A Randomized Clinical Trial of Scenario Planning for Older Adults with Serious Injury (Improving Communication in the ICU)

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INVESTIGATORS PLAN

The Principal Investigator, Dr. Margaret (Gretchen) Schwarze will coordinate and organize all data. Prior to the start of data collection, we will obtain Institutional Review Board (IRB) approval from the University of Wisconsin-Madison (UW). The UW IRB will serve as the IRB of record for all participating sites and has a Federalwide Assurance (FWA) on file with the Office for Human Research Protections (OHRP). All identified participating sites have agreed to rely on the UW IRB and any additional sites added to the study will cede review to the UW IRB as well. All sites have confirmed they will adhere to the single site IRB policy. Prior to initiation of the study, all participating sites will sign an authorization/reliance agreement that will clearly state the roles and responsibilities of the UW IRB and participating sites. This project will use the SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement (SMART IRB Agreement) to support single IRB review in compliance with NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research. UW research staff will distribute correspondence from the UW IRB to site PIs and Research Coordinators (RCs). UW research staff will also maintain a repository of all IRB approved documents and IRB Authorization Agreements. Dr. Schwarze will be responsible for disseminating regulatory information between sites. UW research staff will share information on unanticipated problems, adverse events, protocol deviations, new information about the study, and changes of protocol with participating sites. UW research staff will also report any unanticipated problems, adverse events, protocol deviations and protocol changes to the UW IRB within reporting guidelines. Protocol compliance will be monitored by each enrolling site's Co-PI and Dr. Schwarze.

Dr. Schwarze, Mr. Bushaw, Ms. Buffington and Ms. Fritz will be responsible for project development, data collection, coding and analyzing the data, and/or writing the manuscript.

Dr. Hanlon and Ms. Stalter will advise on data analysis.

The American College of Surgeons (ACS) will develop and execute the Business Agreement/Data Use Agreement required for this collaboration, covering use of TQIP data.

2 PROTOCOL SUMMARY

2.1 SYNOPSIS

Title: A Randomized Clinical Trial of Scenario Planning for Older Adults with Serious Injury (Improving Communication in the ICU)

Study Description: We plan to test the effectiveness of the Best Case/Worst Case-ICU communication tool on quality of communication, clinician moral distress, and ICU length of stay for older adults with serious traumatic injury. This is a multisite, stepped-wedge, randomized clinical trial. At the start of the study, 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 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. 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 Trauma Quality Improvement Program (TQIP) national registry.

The intervention will be administered as a quality improvement activity because its primary purpose is to increase behaviors recommended by professional societies, e.g., timely communication with families and emotional support.

Objectives: 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 Healthcare 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.

Outcomes:

Primary Outcome:

- Family members' ratings of quality of communication assessed at 5 days post admission (Quality of Communication survey)

Secondary Outcomes:

- Patient receipt of goal-concordant care as reported by family members
- Moral distress: Frequency and level of distress of clinician experiences, targeting situations specifically related to serious illness communication (Measure of Moral Distress for Healthcare Professionals)
- Clinician burnout: Emotional Exhaustion, Depersonalization , and low sense of Personal Accomplishment (Maslach Burnout Inventory)
- Cumulative amount of time measured in days patient spent receiving ICU care during the admission for traumatic injury
- Total time measured in days patient spent on a ventilator during admission for traumatic injury
- In hospital patient death
- Time between admission and withdrawal of life supporting treatment at the end of life

Implementation Outcome:

- Practitioner opinion survey and clinician interviews: Trauma surgeons' impressions of the Best Case/Worst Case-ICU communication tool

Study Population: The demographic distribution of the sample is entirely dependent upon those who present to the trauma center with traumatic injury and their family members who are recruited to the study and elect to participate. We are not recruiting participants based on gender or racial/ethnic minority status.

Human subjects research will be performed at the following collaborating sites:

1. Froedtert Hospital (Medical College of Wisconsin)
2. Grady Memorial Hospital (Morehouse School of Medicine)
3. Harborview Medical Center (University of Washington)
4. Lehigh Valley Health Network
5. Rhode Island Hospital
6. Shock Trauma (University of Maryland Medical Center)
7. University of Alabama at Birmingham
8. UC Davis Medical Center

Patients (estimated sample size: 4,500):

- Aged 50 years and older
- Admitted to trauma center ICU for 3 or more days after serious injury

Family members (estimated sample size: 1,500):

- One family member or informally designated "like family" person per patient
- Family members must be at least 18 years old

Clinicians (estimated sample size: 800 (min) - 1,600 (max)):

- Clinicians who provide care in the trauma ICU (including attending trauma surgeons, fellows, residents, advance practice providers, bedside nurses and medical assistants, respiratory techs and physical therapists, social workers, and chaplains)

Phase or Stage: Phase III

Description of Sites/Facilities Enrolling Participants: Multi-site study including 8 trauma centers across the United States, coordinated by the University of Wisconsin-Madison. UW-Madison will not enroll participants at their clinical site.

Description of Study Intervention/ Experimental Manipulation:

As a quality improvement initiative, we will train all members of the trauma team who practice in the ICU to use the Best Case/Worst Case-ICU communication tool routinely for older adults with serious injury. When the study site has moved from observational control to the intervention group, the communication tool will be used on a daily basis in the ICU. The Best Case/Worst Case-ICU Training Program consists of the following:

1. Trauma surgeons and fellows will receive a one-on-one 30-minute training followed by coaching, assessment and additional training, as needed.
2. Residents and advance practice providers will receive a 1-hour group training session focused on completion of the graphic aid on rounds.
3. Bedside nurses and ICU staff will be given a brochure with details about how the trauma team generates the tool and instructions about how to support family interactions with the graphic aid. Clinical educators will also present information about how to refer to the tool during in-service meetings and morning huddles.

Study Duration:

5 years

Participant Duration:

Patients:

- Data collection will be performed by the American College of Surgeons Trauma Quality Improvement Program (ACS TQIP). Chart abstraction will occur during the patient's admission. There will be a one-time review of vital status at 6 months post admission.

Family members:

- Data collection will last up to 30 minutes with a one-time survey.

Clinicians:

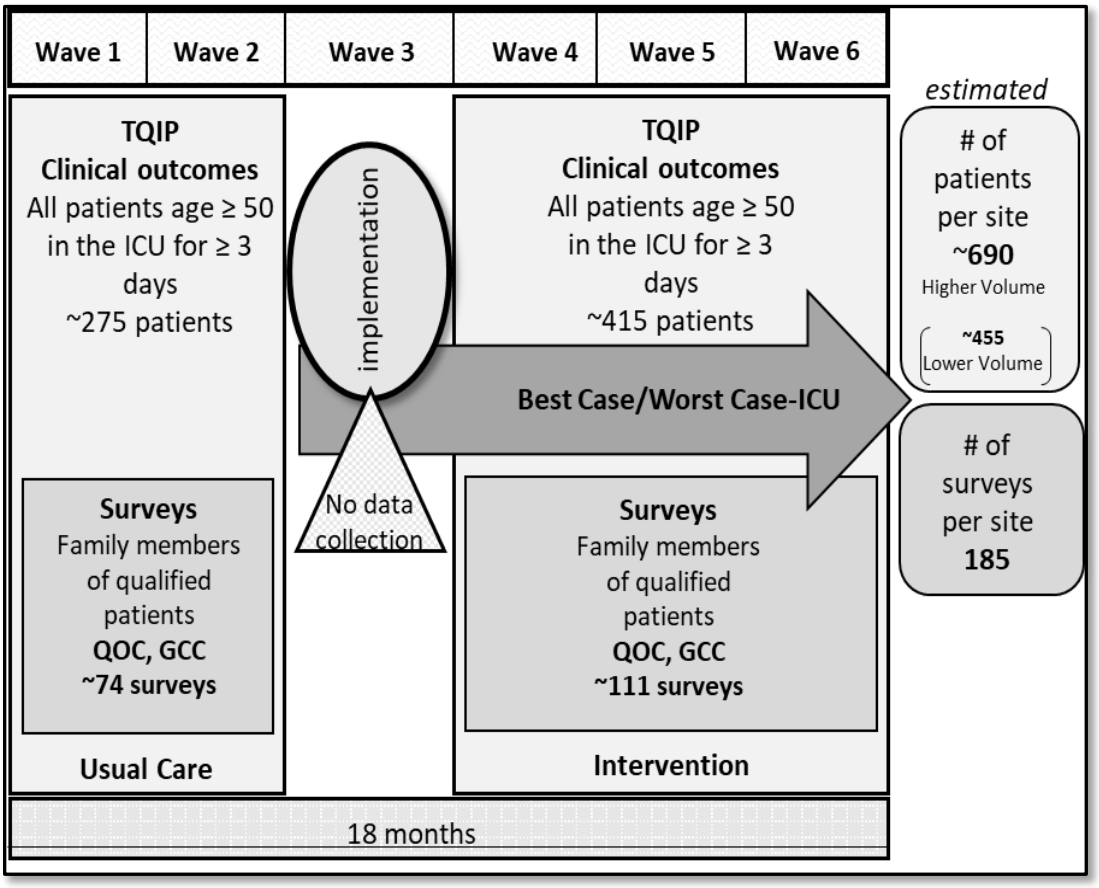
- 4 surveys over 24 months, each one taking about 15 minutes to complete. Clinician interviewees will participate in an interview lasting about 20 minutes and will complete a 5-minute demographic survey after implementation at their site.

