feasibility and reduces regulatory complexity but will limit our ability to interpret some study findings.

Introduction

Background

Each year, half a million adults 50 years or above suffer injury from a fall or other traumatic event.[1, 2] Older adults fare far worse than younger patients with similar injuries due to chronic comorbid conditions and reduced physiologic reserve. As such, traumatic injury is often a pre-terminal event, with 20% in-hospital and 40% one-year mortality.[3] Treatment for traumatic injury frequently involves burdensome treatments (like invasive surgical procedures or prolonged life support) that may be inconsistent with patients' preferences and goals.[4-6] This disconnect between patients' priorities and treatments received can lead to conflict in the intensive care unit (ICU), specifically interpersonal conflict among clinicians (e.g., between nurses and surgeons) and with patients' loved ones (e.g., between surrogate decision makers and the trauma ICU team) during treatment discussions.[7, 8] Moreover, overtreatment at the end of life prolongs dying and contributes $44 billion annually in the United States to healthcare costs.[9] A communication intervention that facilitates the articulation of patient priorities could reduce unwanted invasive procedures and clarify patients' long-term goals, benefiting patients, loved ones, clinicians, and healthcare systems.[10]

The Best Case/Worst Case-ICU Tool

We developed a communication intervention called Best Case/Worst Case-ICU that uses scenario planning, i.e., narrative description of plausible futures, to support decision-making and facilitate dialogue among patients, their loved ones, and the trauma team. Typically, in accordance with standards for informed consent, clinicians present risks as discrete complications for isolated physiologic systems (e.g., a 50% chance of kidney failure) or the binary outcome of mortality (e.g., a 40% chance of survival).[11] Because this language does not describe how a patient might experience treatments or the expected downstream outcomes, such as predictable changes in functional status, prolonged recovery, or need for long-term care in a nursing home, patients and families may struggle to anticipate and

account for the consequences of serious injury and make treatment decisions accordingly. Scenario planning provides an alternative strategy for managing uncertainty that is in distinct contrast to emphasizing isolated risks or discrete treatment effects. Instead, scenario planning generates multiple plausible futures, prompting decision makers to consider causal relationships and visualize a range of outcomes based on sound analysis of the present.[12]

We designed the Best Case/Worst Case-ICU tool to help visualize uncertainty, illustrate the interplay between major events and prognosis, and describe how patients might experience the various treatments received along the course of care. By using a graphic aid to illustrate "what we are hoping for," "what we are worried about,"[13] and the evolution of the patient's story or clinical course over time, including setbacks and improvements, the tool aims to keep everyone (clinicians, patients, and loved ones) well-informed. The tool facilitates clinician delivery of critical prognostic information over the longitudinal course of care, allowing subsequent treatment decisions, e.g., additional operations or prolonged mechanical ventilation, to be made within the context of the patient's overall health status and goals. Ultimately, this tool alerts patients and families to the life-limiting nature of serious injury and provides valuable insight as they consider whether comfort-focused strategies might better support their care needs.

We designed the tool to fit the pace of busy trauma ICU rounds. The trauma team collaboratively completes the graphic aid during the summative systems-based review daily for each patient (Figure 1). With usual care, a clinician (typically a surgical resident) lists each physiologic system, i.e., neuro, cardiac, pulmonary, etc., or individual medical problems with an assessment and plan for each. When using the tool, they add "outlook", i.e., the best case scenario, at the end. While the attending physician or fellow generates this story, another team member records it on the graphic aid. The worst case scenario is modified as needed but does not typically require daily updating. The graphic aid is posted in

the patient's room, where loved ones and clinicians can use it to recall what to expect, visualize uncertainty, and see how things change over the patient's course of care.

The daily stories and the graphic aid provide support and perspective for everyone involved in the care of the patient. If the patient clinically improves, their loved ones are primed for the road to recovery. If the patient worsens, their loved ones will be prepared, and the gravity of the patient's illness will not come as a surprise. Important decisions, such as proceeding with an operation or continuing mechanical ventilation, can be made within the context of the patient's overall health trajectory. We hypothesize that this will lead to improved communication in the ICU, and patients will receive care that better aligns with their health goals. We theorize this will reduce interpersonal ICU conflict that contributes to clinician burnout and moral distress.

Methods and analysis

Design and Setting

We will utilize a multisite, randomized, stepped-wedge design to test the effectiveness of the Best Case/Worst Case-ICU tool.[14] This 18-month study will be executed over six 3-month-long waves (Figure 2). In wave 1, all patients will receive usual care. With each subsequent wave, we will randomly select two sites to enter the implementation phase. Data collection will cease for sites during the implementation wave and the study implementation team will train clinicians to use the Best Case/Worst Case-ICU tool. After the implementation wave, the site will be in the intervention arm, and patients will receive care from a trauma team that routinely uses the Best Case/Worst Case-ICU tool.

We will conduct this study at eight high volume Level I trauma centers from across the United States (Table 1). Data collection began July 1st, 2023 and the estimated date of study completion is December 31st, 2025.

Participants

Patients: We will follow all patients aged 50 and older admitted to the trauma ICU at study sites for three or more days after serious injury.

