A Randomized Clinical Trial of Scenario Planning for Older Adults with Serious Injury
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Statistical Analysis Plan
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Introduction

Background and rationale

Given the burdens of treatment and poor prognosis, severely injured older adults and their family members would benefit from communication interventions that facilitate articulation of patient priorities, which can reduce unwanted invasive procedures and clarify long-term goals.[1]

We theorize that the Best Case/Worst Case-ICU communication tool will improve the quality of communication with downstream effects for patients and families, clinicians, and healthcare systems.

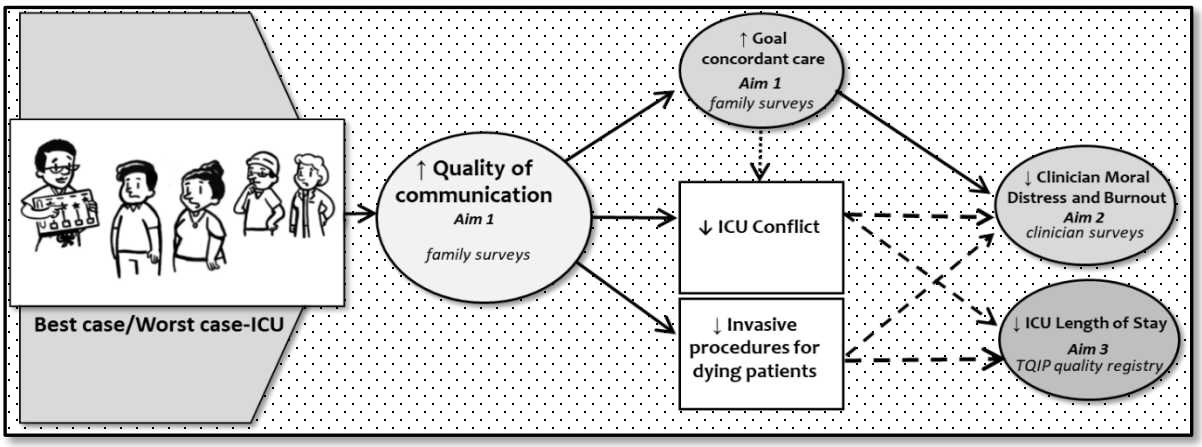


Figure 1: *Theoretical framework behind the Best Case/Worst Case-ICU intervention and this proposal. We will use surveys to measure the quality of communication and receipt of goal concordant care and use the TQIP quality registry to follow all patient demographics and outcomes. We will survey clinicians for moral distress and burnout at the beginning and the end of the study.*

Each year, half a million older adults will suffer injury from a fall or car crash, making traumatic injury the fifth leading cause of death.[2,3] Older adults fare far worse than younger patients with similar injuries due to chronic comorbid conditions and reduced physiologic reserve.[4-7] Traumatic injury is often a terminal event leading to a 20% in-hospital and 40% one-year mortality.[8] Severely injured older adults undergo a series of invasive surgical interventions in the trauma ICU furthering a course of care—including prolonged life support[9] or confinement in a nursing home—that is often inconsistent with patients' preferences and goals.[10,11] Because most older adults would refuse highly burdensome treatment resulting in major functional or cognitive impairment,[12,13] this disconnect between patients' priorities and treatments received can lead to ICU conflict, specifically interpersonal conflict among clinicians (e.g., between nurses and surgeons), and with family (e.g., between surrogate decision makers and the trauma team), during treatment discussions.[14,15] Moreover, overtreatment at the end of life from prolongation of dying contributes $44 billion annually to healthcare costs.[16]

Scenario planning—narrative description of plausible futures—is a strategy to support decision making. Scenario planning was originally developed in the 1950s by the Department of Defense and the RAND Corporation for military planning. It was then popularized for broader use by Pierre Wack,[17,18] an economist at Shell Oil in the 1980s, to translate vast probabilistic information into

narrative description to facilitate strategic decisions. Rather than emphasizing precise isolated risks, this technique generates multiple plausible futures, prompting decision makers to visualize what might happen under different sets of assumptions. Scenario planning is distinct from standard-practice risk prediction and prognostication. It promotes insight by highlighting the interaction between forces that drive change and providing an organized way to consider alternative futures.[19] Although it has been successfully applied to a broad range of decisions in business and government, scenario planning is not widely used in the healthcare setting.