Quality improvement initiative:

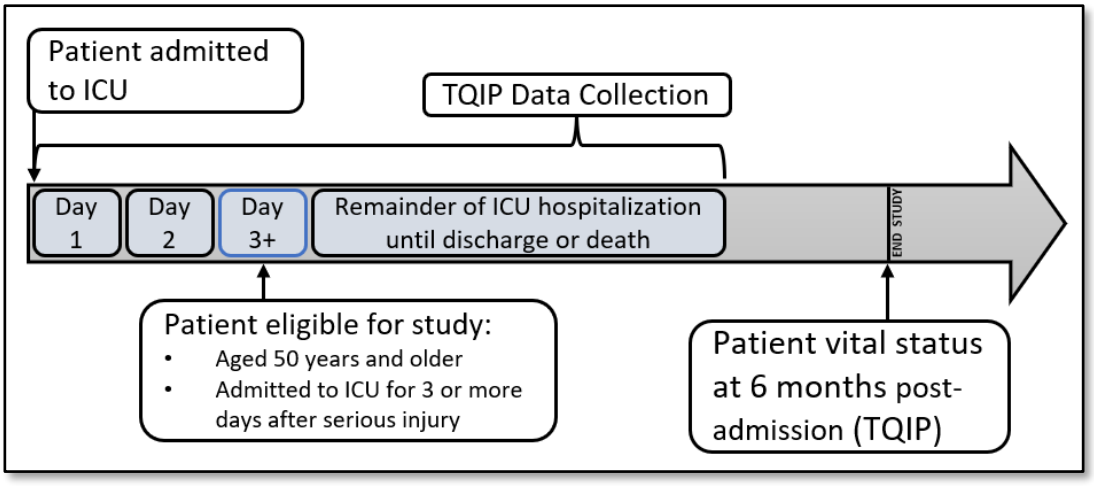
- Training duration described above (in "Description of Study Intervention/Experimental Manipulation" section and varies by provider type.

2.2 SCHEMAS

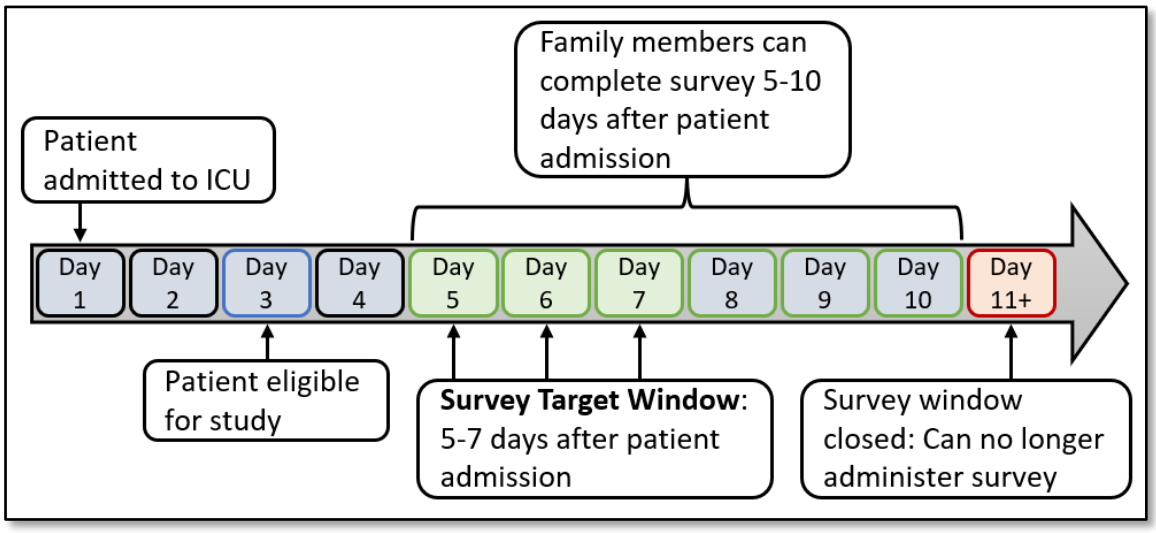
Stepped Wedge Schema



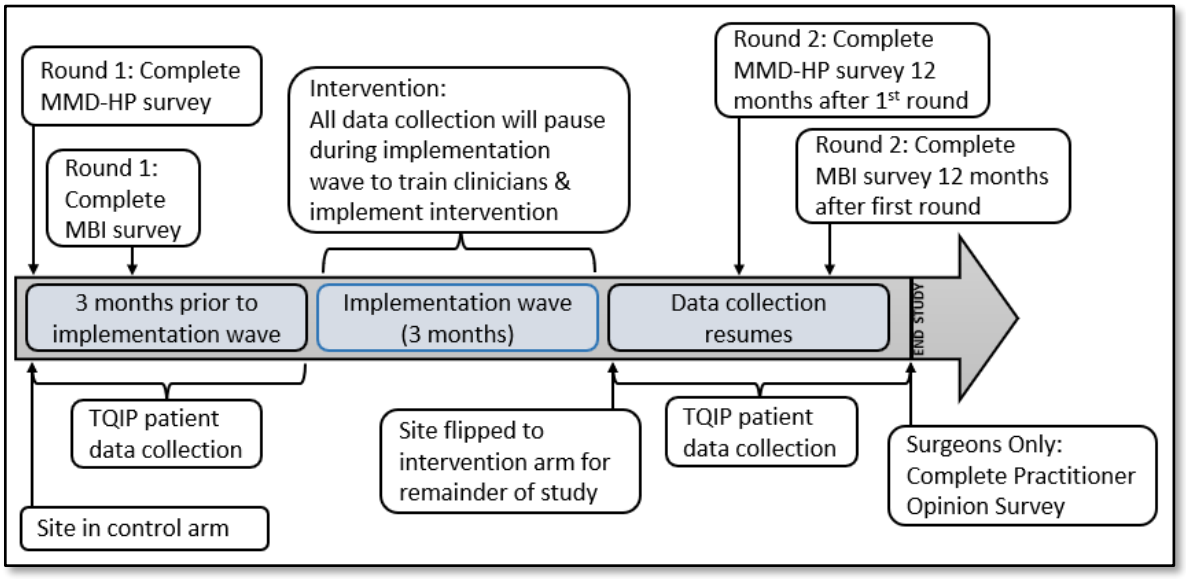
Patient Schema



Family Member Schema



Clinician Schema



2.3 SCHEDULE OF ACTIVITIES

Patients: TQIP will collect clinical data from the time of injury until discharge for their injury-associated admission. At 6 months after admission, TQIP will also collect record of their vital status. Patients in the control group will receive usual care; patients in the intervention group will receive care from a trauma team that has been trained to use the Best Case/Worst Case intervention.

All patients who are admitted to the trauma center will have their clinical data collected by TQIP. TQIP will transfer data to the UW study team only for patients who meet enrollment criteria.

Family Members: RCs will screen the ICU for patients who meet inclusion criteria. When a patient meets those criteria, a family member will be invited to take a 15- to 30-minute survey (QOC and GCC) 5-7 days after the patient is admitted (data will be collected up to 10 days after admission but target window is 5-7 days).

Clinicians: Clinicians will be notified about the study and asked to complete survey 1 (MMD-HP) and survey 2 (MBI) three months prior to their site's implementation wave and again (second round) 12 months later. The pair of surveys will be administered separately, two weeks apart during the first and second rounds.

During patient and family data collection, staggered implementation of the Best Case/Worst Case intervention will begin after 3 months. The intervention will be implemented at trauma centers, to all members of the trauma team. During the implementation wave, clinicians will receive training, coaching, and assessments ensuring they are using the intervention consistently. To evaluate the implementation of the intervention surgeons will also be asked to complete the Practitioner Opinion Survey.

Clinicians may be recruited for a brief, one-time interview and demographic survey after implementation at their site.

3 INTRODUCTION

3.1 STUDY 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.

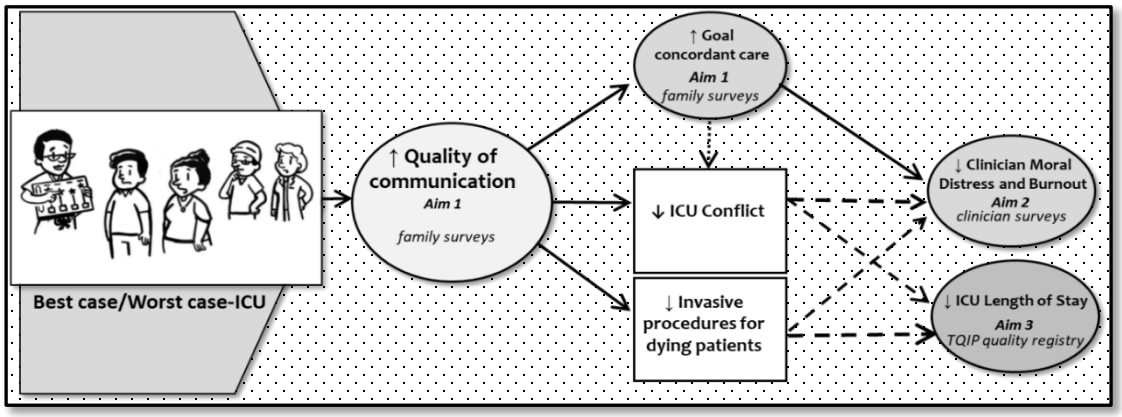


Figure 1: *Theoretical framework behind the Best Case/Worst Case-ICU intervention and this proposal. We will use surveys to measure the quality of communication and receipt of goal concordant care and use the TQIP quality registry to follow all patient demographics and outcomes. We will survey clinicians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

3.2 BACKGROUND

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

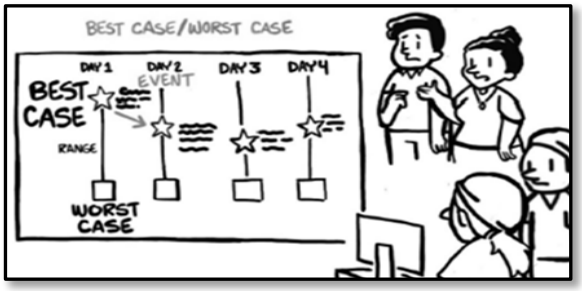


Figure 2: *Best Case/Worst Case-ICU is designed to demonstrate uncertainty, illustrate the interplay between major events and prognosis, & describe how patients might experience the treatments received along the course of care (illustration from YouTube)*

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.

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.

3.3 RISK/BENEFIT ASSESSMENT

3.3.1 KNOWN POTENTIAL RISKS

Patients: There is a risk of loss of privacy for patients whose chart is reviewed as part of the TQIP quality registry. This risk is independent of this study as data abstraction by trained TQIP abstractors occurs regularly, outside of any studies that utilize this data. There is remote potential a patient could be identified by date of admission and study site.

Family members: Completing the study survey may make family members feel uncomfortable. However, in our past work, family members have noted minimal stress associated with survey completion.

Clinicians: Trauma clinicians in the ICU may experience discomfort when filling out study surveys or being interviewed about intervention implementation at their site. However, in our past research, similar surveys and interview questions have been well tolerated.