Family Members: For each patient who receives three or more days of ICU care provided primarily by the trauma ICU team, we will invite one family member or informally designated "like family" member or primary surrogate decision maker (hereafter family) to participate 5-7 days after admission. We will use medical records and nursing referrals to identify the person most frequently engaged in the patient's care. Family members must be at least 18-years-old, speak English or Spanish, and have decision-making capacity.[15] We will approach family members regardless of whether their loved one has been discharged from the ICU or is deceased.

Clinicians: We will invite all clinicians providing care in the trauma ICU to participate in the intervention training. This includes ICU attendings (e.g., trauma surgeons), fellows, residents, advance practice providers (APPs), bedside nurses and medical assistants, respiratory and physical therapists, social workers, pharmacists, and chaplains. We will exclude individuals who do not provide primary care in the trauma ICU, e.g., medical specialists.

Recruitment

In this registry-enabled study, all patient-level data will come from the American College of Surgeons Trauma Quality Improvement Program (ACS TQIP) national registry, which collects demographics and outcomes for all trauma patients at 850 participating centers according to the National Trauma Data Standards.[16] We will not directly recruit patients for this study. A research coordinator (RC) at each site will approach eligible family members in person or via telephone. Qualifying family members will receive a $20 incentive after a one-time survey completion.

We will send clinicians an anonymous link to an electronic survey via their hospital-based email address, with up to three additional email requests. To increase the response rate, RCs will request survey completion in person in the trauma ICU, during multiple shifts over the 4-week data collection period. Additionally, the site Principal Investigator (PI) will encourage completion of study procedures at ICU team meetings and through hospital-generated electronic notification systems (e.g., weekly email updates). Clinicians will receive a $5 incentive for each survey completed (up to $20 total). Attending surgeons and fellows will receive $100 for the completion of the 30-minute one-on-one training.

Randomization and Blinding

We will use permuted block randomization to assign the timing for each site to begin implementation of the intervention and routine use of the Best Case/Worst Case-ICU tool. Study sites will be stratified based on historic patient volume (i.e., very high or high) to increase the likelihood of a balanced distribution of participants across study arms. A study statistician will link treatment group assignment to patient and family member data using the patient's admission date.

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] Clinicians will not be blinded to treatment group. While we will inform all clinicians of the study goals, clinicians will not be told specific study outcomes or hypotheses. TQIP registrars will abstract data throughout the study, in a manner consistent with their normal work processes, without being informed on the status of interventional procedures. To decrease ascertainment bias, on-site research staff will not participate in intervention implementation and will adhere to a strict study script during interactions with clinicians and family members.

Intervention

Delivery of the intervention requires training trauma ICU teams how to use the Best Case/Worst Case-ICU tool. The intervention is considered quality improvement because its primary purpose is to integrate guideline recommended behaviors, e.g., timely communication with families/loved ones and emotional support as part of routine care in the ICU.[19, 20] Because the Best Case/Worst Case-ICU tool is intended for team-based clinician-family communication, the training program is tailored to the clinician's role on the trauma team.

We will invite all attending physicians and fellows who round in the trauma ICU to attend a 30-minute one-on-one instructional program followed by coaching, assessment, and additional training, as needed. Instruction for attendings and fellows will focus on translating clinical knowledge and prognostic information into the Best Case/Worst Case-ICU format. Key topics include daily scenario planning to tell a best case and worst case scenario, identifying major events that change the best case scenario, and completing the graphic aid, while also reviewing skills to support shared decision making for patients with serious illness. Attendings/fellows who do not achieve minimal competence (10 of 14 essential tool elements) on assessment will receive additional training until they reach competence.

For resident trainees and APPs who are rotating in the ICU, we will host a 30 minute to 1 hour group session, which includes a 10-minute instructional video. This session focuses on teaching how to routinely complete the graphic aid on rounds with minimal disruption, specifically, how to include the patient's "outlook" and document the best case scenario. Using a hypothetical case, learners will practice completing the graphic aid and watch a standardized video reviewing the case. We will repeat this training on a regular basis to accommodate new residents brought into the ICU for clinical rotations. For general surgery residents, who often comprise a significant portion of resident trainees in the ICU, we will also offer an institution-wide one-time training.

We will provide education to bedside nurses and other clinical ICU staff during in-service meetings and other routine meetings as guided by on-site nurse managers. Our implementation team will describe the tool, answer questions, and reinforce the "this is what we are hoping for" and "this is what we are worried about" dialogue. To accommodate rotating 24/7 schedules, we will display educational posters and brochures directed toward communicating with nurses throughout the ICU, and include QR codes with links to instructional videos which detail how to use the tool and provide instructions on supporting family interactions with the graphic aid.

To accommodate staff turnover and attrition we will provide individual training for attending physicians and fellows who arrive at the institution after the implementation period using virtual one-on-one instruction. 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.

Following the above intervention training, an implementation liaison (e.g., a surgical resident or APP) at each site will continue to monitor and encourage routine use of the tool on rounds twice weekly to observe BC/WC-ICU in use and provide feedback or support for the rounding ICU team during the implementation phase.