Scenario planning is an innovative strategy for managing uncertainty in the ICU. Scenario planning permits clinicians to say, "I cannot predict the future, but if all goes well, this is what is likely to follow, and if things go poorly, this is what we can expect." Instead of quoting a "75% chance of prolonged respiratory failure," clinicians generate best- and worst-case narratives to demonstrate the logical connection between events (e.g., rib fractures, pneumonia) and underlying conditions (e.g., chronic pulmonary disease) to reveal what may follow, after isolating what is unknown (e.g., the patient's response to treatment). Scenarios allow decision makers (e.g., patients and family) to appreciate causal relationships and imagine a range of outcomes based on sound analysis of the present.[20]

The Best Case/Worst Case-ICU communication tool uses scenario planning to assist patients and families in the trauma ICU after serious injury. We originally developed Best Case/Worst Case for surgical decision making to help frail older adults make decisions about acute care surgery[21] and then modified it for older adults with end-stage kidney disease to support decisions about dialysis[22] (currently under study in a multisite randomized clinical trial).[23] With stakeholder input, we adapted the Best Case/Worst Case tool for the trauma setting (Figure 2). Instead of constructing a discrete treatment decision, this intervention uses scenario planning and a daily report of the interplay between major events and prognosis to illustrate a range of long-term outcomes and the experience of treatment along the way. By using a graphic aid to illustrate "what we are hoping for," "what we are worried about,"[24] and the evolution of the patient's story over time, including setbacks and improvements, the tool aims to keep everyone on the same page and to facilitate dialogue among older adult trauma patients, their families, and the trauma team. Because the tool delivers critical prognostic information over the longitudinal course of care, subsequent treatment decisions, (e.g., additional surgeries or prolonged mechanical ventilation), can be made within the context of the patient's overall health status. This information alerts patients and families to the life-limiting nature of serious injury and provides an entrée for them to consider how comfort-focused strategies might better align with patients' end-of-life goals.

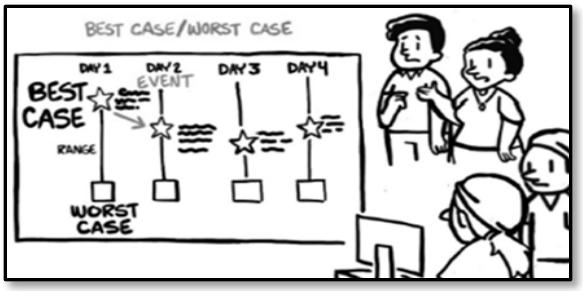


Figure 2: *Best Case/Worst Case-ICU is designed to demonstrate uncertainty, illustrate the interplay between major events and prognosis, & describe how patients might experience the treatments received along the course of care (illustration from YouTube)*

How to use the Best Case/Worst Case-ICU communication tool: The trauma team uses the preprinted graphic aid daily to describe major events over the previous 24 hours and the patient's overall health trajectory. Each column represents one ICU day (Figure 2). Vertical lines represent the range of possible scenarios —stories that are used to describe how this new injury could play

out over time. The star represents the "best case scenario" and the box represents the "worst case scenario." Each day, (starting on the day of admission) a major event is recorded at the top of the column. The star is moved based on how the new event, like a new diagnosis of pneumonia or an improvement in kidney function, 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.

The intervention is designed to fit the pace of busy trauma ICU rounds. The graphic aid is completed with team collaboration during the summative systems-based review for each patient. With usual care, the clinician (typically a surgical resident) lists each physiologic system, e.g., neuro, cardiac, pulmonary…, with an assessment and plan. When using the Best Case/Worst Case-ICU tool they add "outlook" at the end. Outlook describes the best case scenario: a plausible story about the patient's clinical course over time if the patient does as well as they might hope for, including additional treatments needed, time in the hospital, recovery, and long-term functional outcomes. The trauma surgeon generates this story while another team member notes what is said 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 family and clinicians can use it to recall what to expect, visualize uncertainty, and see how things change. Over time, daily updates help everyone as events accumulate. If the patient gets better, the family can anticipate a long road to recovery. If the patient gets worse, their family will be prepared, and the gravity of the illness will not come as a surprise. The daily stories and the graphic aid provide support and perspective for everyone, including consulting clinicians, if there is a big decision to be made like major surgery or the need for prolonged mechanical ventilation.

Specific aims

- Aim 1: To test the effectiveness of the Best Case/Worst Case-ICU communication tool on improving the quality of communication in the trauma ICU. The primary outcome of this study is family members' ratings of the quality of communication assessed at 5 days post admission using the Quality of Communication scale, which includes measurement of end-of-life communication. As a secondary outcome, we will measure patient receipt of goal-concordant care as reported by family members.
- Aim 2: To test the effectiveness of the Best Case/Worst Case-ICU communication tool on reducing clinician moral distress in the ICU. As a proximate measure of the intervention effect on ICU conflict, we will use the Measure of Moral Distress for Health Care Professionals (MMD-HP) to measure center-level distress at the beginning and the end of the study.
- Aim 3: To test the effectiveness of the Best Case/Worst Case-ICU communication tool on reducing ICU length of stay. We will compare the mean length of stay in the ICU between treatment groups.