Quality Improvement initiative: There is a risk that providers may experience concern by participating in the training program and learning to use the communication tool. It is possible that use of the Best Case/Worst Case-ICU communication tool or a family member study survey might result in patients or family members asking more questions of trauma clinicians. Trauma clinicians may find that use of the Best Case/Worst Case-ICU communication tool results in their consultations with patients and family members taking more time than their usual care practices did, although we anticipate use of the tool will both facilitate communication and reduce the time needed for consultations with family.

The likelihood and seriousness of these risks is considered low, and ample protections are in place to minimize the likelihood of their occurrence. Protections against all of the above risks are described below.

3.3.2 KNOWN POTENTIAL BENEFITS

Patients and family members: We do not expect patients and family members in the control arm to directly benefit from participation in this study, but they may indirectly benefit knowing that knowledge gained from this study may benefit future patients. Patients and family members in the intervention arm could benefit by receiving better communication and subsequently receive care that better aligns with the patient's health goals, benefiting their treatment experience. Family members who complete the one-time survey may indirectly benefit knowing that knowledge gained from this study may help future patients, or from having the opportunity to speak about the care their loved one received.

Clinicians: It is possible that clinicians who participate in study surveys will benefit from knowing that the knowledge gained from this study may benefit ICU teams and patients in the future through improvements in communication and reductions in moral distress. They may also benefit from improved communication on the trauma unit as result of implementation and use of the tool.

3.3.3 ASSESSMENT OF POTENTIAL RISKS AND BENEFITS

This study presents minimal risks to participants. A better understanding of how we can help older adult trauma patients and their family members to choose treatments aligned with their preferences and avoid unwanted treatments or interventions may benefit other patients and their loved ones. The risks of this study are outweighed by the possible benefits and there are rigorous plans in place to minimize all risks. The risk of loss of privacy is low because there are ample data security measures in place.

Use of the Best Case/Worst Case-ICU communication tool could result in improved communication during trauma care delivery for older adults, potentially leading to care that is better aligned with the values and goals of patients. This patient-centered approach may improve trauma care for the nearly 500,000 older adult patients who are admitted to the hospital with a traumatic injury annually. If we demonstrate effectiveness of the Best Case/Worst Case-ICU communication tool, this study will provide the evidence needed to support wide adoption by trauma centers because it measures outcomes that are important to patients and families, clinicians, and healthcare systems. The risks of this study are

minimal and reasonable in relation to the importance of knowledge that will be generated. Study staff will remain alert to any changes in the risk/benefit ratio.

4 OBJECTIVES AND ENDPOINTS

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS
Primary		
To test the effectiveness of the Best Case/Worst Case-ICU communication tool on improving the quality of communication in the trauma ICU	We will measure family-reported quality of communication (QOC) using the 20-item Quality of Communication questionnaire, family member version 5-7 days after patient admission (data will be collected up to 10 days after admission but target window is 5-7 days).	This instrument is used widely in studies of communication interventions for patients with serious illness,[25,26] with good internal consistency and construct validity.[27] It includes 7 items specific to end-of-life communication, which if not performed by the clinician, are scored as zero, which will allow us to discriminate between quality of communication attributable to satisfaction with the clinician (with high ceiling effects) versus the quality of the communication about prognosis and outcomes.
Secondary		
To measure receipt of Goal Concordant Care (GCC)	We will measure family member reported receipt of goal concordant care by using the Goal Concordant Care (GCC) survey, which consists of 2 survey items: 1) preferences for care, 2) current receipt of care consistent with preferences 5-7 days after admission. (data will be collected up to 10 days after admission but target window is 5-7 days).	Interventions that orient patients, families, and clinicians to the patient's overall trajectory, rather than each isolated problem to be fixed, may support earlier identification of patients for whom such interventions are inconsistent with their goals.
To test the effectiveness of the Best Case/Worst Case-ICU communication tool on reducing clinician moral distress in the ICU.	We will measure trauma unit staff-reported moral distress with the 27-item Measure of Moral Distress for Healthcare Professionals (MMD-HP) 3 months prior to each implementation wave and again 12 months later.	As a proximate measure of the intervention effect on ICU conflict, we will use the Measure of Moral Distress for Healthcare Professionals (MMD-HP) to measure center-level distress at the beginning and the end of the study. The MMD-HP measures the frequency and level of distress of clinicians' experiences, specifically situations related to serious illness care such as "witnessing providers giving 'false hope'" and "participation in 'care that causes unnecessary suffering or does not adequately relieve pain or symptoms.'"

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS
To measure medical professional burnout	We will measure burnout using the 22-item Maslach Burnout Inventory (MBI) survey 3 months prior to each implementation wave and again 12 months later.	We will measure clinician burnout, a broader and more multifactorial construct than moral distress measuring the effect of chronic workplace stress on clinicians, using the Maslach Burnout Inventory (MBI), because this is a standard measure recommended by the National Academy of Medicine.[28]
To test the effectiveness of the Best Case/Worst Case-ICU communication tool on reducing ICU length of stay	Cumulative amount of time measured in days patient spent receiving ICU care during admission for traumatic injury. Each partial or full day is measured as one calendar day.	We will compare the mean length of stay in the ICU between treatment groups. We hypothesize that improvements in communication will reduce prolongation of invasive treatments for dying patients without changing overall longer-term mortality. We will test the mediating effect of in-hospital death on ICU length of stay and compare 6-month mortality between treatment groups.
To test the mediating effect of in-hospital death on ICU length of stay	Documentation of patient death between admission and 6 months after admission.	
To measure withdrawal of Life-Supporting Treatment	Withdrawal of Life-Supporting Treatment will be measured during patient's index hospital admission: Time between admission and withdrawal of life supporting treatment at the end of life.	Interventions to support families in the ICU can help families transition a patient's treatment to comfort-focused care and withdraw life support when doing so is aligned with the patient's priorities and overall health trajectory.[25]
(Implementation outcome) To measure practitioner opinion of the intervention	Trauma surgeons' impressions of the communication tool (12 items) upon study completion and qualitative interview.	This implementation outcome is collected to help the UW study team continue to develop the communication tool.

5 STUDY DESIGN

5.1 OVERALL 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 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.[29,30] 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 PIs are all trauma surgeons with experience in clinical investigation.

5.2 SCIENTIFIC RATIONALE FOR STUDY DESIGN

We considered several study-design strategies and concluded that randomization by trauma center is required. It is not possible to randomize at the clinician or patient level because the intervention is implemented by the entire trauma ICU (where clinicians' shifts overlap) and it is designed to influence the trauma team's communication practices generally, which would contaminate the control group for patient-level randomization.

We specifically chose the stepped-wedged design because the intervention takes time to implement and cannot be applied to half our study sample simultaneously. The design allows for all 8 trauma centers to receive the intervention. Although randomizing by site requires a substantially larger study population, our study sites include the highest volume trauma centers in the country and access to TQIP data will allow us to follow thousands of patients.

5.3 JUSTIFICATION FOR INTERVENTION

For patients and families, using a daily narrative about treatment and prognosis to provide context for downstream decisions could increase receipt of goal-concordant care. Studies of intensive care show that diagnoses and interventions build over time. With each new diagnosis, treatments are added. Boss et al.[31] note that intensivists initially view each failing organ as a problem to be fixed, while families see their loved one as a whole person, not discrete organ systems. Over time, families and clinicians switch perspectives. As therapeutic options are exhausted the clinical team sees the patient as dying, yet families have adopted the fragmented view and see each new problem as treatable. This building clinical momentum in the ICU is well described.[32-34] Multiple small treatment decisions are made without considering how each discrete intervention aligns with patient preferences until major events, like failure to liberate from a ventilator or imminent death, prompt discussion of goals of care.[35,36] Interventions that orient patients, families, and clinicians to the patient's overall trajectory, rather than each isolated problem to be fixed, may help disrupt clinical momentum and support earlier identification of patients for whom such interventions are inconsistent with their goals.

For trauma team members, including surgeons, trainees, and ICU nurses, improvements in communication could reduce ICU conflict, moral distress, and burnout. Contributors to high workload and low clinician wellbeing include: providing treatments that are inconsistent with patients' goals, prolongation of the dying process, conflict among clinicians about futility, and extended family meetings.[14,37-41] For the trauma team, there is tension between needing to efficiently care for multiple critically ill people simultaneously and providing high quality communication. Although the pressure to manage multiple competing interests cannot be overstated, this is not a zero-sum game. This intervention is designed to take less than 3 minutes when integrated into the systems review on rounds, yet long-term daily use of the tool (implementation and dissemination) will be difficult to achieve unless clinicians understand how it helps them.

For dying patients, improvements in communication could reduce unwanted invasive procedures and decrease ICU length of stay, an important health system outcome. Invasive life-supporting treatments near the end of life are a major contributor to overuse of healthcare resources.[42,43] Although there is some dispute about how much is appropriate to spend on end-of-life care,[44,45] trade-offs between length of life and quality of life are particularly salient for older adults who more often prioritize quality of life,[10] and there is strong consensus that providing care inconsistent with patients' goals and preferences is problematic. Several studies have shown that treatment which accords with patient priorities may lead to shorter survival among those who prioritize comfort over longevity.[25,46] Others have shown that reductions in ICU length of stay for patients who die can occur without significant changes in overall mortality.[47] This suggests that interventions to support families in the ICU can help families transition a patient's treatment to comfort-focused care and withdraw life support when doing so is aligned with the patient's priorities and overall health trajectory.[25]

5.4 END-OF-STUDY DEFINITION

Patients: TQIP data collection for patients will be completed 7 months after admission.

Family members: Family members are considered to have completed the study if they have completed the one-time survey 5-7 days after the patient's admission.

Clinicians: Clinicians are considered to have completed the study when they finish the fourth (final) survey.

6 STUDY POPULATION

Patients: We will follow the outcomes for all patients aged 50 and older admitted to the ICU at study sites for 3 or more days after serious injury.