Adherence

An implementation liaison, who is separate from the research team that conducts surveys, will perform once-weekly audits comparing the number of study-qualified patients to the number who received daily communication using the Best Case/Worst Case-ICU tool, as assessed by graphic aid completion. The implementation liaison will retain a sample of de-identified graphic aids on digital record and note where each was posted in the ICU. The implementation team will use a scoring rubric to judge the completeness of each graphic aid and provide feedback to clinicians as needed. If we find that routine use of the intervention falls below 80% of eligible patients, we will deploy additional strategies to

promote use. 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.

Control

Prior to implementation of the intervention at each site, all patients admitted to the trauma ICU will receive usual care, in accordance with the stepped-wedge study design. The pattern of usual care is well characterized,[11, 21-25] wherein clinician communication often focuses on isolated problems and treatment decisions, which can be disarticulated from the patient's overall health trajectory, prognosis, and long term functional or cognitive outcomes.

Data collection

TQIP registry: Patient-level data (i.e., demographics, clinical data, and patient outcomes, including ICU length of stay (LOS)) are collected as part of the ACS TQIP trauma registry.[16] To promote quality care, participation in the TQIP registry is required for verification as a Level I trauma center and, independent of their participation in this study, each study site contracts trained registrars to abstract data elements for all patients admitted with traumatic injury. For this study, ACS TQIP will provide data, without direct patient identifiers, for each study-qualified patient admitted to the hospital during the study period. The ACS developed an incremental data collection platform (IDCP) for RCs to enter one additional variable not currently collected by TQIP (vital status at 6 months) and one data quality check (ICU LOS). Seven to eight months after a patient's admission to the ICU, RCs will use the patient's Medical Record Number (MRN) and Trauma ID (provided by TQIP abstractors) to record this information into the ACS IDCP, where it will be linked to the TQIP database and the admission of interest. 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.

Family Member Surveys: We will invite one family member per study-eligible patient to complete a one-time questionnaire administered 5-7 days after the patient's admission. The questionnaire consists of the Quality of Communication (QOC) survey,[26] the Receipt of Goal Concordant Care (GCC) survey,[27] and demographic questions about the family member and the patient.

Clinician Surveys: Three months prior to a site's implementation wave and again 12 months later, we will ask clinicians to complete the Measure of Moral Distress for Healthcare Professionals (MMD-HP) and Maslach Burnout Inventory (MBI) questionnaires.[28, 29] To reduce respondent burden, we will administer the two surveys two weeks apart, starting with the MMD-HP. We will also collect demographic information from clinicians including race/ethnicity, gender, role in the ICU, time in current position and time employed at the institution. Upon study completion, we will also ask trauma surgeons to complete the Practitioner Opinion Survey[30] to evaluate use of the intervention clinically.

The Qualtrics data collection platform (Version 2023, Qualtrics, Provo, UT, USA. https://www.qualtrics.com) will be used to store clinician and family survey data and voluntarily provided contact information. All study staff members who have access to identifiable subject information will be HIPAA and Human Subjects trained (e.g., CITI trained) prior to participating in study recruitment, enrollment, data collection and data analysis.

Outcomes

Primary Outcome: We will compare family-reported QOC scores between treatment groups. The QOC instrument includes two subscales, the General QOC and the End-of-Life (EOL) QOC, wherein items not performed by the clinician receive a score of zero.[26] This allows us to discriminate between quality of communication attributable to satisfaction with the clinician, which often has high ceiling effects, and the quality of communication about prognosis and outcomes.

Key Secondary Outcomes: As a proximate measure of the effectiveness of the intervention on reducing ICU conflict, we will compare MMD-HP scores between treatment groups. The MMD-HP multiplies a clinician's reported frequency of experience and level of distress for situations specifically related to serious illness communication.[28] We will also compare treatment groups' scores on the MBI, which is recommended by the National Academy of Science and Medicine to measure clinician burnout.[31, 32]

To test the effectiveness of the intervention on patient outcomes we will compare the mean length of stay in the ICU, measured as the cumulative amount of time spent in the ICU post-injury, between treatment groups.

We outline additional secondary outcomes in table 2.

Planned Analysis

Sample Size Calculation: Based on our primary hypothesis that family members in the intervention arm will be more likely to receive higher quality communication, we estimate the need for 1500 family-reported QOC surveys (750/group) to detect a difference of 0.40 in QOC scores. This detectable difference is consistent with other interventions designed to effectively improve serious illness communication and smaller differences are unlikely to be considered meaningful by clinicians, patients and families, and researchers. Our calculation assumes eight study sites, a 2-sided type 1 error rate of 0.05, a standard deviation of 1.92, and an intraclass correlation coefficient (ICC) of 0.001 based on

preliminary data.[33] Based on these assumptions, we will have 80% power to detect a significant mean difference of 0.40. If we consider the upper limit of the 95% confidence interval for the ICC, i.e., ICC=0.02, the detectable difference increases to 0.48.

Based on 2019 historical TQIP data, we anticipate following approximately 4500 patients. We estimate enrolling up to 1600 clinicians.