Study design

This is a multisite, stepped-wedge, randomized clinical trial. We will randomly assign each site to the time when our intervention team will train all trauma surgeons, trainees, and ICU clinicians to use the Best Case/Worst Case-ICU tool. Patients in the control group will receive usual care. Patients

in the intervention group will receive care from a trauma team that routinely uses the Best Case/Worst Case-ICU communication tool. We plan to follow approximately 4,500 patients with the highest post-injury mortality: aged 50 years and older with an ICU length of stay of 3 or more days, using the ACS TQIP as a data collection platform. Our power analysis requires 8 sites to adequately power this study. We will administer surveys to family members (quality of communication) and clinicians (moral distress) and obtain patient-level outcomes (ICU length of stay (LOS)), clinical data, and demographics from the TQIP national registry.

All patient-level data will come from the TQIP trauma registry, which collects demographics and outcomes for all trauma patients at 850 participating centers. The intervention will be implemented as a quality improvement initiative for older adults in the trauma ICU as its primary purpose is to increase behaviors recommended by professional societies, e.g., timely communication with families and emotional support.[25,26] We will not obtain patient consent for randomization or intervention implementation. We will obtain family member participant consent for surveys only. The primary outcome, quality of communication, will be measured with one-time surveys of family members.

We will conduct this study at Level I trauma centers that are members of Coalition for National Trauma Research (CNTR) and provide data on all trauma patients to TQIP. We have selected 8 trauma centers from across the country based on their high-volume of trauma patients and to ensure we have included a broad and diverse range of participants including high/low literacy, and racial/ethnic minority groups. These sites are committed to participating in this study and, as shown by preparatory data from TQIP, have enough qualified patients to reach our enrollment goals. Site PI's are all trauma surgeons with experience in clinical investigation.

Outcome Measures and Covariates of Interest

Patients: Patients are not being recruited directly for this study. All patient data (demographics, injury severity, disposition (including in-hospital death)) will come from the TQIP registry, which uses the National Trauma Data Standards (NTDS) and quality improvement infrastructure of the ACS. In 1989, the National Trauma Data Bank was established through consensus panels of trauma stakeholders and the Center for Disease Control to define data elements. The data dictionary was developed by the ACS, Health Resources and Services Administration, and state trauma managers. Participation is required for verification as a Level I trauma center. Each center (hospital) currently contracts with trained registrars to abstract data elements via chart review for ***all*** patients admitted with traumatic injury. TQIP will provide data, without direct identifiers, from the hospital admission for each study-qualified patient during the period of study performance. Treatment group assignment will be linked to patient data by the patient's admission date. All TQIP data elements will be collected according to NTDS data standards.[27]

Registrars undergo extensive training and evaluation to ensure patient privacy protection and high quality data collection. Patient data provided by TQIP cannot be linked to family member data collected by the study teams.

Our primary patient outcome is ICU length of stay (LOS), quantified as the total time measured in days patients received ICU care during admission for traumatic injury. Primarily, we are interested in the time between admission and placement of discharge orders, as this captures when patients

received care from the ICU team. We will also explore ICU LOS up to when patients physically left the ICU as a sensitivity analysis.

Family member survey: The family member survey is a one-time questionnaire administered 5-7 days after the patient's admission. It consists of the Family-reported Quality of Communication (QOC), the Receipt of Goal Concordant Care (GCC), and demographic questions about the family member and the patient. The QOC is an assessment of physician communication. Unlike other measurements of physician communication that have high ceiling effects and limited ability to measure change, the QOC includes 7 items specific to end-of-life communication, which, if not performed by the clinician, are scored as zero. This will allow us to discriminate between quality of communication attributable to family member satisfaction (with high ceiling effects) versus content. This survey will also include 2 questions from the GCC asking the family member about the care their loved one wanted and received. Research staff will time stamp the survey with the patient's date of admission and the date of survey completion. The survey will not collect any direct patient identifiers (e.g., name, date of birth) and will not be linked to the patient's data in the TQIP registry. After survey completion, family members will receive a link to the study website, produced by CNTR, which describes the study and provides updates over time.