Family members: We will invite one family member or informally designated "like family" or primary surrogate decision maker per qualified patient to participate. We will use chart notes and nursing referrals to identify the person most frequently engaged in the patient's care. Family members must be at least 18 years old and speak English or Spanish. We will exclude family members who do not have decision-making capacity.[48]

Clinicians: We will invite all clinicians providing care in the trauma ICU to complete surveys of moral distress and burnout. This includes attending trauma surgeons, fellows, residents, advance practice providers, bedside nurses and medical assistants, respiratory, and physical therapists, social workers, and chaplains. We will exclude people who do not directly provide care in the trauma ICU. These clinicians

will also participate in training of the intervention as part of a quality improvement initiative at their study site.

6.1 INCLUSION CRITERIA

Patients:

- Aged 50 years and older
- Admitted to trauma center ICU for 3 or more days after serious injury

Family members:

- At least 18 years old
- Speaks English or Spanish
- Loved one (patient) received 3 or more days of ICU care provided primarily by the trauma ICU team

Clinicians:

- Employed at study site and provide care in the trauma ICU (e.g., attending trauma surgeons, fellows, residents, advance practice providers, bedside nurses and medical assistants, respiratory techs and physical therapists, social workers, and chaplains)

6.2 EXCLUSION CRITERIA

Patients:

- None

Family members:

- Does not have decision-making capacity

Clinicians:

- Do not provide care in the trauma ICU

6.3 STRATEGIES FOR RECRUITMENT AND RETENTION

Patients: Patients are not being recruited directly for this study. Patient-level data will come from the Trauma Quality Registry (TQIP), administered by the ACS for all patients at study participating trauma centers for quality purposes. We plan to follow 4,500 patients. ACS will develop and execute the Business Agreement/Data Use Agreement required for this collaboration, covering use of TQIP data including admission date and site (these variables will not be used to identify patients but to link them to treatment groups) and vital status at 6 months. Vital status at 6 months is not currently collected by TQIP but they have agreed to collect it for this study and are interested in piloting this outcome variable assessment for future use for all patients. The data will be shared under a collaboration with TQIP, rather than a release of their standard participant use file (which typically does not include admission date and site).

TQIP data will be transferred via the American College of Surgeon's secure Dropbox account to the UW study team. Dropbox encrypts network traffic with SSL/TLS and uses 256-bit AES encryption for file security.

Family members: Study staff at each trauma center will screen the ICU roster to identify patients who meet inclusion criteria. All study staff will be part of the Health Care Component of Affiliated Covered Entity at each site.

We will invite one family member for each patient aged 50 and older who has been in the ICU for 3 or more days to complete a one-time survey. If a Spanish speaking participant has limited English proficiency, we will obtain the services of an interpreter fluent in both English and Spanish. This service may be provided by a professional healthcare interpreter, a member of the local study team, or a family member or friend of the participant.

The following recruitment methods are options, as allowable by each site's policies/guidelines:

- If in a private setting (hospital room), permission to approach will be obtained before the local study team approaches
- If approaching in waiting areas, appropriate permissions from the care team will be obtained to allow this
- Brochure
- Telephone
- Mailed letter

Family members will be approached regardless of the patient's location (not in the ICU) or health status (alive/dead). We estimate enrolling 1,500 family members but depending upon response rate, we may enroll up to 3,000.

As family members' participation in the study is limited to a one-time survey, there is no formal retention plan. Family members will receive a link to the study website produced by The CNTR describing the study and providing updates over time. The family member consent script will include 2 questions: (1) Asking the participant for permission for future contact to share study updates and results with them, and (2) Requesting permission to contact them again (by mail or email) should there be an opportunity for additional research studies. This information will be saved separate from their survey responses in a secure Excel file and deleted 2 years after analysis is complete.

Clinicians: We will invite all trauma team members (surgeons, fellows, residents, advance practice providers) and trauma ICU clinical staff (bedside nurses, medical assistants, respiratory and physical therapists, social workers, chaplains, and case managers) to participate in study surveys. Clinicians will be contacted initially via their hospital-based email address with an anonymous link to an electronic survey. Clinicians may be contacted 3 additional times for survey completion. In-person paper surveys will also be available if the clinician prefers. Study staff will be present in the trauma ICU during multiple shifts over a 4-week period with an iPad for face-to-face encouragement of survey completion to increase the cooperation rate. The site PI will notify all clinicians about the study at team meetings and through hospital generated electronic notification systems (e.g., weekly email updates) to generate enthusiasm about the research and completion of study procedures.

Clinicians will receive training for the Best Case/Worst Case-ICU communication tool based on standards for each study site for learning and quality improvement, including invitations via email, team meetings, and routine educational events. Individual training will be scheduled directly with trauma surgeons and fellows using a contact strategy they designate as preferred. Resident and advance practice provider education will be conducted using site-specific educational meetings. Clinician educators will also speak about the training during in-service meetings, morning huddles and via direct observation on daily rounds. Because of turnover and staff attrition, recruitment for training will be ongoing and a local educational implementation liaison resource will ensure support for routine use of the intervention.

For clinician interviews, after implementation at each site we will invite clinicians to participate in a brief, one-time interview and demographic survey. Clinicians may be recruited by email (which may be sent up to 3 times by a member of the UW or local study team, or a member of the clinical unit who will forward an email from the UW or local study team to clinical care team members), or in person in the trauma unit. There is a recruitment flyer that may be given to clinicians during in-person recruitment.

Incentives: Family members will receive a $20 incentive after a one-time survey completion. Clinicians will receive a $5 incentive for each survey completed (4 surveys up to $20 total). Surgeons and fellows will receive $100 for completion of training as part of the quality improvement initiative. Clinicians who are interviewed will receive $20.

7 STUDY INTERVENTION OR EXPERIMENTAL MANIPULATION

7.1 STUDY INTERVENTION OR EXPERIMENTAL MANIPULATION ADMINISTRATION

7.1.1 STUDY INTERVENTION OR EXPERIMENTAL MANIPULATION DESCRIPTION

The stepped-wedge design will be implemented in 6 waves. (Figure 3) The duration of each wave is 3 months. We will randomly assign the timing for each site to flip from control to intervention and collect data on all patients meeting study criteria from the TQIP registry. Treatment group assignment will be based on the patient's date of admission. After the implementation wave, all subsequent patients who meet study criteria will be included in the intervention group.

At the start of the study, all patients will receive usual care; in wave 6 all patients will receive care from a trauma team that routinely uses the Best Case/Worst Case-ICU communication tool. With each successive wave, 2 sites will have implementation of the intervention according to the randomization strategy. During the implementation wave, data collection will cease, and the 3-month wave will be used to train the entire trauma team to use the Best Case/Worst Case-ICU tool and confirm that it is used routinely in the ICU for older adults. The 3-month waves are designed to allow ample time for intervention implementation and to accommodate the seasonal variation in volume of patients who receive trauma care.

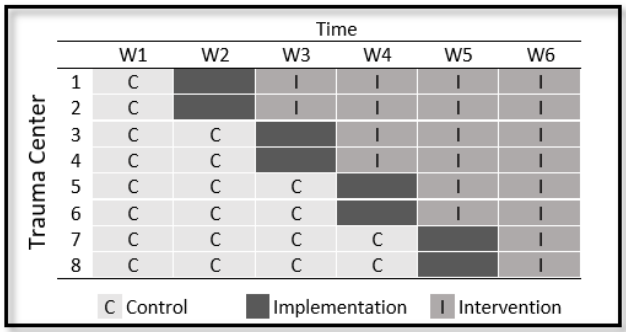


***Figure 3**: Stepped-wedge design. Each wave (W) is 3 months, data collection will cease during implementation.*

7.2 FIDELITY

7.2.1 INTERVENTIONIST TRAINING AND TRACKING

We have trained over 150 clinicians to use scenario planning and the Best Case/Worst Case tool with competence and fidelity, as measured by trainer and learner assessment. Our training program is modeled on Kolb's cycle of experiential learning[49] that promotes attainment of new skills through practice. We also incorporate Ericsson's work[50] in deliberate practice and mastery learning by providing individual coaching with feedback to ensure steady progression to competence and expertise. Because the Best Case/Worst Case-ICU tool is used for team-based clinician-family communication, the training

program is individualized for each role filled by trauma team members. For example, the surgeon describing the best case scenario will need to develop different skills than team members who are updating the graphic aid. Our implementation team will travel to all 8 sites to observe and support the use of the tool within the daily work of trauma team in their local environment. Using observation and feedback, we anticipate coaches will initially direct the team, then cue them, and gradually remove any support as the team demonstrates proficient and consistent use of the tool. Given the rotating nature of clinical shifts, we allow 3 months and multiple site visits for implementation to ensure routine use at each site. If this intervention is found to be effective, our training program is scalable for future implementation and dissemination studies using locally available resources.[51]

Implementation: Our strategy follows best practices for treatment fidelity as described by the NIH Behavior Change Consortium.[52] First, our implementation team will work with the trauma team to target learner-identified barriers for using this tool with patients and family. Using previously successful strategies, the team will start by observing daily rounds on site at the trauma center, interviewing trauma team members and nursing team leaders to identify site-specific strategies for completing documentation on the graphic aid and where specifically to post a copy of the graphic aid in the patient's room. We recognize each trauma center will have unique practices for daily rounds and that rounds are hectic given the intensity of illness and the high volume of patients. We have designed the tool to be minimally disruptive using teamwork, rather than rigidly assigning one person responsibility for this task. After obtaining input from the trauma team on the best local strategy, our intervention team will join daily rounds to facilitate the best team process and to ensure the tool is used with consistency. Training addresses the needs of 3 groups:

1. Trauma surgeons and fellows who will translate their knowledge about trauma care and outcomes into scenarios
2. Residents and advance practice providers who will prompt the surgeon to discuss outlook on rounds and document this on the graphic aid
3. Bedside nurses and ICU staff who will refer to the completed graphic aid when talking with patients and families.

Attending trauma surgeons and trauma fellows: Training begins with a one-on-one 30-minute instructional program followed by coaching, assessment, and additional training, as needed. It includes a 10-minute video introduction followed by coach demonstration, then individual preparation and practice and one-on-one expert feedback. The training program culminates in an assessment of the surgeon's use of the tool with a detailed hypothetical clinical scenario. Instructors will teach surgeons how to translate clinical knowledge and prognostic information into the Best Case/Worst Case-ICU format, using scenario planning ***daily*** to describe the course of illness, identify major events that change the best case scenario over time, and complete the pre-printed graphic aid. While most of the training focuses on how to generate scenarios, it also includes review of skills to support shared decision making for patients with serious illness. Surgeons and fellows will receive $100 for completion of training.