Primary outcomes analysis: Using an intent-to-treat analysis, we will use a linear mixed-effects model to test the effect of the tool on family-reported quality of communication as compared to usual care. The model will include a treatment indicator variable, a fixed effect for time (measured categorically by wave), and a random-intercept for site.[34]

Key secondary outcomes analysis: We will examine the effect of the intervention on key secondary outcomes in the context of linear mixed-effects models. Models examining clinician outcomes, i.e., MMD-HP and MBI scores, will include a post-study indicator variable and a random-intercept for site. For patient health outcomes, specifically ICU LOS, we will include a treatment indicator variable, as well as fixed effects for time, patient comorbidity and injury severity, and a random-intercept for site.

Exploratory analysis: Given the intricacies of examining ICU LOS when follow-up may be truncated due to patient death,[35] we will perform two exploratory analyses. First, we will examine ICU LOS among decedents only (i.e., those who died during their ICU hospitalization) using a linear mixed-effects model. Second, we will implement causal mediation analysis to determine if the effect that Best Case/Worst Case intervention has on ICU LOS is mediated by in-hospital mortality.

Missing data

Following the principles of the National Research Council (NRC) report, we designed this study to minimize the potential for missing data.[36] We expect missing outcomes will be minimal for QOC as it is

collected in person or via telephone at the time of family member enrollment. We will handle missing data due to item non-response in a manner consistent with QOC scoring guidelines, i.e., we will impute unanswered survey questions with the respondent's median score for all answered questions within the subsection (general QOC or EOL QOC) if at least half the questions were answered.[26] We will require respondents to have subscale scores to receive an overall QOC score. We anticipate low rates of missing data for patient outcomes related to their trauma admission, since all participating trauma centers report this information to the TQIP registry for quality assurance purposes.

Patient and Public Involvement

Patients and members of the public were not involved in the design or conduct of the study. There is planned engagement of patients and family stakeholders via the Coalition for National Trauma Research (CNTR) and the Injury Research Engagement Panel for reporting and dissemination of this research.

Ethics and Dissemination

Ethical Review

This study presents minimal risks to participants. Following an approach well described in health services research,[37, 38] we will implement a quality improvement initiative within an interventional research study. Implementing the Best Case/Worst Case-ICU communication tool is considered a quality improvement initiative because it aims to improve guideline-recommended standard practice for discussing care with patients and families. Our systematic investigation of the effect of the Best Case/Worst Case-ICU communication tool on clinician and family member experiences and patient outcomes aligns with the federal definition of research.[39] We will not obtain patient consent for randomization to treatment group or delivery of the intervention because the intervention qualifies as quality improvement, compares guide-line recommended care to usual care, and implementation occurs at the study-site level. Additionally, we will not obtain patient consent for clinical data collection as the

TQIP quality registry collects all patient data regardless of study participation. We will not obtain consent for clinician training as the tool is an educational initiative to support both clinicians and patients in having high-quality conversations. We will obtain verbal consent for study procedures, specifically family member and clinician surveys at the time of survey completion and participants may withdraw at any time (Supplementary Materials 1 and 2). Study participation will not affect the care a patient receives nor clinicians' professional standing. Institutional Review Board (IRB) approval was granted at the University of Wisconsin (UW), and study sites ceded review to the primary IRB. An independent Data Safety Monitoring Board (DSMB), representing a variety of backgrounds, including biostatistics and trauma care, will serve as the data and safety advisory group for all study sites. The DSMB met prior to study initiation, and will meet again after 12 months of family-member data collection and at the end of data collection. We will submit all reportable events to the DSMB and the primary IRB in accordance with their reporting guidelines. As this is a minimal risk study, there are no predefined stopping points due to futility, efficacy, or harms.

Relevance and Dissemination

Our intervention uses scenario planning to disrupt the clinical momentum that promotes passive accumulation and escalation of life-supporting treatments without active consideration of whether these treatments and their associated outcomes are consistent with the patient's overall health goals and prognosis. If shown to be effective, our intervention could support improved patient centered outcomes for families, clinicians, and patients with serious illness in the ICU and reduce strain on ICU resources. We plan to publish study results in peer reviewed journals. Information about the intervention, including training materials, is available at https://patientpreferences.org/bcwc-icu/. A de-identified data set comprised of survey data, metadata, and analytic code will be made available through the National Archive of Computerized Data on Aging (NACDA), or comparable NIH-supported repository. Patient-level data collected by the TQIP registry is available upon request from the American

College of Surgeons (ACS), who administer the TQIP program. Evidence of the effectiveness of the Best Case/Worst Case-ICU communication tool would support investment in clinician communication training, wide adoption by trauma centers, and provide new knowledge about how scenario planning can assist decision makers during serious illness.

Authors' Contributions: MS is the principal investigator for this study. She developed the original study design and protocol with KLK and BMH, who provided input on study design, and the site principal investigators DMS, CSC, JJ, K Brasel, KO, MC, PAC, RM, RG, RK, AR and SL. K Bushaw and AB are study managers. AZ and MF developed the educational materials. LS, MS, and BMH drafted this manuscript. MS is the guarantor. All authors reviewed and approved this manuscript.

