A Communication Tool to Assist Severely Injured Older Adults

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Investigators Plan

The Principal Investigator, Dr. Margaret (Gretchen) Schwarze will serve to coordinate and organize all data. UW will serve as lead site and coordinating center for this study and monitor study progress and methods for other sites. Three sites will participate in this study: University of Wisconsin-Madison, Oregon Health & Science University (PI: Karen Brasel), and University of Texas Southwestern Medical Center at Parkland Memorial Hospital (PI: Thomas Shoultz). Toby Campbell will be involved in development of a training program to be used at OHSU and UT-S.

Dr. Schwarze, Ms. Buffington, Ms. Tucholka and Mr. Fox will be responsible for project development, data collection, coding and analyzing the data, and/or writing the manuscript. Ms. Sisavath and Ms. Lape will be responsible for overseeing screening, recruitment, enrollment and data collection at their respective sites. Ms. Buffington will be the point of contact and coordinator for the study, managing and organizing data and records.

UW Co-Investigator Dr. Rathouz, is a senior advisor to the project and will assist in oversight of project development, implementation and data analysis of coded and de-identified data.

Protocol Control

To ensure that all investigators have the most current version of the UW protocol, UW will send each site Co-Investigator a copy of the UW protocol after any major changes and minor amendments are made. UW will communicate changes to the protocol to UT-S and OHSU and these changes will be reported to each site IRB by the site Research Coordinator as required.

Multisite Plan

UW will request that UT-S and OHSU's IRB cede review to the UW Health Sciences IRB. Study staff at the UW site will oversee this process and offer assistance to other sites with the reliance process. All 3 institutions have a Federalwide Assurance (FWA) on file with the Office for Human Research Protections (OHRP). The lead site Principle Investigator (PI), Dr. Schwarze, will be responsible for disseminating information between sites. Unanticipated problems, adverse events, protocol deviations, new information about the study, and changes of protocol will be communicated between the sites within 48 hours of discovery and will be reported to the UW and site IRBs within reporting guidelines. Protocol compliance will be monitored by the PI at each site. In addition, the UW site will conduct regular quality checks on data collected by each site. Any changes to the protocol will be communicated between sites by the UW team and will be reported to each IRB as required.

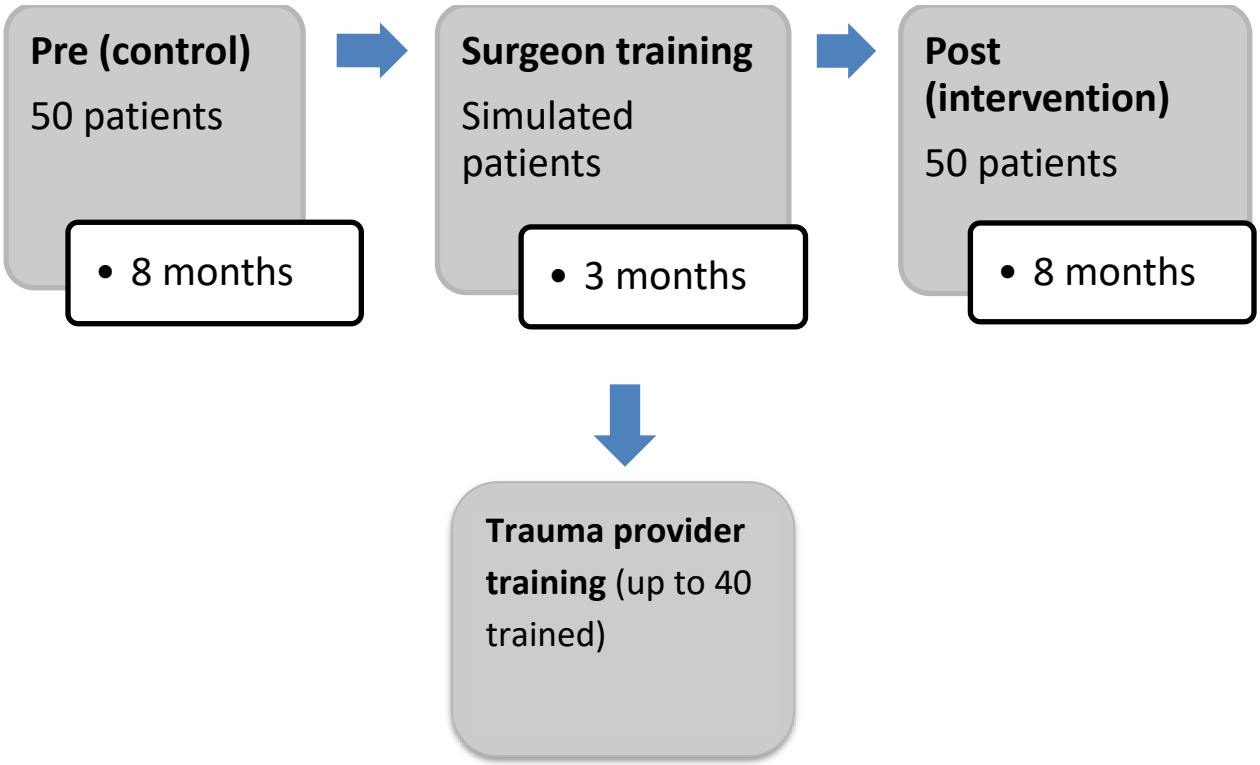
Dr. Schwarze, Anne Buffington and Jennifer Tucholka will communicate with the Research Coordinators at other sites through regular conference calls and contact via phone and email to ensure that there is adherence to the protocol and to conduct regular checks on issues relating to data quality. Regular webinars with the Co-Investigators at other sites will be scheduled monthly and as needed.

Project Summary and Timeline

The purpose of this study is test the effect of the "best case/worse case" communication tool on the quality of communication with older patients admitted to two trauma units and to collect feedback on the tool to help adapt it to the trauma setting. The intervention was developed and tested with acute care surgical patients at the University of Wisconsin (UW) and the present study seeks to test whether the intervention will work in a different setting.

To adapt the tool to trauma settings, we will conduct focus groups at UW Health Oregon Health Sciences University (OHSU) and Parkland Memorial Hospital (PMH) at the University of Texas-Southwestern (UT-S). Because trauma care is delivered by a multidisciplinary team, we will include attending trauma surgeons, surgical residents, ICU nurses, nurse practitioners, consulting physicians (e.g. orthopedic surgeons) and others on the trauma care team. Up to 60 trauma care providers will participate in focus groups across the three sites. We will test the intervention with severely injured older adults at OHSU and UT-S/PMH. In the first year, UT-S/PMH and OHSU will recruit and enroll 50 patients total in the control arm and train trauma providers to use the best case/worst case tool. Trauma providers trained on the tool will be interviewed after training to explore their thoughts on how the tool works in their trauma unit. In the second year, UT-S/PMH and OHSU will recruit and enroll 50 patients total in the intervention arm. UW will compare survey-reported and chart-derived measures before and after clinicians learn to use the best case/worst case tool.