Assessment: To ensure fidelity to the use of scenario planning, instructors will assess the trauma surgeon's use of the tool with a test case and an instructor and learner evaluation form that scores learner competence to perform essential tool elements. Surgeons who do not achieve minimal competence (8 of 10 essential tool elements) will receive additional training until they achieve competence.

Intervention adherence: To confirm adherence to use of scenario planning over time, our UW-based clinician educator will conduct debriefings (remotely) every 2 months with trauma surgeons during the intervention period. Instructors will contact surgeons via secure webinar for a brief 15-minute coaching sessions using copies of the graphic aid completed during the surgeon's most recent clinical coverage of the trauma ICU. Instructors will review the graphic aid, provide feedback on fidelity, and take field notes about training and implementation.

Resident trainees and advance practice providers (APPs): Trainees and APPs will receive a 1-hour group session with a presentation, anchored by the 10-minute instructional video and teaching focused on completion of the graphic aid on rounds; specifically, how to include the patient's "outlook" at the end of the systems-based review and document the best case scenario, as reported and confirmed by the attending or trauma fellow, on the graphic aid. Learners will practice in pairs using hypothetical cases, where they will alternate practicing the role of the resident and then report to the group on their performance. The instructor will circulate during practice for additional coaching and review graphic aids to offer feedback. We aim to train surgical residents concurrently, regardless of their clinical rotation at the time of implementation.

Bedside nurses and other clinical ICU staff: During in-service meetings and morning huddles 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, all bedside nurses will also receive a brochure with details about use of the tool, instructions about how to support family interactions with the graphic aid, and QR codes with links to videos showing how the trauma team generates the graphic aid on rounds. We will train an on-site resource nurse champion for as needed nurse education.

Turnover and staff attrition: Busy trauma centers have staff turnover and rotation of trainees. Consequently, we will provide individual training for trauma surgeons and fellows who arrive at the institution after the implementation period using virtual one-on-one instruction, a technique our team used effectively during the pandemic for our current R01 study. We will conduct group sessions for trainees and APPs at times of known transitions in clinical roles, e.g., July, and when the trauma team identifies a significant cohort of new residents or APPs who have not had prior exposure to use of the tool. New nurses and ICU clinical staff will receive in-the-moment training as needed from peers and the implementation team.

Comparator – *Usual Care*: Prior to implementation of the intervention, patients admitted to the trauma ICU will receive usual care. Usual care is well described by our team and others,[31,35,36,53-55] whereby clinician's conversations are focused on isolated problems, disarticulated from the patient's overall health trajectory. This is typified by the systems-base review, routinely summarizing each patient on rounds where the clinician lists each physiologic system, (e.g., neuro, cardiac, pulmonary…) with an assessment and plan to "fix" each abnormality with a new treatment. Deliberation about how these individual treatments align with patient preferences is only prompted by major events like failure to liberate from a ventilator or imminent death. This pattern of usual care is well characterized and differs from daily scenario planning with the Best Case/Worst Case-ICU communication tool.

7.3 MEASURES TO MINIMIZE BIAS: RANDOMIZATION AND BLINDING

We will randomize the timing at which implementation and routine use of the Best Case/Worst Case-ICU tool begins at each site. The study statistician, blinded to study-site name, will use random permutation to assign a site from each strata to each intervention implementation wave.

Sites will be randomized to move from usual care to intervention in one of five cross-over waves. Best Case/Worst Case-ICU training will be provided to trauma clinicians at each site at the end of the control wave. Prior to that training, patients will receive usual care. Treatment group assignment will be linked to patient data and family member data by the patient's admission date.

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 UW study and intervention implementation teams 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.

7.4 STUDY INTERVENTION/EXPERIMENTAL MANIPULATION ADHERENCE

To confirm adherence to the use of scenario planning over time, the UW-based clinician educator will conduct debriefings every 2 months with attending trauma surgeons during the intervention period. The clinician educator will contact surgeons via secure webinar for a brief 15-minute coaching session using copies of the graphic aid completed during the surgeon's most recent clinical coverage of the trauma ICU. The clinician educator will review the graphic aid, provide feedback on fidelity, and take field notes about training and implementation.

Routine and sustained use of the tool using audit feedback and integrated personnel: Before leaving the trauma center, the implementation team will ensure the intervention is routinely used on daily rounds. We have budgeted for on-site personnel to support and confirm sustained use of the tool after the implementation wave. Separately from the UW study team, this implementation liaison (a surgical resident or APP) will attend rounds to remind the trauma team to include outlook in the systems-based review, articulate the best case scenario and document it on the graphic aid. They will perform once-weekly audits

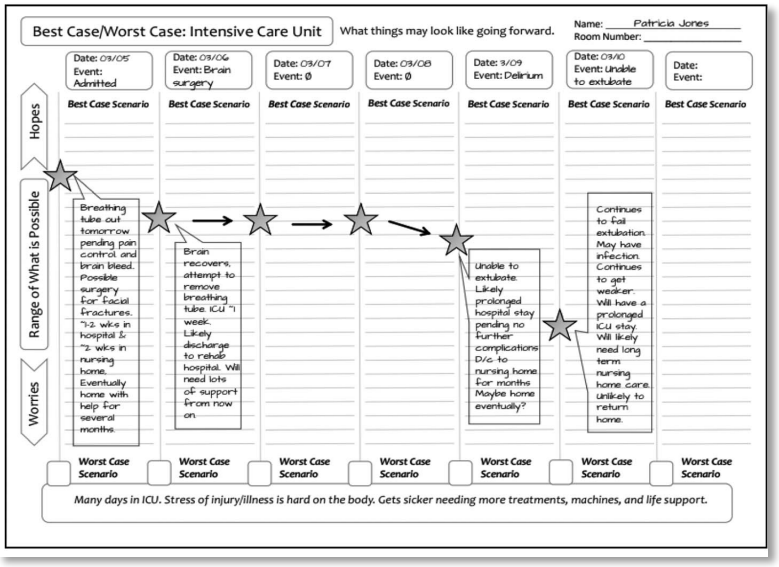


***Figure 4**: Pre-printed graphic aid will be completed, and a copy retained to estimate routine use of the intervention.*

comparing the number of study-qualified patients to the number who received *daily* communication using the Best Case/Worst Case-ICU tool based on graphic aid completion. They will retain a (de-identified) snapshot of the completed graphic aid (Figure 4) and note where it was posted in the ICU. Results of the audit will be fed back to the attending trauma surgeon *formatively* by the site PI, to stimulate improvement during their assigned period covering the ICU. Weekly audits will be tabulated by site and used to evaluate the pragmatic nature of this trial. Given our previous experience in the ICU, we anticipate 80% of study-qualified patients will receive daily communication using the Best Case/Worst Case-ICU tool.

8 STUDY INTERVENTION/EXPERIMENTAL MANIPULATION DISCONTINUATION AND PARTICIPANT DISCONTINUATION/WITHDRAWAL

8.1 PARTICIPANT DISCONTINUATION/WITHDRAWAL FROM THE STUDY

Patients: Patient data will be collected by the TQIP registry regardless of whether their family members participate in the study.

Family members: Family members will be asked to complete a one-time survey and thus we do not expect any family members to withdraw from the study; they would simply choose not to participate.

Clinicians: Clinicians who are completing study surveys or an interview may stop the survey or interview at any time or skip any questions they do not wish to answer.

9 STUDY ASSESSMENTS AND PROCEDURES

9.1 ENDPOINT AND OTHER NON-SAFETY ASSESSMENTS

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.[56]

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 local study teams.

Table 1: Outcomes Measures for Each Aim				
Construct	Specific Measure	Administered	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 7-item subscale measuring end-of-life communication (20 items)	In-person paper, web	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	In-person paper, web, phone	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 clinicians' experiences, targeting situations specifically related to serious illness communication (27 items)	In-person paper, web	Clinician survey	3 months prior to implementation wave and again 12 months later
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)	In-person paper, web	Clinician survey	3 months prior to implementation wave and again 12 months later
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	N/A	TQIP chart review	During hospitalization
Total ventilator days	Total time measured in days patient spent on a ventilator during admission for traumatic injury	N/A	TQIP chart review	During hospitalization
Death	In hospital patient death	N/A	TQIP chart review	During Hospitalization
	Patient death at 6 months	N/A	TQIP chart review	6 months
Withdrawal of Life-Supporting Treatment	Time between admission and withdrawal of life supporting treatment at the end of life	N/A	TQIP chart review	During hospitalization
Implementation Outcome				
Practitioner Opinion Survey	Trauma surgeon's impressions of the communication tool	Web survey	Surgeon	Upon study Completion
Graphic aid photo-documentation	De-identified digital image	N/A	Generated by surgeon	Collected during once-weekly audits

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

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 family members 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. Family members will receive a link to the study website, produced by CNTR, which describes the study and provides updates over time.

Clinician surveys: Three months prior to each implementation wave and again 12 months later, we will survey trauma team members and ICU clinical staff. 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 clinicians' 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.

Clinician Interview and Demographic Survey: A brief, one-time interview may be conducted with clinicians after implementation at their site. The interview will last about 20 minutes and include questions on opinions of the intervention and barriers and facilitators towards its use. The interview is followed by a brief demographic survey.

The interview may be conducted in person or virtually by a member of the UW or local study team. The UW study team may also request that implementation liaisons assist in clinician interviews. Liaisons may then assist the UW study team by conducting clinician interviews and coding transcriptions of clinician interviews at any study site.

Interviews will be transcribed, and while the interviewer will request that respondents avoid sharing any personal or patient-related identifiable information, any incidentally disclosed identifying details present in study audio recordings (e.g., proper names of individuals or locations), will be redacted during transcription. After transcription is complete, the audio recording will be deleted, not to be further analyzed or otherwise used for the research. Feedback during analysis and coding of the initial interview transcripts will be used to improve the interviewer's performance for subsequent participants and to prompt additional questioning on emerging themes and trends, a critical technique for qualitative research. The interview guide specifies overall question domains, which will remain consistent across interviews, while follow up questions and probes will vary based on the participant's responses. The interviewer may ask questions to follow up on or clarify what a participant has stated that are not

included in the interview guide, or to get a participant to talk more about a critical topic area. Analysis may lead to even more specific substantive probes around emergent ideas and themes.