Clinician surveys: We will survey trauma team members and ICU clinical staff at two time points: three months prior to site implementation (T0) and 1 year later (T1). The clinician surveys will include questions from the Measure of Moral Distress for Healthcare Professionals (MMD-HP) and Maslach Burnout Inventory (MBI) questionnaires. The MMD-HP is a 27-item survey that measures the frequency and level of distress of clinician experiences, targeting situations specifically related to serious illness communication. The 22-item MBI will cover 3 areas: emotional exhaustion, depersonalization, and low sense of personal accomplishment. The MMD-HP and MBI surveys will be administered separately (MMD-HP first; 2 weeks apart) to reduce respondent burden and contamination of concepts (distress about futile care vs. exhaustion and depersonalization) for busy clinicians. We will also collect demographic information from clinicians including race/ethnicity, gender, role, time in current position and time employed at the institution.

Moral distress and intervention duration: To avoid contamination of study measures, clinician MMD-HP surveys will be administered before and after data collection for other outcomes. As such, there will be variation in the duration of exposure to the intervention prior to assessment. We will use this opportunity to perform sensitivity analysis to examine the relationship between the duration of intervention exposure and the effect on clinician moral distress and burnout using a linear time-on-treatment effect.

Practitioner Opinion Survey: Upon study completion, we will survey trauma surgeon's impressions of the Best Case/Worst Case ICU communication tool.

Table 1: Outcomes Measures for Each Aim				
Construct	Specific Measure	Type; range	Source	Timing
Aim 1: Quality of Communication and Goal Concordant Care				
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
Aim 2: Clinician Moral Distress and Burnout				
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
Maslach Burnout Inventory (MBI)[57]	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
Aim 3: ICU Length of Stay				
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
Implementation Outcome				
Practitioner Opinion Survey	Trauma surgeon's impressions of the communication tool (12 items)	Ordinal; 5-point Likert scale	Surgeon	Upon study Completion

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

Table 2: Covariates		
Construct	**Variables Measured**	**Source**
Patient demographics	Age, race/ethnicity, sex	TQIP chart review
Patient severity of injury	Injury Severity Score, ICD-10 injury diagnosis, Glasgow Coma Scale	TQIP chart review
Patient interventions	Surgery, transfusion of blood products, cerebral monitoring	TQIP chart review
Patient comorbidity	Preexisting conditions documented in NTDS	TQIP chart review
Patient advance directive	Preexisting advance directive	TQIP chart review
Family member demographics	Age, relationship to patient, gender, race/ethnicity, education, literacy	Family member Survey
Family member-reported patient demographics	Age, race/ethnicity, gender, educational attainment	Family member Survey
Clinician demographics	Role, age, time at current position, gender, race/ethnicity	Clinician Survey

ICD = International Classification of Diseases, NTDS = National Trauma Data Standards

Blinding

Patients and family members will be blinded to the objectives of this study. Family members will be told that the study goal is to evaluate clinician-patient communication. Clinicians will not be blinded to treatment group. We will inform all clinicians about the goals of this study, specifically that this is a study testing an intervention to improve communication about trauma care. Clinicians will not be apprised of specific study outcomes. We will coordinate the randomization assignment and intervention allocation centrally through UW where the research team and the intervention implementation team comprise different study personnel. TQIP registrars collecting patient data will be blinded to treatment group. 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 during survey administration with family members.

Data and Safety Monitoring Plan

No formal interim analyses are planned during this study, and all study outcomes will be assessed at the completion of the study.

The DSMB will conduct interim safety monitoring on Quality of Communication (QOC) survey data. If they find clustering of poor quality communication related to the intervention, the PI and the DSMB, along with the IRB and the site PI, will discuss possible remedies, including re-training in use of the communication tool. The study may resume once concerns about safety, protocol compliance, or data quality are addressed and satisfy the sponsor, IRB, and/or DSMB.

The DSMB will meet three times: prior to study initiation, after 12 months of data collection, and at the end of data collection. DSMB interim report templates will be prepared by a study statistician with assistance from the PCRC and the Data, Informatics and Statistics Core (DISC), to be reviewed by the DSMB members at the first meeting.

Analysis of Primary Outcomes

The sample size estimate, 1500 family Quality of Communication (QOC) surveys (750/group), is based on the primary hypothesis that family members in the intervention arm will be more likely to receive high quality communication, particularly communication about serious illness. The study is powered to detect a difference in QOC scores between 0.4 and 0.48 consistent with other interventions designed to effectively improve serious illness communication. Smaller differences are unlikely to be considered meaningful to clinicians, patients and families, or researchers. We desire a 2-sided type I error rate of 0.05 with 80% power. We computed the intraclass correlation coefficient (ICC) based on preliminary data together with its 95% confidence interval; we estimate the detectable difference considering ICC ranging from the point estimate to the upper confidence limit. Assuming the standard deviation for the QOC measure is 1.92 together with an ICC of 0.001, the study is powered to detect a clinically significant mean difference of 0.4. Increasing the ICC to 0.02, increases the detectable difference to 0.48.