UT-S/PMH and OHSU research team members will survey family members of trauma patients to compare the quality of communication for severely injured geriatric trauma patients cared for by trauma teams. When possible, UT-S/PMH and OHSU will survey patients on their quality of life. UT-S/PMH and OHSU will survey the patient's primary nurse on the quality of communication patients and will survey patient's families about their thoughts on the quality of communication as well. UT-S/PMH and OHSU will survey trauma unit staff before and after clinicians learn to use the best case/worst case tool, to assess whether the communication intervention improves feelings of moral distress. UT-S/PMH and OHSU will use chart review to collect downstream clinical outcomes including intensity of treatment and receipt of palliative care. UT-S/PMH and OHSU will archive de-identified graphic aids used by trauma surgeons with intervention patients to explore how the intervention was enacted.



Background and Significance

Improvements in medical care that have increased life expectancy have shifted the end-of-life trajectory for older adults who are now increasingly vulnerable to traumatic injury.[1] Each year, half a million older adults will suffer injury from a fall or car crash, making it the fifth leading cause of death. Older adults fare far worse than younger patients with similar injuries due to presence of chronic comorbid conditions and reduced physiologic reserve.[2-4] Traumatic injury is often a terminal event that leads to a 20% in-hospital and 40% one-year mortality.[5] Severely injured older adults undergo a series of invasive surgical interventions furthering a course of care—including prolonged life support[3] or confinement in a nursing home—that is often inconsistent with patients' preferences and goals. Given the burdens of treatment and poor prognosis, severely injured older adults would benefit from decision support interventions to facilitate early access to palliative care which can reduce unwanted invasive procedures, address symptoms and clarify long-term goals.[6,7]

Trauma surgeons are in a unique position to help older patients and their families make difficult treatment decisions. Surgeons meet patients in the acute setting often at off-hours, to consider invasive treatments with profound implications. They also have access to robust prognostic information, specifically the Geriatric Trauma Outcomes Score (GTOS),[4] a predictive nomogram that is easily understood by clinicians, simple to calculate, and pragmatically based on variables that are readily available. Although these decisions might be better led by primary care physicians who know the patient, those physicians are frequently not available for inpatient care and lack knowledge about traumatic injury. Moreover, patients' preferences are often not clearly articulated in a living will or advance directive—or may shift in the context of acute illness, injury or potential invasive treatment.[8-13]

Although surgeons endorse palliative strategies, especially for this population, current communication practices make it difficult for patients and families to associate their personal values with the likely consequences of complex treatment decisions. Our previous studies have shown that surgeons routinely *name* (e.g. heart attack), but do not *describe* unwanted outcomes and their associated treatments.[14] Moreover, much attention is paid in the surgical literature to precise risk prediction;[15-17] and surgeons rely on the decontextualized language of informed consent, which presents the overall hazards of treatment as discrete complications for isolated physiologic systems (e.g., a 50% chance of ventilator dependence) to explain these risks to patients.[18] This language does not provide a narrative about how patients might experience surgical interventions, or even expected downstream outcomes, such as additional invasive treatments or predictable changes in functional status. Reliance on risk disclosure with informed consent makes it difficult for patients to associate their personal values with the likely consequences of surgery and other invasive procedures.[18-20]

To make decisions consistent with their preferences, older adults and their families need information about possible interventions such as life support or surgery contextualized into a personal framework.[21-23] Shared decision making, in contrast to informed consent, allows patients to express values and outcome preferences so physicians can, in turn, recommend treatments that best support these values.[24]

We have developed a decision support intervention specifically for face-to-face clinical interactions that promotes dialogue and patient deliberation, and supports shared decision making in the context of life-limiting illness. Building on a conceptual model of shared decision-making proposed by Elwyn,[25,26] and the practice of scenario planning[27,28] our intervention is designed "to engage patients in a discussion about preferences" and to "assist them with the emotional work of considering future prospects."[25]

Scenario planning is a strategy used to facilitate decision making in the setting of uncertainty. By appealing to deeply held concerns of decision makers, a well-constructed scenario can encourage people to comprehend a new, previously unimaginable reality and prepare for major shifts in a way simple forecasting cannot.[27-29] The "best case/worst case" communication tool uses short statements and graphics to help patients and families visualize options, organize information and deliberate. It also uses narrative, rather than statements about risk, to describe how patients might experience a range of outcomes, helping them consider the value of future health states. It results in a handwritten diagram used by the surgeon, family and patient as the basis for further dialogue, so patients can express preferences and surgeons can recommend treatment corresponding to preferences.[25]

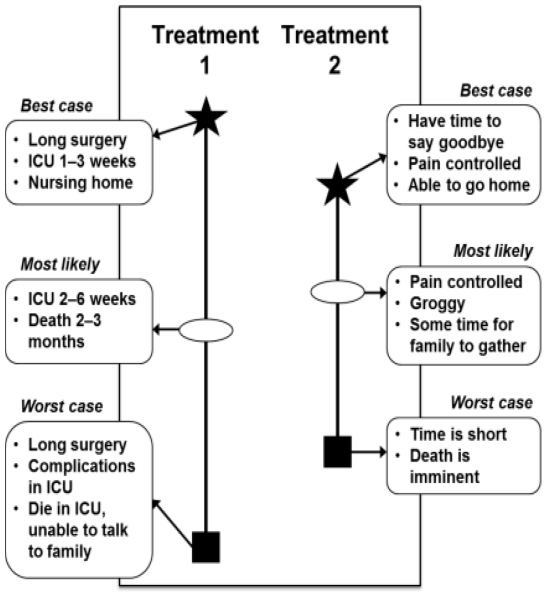


Figure 1: Visual aid of "best case/worst case" with written details.

How the "Best Case/Worst Case" Tool Works: The surgeon verbally describes the "best case," "worst case," and "most likely" outcomes for each treatment option—incorporating rich narrative from clinical experience and translation of

probabilistic information—while drawing a diagram of those options (Figure 1). Vertical bars represent treatment options; their length shows the range of outcomes and the magnitude of the difference between the "best case" (star), the "worst case" (box) and a "most likely case" (oval).[30] The surgeon also writes details about each option on the diagram. The narrative and graphic help family and patients formulate and express preferences.