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.

Graphic aid photo- documentation: The implementation liaison (a surgical resident or APP) will perform once-weekly audits of study-qualified patients and as part of this process, they will retain a de-identified snapshot of any completed graphic aids for study-qualified patients, recording where they were posted in the ICU.

9.2 ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

9.2.1 DEFINITION OF ADVERSE EVENTS

An adverse event (AE) is defined for this study as a negative reaction to study procedures such as survey questions—for example, reports of feeling anxious or conflicted about trauma care or study procedures that require sustained mental health treatment.

9.2.2 DEFINITION OF SERIOUS ADVERSE EVENTS

A serious adverse event (SAE) is defined by the department of Health and Human Services as any adverse event temporally associated with the subject's participation in research that meets any of the following criteria:

- results in death
- is life-threatening (places the subject at immediate risk of death from the event as it occurred)
- requires inpatient hospitalization or prolongation of existing hospitalization
- results in a persistent or significant disability/incapacity
- results in a congenital anomaly/birth defect
- any other adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health, and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition (examples of such events include allergic bronchospasm requiring intensive treatment in the emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse).

Patient-level medical events that are usually considered SAEs in RCTs of non-behavioral interventions (e.g., venous thromboembolism, etc.) are NOT considered study-related in this trial and are therefore NOT considered an SAE for this study. Moreover, some patients followed in this study are expected to die during the study period given the nature of their trauma and the aim of this study is to test the effect of

the intervention on end-of-life care. As such, death is not considered an SAE in the context of this study. Nevertheless, we will summarize data on patient deaths at completion of this study.

9.2.3 CLASSIFICATION OF AN ADVERSE EVENT

9.2.3.1 SEVERITY OF EVENT

Adverse events associated with this stud will be classified as:

- **Minimal:** Increased stress related to study procedures, but this is easily tolerated and does not require participants to alter their normal activities. Symptoms are transient and do not require a mental health evaluation or therapy.
- **Mild:** Stress and inability to cope related to study procedures resulting in a minor alteration of normal activities and functioning. May require mental health evaluation or therapy but are usually improved by simple therapeutic measures and do not persist past treatment.
- **Moderate:** Stress and inability to cope related to study procedures that significantly interrupts the participant's normal daily activities and generally requires on-going mental health services.

9.2.3.2 RELATIONSHIP TO STUDY INTERVENTION/EXPERIMENTAL MANIPULATION

Attribution or relatedness to study procedures and intervention will be classified as:

- **Definitely Related:** The adverse event is clearly related to study procedures (such as a survey), i.e., it is an event that follows a reasonable temporal sequence from study procedures and could not be reasonably explained by the known characteristics of the subject's clinical state.
- **Possibly Related:** An adverse event that follows a reasonable temporal sequence from study procedures, but that could readily have been produced by a number of other factors.
- **Not Related:** The adverse event is clearly not related to the study procedures - i.e., another cause of the event is most plausible, particularly the participant's health state or health state of their loved one.

9.2.3.3 EXPECTEDNESS

The expectedness of AE's and SAE's will be categorized as:

- **Unexpected:** The nature or severity of the event is not consistent with prior information about study procedures.
- **Expected:** At this time, no adverse events are known to be associated with study procedures.

9.2.4 TIME PERIOD AND FREQUENCY FOR EVENT ASSESSMENT AND FOLLOW-UP

In accordance with NIA guidance, adverse events that are both serious (SAE) and unexpected will be reported to the IRB, NIA PO and to the DSMB, within 48 hours of the study's knowledge of SAE. The summary of all other SAEs known to study investigators will be reported to NIA PO and to the DSMB prior to each DSMB meeting, unless otherwise requested by the DSMB. The AE report will provide a high-level narrative, detailing the event as well as the conditions under which the event occurred and how this event is related to study participation. The PI will review any adverse events to assess the likelihood they were related to study procedures, i.e., surveys. The UW PI will distribute DSMB and adverse event reports to investigators at all sites.

9.2.5 ADVERSE EVENT REPORTING

Although not expected, research staff will be prepared to address any adverse events. Any adverse events will be reported to the UW PI immediately. Research staff will complete an adverse event report

form which will provide a high-level narrative, detailing the event as well as the conditions under which the event occurred and how the event is related to study participation. The severity of adverse events will be classified, and the PI will assess their relatedness to study procedures. No serious adverse events (SAEs) related to study procedures are expected. All negative reactions to study procedures will be reviewed by the study PI to determine whether a change in protocol is necessary and assess the likelihood that they were related to study participation. We will submit all reportable events to the DSMB and the UW IRB in accordance with their reporting guidelines.

The study PI will review the research study and the accrued data in monthly project meetings to ensure the validity and integrity of the data and to evaluate whether changes to the anticipated benefit-to-risk ratio of study participation have occurred. The PI will report any policy violations to the UW IRB immediately. The UW PI will distribute DSMB and adverse event reports to investigators at all sites.

9.3 UNANTICIPATED PROBLEMS

9.3.1 DEFINITION OF UNANTICIPATED PROBLEMS

This protocol uses the definition of Unanticipated Problems as defined by the Office for Human Research Protections (OHRP). OHRP considers unanticipated problems involving risks to participants or others to include, in general, any incident, experience, or outcome that meets all of the following criteria:

- Unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the IRB—approved research protocol and informed consent document; and (b) the characteristics of the participant population being studied;
- Related or possibly related to participation in the research ("possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- Suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

9.3.2 UNANTICIPATED PROBLEMS REPORTING

The principal investigator will report unanticipated problems (UPs) to the reviewing IRB. The UP report will include the following information:

- Protocol identifying information: protocol title and number, PI's name, and the IRB project number
- A detailed description of the event, incident, experience, or outcome
- An explanation of the basis for determining that the event, incident, experience, or outcome represents an UP
- A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the UP

To satisfy the requirement for prompt reporting, UPs will be reported using the following timeline:

- Any UP will be reported to the IRB and to the funding agency within 14 business days of the investigator becoming aware of the problem
- All UPs should be reported to appropriate institutional officials (as required by an institution's written reporting procedures), the supporting agency head (or designee), and the Office for

Human Research Protections (OHRP) within 14 business days of the IRB's receipt of the report of the problem from the investigator

10 STATISTICAL CONSIDERATIONS

10.1 STATISTICAL HYPOTHESES

We hypothesize that using the Best Case/Worst Case-ICU communication tool will improve quality of communication, reduce clinician moral distress, and reduce ICU length of stay.

Primary outcome:

- 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.

Key secondary outcomes:

- 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 Healthcare Professionals (MMD-HP) to measure center-level distress at the beginning and the end of the study. MMD-HP measures the frequency and level of distress of clinician experiences, specifically situations related to serious illness care such as "witnessing providers giving 'false hope'" and "participation in 'care that causes unnecessary suffering or does not adequately relieve pain or symptoms.'"
- 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. We will test the mediating effect of in-hospital death on ICU length of stay and compare 6-month mortality between treatment groups.

10.2 SAMPLE SIZE DETERMINATION

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.

Missing data: We expect missing outcomes will be minimal for QOC (Aim 1) because it is measured in close proximity to the patient's post-injury care. We anticipate some missing data due to item non-response or "unsure" responses. For unanswered survey questions we will impute the value for that

question with the respondent's median score for all answered questions within the subsection (general communication or EOL communication) if at least half the questions have been answered. To understand the impact on non-responders for Aim 2, we will perform sensitivity analysis between outcomes of early and late respondents and characterize the differences in demographic characteristics between responders and non-responders. Given the reporting requirement for trauma center verification, we anticipate very low rates of missingness for in-hospital outcomes for the patient cohort in Aim 3.

10.3 STATISTICAL ANALYSES

10.3.1 ANALYSIS OF THE PRIMARY ENDPOINT(S)

We will use an intention to treat analysis based on all available data from participants based on group assignment. The intervention effect will be tested in the context of linear mixed effects models.

- For Aim 1, we will assess the treatment effect 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.
- For Aim 2, we will assess the post-intervention effect 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.
- For Aim 3, we will assess 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.

A full statistical analysis plan (SAP) will be published and available on CT.gov.

10.3.2 ANALYSIS OF THE SECONDARY ENDPOINT(S)

We will conduct secondary outcomes analyses with intervention as the main predictor while adjusting for demographic and clinical covariates as appropriate for the study cohort. For Aim 1 and 3 outcomes, the intervention effect will be tested in the context of generalized linear mixed models with a treatment dummy variable, site random effect, and time dummy variables. For Aim 2, Maslach Burnout (MBI) will be analyzed with a linear mixed effects model with a post-study dummy variable and a site random effect. We will use mixed methods (qualitative content analysis and descriptive statistics) to summarize field notes from implementation, intervention fidelity (graphic aid documentation) and practitioner opinion surveys.

10.3.3 BASELINE DESCRIPTIVE STATISTICS

We will use summary statistics to describe, by group, patient characteristics such as age, sex, preexisting conditions and injury severity, family member characteristics including gender and relationship to patient, and clinician characteristics including role, age, and time in current position.

10.3.4 PLANNED INTERIM ANALYSES

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.

10.3.5 EXPLORATORY ANALYSES

We will perform exploratory sensitivity analyses to evaluate the consistency of the intervention effects over time during the trial period and across ICUs, particularly if there is significant site variation in routine use.

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, we will perform two exploratory analyses:

   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.

11 SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

11.1 REGULATORY, ETHICAL, AND STUDY OVERSIGHT CONSIDERATIONS

11.1.1 INFORMED CONSENT PROCESS

Patients: Because the data is collected for the TQIP quality registry, and the intervention qualifies as quality improvement and is implemented at the institutional study-site level, we will not obtain patient consent for randomization to treatment group, or delivery of the intervention (a tool to facilitate communication). We will receive limited Identifiable Private Information (patient admission dates, location) from TQIP in order to link patient data to their treatment group assignments. A waiver of consent is requested for collection, receipt, and use of patient data.

A waiver of HIPAA authorization is requested for all patient data. This includes pre-screening patient records (to get in contact with family members), and the receipt of protected health information (PHI) with limited identifiers (date of admission, location) from family members about the patients. Pre-screening eligibility review of medical records involves no more than minimal risk because the person accessing the information has undergone training in confidentiality of medical records and the records are viewed solely to pre-screen for eligibility criteria. Only minimal information will be recorded for research purposes, and this limited information is needed to know whether the patient's location was receiving the QI intervention. Names of patients (and other unique identifiers) that are deemed ineligible will not be recorded.