General Analysis Plan

Primary Outcome

1. For overall family-reported **Quality of Communication (QOC)** within 5-7 days of ICU admission, for each treatment arm, we will report the mean and standard deviation of the 13-item composite scores. The treatment effect will be assessed using a LRT of the fixed effect from the linear mixed-effects model. The linear mixed-effects model will include a random-intercept for site, and will include fixed effects for a treatment dummy variable and a time dummy variable.

   Null Hypothesis: There is no difference in average overall QOC scores between control patients and Best Case/Worst Case intervention patients.

   Alternative Hypothesis: There is a difference in average overall QOC scores between control patients and Best Case/Worst Case intervention patients.

Secondary outcomes

1. For family-reported **General Quality of Communication (QOC)**, within 5-7 days of ICU admission, for each treatment arm, we will report the mean and standard deviation of the 6-item subscale scores. The treatment effect will be assessed using a LRT of the fixed effect from the linear mixed-effects model. The linear mixed-effects model will include a random-intercept for site, and will include fixed effects for a treatment dummy variable and a time dummy variable.

   Null Hypothesis: There is no difference in average General QOC scores between control patients and Best Case/Worst Case intervention patients.

   Alternative Hypothesis: There is a difference in average General QOC scores between control patients and Best Case/Worst Case intervention patients.

2. For family-reported **End-of-Life (EOL) Quality of Communication (QOC)**, within 5-7 days of ICU admission, for each treatment arm, we will report the mean and standard deviation of the 7-item subscale scores. The treatment effect will be assessed using a LRT of the fixed effect from the linear mixed-effects model. The linear mixed-effects model will include a random-intercept for site, and will include fixed effects for a treatment dummy variable and a time dummy variable.

   Null Hypothesis: There is no difference in average EOL QOC scores between control patients and Best Case/Worst Case intervention patients.

   Alternative Hypothesis: There is a difference in average EOL QOC scores between control patients and Best Case/Worst Case intervention patients.

3. For proportion of **Goal Concordant Care (GCC)** at 5-7 days post ICU admission, for each treatment arm, we will report sample counts and percentages. The treatment effect will be assessed using a LRT of the fixed effect from the logistic mixed-effects model. The logistic mixed-effects model will include a random-intercept for site, and will include fixed effects for a treatment dummy variable and a time dummy variable.

   Null Hypothesis: There is no difference in the proportion of family members reporting GCC between control patients and Best Case/Worst Case intervention patients.

   Alternative Hypothesis: There is a difference in the proportion of family members reporting GCC between control patients and Best Case/Worst Case intervention patients.

4. For **Measure of Moral Distress for Healthcare Professionals (MMD-HP)** at T0 and T1, we will report the mean and standard deviation of the 27-item survey scores. The post-intervention effect will be assessed using a LRT of the fixed effect from the linear mixed-effects model. The linear mixed-effects model will include a random-intercept for site and a fixed effect for a treatment dummy variable.

   Null Hypothesis: There is no difference in average MMD-HP scores pre- and post-implementation of the Best Case/Worst Case intervention.

   Alternative Hypothesis: There is a difference in average MMD-HP scores pre- and post-implementation of the Best Case/Worst Case intervention.

5. For **Maslach Burnout Inventory (MBI)-Emotional Exhaustion (EE)** at T0 and T1, we will report the mean and standard deviation of the 9-item subscale scores. The post-intervention effect will be assessed using a LRT of the fixed effect from the linear mixed-effects model. The linear mixed-effects model will include a random-intercept for site and a fixed effect for a treatment dummy variable.

   Null Hypothesis: There is no difference in average MBI-EE scores pre- and post-implementation of the Best Case/Worst Case intervention.

   Alternative Hypothesis: There is a difference in average MBI-EE scores pre- and post-implementation of the Best Case/Worst Case intervention.

6. For **Maslach Burnout Inventory (MBI)-Depersonalization (DP)** at T0 and T1, we will report the mean and standard deviation of the 5-item subscale scores. The post-intervention effect will be assessed using a LRT of the fixed effect from the linear mixed-effects model. The linear mixed-effects model will include a random-intercept for site and a fixed effect for a treatment dummy variable.

   Null Hypothesis: There is no difference in average MBI-DP scores pre- and post-implementation of the Best Case/Worst Case intervention.

   Alternative Hypothesis: There is a difference in average MBI-DP scores pre- and post-implementation of the Best Case/Worst Case intervention.

7. For **Maslach Burnout Inventory (MBI)-Personal Accomplishment (PA)** at T0 and T1, we will report the mean and standard deviation of the 8-item subscale scores. The post-intervention effect will be assessed using a LRT of the fixed effect from the linear mixed-effects model. The linear mixed-effects model will include a random-intercept for site and a fixed effect for a treatment dummy variable.