The conceptual framework of the best case/worst case communication tool and this proposal is based on the theories of self-determination[31] and relational autonomy[32,33] that support shared decision making as described by Elwyn.[26] The best case/worst case tool uses scenario planning to target the structural and interactional barriers that inhibit family members' and patients' participation in decision making. By supporting autonomy and relatedness through improving family members' and patients' capacity to participate, this intervention supports shared decision making so that decisions are aligned with personal preferences and based on expectations that reflect the patient's clinical reality**.**

We theorize that teaching trauma surgeons to use the best case/worst case tool—in conjunction with the Geriatric Trauma Outcomes Score (GTOS)[4]—will improve communication between families, patients and surgeons and ultimately identify the need for palliative care sooner in the treatment plan. Because the GTOS[4] can help identify patients with poor prognosis early in their post-injury course, surgeons can use the best case/worst case tool to translate this prognostic information during treatment decisions. When discussions about treatment use narrative to interpret evidence about the patient's overall health state—including symptoms, events like ICU care, invasive procedures and prognosis—surgeons, patients and their family members can recognize that palliative care can assist with these burdens and limit treatments that are not aligned with the patient's goals.

Preliminary Studies

The UW research team performed an NIA (GEMSSTAR) funded study to test the feasibility of teaching surgeons to use the best case/worst case communication tool with frail older patients with acute general and vascular surgical problems at UW. All but one eligible surgeon enrolled in this study and 25 of 29 surgeons completed the best case/worst case training. Using a consensus checklist of best case/worst case elements, surgeons completed a mean of 9.8 of 11 elements with enrolled study patients.[34] Three months after training, 70% reported actively using the tool in clinical practice. In this pre-post study, observed patient engagement as measured by the OPTION 5 score[35] improved from a mean of 41 (IQR 26-66) before training to 74 (IQR 60-81) after surgeons completed the best case/worst case training.[36] (Figure 2) Measures of decision quality (e.g. decisional conflict)[37] had a high ceiling effect at baseline and did not correlate with the deliberative process used by patients and families. Measures of post-treatment distress (e.g. impact of event scale)[38] depended on patient survival which was highly variable.

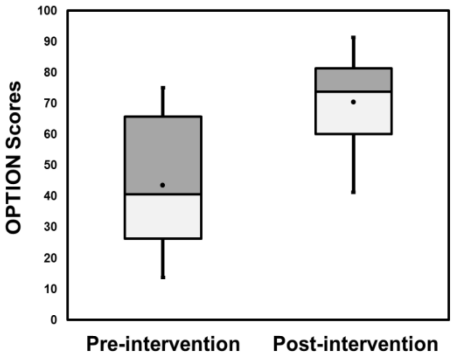


Figure 2: OPTION 5 scores from

Importantly, the framework promoted dialogue about treatment options: patients and family expressed preferences about outcomes, thereby enabling surgeons to recommend preference-concordant treatments. For example, one surgeon explained to his patient's family, "This is what

I know about her …that she didn't want a lot of these interventions…and we're gonna do a maximum amount of those things if we decide to go for surgery …so my general thought is that, surgery where she ends up in a nursing home, with complications from surgery, is not something that she ever wanted."[39] In interviews 30 days after enrollment, patients and/or family members reported that Best Case/Worst Case facilitated dialogue about options and allowed them to anticipate unwanted outcomes. (Table 1)

Table: Patient and family interviews 30 days after

Facilitates dialogue about options	"Seeing this allows questions to be easier to form, because if there was anything here someone didn't understand, they could say, 'worst case, after the ventilator…' it gives you an avenue to ask questions."
Helps prepare for unwanted outcomes	"I think it even says something about, you know, death. I mean that's there. I knew that. So that was not a surprise to me."
Presents options	"It was quite a relief actually to hear that maybe we could not have that [surgery]."

Study Aims

This project has two aims:

1. We will conduct focus groups to assess how the best case/worst case tool may be adapted to the trauma setting.
2. We will test the effect of teaching trauma care providers to use the best case/worst case tool on the quality of communication.

Selection of Participants

Inclusion Criteria

Trauma providers

Focus groups: There will be two rounds of focus groups. During Round 1 we will invite trauma surgeons, trauma fellows (including consulting physicians such as orthopedic surgeons) to participate.

During Round 2: All of those invited to Round 1 will be invited as well as: specialists who work in trauma (orthopedics, neurology), mid-level providers, ICU nurses, social workers, chaplains, palliative care trained surgeons, PGY-5 senior residents and others whose primary work is patient care in the trauma setting.

For both rounds, participants' primary job must be in trauma (except for senior residents), they must have at least one year of experience in a trauma center setting, they must have more than 2 years experience at the research site trauma unit (with the exception of trauma fellows).

Best case/worst case tool training and subsequent follow up interviews: All attending surgeons,

trauma fellows and mid-level trauma providers (NP/PA) from the OHSU and UT-S/PMH sites will be invited to participate in "best case/worst case" communication tool training.

Nurse survey: The nurse responsible for care of the enrolled patient at 3 days post-admission will be invited to complete a Quality of Communication (QOC) survey assessment.

Moral distress survey: All trauma unit nurses and physicians will be invited to participate in this survey.

Family members and patients

Family members: Family members are the primary participants in this study and the primary outcome is family-reported quality of communication. We anticipate that few patients will be well enough or have decision making capacity (DMC) to participate. Patients will participate with a family member who is present and is a formally or informally designated decision maker. If a patient has DMC, they will be asked by a UT-S/PMH or OHSU research team member to designate a family member to enroll in the study as the "study partner". Patients cannot be enrolled without a family member study partner as our primary outcome is the family member's perception of the quality of communication. If a patient lacks DMC, their family member or surrogate decision maker will be identified and approached. In this circumstance, the surrogate decision maker and study partner do not have to be the same person; a surrogate decision maker may provide consent for the patient chart review and re-contact at 30 days if they have regained DMC whereas another family member serving as study partner may participate in the surveys. In this circumstance (where the study partner is the only one to have consented), if the patient is alive at 30 days, the study partner will complete 3 surveys (including the Trauma Quality of Life survey at 30 days). If they are deceased, the study partner will complete the first two surveys only.

Patients:

We will include traumatically injured patients 50 and older admitted to the ICU.

We will include both patients who have or lack DMC, as described in the "Consent and HIPAA Authorization" section. Given the nature of traumatic injury in the study patient population we anticipate few, if any, patients will have DMC.

Exclusion Criteria:

Trauma providers

Focus groups: Potential participants must not be on call at the time of the focus group.

Best case/worst case tool training and subsequent follow up interviews: We will exclude residents who have not had at least 5 years of postgraduate training. We will also exclude care providers who do not directly provide primary trauma care in the ICU. Trauma consultants including for example, neurosurgeons, orthopedic surgeons, otolaryngologists will be excluded from best case/worst case training.

Nurse survey: No exclusion criteria.