A data use agreement (DUA) for the receipt of limited HIPAA identifiers is requested to cover receipt and use of TQIP data. The research presents no more than minimal risk of harm to participants, the research could not be practically carried out without the waivers, and the waivers will not adversely affect the rights and welfare of participants.

Family members: Research staff will talk with the family members about the study, stressing that it is voluntary and explaining risks and benefits. Research staff will answer any questions they have about the study. If the family member is interested in participating, consent script text will precede the survey, and a copy will be provided for them to keep.

We request a waiver of documentation of consent and altered HIPAA authorization for family member surveys, justified as the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context. Only minimal information will be recorded for research purposes, and this limited information is needed to know whether the family member's location was receiving the QI intervention and to aid in survey completion and remuneration payments (i.e., enrollment logs).

Family members will indicate their willingness to participate by advancing in or completing the survey. The readability of the consent script will be assessed by readability formulas (such as Flesch-Kincaid), in order to ensure that the materials facilitate comprehension by potential study participants. Consent scripts and surveys will be available in both English and Spanish.

Clinicians: We will request a waiver of signed consent and altered HIPAA authorization for clinician surveys, justified as the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context. We will not obtain consent for provider training as the Best Case/Worst Case-ICU communication tool is considered quality improvement because its primary purpose is to increase behaviors that are recommended in practice statements from professional societies, e.g., timely communication with families and emotional support. Clinicians may indicate their willingness to participate by advancing in the survey, or study staff may obtain verbal consent for survey completion after reviewing the benefits and risks described in a consent script.

Clinician interviews: We request a waiver of documentation of consent for clinicians who are interviewed about intervention implementation. The consent process will consist of the UW or local study team member orally reviewing an information sheet with the potential subject and ensuring they understand what the study is about and why they are being asked to participate. Ample time will be provided for the clinician to answer questions. They will be asked whether they verbally agree to participate, and the date/time of this response will be recorded by a member of the UW or local study team.

11.1.2 STUDY DISCONTINUATION AND CLOSURE

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. The suspending or terminating party will provide written notification, documenting the reason for study suspension or termination, to study participants, investigators, funding agency, and regulatory authorities. If the study is prematurely terminated or suspended, the PI (Dr. Schwarze) will promptly inform study participants, the IRB, DSMB, NIA, and NIH and will provide the reason(s) for the termination or suspension. Study participants will be contacted, as applicable, and be informed of changes to the study visit schedule.

Circumstances that may warrant termination or suspension include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to participants
- Demonstration of efficacy that would warrant stopping
- Insufficient compliance of study staff to the protocol (i.e., significant protocol violations)
- Data that are not sufficiently complete and/or evaluable
- Determination that the primary endpoint has been met
- Determination of futility

The study may resume once concerns about safety, protocol compliance, and data quality are addressed, and satisfy the funding agency, sponsor, IRB, NIH, or other relevant regulatory or oversight bodies (NIA, DSMB).

11.1.3 CONFIDENTIALITY AND PRIVACY

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. Data will be managed and protected rigorously at each study site. We will keep all hard-copy research files (including telephone survey data collection forms) in secure, locked offices. All computer research files will be kept on secure, password-protected computers on secure servers. We will shred excess copies of paper documents throughout the study. Only indirectly identifiable information will be collected on study surveys.

Study information will be saved in two places: a screening and enrollment log, and UW Qualtrics projects:

- Screening and Enrollment log: The screening and enrollment log will be used to keep track of screening, recruitment, enrollment, incentive tracking, and to populate a study CONSORT diagram, which will list how many patients were assessed for eligibility, how many family members were approached, how many enrolled, how many declined participation, etc. The log will consist of two tabs: one for screening and one for enrollment.
    - Screening tab: The screening tab will provide a comprehensive list of all subjects who were screened for eligibility. During screening, RCs will add all patients from their ICU roster aged 50 and over to the screening tab. They may temporarily include patient names, medical record numbers (MRNs), admission dates (to calculate 3-day eligibility) patient location, and age (ranging from 50 to >89). Recording this information in the screening tab will help RCs identify and track patients in subsequent screenings and help prevent them from adding duplicate patients to the screening tab more than once.
        - Patient names and MRNs will be deleted from the screening tab on a rolling basis as data collection is completed.
        - Each site will provide regularly updated screening information to the UW Study team—weekly or biweekly, or by request. Screening information sent to the UW study team will include the number of patients assessed for eligibility in the ICU but will not include any PHI (names, MRNs) or limited Identifiable Private Information (patient admission dates, location).
    - Enrollment tab: The enrollment tab will provide a working space to track recruitment and enrollment. Once a patient becomes eligible, RCs will record their MRN, Trauma ID (unique patient ID generated by each TQIP registry), dates of admission, and their family member's name and contact information in the enrollment tab. After the family member completes the survey, or the survey window closes (whichever is soonest), RCs will delete the family member's name and contact information so that the only information remaining for them is how many times they were contacted, the recruitment outcome, and whether they were provided an incentive for participation.
        - Patient MRNs and Trauma IDs will be deleted from the enrollment tab on a rolling basis as data collection is completed.
        - To add data into the ACS TQIP data set, RCs must temporarily record the patient MRN and Trauma ID (provided by TQIP abstractors) in the enrollment tab. Seven

to eight months after the patient was admitted to the ICU, RCs will record their vital status and ICU length of stay into the ACS IDCP. Then, RCs will delete the MRN and Trauma ID from the log.
        - Each site will provide regularly updated recruitment and enrollment information to the UW Study team—weekly or biweekly, or by request. Recruitment and enrollment information will include the number of patients found eligible, how many family members were approached, how many declined to participate, and how many completed the survey. Recruitment and enrollment information sent to the UW study team will not include any PHI.
    - At the end of recruitment, each site will securely transfer requested data from the screening and enrollment log to UW-Madison via SharePoint, Globus, or another UW-approved method for data transfer. No PHI will be transferred. The requested variables for return include: (1) patient study arm (control or intervention), (2) patient inclusion criteria (admitted to ICU post-trauma and admitted to ICU for three or more days), (3) patient screening eligibility outcome, and (4) family member enrollment outcome. After confirmation of successful file transfer, the site will delete their copy of the log file. UW-Madison will then store the de-identified screening and enrollment data on secure servers at UW for a minimum of 7 years post publication. We will not collect or record any information on patients who do not meet study eligibility criteria.
- UW Qualtrics projects: The Qualtrics data collection platform will be used to store clinician and family member survey data and voluntarily provided contact information. The survey projects will have automatically generated family member and clinician subject ID numbers only, with no PHI related to any patient, family member, or clinician participant included. Contact information projects will be stored in separate projects from survey data.
    - Clinicians who complete surveys via anonymous email link invitations may voluntarily provide their contact information to receive their participation incentive. Alternatively, they may complete the survey in person and receive the incentive directly following participation. If they choose to provide their contact information at the end of the survey, they will be automatically directed to a separate UW Qualtrics project which will not be linked to any of the data they provided on the survey.
    - At the end of the survey, family members may voluntarily provide their contact information to consent to future contact for study updates, opportunities to participate in future research, or both. If they choose to provide their contact information at the end of the survey, they will be automatically directed to a separate UW Qualtrics project which will not be linked to any of the data they provided on the survey.
- After data analysis is complete and the screening and enrollment log is deleted, the exported de-identified data set from Qualtrics will be stored on secure servers at UW for a minimum of 7 years post publication.

To protect data from family members who decide to participate in the study, we will keep electronic study data in two separate databases for each site—the Screening and Enrollment Logs (which will maintained at each site separately and will not be shared with anyone, including the UW Study team), and the UW Qualtrics projects.

Site investigators will be alert for any potential harm to participants, including breaches of confidentiality or distress during survey completion. We will report any breach of confidentiality to the UW lead site IRB upon its discovery. The risk of breach of confidentiality is low because we will only

collect information related to the research question and adequate provisions are in place to ensure that breach of confidentiality will not occur. Protection against unique risks to participant groups are described below.

Patients: Only TQIP data will be analyzed. ACS will develop and execute the BA/DUA required for this collaboration. The TQIP data set will contain no direct identifiers and three indirect identifiers (dates of service). Age of patients 90 years or older will be aggregated into a "90 or above" age group. All the data to be provided is routinely included in the TQIP Participant Use File (PUF), except for 5 additional data elements unique to this study: date of patient admission, trauma center, vital status at 6 months, date/time transfer orders written/placed, and date/time discharged from ICU (nurse handoff to the floor). These additional data elements will be used to link patients to the treatment group and perform a data quality check on ICU length of stay. They will not be used to identify patients.

Data included in the TQIP data set is recorded by TQIP trauma registrars and abstractors who complete HIPAA and confidentiality training. One additional variable (vital status at 6 months) and one data quality check (ICU length of stay) will be recorded by RCs for study eligible patients at each study site. ACS has developed an incremental data collection platform (IDCP) specifically for RCs enter these data directly into the TQIP database, linking them with larger data set. ACS will provide login credentials and restricted permissions to RCs, so they are able to add the variable and data quality check into the TQIP platform without having access to any additional patient data collected by TQIP trauma registrars and abstractors.

The registry data stored by the ACS is restricted, password protected and not accessible to anyone except the registrars, abstractors and TQIP trauma nurse supervisor. Actions to protect confidentiality are firmly integrated in the administration of the registry so that identifying information is available only to people who have a need to know. TQIP data will be transferred via the American College of Surgeon's secure Dropbox account to the UW study team. Dropbox encrypts network traffic with SSL/TLS and uses 256-bit AES encryption for file security. The ACS will provide the UW study team with a single-use, password-protected link to download the produced data set files. The password will arrive in a separate email following internet security best practices.

The implementation teams will retain a de-identified snapshot of the patients' completed graphic aids, storing them in a secure, locked office.

Family members: Research staff and survey instructions will remind family members that they do not need to answer any survey questions that make them uncomfortable. Research staff will also check in with family members after they fill out the study survey. Family members who participate in the study in-person will be given the option to complete the survey in a private room.