Acknowledgments: We would like to thank the ACS and the Coalition for National Trauma Research (CNTR) for their collaboration. Specifically, we would like to acknowledge the support of Bhavin Patel (ACS) and Dr. Michelle Price (CNTR). We would also like to thank the Research Coordinators for their dedication.

Funding Statement: This work was supported by the National Institutes of Health grant number *R01AG078242*.

Competing Interests Statement: The authors declare no competing interests.

Table 1. Study sites with annual number of eligible patients based on 2019 ICU volume.

Trauma Center	Location	Patients Meeting Study Eligibility Criteria	Stratification for Randomization
Harborview Medical Center (University of Washington)	Seattle, WA	702	Very High
University of Alabama at Birmingham	Birmingham, AL	615	Very High
Grady Memorial Hospital (Morehouse School of Medicine)	Atlanta, GA	583	Very High
Lehigh Valley Health Network	Allentown, PA	507	Very High
Rhode Island Hospital	Providence, RI	504	High
Shock Trauma (University of Maryland Medical Center)	Baltimore, MD	398	High
Froedtert Hospital (Medical College of Wisconsin)	Milwaukee, WI	321	High
UC Davis Medical Center	Sacramento, CA	289	High

Table 2. Primary and secondary outcomes

Construct	Specific Measure	Type; range	Source	Timing
Primary Study Outcome				
Family-reported Quality of Communication (QOC)	The Quality of Communication questionnaire, including 6-item General communication subscale and 7-item end-of-life (EOL) communication subscale (20 items)	Continuous; 0-10	Family member survey	5-7 days after admission
Secondary Outcomes				
Family-reported General Quality of Communication (QOC)	The General communication subscale or the Quality of Communication questionnaire (6 items)	Continuous; 0-10	Family member survey	5-7 days after admission
Family-reported End-of-Life (EOL) Quality of Communication (QOC)	The EOL communication subscale or the Quality of Communication questionnaire (7 items)	Continuous; 0-10	Family member survey	5-7 days after admission
Receipt of Goal Concordant Care (GCC)	The Goal Concordant Care survey 2 items: 1) preferences for care, 2) current receipt of care consistent with preferences	Binary; 1/0	Family member survey	5-7 days after admission
Moral Distress (MMD-HP)	MMD-HP measures the frequency and level of distress of clinician experiences, targeting situations specifically related to serious illness communication. (27 items)	Continuous; 0-432	Clinician survey	T0 & T1[a]
Maslach Burnout Inventory (MBI)	Emotional Exhaustion (EE) subscale of MBI for Medical Personnel (22 items total, 9 items on subscale)	Continuous; EE: 0-54	Clinician survey	T0 & T1
	Depersonalization (DP) subscale of MBI for Medical Personnel (22 items total, 5 items on subscale)	Continuous; DP: 0-30	Clinician survey	T0 & T1
	Personal Accomplishment (PA) subscale of MBI for Medical Personnel (22 items total, 8 items on subscale)	Continuous; PA: 0-48	Clinician survey	T0 & T1
ICU length of stay (LOS)	Total time measured in days patient spent receiving ICU care during admission for traumatic injury (not necessarily concurrent)	Continuous (log-transformed)	TQIP chart review	During hospitalization
Total ventilator days	Total time measured in days patient spent on a ventilator during admission for traumatic injury	Continuous	TQIP chart review	During hospitalization
Death	In hospital patient death	Time-to-event	TQIP chart review	During Hospitalization
	Patient 6-month mortality	Binary; 1/0	TQIP chart review	6 months
Withdrawal of Life-Supporting Treatment	Time between admission and withdrawal of life supporting treatment at the end of life	Time-to-event	TQIP chart review	During hospitalization
Practitioner Opinion Survey	Trauma surgeon's impressions of the communication tool (12 items)	Ordinal; 5-point Likert scale	Surgeon	Upon study Completion

[a]T0= 3 months before implementation, T1: 1 year after T0

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Figure Legend

Figure 1. Example of the Best Case/Worst Case-ICU graphic aid. On each day of a patient's ICU stay, the trauma team uses a preprinted graphic aid to review major events from the previous 24 hours and describe the patient's overall health trajectory. On the graphic aid, each ICU day corresponds to a column, and the range of possible scenarios, i.e., stories describing how this new injury could play out over time, are designated on a vertical line. A star distinguishes the "best case scenario" and a box designates the "worst case scenario." Each day, the trauma team will record any new major events at the top of the column. The star is moved based on how a new event, like a diagnosis of pneumonia or an improvement in neurologic function after a stroke, changes the best case scenario. Over time, the placement of the star goes up or down depending on how these events change the patient's overall story.

Figure 2. Using a stepped-wedge design, we will conduct this study over six 3-month-long waves at eight high volume trauma centers. During the first wave, all patients will receive usual care. With each subsequent wave, two randomly selected sites will enter the implementation phase. Data collection will cease during implementation and the study implementation team will train clinicians to use the Best Case/Worst Case-ICU tool. Following the wave for implementation training, patients will receive care from a trauma team that routinely uses the Best Case/Worst Case-ICU tool.