Moral distress survey: No exclusion criteria.

Patients and family members

Family members: We will exclude patients whose family members do not speak English, are under the age of 18, lack decision making capacity (DMC) or have a severe hearing or vision impairment. Family members who will serve as study partners must have been present at bedside after admission so that they can report on the quality of care and communication with the treating team.

Patients: Surgeons will have an opportunity to exclude a patient or family who, in the physician's judgment, would not be an appropriate participant. Reasons for exclusion include the surgeon's assessment that there is a legal or risk management concern for serious psychiatric illness for example schizophrenia. We will also exclude patients who have a Physician Orders for Life-Sustaining Medical Treatment (POLST) or Medical Orders for Life-Sustaining Medical Treatment (MOLST) form on file in their medical record that specifies that the patient or their decision maker wishes them to receive no intervention. Additionally, we will exclude patients with an isolated head injury as defined by a Head Abbreviated Injury Scale (AIS) score of 2 or less and an External AIS score of 1 or 0 and a Glasgow Coma Scale (GCS) score of 15. This serves to exclude the mildly traumatically brain injured patients with minimal external injuries who require ICU-level monitoring for a short period of time only.

Research Design and Methods

Research Design

We will conduct two 90-minute focus groups at each of three sites with five to ten participants per group, for a total of up to 60 participants. Participants will be trauma providers from UW, UT-S/PMH and OHSU. The first focus group at each site will include trauma surgeons and trauma fellows. The second focus group at each site will include trauma surgeons, trauma fellows, specialists who work in the trauma unit (such as orthopedic or neurology specialists), ICU nurses, social workers, chaplains, and others engaged in caring for trauma patients.

We will conduct a pre/post interventional study at the trauma centers within OHSU and UT-S/PMH. Research team members at UT-S/PMH and OHSU will recruit 50 patients in the control arm and 50 patients in the intervention arm, aiming to balance patients who receive usual care with those who receive intervention from each participating surgeon. As close as possible to 72 hours of injury, study staff at UT-S/PMH and OHSU will administer the Quality of Communication (QOC) questionnaire family version[40] to the patient's family member present (study partner) for care discussions. At 10 days post-admission, study staff will administer The Family Inpatient Communication Survey (FICS)[41] and the Goal Concordant Care survey[42]. At thirty days after admission, if the patient is still living and has DMC, they will be given The Trauma Quality of Life (T-QoL)[43] survey and their enrolled family member will complete an adapted T-QoL. If the patient is alive but lacks DMC at 30 days after admission, their family member will complete an adapted T-QoL. If the patient has died by 30 days after admission, the Family Member will only complete the first two family member surveys. Study staff at UT-

S/PMH and OHSU will conduct chart reviews 30 days after admission to record treatments received including surgery, intensive care unit days and palliative care.

Using our best case/worst case training program, a trainer at the UT-S/PMH and OHSU sites will train all consenting attending trauma surgeons and trauma team members. As part of the training, participants (estimated 15 participants per site, no more than 20) will participate in an assessment session, demonstrating their use of the tool with a standardized patient and scripted clinical scenario. Standardized patients for these teaching sessions will be hired at UT-S and OHSU and will not be study subjects (do not need to sign consent). In the second hour of the session, surgeons will practice these skills and use the communication tool with two standardized patients in audio recorded sessions. Surgeons will then receive immediate feedback and encouragement from an expert observer after each interaction with the standardized patient. UW research team members will assess the fidelity of participant use of the tool using an 11-item checklist of adherence criteria and give feedback until they achieve an acceptable level of competence. Training participants will be asked to participate in a one-time brief interview following the training to explore their thoughts on how the tool has worked/could work in their trauma unit.

As close as possible to 72 hours after injury, study staff at UT-S/PMH and OHSU will give the patient's primary nurse the clinician version of the QOC

Study staff at UT-S/PMH and OHSU will also archive a copy of the graphic aid that surgeons used with study-enrolled family members and patients. Study staff at UT-S/PMH and OHSU will give all trauma unit nurses and physicians the Moral Distress Scale-Revised (MDS-R)[44], physician and nurse versions at the start and end of the study.

There will be two groups of patient participants at UT-S/PMH and OHSU in this study:

Group A (control): Before the surgeon has been taught to use the best case/worst case tool, we will enroll patients and their family member. These patients will have been provided usual care.

Group B (intervention): After the surgeon has been taught to use the best case/worst case tool, patients and family members will be enrolled and will follow the same data collection schedule as for control patients. The study team will archive a copy of the "best case/worst case" graphic aids created by the surgeon in the intervention arm as well.

Training Program

Our current training program, based on David Kolb's cycle of experiential learning,[45] includes a 10-minute introduction[46] explaining use of the tool followed by two hours of practice with standardized patients and expert feedback, i.e. coaching.[34] During training, surgeons learn how to translate clinical knowledge and prognostic data into the best case/worst case format, how to use phrases that encourage deliberation[47] and how to use the communication tool to elicit preferences and support value-concordant decisions.[39] Two to three surgeons will participate in each training session. Using principles of adult learning theory, these small-group sessions will provide skills training, skills practice and expert feedback. In the skills training, surgeons will first learn how to translate clinical knowledge and statistical data into the "best case/worst case"

format, how to use phrases that encourage deliberation and how to use the communication tool as part of a decision-making conversation (first hour).

In the second hour of the session, surgeons will practice these skills and use the communication tool with two standardized patients. This component of the training will be audio-recorded and surgeons will receive immediate feedback and encouragement from an expert observer after each interaction with the standardized patient. This assessment component of the training will utilize an 11-point Tool Completion Checklist to determine whether surgeon trainees have correctly used the communication tool. UW research staff will fill out this checklist for each surgeon though no identifiers will be recorded on it. In past work, an acceptable level of fidelity was achieved with more than 90% of participants within one training session.

The audiotaped recordings of the surgeon practice with a standardized patient will be used as quality control for the training, to judge its effectiveness. The UW study team will review audiotape transcriptions of surgeons using the communication tool with standardized patients, in addition to archiving the best case/worst case graphic diagrams created. The audiotape, transcript, graphic diagrams and checklists will all be de-identified and not linked to any particular study surgeon; they will only be labeled with a random number (not their study ID number) that cannot be linked back to them.

The training will be scheduled at a convenient time and surgeons will receive compensation (described in the Incentives section) for their time.

To troubleshoot problems and reinforce essential elements of the tool, coaches may meet with surgeons for one-on-one debriefing after they have had an opportunity to use the tool in clinical practice. This optional feedback session will be informal and based on the interest and needs of any surgeons who request it. After training, while recruitment of individuals to the intervention arm is underway, training participants will be invited to participate in a brief, one-time interview to discuss their thoughts on the communication tool.