   Null Hypothesis: There is no difference in average MBI-PA scores pre- and post-implementation of the Best Case/Worst Case intervention.

   Alternative Hypothesis: There is a difference in average MBI-PA scores pre- and post-implementation of the Best Case/Worst Case intervention.

8. For **ICU length of stay (LOS)**, for each treatment arm, we will report the mean and standard deviation of the total number of days spent in the ICU during the admission after traumatic injury (not concurrent), defined as the time between admission and when discharge orders were placed. The treatment effect on log-transformed ICU LOS will be assessed using a LRT of the fixed effect from the linear mixed-effects model. The linear mixed-effects model will include a random-intercept for site, and will include fixed effects for: a treatment dummy variable, a time dummy variable, patient comorbidity and injury severity.

   Null Hypothesis: There is no difference in average ICU LOS between control patients and Best Case/Worst Case intervention patients.

   Alternative Hypothesis: There is a difference in average ICU LOS between control patients and Best Case/Worst Case intervention patients.

9. For **total time on ventilator** per patient, for each treatment arm, we will report the mean and standard deviation. The treatment effect on time of ventilator will be assessed using a LRT of the fixed effect from the linear mixed-effects model. The linear mixed-effects model will include a random-intercept for site, and will include fixed effects for: a treatment dummy variable, a time dummy variable, patient comorbidity and injury severity.

   Null Hypothesis: There is no difference in average time on ventilator between control patients and Best Case/Worst Case intervention patients.

   Alternative Hypothesis: There is a difference in average time on ventilator between control patients and Best Case/Worst Case intervention patients.

10. For **time to in-hospital death**, for each treatment arm, we will report the in-hospital survival rate and median survival time. The treatment effect will be assessed using a LRT of the fixed effect from the mixed-effects Cox regression model. The mixed-effects Cox regression model will include a random-intercept for site, and will include fixed effects for a treatment dummy variable and a time dummy variable.

    Null Hypothesis: There is no difference in time to in-hospital death between control patients and Best Case/Worst Case intervention patients.

Alternative Hypothesis: There is a difference in time to in-hospital death between control patients and Best Case/Worst Case intervention patients.

11. For **6-month mortality**, for each treatment arm, we will report sample counts and percentages of patients who have been confirmed as deceased and those that are assumed alive or whose death has not been confirmed. The treatment effect will be assessed using a LRT of the fixed effect from the mixed-effects logistic regression model. The mixed-effects logistic regression model will include a random-intercept for site, and will include fixed effects for: a treatment dummy variable, a time dummy variable, patient comorbidity and injury severity.

    Null Hypothesis: There is no difference in 6-month mortality between control patients and Best Case/Worst Case intervention patients.

    Alternative Hypothesis: There is a difference in 6-month mortality between control patients and Best Case/Worst Case intervention patients.

12. For **time to withdrawal of life supporting treatment**, for each treatment arm, we will report the withdrawal rate and median time to withdrawal. The treatment effect will be assessed using a LRT of the fixed effect from the mixed-effects Cox regression model. The mixed-effects Cox regression model will include a random-intercept for site, and will include fixed effects for: a treatment dummy variable, a time dummy variable, patient comorbidity and injury severity.

    Null Hypothesis: There is no difference in time to withdrawal of life supporting treatment between control patients and Best Case/Worst Case intervention patients.

    Alternative Hypothesis: There is a difference in time to withdrawal of life supporting treatment between control patients and Best Case/Worst Case intervention patients.

13. For each question on the **Practitioner opinion survey**, we will report the frequency and percentage of each response.

Sensitivity analysis

1. For **6-month mortality (sensitivity analysis)**, for each treatment arm, we will report sample counts and percentages of patients who have been confirmed or suspected as deceased and those that are assumed alive. The treatment effect will be assessed using a LRT of the fixed effect from the mixed-effects logistic regression model. The mixed-effects logistic regression model will include a random-intercept for site, and will include fixed effects for: a treatment dummy variable, a time dummy variable, patient comorbidity and injury severity.

    Null Hypothesis: There is no difference in 6-month mortality between control patients and Best Case/Worst Case intervention patients.

Alternative Hypothesis: There is a difference in 6-month mortality between control patients and Best Case/Worst Case intervention patients.