Best Case/Worst Case: ICU

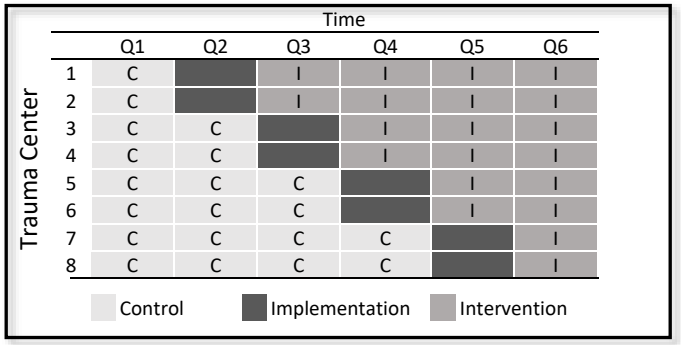
What things may look like going forward

Pt Initials: PJ

Room Number: 56

	Date: 1/3 Event: Car accident	Date: 1/4 Event: Ø	Date: 1/5 Event: stroke	Date: 1/6 Event: fevers	Date: 1/7 Event: Planned surgery
Hopes	**Best Case Scenario**	**Best Case Scenario**	**Best Case Scenario**	**Best Case Scenario**	**Best Case Scenario**
Range of What is Possible	-get breathing tube out in 1-2 days -hospital 1-2 wks -will need rehab 6-8 weeks -Return home, goes a bit slower, mostly like he was before		-may need breathing tube longer -long time in SNF to recover, 8-12 weeks -return home, will need close support, mostly like he was before but slower	-a bit more time in ICU, but mostly the same	-Tracheostomy and feeding tube for 3-4 months until feeling better -expecting to get home but will need much help ~4-6 months
Worries	**Worst Case Scenario**	**Worst Case Scenario**	**Worst Case Scenario**	**Worst Case Scenario**	**Worst Case Scenario**

Worry he could die from this →



Supplementary Material 1: Family member survey consent script

The following text appears on the opening screens of an electronic version of the survey or a cover sheet for a paper survey. The University of Wisconsin – Madison Institutional Review Board approved this script. Some language may be altered to align with site-specific policies and procedures.

[Site Name]

Support for older adults and families in the trauma ICU

Principal Investigator: [Site PI name]; phone: (XXX) XXX-XXXX; email:

Thank you for your interest in this research study. We are studying how to improve communication between trauma ICU teams, patients, and family members so that patients and their loved ones can feel supported in the ICU. You have been asked to participate because your loved one was recently admitted to the [UNIT NAME] at [SITE NAME]. This confidential survey will take about 15-30 minutes to complete and includes questions about care your loved one received and the communication from the doctor.

Although you are not expected to benefit directly from participating in this study, your participation may benefit other patients in the future by helping us learn more about communication in the ICU. You will be paid $20 for completing this survey, which will be given to you as [DESCRIBE INCENTIVE FORMAT: CASH, CHECK, GIFT CARD, COFFEE CARD, ETC.]

Your survey responses will remain confidential and only trained research staff will access your responses for study purposes. The information collected from you during this study will be used by the researchers and research staff of the [SITE NAME], as well as research collaborators at the University of Wisconsin-Madison and The National Institutes of Health, the study sponsor. We will keep your survey data for an indefinite period of time, meaning we have no plans of ever destroying them. Keeping data for future research is called "banking." The banked data will be kept in a secure location for use by researchers. The data may be shared with other researchers at the University of Wisconsin-Madison and outside the university. Outside researchers may be at other universities, private companies, or other kinds of organizations. Banked data will not be shared with your health care providers or used in your or your loved one's treatment. Because your data do not include any information that can identify you, it cannot be removed from this data set.

The study has a Certificate of Confidentiality from the National Institutes of Health. A Certificate of Confidentiality prohibits researchers from disclosing information that may identify you in a legal proceeding or in response to a legal request without your consent.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

You may have some anxiety from answering questions about the care your loved one received and your communication with medical staff. If you feel uncomfortable while filling out the survey, you may stop at any time. You may also skip any questions that you don't want to answer. Your participation is voluntary and you may stop taking the survey at any time. Please take your time deciding if you want to

participate. If you choose not to participate or to leave the study, your choice will not affect your or your loved one's healthcare or any services. No matter what decision you make, and even if your decision changes, there will be no penalty to you or your loved one. You or your loved one will not lose medical care or any legal rights.

This study is being conducted by [SITE PI NAME AND CONTACT INFORMATION]. If you have any questions about this study, contact [SITE RESEARCH COORDINATOR NAME, EMAIL AND PHONE NUMBER]. If you have any questions about your rights as a research participant or have complaints about the research study or study team, contact the [SITE PATIENT RELATIONS OR IRB OFFICE NAME AND CONTACT INFO].

[The following sentence will only be included on a paper, hardcopy version of this information sheet/consent script] By proceeding to the next page, you indicate your consent to participate in this study.

[The following sentence will only be included the web survey version of this information sheet/consent script] By clicking to advance to the next page, you indicate your consent to participate in this study.