Study Procedures

Screening and Recruitment

Trauma providers

Focus groups: Research team members at each of the three sites will use staff lists from their site to invite surgeons and trauma care providers to the study by email. Researchers will send this recruitment email up to three times over the course of a month. The email will encourage anyone who is interested in attending to call a research coordinator at the site. For ICU nurses specifically, their e-mail will contain a link to an electronic survey which will assess how many trauma patients the nurse has cared for in the past month as a means of screening out those who do not take care of traumatically injured patients very often. No information will be collected from this survey, and responses will not be kept. Those who meet a pre-determined cutoff for volume of trauma patients cared for (which will be unique at each center) will be given more information about the study and the site coordinator's contact information for participation in the

focus group. The research coordinator will then ask a few brief questions to determine eligibility and collect demographic information. If interested individuals respond via e-mail, they will be contacted via telephone for confirmation and in order to complete a brief phone screen which will determine eligibility and collect demographic information. From willing respondents we will select participants to capture a broad variety of trauma care perspectives based on professional role, years in practice, and gender.

Best case/worst case tool training: Researchers at UT-S/PMH and OHUS will use staff lists from their site trauma divisions to invite surgeons and trauma care providers to the study. After initial introduction of the study by email, they will contact eligible physicians (or their administrators) in-person or by email again if there is no response (3 total contact attempts). The recruitment email will include information about study components and ask if they would be interested in meeting in-person with study staff to discuss the study in-depth. This in-person meeting by study staff will include explanation of the study, inquiry of whether the surgeon would like to participate, and written informed consent.

Trauma provider interviews following best case/worst case tool training: Those who have completed the training will be contacted by phone or emailing them inviting them to participate in an optional interview.

Nurse survey: Those included in clinic staff lists will be emailed information about the study and will then be approached in clinic by a member of the research team if they are the primary nurse caring for an enrolled study patient. For the nurse-reported QOC surveys, the primary nurse caring for an enrolled study patient will be approached by a UT-S/PMH or OHSU research team member during their work shift and asked to participate by filling out a survey that assesses the quality of communication the patient and family have received over the prior 72 hours.

Moral distress survey: All nurses and physicians of the trauma units at UT-S/PMH and OHSU will be invited to participate in this survey. Those included in clinic staff lists will be emailed information about the study and will then be approached in clinic by a member of the research team.

<u>Family members and patients</u>

UT-S/PMH and OHSU surgeons and their team will assist authorized site study staff in pre-screening inpatient trauma-ICU rosters daily for newly admitted patients who are eligible for participation. Study staff will confirm with each site's trauma team that the patient is eligible to participate based on their age, ICU status, and presence of a family-member decision maker. If the patient has an isolated head injury, its severity will be calculated via the AIS score and the GCS scores and confirmed by study staff. Screening will occur through contact with service teams as well as through medical chart review.

In order to conduct these pre-screenings, we are requesting a waiver of consent for pre-screening as it will be impractical to obtain consent to screen for all eligible patients. A waiver of informed consent for pre-screening is justified because:

1. Pre-screening eligibility review of medical records by clinical research staff does not adversely affect the rights or welfare of subjects because medical record information is

screened to establish preliminary eligibility prior to approaching a potential subject about a study,
2. Pre-screening eligibility review of medical records cannot practicably be done without the waiver due to the number of patients. Pre-screening decreases the burden on patients; those who are found ineligible via chart review will not be presented with study information that does not apply to them,
3. 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. Further, only minimal information collected in the pre-screening process will be recorded for research purposes. Names of patients (and other unique identifiers) that are deemed ineligible will not be recorded.

Based on others' experience,[48,49] daily in-person contact with clinical staff is also critical to successful recruitment in a busy hospital setting. In addition to medical record review, each day, study staff will talk with the clinical staff on the trauma service (such as residents, nurses or midlevel providers) to identify patients who are appropriate for this study.

Ineligible patients:
No data on patients who are deemed ineligible will be collected or recorded.

Patients who decline to participate: No data after patients decline participation will be collected by UT-S/PMH and OHSU research team members, except for reason for non-participation and screening data. Screening data will include gender, race, and ages of individuals as well as GTOS score (and Trauma Injury Severity Score (TRISS) score for patients aged 50-64) and reason for non-participation. We will not record identifiable information such as patient name or medical record number, instead UT-S/PMH and OHSU research team members will assign a unique identifier (such as D001) to this information, to assist us in tracking the number of declines and maintaining accurate data entry. These data will be recorded so that we may determine whether participants (both in the usual care and intervention group) are categorically different than non-participants.

Consent and HIPAA authorization

Trauma providers

Focus groups: Prior to the start of the focus group, the focus group facilitator will give all participants the info sheet. Participants will be provided with ample time to review it and given the opportunity to ask questions.

Best case/worst case tool training: After a surgeon has expressed interest in learning more about the study, UT-S/PMH or OHSU research staff will meet with them in a private meeting space, explain study procedures and obtain written informed consent. Surgeons who enroll will consent to participating in both the training and to having their patients screened and enrolled in the

study, including having family members and nurses answer survey questions regarding their communication. Given high participation by surgeons in our initial study and endorsement from the chief of trauma at both institutions we anticipate the majority of surgeons at each center will participate. Interested physicians will complete written informed consent prior to participating in the control arm and the surgeon training session.

Trauma provider interviews following best case/worst case tool training: A member of the research team will give an information sheet to trauma providers who participated in best case/worst case communication tool training and are interested in participating in an interview. This will be done in person, if the interview is to be conducted face-to-face. Or, if the interview will be conducted by phone/Skype, a member of the research team will send the information sheet to the trauma provider in advance. In either case, the research team member will answer any questions the clinician has before starting the interview.

Nurse survey:
UT-S/PMH or OHSU research staff will meet with the provider in a private space at a convenient time to explain the study and inquire whether the provider would like to participate. We are requesting a waiver of signed consent for this study activity. This is justified because the study activity is a brief survey for which completion of the survey would indicate the subject's willingness to participate in the research.

Moral distress survey:
UT-S/PMH or OHSU staff members in the trauma unit will be approached by a member of the research team and asked to complete a paper survey. If they are interested, the researcher will give them an information sheet and answer any questions they have. No identifiable information will be collected as part of this survey and no participant identifiers are collected at any point for this study activity. Returned paper surveys will be labeled only with a sequential number that is used strictly for tallying how many surveys have been returned. We are requesting a waiver of signed consent for this study activity. This is justified because the study activity is minimal risk, comprised of a brief anonymous survey given at two time points. Completion of the surveys would indicate the subject's willingness to participate in the research and a signed consent form would constitute the only link between the data and the participant's identity.