Clinicians: The MMD-HP, MBI and interviewee demographic surveys will not collect or retain any direct or indirect links to individuals. Clinicians will be contacted initially via their hospital-based email address with an anonymous link to an electronic survey. Alternatively, in-person electronic (iPad) or paper surveys may be administered per the clinician's preference. Survey instructions will remind participants that they may skip any questions they do not wish to answer. Only the minimum amount of information that is necessary to achieve the aims of the research will be collected. Clinicians participating in training will be given the opportunity to stop at any time. Clinicians who fill out study surveys in-person will be given the option to complete the surveys in a private room. For clinician interviewees, the brief demographic survey may be completed via Qualtrics or paper version of the survey or the questions may be read aloud by the interviewer at the end of the interview.

We do not anticipate any incidental findings, as we are not using research imaging, screening tests or paternity tests.

The risks in this study are minimal and reasonable in relation to the importance of knowledge that will be generated. Study staff will remain alert to any changes in the risk/benefit ratio.

Vulnerable Participants
It is likely that some patients and family members in the study may be homeless or have undocumented immigration status. The UW and local study teams will not be aware, however, as this data will not be collected. Additionally, some older adult patients with dementia will be included in the TQIP data set. We recognize these are vulnerable populations.

Patient participation in this study will be limited to inclusion in the TQIP data set and patients with these vulnerable statuses are not excluded from the data set. Family member participation is limited to completing a one-time study survey. We do not wish to exclude homeless or undocumented immigrant family members because we believe it is important to test the effectiveness of the intervention across the full population of older adults with serious injury and understand how it may affect different groups differently. Family member study consent scripts, which will be available in English and Spanish, will stress the voluntary nature of participation and that their willingness to participate will not influence their loved one's care. The consent script will also assure participants that their loved one's clinicians will not be able to access study data. We believe the incentive provided to family members, $20, is low enough that it will not be experienced by respondents as coercive.

11.1.4 FUTURE USE OF STORED SPECIMENS AND DATA

After data analysis is complete, the screening and enrollment log will be destroyed and the exported de-identified data set from Qualtrics will be stored on secure servers at UW for a minimum of 7 years post publication. These files will not contain patient, family member, or clinician identifiers. Patient MRNs and Trauma IDs, which are temporarily recorded in the screening and enrollment log, will be deleted approximately 7 to 8 months post-admission, when patient-level data collection is complete.

After data analysis is complete and manuscripts have been accepted for publication, all hard copies of research files will be destroyed. Only the minimum amount of information that is necessary to achieve the aims of the research will be collected. Each site will operate within regulatory guidelines as specified by the UW IRB, which will serve as IRB of record for the study.

Contact information for family members who agreed to future contact will be saved separate from their survey responses in a secured Excel file and will be deleted 2 years after analysis is complete.

11.1.5 SAFETY OVERSIGHT

The UW PI will be responsible for ensuring participants' safety in daily study operations. We will work with an independent Data Safety Monitoring Board (DSMB), which will serve as the data and safety advisory group for all study sites. Experienced members of the DSMB will represent a variety of backgrounds and disciplines, including biostatistics and trauma care. The DSMB will consist of five members approved by the NIA Program Officer. Three members will constitute a quorum. As this is a minimal risk study, there are no predefined stopping points due to futility, efficacy, or harms. The DSMB will discharge itself from its duties when the last participant completes the study.

The DSMB responsibilities are to:

- Review the research protocol and plans for data safety and monitoring.
- Evaluate the progress of the trial, including periodic assessments of data quality and timeliness, recruitment, accrual, participant risk versus benefit, performance of the trial sites, and other factors that can affect study outcome.
- Review study performance, make recommendations and assist in the resolution of problems reported by the Principal Investigator.
- Protect the safety of the study participants.
- Report to NIA on the safety and progress of the trial.
- Make recommendations to the NIA and the Principal Investigator concerning continuation, termination or other modifications of the trial based on the observed beneficial or adverse effects of the intervention under study.
- Ensure the confidentiality of the study data and the results of monitoring; and,
- Assist the NIA by commenting on any problems with study conduct, enrollment, sample size, and data collection.

Frequency of data and safety monitoring: In providing oversight for the conduct of this study, the DSMB will meet three times: prior to study initiation, after 12 months of family member data collection (at the end of wave 4), and at the end of data collection. Additional meetings may be scheduled as determined by the DSMB or as requested by the PI.

Content of data and safety monitoring reports: The DSMB members will review protocol-specific reports created by an independent statistician who serves in a non-voting member role on the DSMB. Reports will include an overview of study objectives, a review of actual and projected accrual rates, an evaluation of family member participant demographics, and a summary of the number and seriousness of adverse events. At DSMB meetings and in reports, data will be presented in aggregate and no participant identifiers will be included. During the open session of the DSMB meeting, attended by the Principal Investigator and key members of the UW study team, only blinded data will be presented. The closed session will be attended by the DSMB members and the NIA representative(s) and will include unblinded data.

11.1.6 QUALITY ASSURANCE AND QUALITY CONTROL

Quality Assurance Activities

The UW study team will conduct a variety of quality assurance activities to prevent defects in project data. Research staff at UW will design the Qualtrics project used to store family member and clinician survey data, incorporating real-time, field-level validation checks (e.g., range checks) into the platform wherever possible. The UW study team will generate monthly data monitoring reports—in aggregate and by site—summarizing accrual, data return and data quality. UW team members will share these reports with staff at each site during biweekly or monthly conference calls with RCs.

The UW study team will provide initial training to all study site RCs at the start of the study, as well as to any RCs who join once the study is underway. The initial training will consist of a thorough introduction to the Qualtrics project. The training will emphasize the importance of consistent questionnaire administration and timely data entry when required (preferably within 48 hours of collection). The UW data manager will hold biweekly or monthly RC calls, during which data quality issues will be discussed. Additional RC training will be provided as needed.

Quality Control Activities
Quality Control activities will occur continuously throughout the study in order to provide real-time identification and correction of any defects in project data. UW team members will use the Qualtrics ExpertReview feature to conduct biweekly data quality checks. These checks will help us:

- Assess the completeness of data per data collection point
- Flag missing or illogical information necessary for primary and secondary endpoints
- Conduct outlier assessment and range checking
- Identify patterns of unanswered questions and/or "straightlining"

11.1.7 DATA HANDLING AND RECORD KEEPING

11.1.7.1 DATA COLLECTION AND MANAGEMENT RESPONSIBILITIES

Data collection will be the responsibility of research staff at each site under the supervision of the site Co-Investigator. The investigator will be responsible for ensuring the accuracy, completeness, and timeliness of the data reported.

At each clinical site, family members, clinicians, or RCs will enter data directly into the UW Qualtrics project, under monitoring by UW. All project data will be stored in the Qualtrics project. RCs will collect study data directly from family members and clinicians using standardized questionnaires.

For patients, only TQIP data will be analyzed. Data included in the TQIP data set is recorded by TQIP trauma registrars and abstractors who complete HIPAA and confidentiality training. One additional variable (vital status at 6 months) and one data quality check (ICU length of stay) will be recorded into the TQIP platform by RCs for study eligible patients at each study site. The registry data stored by the ACS is restricted, password protected and not accessible to anyone except the registrars, abstractors and TQIP trauma nurse supervisor.

11.1.7.2 STUDY RECORDS RETENTION

No tissue or other physical specimens will be collected for this study. All research files will be kept in secure, locked offices, all computer files will be kept on a secure, password protected computer, and excess copies of paper documents will be shredded. The hard copies of research files (such as paper surveys) will be destroyed once the data has been analyzed. The information in spreadsheets recording the answers from the questionnaires will be coded—no names or other identifiers will be attached to these and only the unique participant study number will be associated with these data.

11.1.8 PUBLICATION AND DATA SHARING POLICY

This study will be conducted in accordance with the following publication and data sharing policies and regulations:

- *The National Institutes of Health (NIH) Public Access Policy*, which ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central upon acceptance for publication.
- *The NIH Data Sharing Policy and Policy on the Dissemination of NIH-Funded Clinical Trial Information* and the *Clinical Trials Registration and Results Information Submission rule*. As such, this trial will be registered at ClinicalTrials.gov, and results information from this trial will be

submitted to ClinicalTrials.gov. In addition, every attempt will be made to publish results in peer-reviewed journals.

Data sharing plan: A de-identified data set comprised of survey data, metadata, and analytic code will be deposited and made available through the National Archive of Computerized Data on Aging (NACDA), or comparable NIH-supported repository. A de-identified data set about the implementation of the intervention will also be made available through the repository. This will include dates of cross-over into the intervention arm, as well as other intervention data such as training dates and notes from training sessions. The data manager will create and share a data supplement that includes general information about the project that will be necessary for other researchers to understand the context of the data. This will include a final study protocol, data dictionary, consent scripts, and copies of all survey data collection tools. No transformations will be made to the data beyond created and derived variables pre-specified in our data dictionary. All de-identified data will be made available within one year of the completion of the funded project period or upon acceptance of the data for publication, whichever is earlier.

Data housed in NACDA or comparable NIH-supported repository will be restricted and researchers seeking access must complete a Restricted Data Use Agreement required by the repository, including documenting how regulatory requirements at their institution have been met and providing a data security plan. Once the repository receives and approves the agreement, repository staff will send the requestor an encrypted link to obtain the data files. NACDA and comparable repositories do not require return of data once a project is finished but will require those requesting data to specify their plans for deletion or retention of data, as well as where and how data will be stored at their institution.

These data may be of interest to other researchers studying trauma care and communication about serious illness. UW supports the Final NIH Statement on Sharing Research Data and will provide assistance to all investigators and personnel to ensure compliance. Consistent with OMB Circular A-110 and subsequent NIH Grants Policy Statements, UW will provide access to data collected as part of UW-supported investigations, insofar as access is consistent with IRB/CHR rules, local, state, and Federal laws and regulations, and the HIPAA Privacy Rule. Participant consent scripts will inform participants of plans for de-identified survey data sharing. The de-identified data will also be stored on a secure server at the University of Wisconsin.

Patient-level data used for this project, originally collected by the Trauma Quality Improvement Program (TQIP) Registry, will not be made available for sharing by the University of Wisconsin. This data is available upon request from the American College of Surgeons (ACS), who administer the TQIP program.

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