[FOR THOSE COMPLETING A PAPER SURVEY, THE FOLLOWING TEXT WILL BE ON A SEPARATE PAGE TO ACCOMPANY THE INFORMATION SHEET SO THAT THEY CAN KEEP THE INFORMATION SHEET BUT GIVE THE CONTACT INFORMATION PAGE TO A MEMBER OF THE RESEARCH STAFF, IF THEY FILL IT OUT]

Thank you so much for participating in this study. There are two other optional things we'd like to ask you about:

1. Would you like us to send you updates and results from this study?
   - ☐ Yes
   - ☐ No
2. May we contact you about future research opportunities? We may do future studies about trauma care. We hope to improve communication in the trauma unit and your perspective is valuable.
   - ☐ Yes
   - ☐ No

If you answered "Yes" to *either* question above, please fill in your contact information below. Please note that your name and information will not be connected to your responses on the study you agreed to participate in today. The information you provide on this form will not be used for any other purposes. It will be kept in a locked and secure location, which only study staff can access and use. By providing your contact information, you agree that study staff can contact you for the uses described above.

Your name: _____

Mailing Address: _____

Home phone number: _____

Mobile phone number (if applicable): _____

What's the best time of day to call you? _____

Email address (if applicable): _____

Please note: We will not send any health information via email to you but you should know that we also recommend that you do not send us anything about your or your loved one's health by email. Email is generally not a secure way to communicate about your health as there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email. Email should also not be used to convey information of an urgent nature. If you need to talk to someone immediately, please contact your loved one's medical provider's office. You do not have to provide your email address to participate in this study.

What's the best way to reach you? _____

[FOR THOSE COMPLETING A WEB SURVEY, THE FOLLOWING TEXT WILL APPEAR ON A FINAL SURVEY PAGE BUT THE SECTION WHERE THEY CAN ENTER THEIR INFORMATION WILL BE COLLECTED AFTER THEY CLICK ON A LINK TAKING THEM TO A SEPARATE FORM TO COMPLETE. THIS WAY, THEIR NAME AND CONTACT INFORMATION WILL NOT BE LINKED TO THEIR SURVERY RESPONSES]

Thank you so much for participating in this study. There are two other optional things we'd like to ask you about:

1. Would you like us to send you updates and results from this study?
   - ☐ Yes
   - ☐ No
2. May we contact you about future research opportunities? We may do future studies about trauma care. We hope to improve communication in the trauma unit and your perspective is valuable.
   - ☐ Yes
   - ☐ No

If you answered "Yes" to either question above, please fill in your contact information below. Please note that your name and information will not be connected to your responses on the study you agreed to participate in today.

Your name: _____

Mailing Address: _____

Home phone number: _____

Mobile phone number (if applicable): _____

What's the best time of day to call you? _____

Email address (if applicable): _____

Please note: We will not send any health information via email to you but you should know that we also recommend that you do not send us anything about your or your loved one's health by email. Email is generally not a secure way to communicate about your health as there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email. Email should also not be used to convey information of an urgent nature. If you need to talk to someone immediately, please contact your loved one's medical provider's office. You do not have to provide your email address to participate in this study.

What's the best way to reach you? _____

Supplementary Material 2: Clinician survey consent script

The following text appears on the opening screens of an electronic version of the survey or a cover sheet for a paper survey. The University of Wisconsin – Madison Institutional Review Board approved this script. Some language may be altered to align with site-specific policies and procedures.

[SITE NAME]

A Communication Tool to Assist Severely Injured Older Adults

Principal Investigator: [SITE PI NAME]; phone: (XXX) XXX-XXXX; email:

Thank you for your interest in this research study. We are studying a strategy to improve communication between trauma ICU teams, patients, and family members so that patients and their loved ones can feel supported in the ICU. We invite you to participate in four brief surveys over the course of the study because you work in the [UNIT AND SITE NAME LIKE TRAUMA UNIT AT UNIVERSITY OF WISCONSIN]. These confidential surveys will each take about 10-15 minutes to complete and include questions on your feelings about your work and situations you may have encountered. Although you are not expected to benefit directly from participating in this study, your participation may benefit other people in the future by helping us learn more about communication between trauma providers, patients and their family members. You will be paid $5 for completing each survey, which will be given to you as [DESCRIBE INCENTIVE FORMAT: CASH, GIFT CARD, COFFEE CARD, ETC.]

We will not collect any information from you that could be used to identify you and your survey responses will remain confidential. Only trained research staff will access your survey responses and will only use them for study purposes. The information collected from you during this study will be used by research staff at [SITE NAME], as well as research collaborators at the University of Wisconsin-Madison and The National Institutes of Health, the study sponsor. We will keep your survey data for an indefinite period of time, meaning we have no plans of ever destroying them. Keeping data for future research is called “banking.” The banked data will be kept in a secure location for use by researchers. The data may be shared with other researchers at the University of Wisconsin-Madison and outside the university. Outside researchers may be at other universities, private companies, or other kinds of organizations. Because your data do not include any information that can identify you, it cannot be removed from this data set.