<u>Family members and patients</u>

Family member study partners are the primary participants in this study and the primary outcome is family member-reported quality of communication. We anticipate that few patients will be well enough to participate or have decision making capacity (DMC). If a patient meets the eligibility criteria, study staff will approach the enrolled provider caring for the patient to confirm eligibility. A research team member will check in the patient's chart or with their care team as to whether the patient is intubated. If they are intubated, the research team member will proceed as though they do not have DMC. For non-intubated patients, a member of the research team will check the patient's chart or ask a member of the care team to determine whether capacity has already been assessed. If there remains a possibility a potential subject has limited cognitive abilities, a qualified member of the study team (MD) will determine the patient's decision-making capacity and need for a representative.

If the patient is deemed eligible and is found to lack DMC, a member of the patient's treating team will approach or contact an individual who is consenting on behalf of the subject for other medical procedures (formal or informally designated decision maker), and ask if they would be willing to speak with study staff. A member of the study team may also approach a patient or individual who is consenting on behalf of the patient at the OHSU site. The patient's representative will consent for the patient to participate in this study. We anticipate that many eligible patients will lack DMC. Adult subjects are commonly sedated and/or intubated upon admission and may remain so for much of their initial inpatient course. These subjects are of diminished capacity due to alterations in consciousness resulting from injury/illness and/or to medications administered for the purposes of treatment.

The UT-S/PMH and OHSU research teams will follow applicable IRB and state law guidance for assessment of incapacity and the need for a surrogate decision maker. These sources (along with direction from the trauma service) will also be used to determine the appropriate decision maker. At the time study staff approaches the subject and obtains consent, the study team will instruct the subject's representative that he or she should make a decision about research participation based on (1) what the subject would have decided if capable of consenting or (2) what is in the best interest of the potential subject.

If the patient is found to be eligible and has DMC, a member of the patient's treating team will approach the patient to ask if they and their family member would be willing to speak with study staff. (At OHSU a member of the study team may also approach a patient or family member to ask if they are willing to hear about a research study participation opportunity.) Patients will only be enrolled if a family member or support person is willing to enroll with them as a study partner. Family members cannot participate as a study partner if the patient has DMC and declines to participate. The activities for patient participation include only chart review and a survey on quality of life if the patient regains capacity while in the hospital (as documented in their medical record). If the patient's representative does not consent to participate, the patient will not be enrolled.

If a family member or a patient with DMC and their family member are willing, a member of the research team will meet with them in the patient's room or another private clinic exam room. Family members and patients (if they have DMC) will be approached within 24-48 hours of injury. The research team member will explain study procedures and obtain written informed consent from the patient and family member (if they have DMC) or family member only (if patient does not have DMC).

If a patient lacks DMC their surrogate decision maker will be approached or contacted regarding surrogate consent. This consent process will occur either face-to-face (if the family member providing surrogate consent is available locally) in which case written consent will be collected OR may be provided via phone or web survey (if the family member providing surrogate consent is out of the area), in which case verbal consent or consent via clicking a survey answer will be collected. In cases where the family member providing surrogate consent is not available locally, the first contact with them will always be made via phone, at which time they will be given the option of a verbal consent or web-based consent process.

Table: Consent and enrollment options

Patient has DMC

• Patient wants to participate • Family member wants to participate as study partner	Enroll patient and family member
• Patient wants to participate • Family member does not want to participate as study partner	Do not enroll in study
• Patient does not want to participate • Family member wants to participate as study partner	Do not enroll in study

Patient does not have DMC and LAR/surrogate is bedside

• LAR wants to participate as both surrogate and study partner	Enroll LAR as surrogate and study partner
• LAR does not want to participate as surrogate or study partner and no other family member agrees to be study partner	Do not enroll in study
• LAR does *not* want to participate as surrogate • Another family member agrees to be study partner	Enroll study partner. Do not enroll LAR/patient (no chart review or P1 data collected)

Patient does not have DMC and LAR/surrogate is not bedside/is out of area

• LAR wants to participate as surrogate • Bedside family member wants to participate as study partner	Enroll LAR as surrogate and family member as study partner
• LAR does not want to participate as surrogate • Bedside family member wants to participate as study partner	Enroll family member as study partner. Do not enroll LAR/patient (no chart review or P1 data collected)
• LAR wants to participate as surrogate • Bedside family member does not want to participate as study partner	Do not enroll LAR/patient or family member

• LAR does not want to participate as surrogate • Bedside family member does not want to participate as study partner	Do not enroll LAR/patient or family member

Definitions:

Patient consent: Patient with DMC consents to chart review and P1 survey

Study partner consent: A family member or caregiver present at bedside who consents to completing F1-F3 surveys. This person may or may not be the same as the surrogate LAR

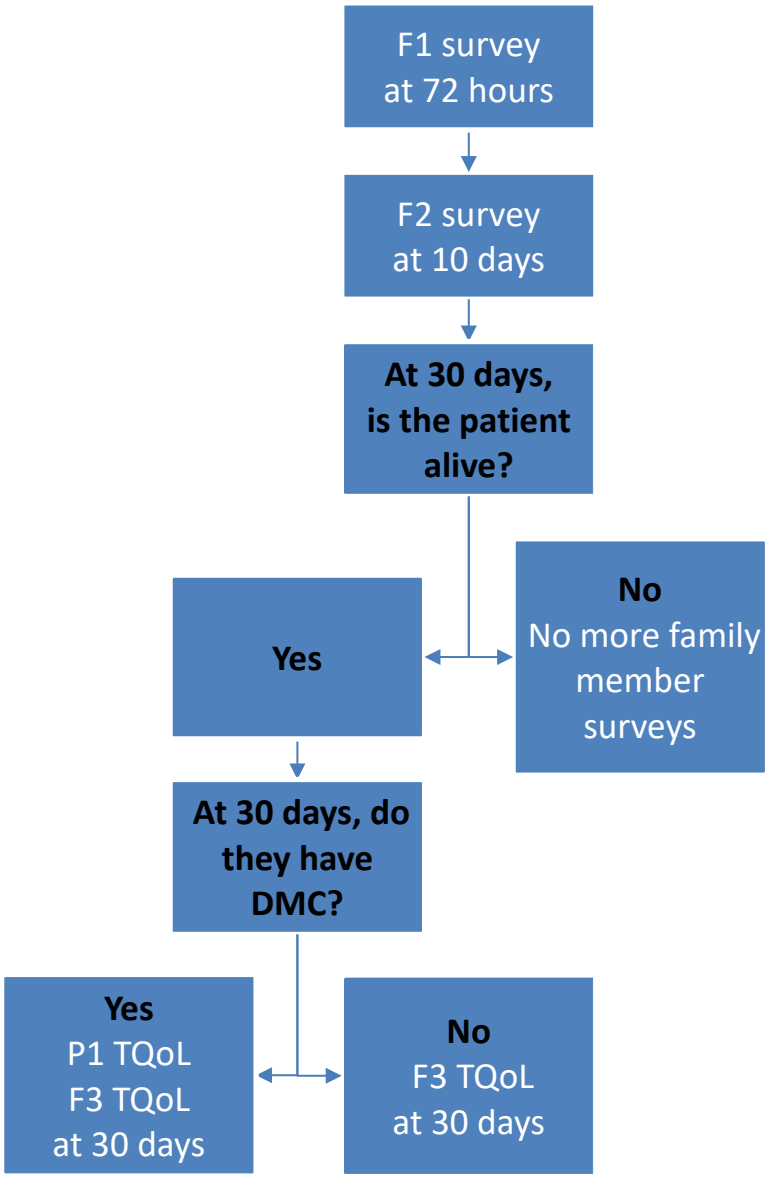
Surrogate consent: In case of patient who lacks DMC, the appropriate surrogate decision maker or legally authorized representative (LAR) provides consent for patient chart review and for researchers to contact patient for P1 if they have regained DMC