2. For **ICU LOS (sensitivity analysis)**, for each treatment arm, we will report the mean and standard deviation of the total number of days spent in the ICU during the admission after traumatic injury (not concurrent), defined as the time between admission and when a patient was discharged from the ICU. The treatment effect on log-transformed ICU LOS will be assessed using a LRT of the fixed effect from the linear mixed-effects model. The linear mixed-effects model will include a random-intercept for site, and will include fixed effects for: a treatment dummy variable, a time dummy variable, patient comorbidity and injury severity.

   Null Hypothesis: There is no difference in average ICU LOS between control patients and Best Case/Worst Case intervention patients.

   Alternative Hypothesis: There is a difference in average ICU LOS between control patients and Best Case/Worst Case intervention patients.

Exploratory analyses

1. Heterogeneity of treatment effects:

   To determine the impact of the intervention on different subgroups of interest, heterogeneity of treatment effects will be explored whenever a main treatment effect is detected. Mixed-effects models with random-intercepts for site will be fit for the primary endpoint in each aim. When examining family reported outcomes, models will be fit with a fixed-effect interaction term between intervention status and the following subgroup variables: race/ethnicity (minority/non-minority), health literacy (low/high) and language spoken (English/Spanish). When investigating patient outcomes, we will examine a fixed-effect interaction term between intervention status and the following subgroup variables: race/ethnicity (minority/non-minority) and patient age (less than 80/older than 80). Significance in interaction fixed-effects will indicate heterogeneity of treatment effect.

   When a main treatment effect is detected, we will explore heterogeneity of treatment by site by adding a site by treatment interaction to the main analysis model.

2. Sex as a biologic variable:

   We will perform exploratory analyses to explore how the effect of patient sex influences the effect of the intervention on ICU LOS.

3. Gender as a social variable:

   We will assess whether clinician gender influences the effect of the intervention on responses to the MMD-HP and MBI surveys and whether family-reported gender (respondent gender and patient gender) influences the effect of the intervention on QOC.

4. Neurological function:

For patient outcomes, we will examine whether neurological function (based on Glasgow Coma Scale score at 24 hours) influences the effect of the intervention.

5. Given the intricacies of examining ICU LOS when follow-up may be truncated due to patient death[28], we will perform two exploratory analyses, using the time ICU discharge orders were placed:
    a. We will examine ICU LOS among decedents only (i.e., those who died during their ICU hospitalization). The treatment effect on log-transformed ICU LOS will be assessed using a LRT of the fixed effect from the linear mixed-effects model among decedents only. The linear mixed-effects model will include a random-intercept for site, and will include fixed effects for: a time dummy variable, patient comorbidity and injury severity.
    b. 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. To determine significance of the mediating factors, we will use the bootstrapping procedure for mediation analysis.

6. Receipt of Goal Concordant Care (GCC):

    We will examine the association between family members' response to question 1 of the GCC survey (i.e., for their loved one, they prefer a course of treatment that focuses on extending life as much as possible or they prefer a plan that focuses on relieving pain and discomfort as much as possible) with whether care was concordant with those preferences. We will use mixed-effects logistic regression with a random-intercept for site.

7. MMD-HP root cause:

    We will conduct exploratory analysis examining four subscales of the MMD-HP based on factor clusters determined by Epstein et al[29]. The factor clusters represent root causes of moral distress driven by system-level factors, patient-level factors, compromises to personal integrity, and a breakdown in the team's communication with patients and families.

8. Adherence to the intervention:

    We will examine the effect of adherence to the intervention on family-reported QOC within 5-7 days of ICU admission. We will use a linear mixed-effects model with a random-intercept for site, and fixed effects for a wave-level adherence variable and a time dummy variable.

References

1. Mosenthal AC, Murphy PA. Trauma care and palliative care: time to integrate the two? *J Am Coll Surg.* 2003;197(3):509-516.
2. Thompson HJ, McCormick WC, Kagan SH. Traumatic brain injury in older adults: epidemiology, outcomes, and future implications. *J Am Geriatr Soc.* 2006;54(10):1590-1595.