The study has a Certificate of Confidentiality from the National Institutes of Health. A Certificate of Confidentiality prohibits researchers from disclosing information that may identify you in a legal proceeding or in response to a legal request without your consent.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

You may have some anxiety from answering questions about your work. If you feel uncomfortable while filling out the survey, you may stop at any time. You may also skip any questions that you don’t want to answer. The questionnaires you will complete in this study ask about symptoms of emotional distress

such as worry and fatigue. We are using the questionnaires only for research, not to diagnose mental health issues. We will not tell you the results. If you are experiencing emotional distress, you should contact your physician or other health care provider, such as a mental health professional or your [EMPLOYEE ASSISTANCE PROGRAM OR COMPARABLE SITE-SPECIFIC RESOURCE].

Your participation is voluntary and you may stop taking the survey at any time. Please take your time deciding if you want to participate. If you choose not to participate or to leave the study, your choice will not affect your job or any services you receive. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose any legal rights.

This study is being conducted by [SITE PI NAME AND CONTACT INFORMATION]. If you have any questions about this study, contact [SITE RESEARCH COORDINATOR NAME, EMAIL AND PHONE NUMBER]. If you have any questions about your rights as a research subject or have complaints about the research study or study team, contact the [SITE PATIENT RELATIONS OR IRB DEPARTMENT NAME AND CONTACT INFO].

[The following sentence will only be included on a paper, hardcopy version of this information sheet/consent script] All your answers are confidential and will be shared only with the research team. All data collected will be de-identified and not traceable to you. Results will only be released in aggregate. Your data may be kept for future research. By proceeding to the next page, you indicate your consent to participate in this study.

[The following sentence will only be included the web survey version of this information sheet/consent script] All your answers are confidential and will be shared only with the research team. All data collected will be de-identified and not traceable to you. Results will only be released in aggregate. Your data may be kept for future research. By clicking to advance to the next page, you indicate your consent to participate in this study.

SPIRIT-Outcomes 2022 Checklist (for combined completion of SPIRIT 2013 and SPIRIT-Outcomes 2022 items)[a]

Section	Item No.	SPIRIT 2013 Item	SPIRIT-Outcomes 2022 item	Location Reported[b]
Administrative information				
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	-	
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	-	
	2b	All items from the World Health Organization Trial Registration Data Set	-	
Protocol version	3	Date and version identifier	-	
Funding	4	Sources and types of financial, material, and other support	-	
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	-	
	5b	Name and contact information for the trial sponsor	-	
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	-	
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	-	
Introduction				
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	-	
	6b	Explanation for choice of comparators	-	
Objectives	7	Specific objectives or hypotheses	-	

Section	Item No.	SPIRIT 2013 Item	SPIRIT-Outcomes 2022 item	Location Reported[b]
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	-	
Methods: Participants, interventions, and outcomes				
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	-	
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	-	
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered (for specific guidance see TIDieR checklist and guide)	-	
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	-	
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	-	
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	-	
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	-	

Section	Item No.	SPIRIT 2013 Item	SPIRIT-Outcomes 2022 item	Location Reported[b]
	12.1		Provide a rationale for the selection of the domain for the trial's primary outcome	
	12.2		If the analysis metric for the primary outcome represents within-participant change, define and justify the minimal important change in individuals	
	12.3		If the outcome data collected are continuous but will be analyzed as categorical (method of aggregation), specify the cutoff values to be used	
	12.4		If outcome assessments will be performed at several time points after randomization, state the time points that will be used for analysis	
	12.5		If a composite outcome is used, define all individual components of the composite outcome	
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	-	
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	-	
	14.1		Define and justify the target difference between treatment groups (eg, the minimal important difference)	
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	-	
Methods: Assignment of interventions (for controlled trials)				
Allocation:				
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	-	

Section	Item No.	SPIRIT 2013 Item	SPIRIT-Outcomes 2022 item	Location Reported[b]
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	-	
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	-	
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	-	
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	-	
Methods: Data collection, management, and analysis				
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	-	
	18a.1		Describe what is known about the responsiveness of the study instruments in a population similar to the study sample	
	18a.2		Describe who will assess the outcome (eg, nurse, parent)	
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	-	

Section	Item No.	SPIRIT 2013 Item	SPIRIT-Outcomes 2022 item	Location Reported[b]
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	-	
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	-	
	20a.1		Describe any planned methods to account for multiplicity in the analysis or interpretation of the primary and secondary outcomes (eg, coprimary outcomes, same outcome assessed at multiple time points, or subgroup analyses of an outcome)	
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	-	
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	-	
Methods: Monitoring				
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	-	
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	-	
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	-	

Section	Item No.	SPIRIT 2013 Item	SPIRIT-Outcomes 2022 item	Location Reported[b]
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	-	
Ethics and dissemination				
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	-	
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	-	
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	-	
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	-	
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	-	
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	-	
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	-	
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	-	
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	-	
	31b	Authorship eligibility guidelines and any intended use of professional writers	-	

Section	Item No.	SPIRIT 2013 Item	SPIRIT-Outcomes 2022 item	Location Reported[b]
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	-	
Appendices				
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	-	
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	-	

[a]It is strongly recommended that this checklist be read in conjunction with the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) Statement paper for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license and is reproduced with permission.

[b]Indicates page numbers and/or manuscript location: to be completed by authors.