Instruments

Instrument	Definition	When administered	How administered/obtained	Specific Measures
Focus group guide	Used in each focus group to guide discussion	During focus groups	Facilitator will draw on questions from the guide.	N/A
Interview guide	Used in interviews follow trauma provider training	Interviews with trauma providers following their BC/WC training	Interviewer will pose questions from the guide	N/A
F1: Family Survey 1	First survey administered to family member study partner	As close as possible to 72 hours after admission	In-person (if family member available in hospital) Telephone	QOC[40], family version Single Item Literacy Screener[50] Family member demographics, including relationship with patient
N1: Nurse survey	Survey given to primary nurse for patient	As close as possible to 72 hours after admission	In-person Email/web survey	QOC[40], nurse version (During the intervention arm, this survey will contain several addition questions on whether the surgeon used best case/worst case. These

				will be submitted as part of a Change of Protocol)
F2: Family Survey 2	Second survey administered to family study partner	10 days post-admission	In-person (if family member available in hospital) Telephone	FICS[41] Goal Concordant Care[42]
F3: Family Survey 3	Third survey administered to family study partner	30 days post-admission	In-person (if family member available in hospital) Telephone	T-QoL[43], if patient is alive. If patient is deceased, no survey given
P1: Patient Survey (Only given to patients with DMC)	Survey given to patients with DMC	30 days post-admission	In-person (if patient member available in hospital) Telephone	T-QoL[43]
U1: Unit-wide moral distress survey (pre)	Start of study, prior to any patient enrollment	Before best case/worst case training	Anonymous paper survey	MDS-R[44] Physician and nurse versions
U2: Unit-wide moral distress survey (post)	End of study, after all intervention patients are enrolled	After best case/worst case training	Anonymous paper survey	MDS-R Physician and nurse versions
Graphic aid photo-documentation	Graphic aid created by surgeon	As close as possible to 24-72 hours after admission	De-identified digital image	N/A

As shown below, research team members at UT-S/PMH and OHSU will administer 2-3 surveys to family member study partners (number dependent upon whether the patient is alive at 30 days). If the patient has DMC at 30 days, they will be contacted for a single survey.



Data Collection Administration

Focus groups:

A skilled focus group facilitator familiar with technical constructs relating to the topic area will lead the focus group discussions. Focus group discussions will last approximately 90 minutes and will include questions on the challenges providers face when talking with family members of older patients with serious traumatic injury about treatment and prognosis. The focus group moderator will also describe a hypothetical patient and ask focus group participants how they might discuss prognosis and treatment options with the patient's family. Participants will then watch a brief video depicting a surgeon describing treatment options to a patient using the best case/worst case communication technique. After viewing the video, the focus group moderator will ask attendees how best case/worst case could be used in their practice. Focus group guide questions are sample questions and in some cases the facilitator may ask follow up questions not included on the guide.

We will give focus group participants a brief exit survey to complete at the conclusion of the focus group. The exit survey will includes demographic questions, as well as questions about the participant's professional role and training. The exit survey will not include collection of any identifiers.

Digital audiotapes of the focus groups will be transferred from UTS/PMH and OHSU to UW for transcription. The files will be sent via a secure, password protected UW server file-transfer service. Once the audio files are securely transferred to UW, the audiotapes at the collection site will be destroyed so that only one digital audiotape recording will exist. Along with all other computer files associated with this project, these audio files will be stored on a secure UW server which is backed up regularly.

Trauma provider interviews following best case/worst case tool training: A skilled interviewer familiar with technical constructs relating to the topic area and what was covered during best case/worst case training will conduct the interviews at both sites. Interviews will last 20-30 minutes and will be conducted either in-person or by phone. The same procedure will be followed for transfer of digital recordings as was used for focus group recordings.

F1: Family Survey 1 (for study partners)

Research team members at UT-S/PMH and OHSU will aim to collect the F1 survey as close as possible to 72 hours after the patient's admission. This survey consists of the family Quality of Communication[40] (QOC) survey and will be administered in person or by phone. This 19-item survey includes questions on how well their family member or friend's doctor talked with them about their care. We will also measure the health literacy of enrolled family members using the Single Item Literacy Screener ("How often do you need to have someone help you when you read instructions, pamphlets or other written material from your doctor or pharmacy?")[50] and will collect basic demographic information. Participants will be reminded at the start of the survey that they do not need to answer any questions that may make them feel uncomfortable. Research team members will make multiple attempts to collect this data in person, when the family member is available at the patient's bedside. If the family member cannot be reached in person,

research team members will reach out to them by phone and may administer the survey over the phone.

F2: Family Survey 2 (for study partners)
Research team members at UT-S/PMH and OHSU will aim to collect the F2 survey 10 days after the patient's admission. The Family Inpatient Communication Survey (FICS)[41] will be administered as part of this survey. This instrument is designed for family members of patients to measure communication and care coordination. FICS includes 30 questions, 18 of which assess information and 12 of which assess emotional support. Two additional survey questions taken from the SUPPORT study[42] will also be asked, to assess goal concordant care. The family member surveys are independent; unless a family member withdraws their participation from the study, we will contact them to complete all surveys, regardless of whether they have completed prior ones.

Research team members will make multiple attempts to collect this data in person at 10 days after admission if the patient is still receiving care in the trauma unit and if the family member is available at the patient's bedside. If the family member cannot be reached in person or the patient is no longer receiving care in the hospital, research team members will reach out to them by phone and may complete the survey by phone.

F3: Family Survey 3 (for study partners)
Chart review conducted by research team members at UT-S/PMH and OHSU will be used to assess whether patients are alive and, if so, have DMC at 30 days.