3. Control NCfIPa. 10 Leading Causes of Nonfatal Injuries, United States, 2014, All Races, Both Sexes, Disposition: All Cases, Ages: 65-85 https://webappa.cdc.gov/sasweb/ncipc/nfilead2001.html. Accessed June 1, 2016.
4. Cocanour CS. End-of-life care in trauma. *J Trauma Acute Care Surg.* 2015;79(6):891-896.
5. Zhao FZ, Wolf SE, Nakonezny PA, et al. Estimating Geriatric Mortality after Injury Using Age, Injury Severity, and Performance of a Transfusion: The Geriatric Trauma Outcome Score. *J Palliat Med.* 2015.
6. Jin K, Simpkins JW, Ji X, Leis M, Stambler I. The critical need to promote research of aging and aging-related diseases to improve health and longevity of the elderly population. *Aging Dis.* 2015;6(1):1.
7. Bala M, Kashuk JL, Willner D, Kaluzhni D, Bdolah-Abram T, Almogy G. Looking beyond discharge: clinical variables at trauma admission predict long term survival in the older severely injured patient. *World J Emerg Surg.* 2014;9(1):1-8.
8. Fleischman RJ, Adams AL, Hedges JR, Ma OJ, Mullins RJ, Newgard CD. The optimum follow-up period for assessing mortality outcomes in injured older adults. *J Am Geriatr Soc.* 2010;58(10):1843-1849.
9. Taylor MD, Tracy JK, Meyer W, Pasquale M, Napolitano LM. Trauma in the elderly: intensive care unit resource use and outcome. *J Trauma Acute Care Surg.* 2002;53(3):407-414.
10. Fried TR. Shared Decision Making—Finding the Sweet Spot. *N Engl J Med.* 2016;374(2):104-106.
11. Halpern J, Arnold RM. Affective forecasting: an unrecognized challenge in making serious health decisions. *J Gen Intern Med.* 2008;23(10):1708-1712.
12. Fried TR, Bradley EH, Towle VR, Allore H. Understanding the treatment preferences of seriously ill patients. *N Engl J Med.* 2002;346(14):1061-1066.
13. Fried TR, Tinetti ME, Iannone L, O'Leary JR, Towle V, Van Ness PH. Health outcome prioritization as a tool for decision making among older persons with multiple chronic conditions. *Arch Intern Med.* 2011;171(20):1854-1856.
14. Danjoux Meth N, Lawless B, Hawryluck L. Conflicts in the ICU: perspectives of administrators and clinicians. *Intensive Care Med.* 2009;35(12):2068-2077.
15. Fassier T, Azoulay E. Conflicts and communication gaps in the intensive care unit. *Curr Opin Crit Care.* 2010;16(6):654-665.
16. Shrank WH, Rogstad TL, Parekh N. Waste in the US health care system: estimated costs and potential for savings. *J Am Med Assoc.* 2019.
17. Wack P. Uncharted waters ahead. *Harv Bus Rev.* 1985.
18. Wack P. Shooting the rapids. *Harv Bus Rev.* 1985.
19. Song MK, Lin FC, Gilet CA, Arnold RM, Bridgman JC, Ward SE. Patient perspectives on informed decision-making surrounding dialysis initiation. *Nephrol Dial Transplant.* 2013;28(11):2815-2823.
20. Schwarze M, Taylor LJ. Managing uncertainty—harnessing the power of scenario planning. *N Engl J Med.* 2017;377(3):206-208.
21. Taylor LJ, Nabozny MJ, Steffens NM, et al. A Framework to Improve Surgeon Communication in High-Stakes Surgical Decisions: Best Case/Worst Case. *JAMA Surg.* 2017;152(6):531-538.
22. Zimmermann CJ, Jhagroo RA, Wakeen M, et al. Opportunities to improve shared decision making in dialysis decisions for older adults with life-limiting kidney disease: a pilot study. *J Palliat Med.* 2020;23(5):627-634.
23. Schwarze M, Bansal A, Cheung K, et al. (2020, November - 2025, January) Best Case/Worst Case: A Multisite Randomized Clinical Trial of Scenario Planning for Patients With End-Stage Kidney Disease. Identifier NCT04466865. https://clinicaltrials.gov/ct2/show/NCT04466865. Accessed August 14, 2021.

24. Lakin JR, Jacobsen J. Softening our approach to discussing prognosis. *JAMA Intern Med.* 2019;179(1):5-6.
25. Kon AA, Davidson JE, Morrison W, Danis M, White DB. Shared Decision Making in Intensive Care Units: Executive Summary of the American College of Critical Care Medicine and American Thoracic Society Policy Statement. *Am J Respir Crit Care Med.* 2016;193(12):1334-1336.
26. Truog RD, Campbell ML, Curtis JR, et al. Recommendations for end-of-life care in the intensive care unit: a consensus statement by the American College [corrected] of Critical Care Medicine. *Crit Care Med.* 2008;36(3):953-963.
27. Trauma ACoSCo. National trauma data standard data dictionary. *Chicago, IL: American College of Surgeons.* 2019.
28. Harhay MO, Ratcliffe SJ, Small DS, et al. Measuring and Analyzing Length of Stay in Critical Care Trials. *Med Care*. 2019;57(9):e53-e59.
29. Epstein EG, Whitehead PB, Prompahakul C, et al. Enhancing Understanding of Moral Distress: The Measure of Moral Distress for Health Care Professionals. AJOB Empir Bioeth. 2019;10(2):113-124.