If the patient is alive, a member of the research team will contact the enrolled family member to schedule a good time to conduct this survey over the phone or in person in the hospital setting, if the patient is still receiving care there. This F3 survey consists of The Trauma Quality of Life (T-QoL)[43] survey, adapted for reporting by family members. This 43-item survey is designed assess posttraumatic quality of life.

If the patient has died in between admission and 30 days post-admission, there is no third family survey.

P1: Patient Survey

A member of the research team will check the patient's chart and, if needed, check with the care team to determine whether the patient is alive at 30 days and, if so, if they have DMC at that time. If patients are alive at 30 days and have DMC, they will be contacted by UT-S/PMH or OHSU research team members either in-person (if still receiving care in the hospital) or by phone (if they have been discharged), to complete the P1 survey. (If patients did not have DMC at the time of their family member enrollment but have regained it, as noted in their medical chart, they will be mailed a copy of the consent form or be consented in person if they remain hospitalized so that they may participate in the P1 survey.) The P1 survey consists of The Trauma Quality of Life (T-QoL)[43] survey. This 43-item survey is designed assess posttraumatic quality of life.

N1: Nurse survey

Research team members at UT-S/PMH and OHSU will give the N1 survey to the patient's primary nurse as close as possible to 72 hours after admission. The nurse-specific Quality of Communication (QOC) survey[40] is comprised of 18 items asking how well a provider talks with his or her patients about their care. Research team members at UT-S/PMH and OHSU will make multiple attempts to collect this data in person, 72 hours after admission, if the nurse is still on shift and in the clinic. If the nurse cannot be reached in person, research team members will reach out to them by email to complete a web version of the QOC.

U1: Unit-wide moral distress survey (pre-intervention) and U2: Unit-wide moral distress survey (post-intervention)

All trauma unit nurses and physicians at UT-S/PMH and OHSU will be invited to participate in this anonymous paper survey at two time points: at the start of the study (prior to any patient enrollment) and the end (after all study patients are enrolled). Research staff will approach trauma unit clinicians in person to invite them to complete a paper copy of this survey. The survey consists of the Moral Distress Scale-Revised (MDS-R) [44], physician and nurse versions. The survey describes brief descriptions of 21 situations which may occur in clinical practice, asking the frequency and level of disturbance that each situation causes.

Chart review

Chart reviews will be conducted at 10 and 30 days after admission by research team members at UT-S/PMH and OHSU. Team members will use the Therapeutic Intervention Scoring System to guide chart data abstraction in order to measure treatment intensity for the first 10 days after injury.[51-55] We will record the number and duration of life supporting treatments received[56] within 30 days of admission using six well described data fields: intubation and mechanical ventilation, tracheostomy, feeding tube insertion, hemodialysis, enteral or parenteral nutrition, and cardiopulmonary resuscitation. We will also record measures of high quality palliative care including initiation and timing of palliative care consultation, documentation of care preferences within 48 hours of admission, timing of Do Not Resuscitate orders and discharge to Hospice.[57] We will collect the following patient-level covariates: Injury Severity Score, GTOS, TRISS for patients age 50-64, pre-existing comorbid illnesses, age, race and ethnicity, gender, insurance status, educational attainment.

Best case/worst case graphic aid retention

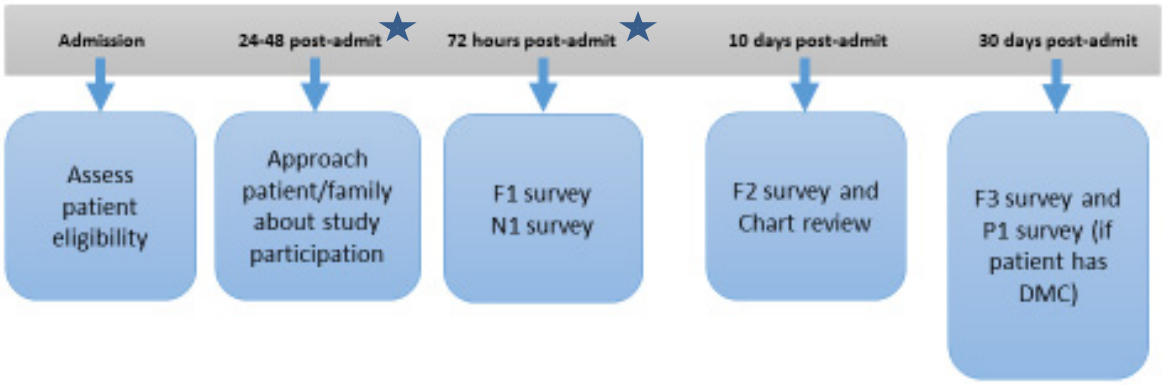
A coded digital image of the graphic aid that accompanies the communication intervention (labeled only with study ID number) will be archived by research team members at UT-S/PMH and OHSU. This graphic aid is created as part of the intervention and before it is given to the patient's family a member of the research or clinical teams will take a picture of it for archival.

Primary outcomes: **Primary outcome**: The QOC questionnaire[40] is a 19-item scale with two domains: general communication (8 items) and end-of-life communication (11 items). The instrument is available in patient-specific and family member-specific versions and has acceptable internal consistency and construct validity.

Data analysis plan: The intervention effect, QOC, will be tested in the framework of generalized linear mixed effects models[58,59] comparing the pre-intervention with post-intervention periods with a treatment dummy variable, surgeon random effect, and site dummy variables to control for site-specific effect. UW analysts will adjust for covariates to increase the

statistical precision of our treatment effect estimation. Our exploratory analyses will examine other patient endpoints such as intensity of treatment and palliative care received. We will use linear mixed effects models for continuous responses, logistic random effects models for binary responses and log-linear random effect models for count-dependent variables.

Schedule of Events



★ Patient/family will be approached as close as possible to 24-48 hours post-admit (up to 7 days post-injury) and F1/N1 surveys will be conducted as close as possible to 72 hours post-admit.

Incentives

Trauma providers

Focus groups: To compensate participants for their time during the focus groups, each participant will receive $200 at the completion of the focus group.

Best case/worst case tool training: To encourage surgeons to participate as research subjects in the "Best Case/Worst Case" training session, incentives will be required as the training will take 2 hours of their time. Using incentives with physicians as research subjects is well-documented in the survey-research literature. Participation is significantly more likely with increased remuneration.[60,61] Previously, about $250 per physician has proven a successful incentive for our research; this is the amount given to participants in our surgeon focus groups. We will be giving surgeons $245 for their time so we do not have to collect social security numbers from surgeon participants at OHSU ($250 is a common limit for collecting social security numbers from research participants). In addition, we will provide refreshments for surgeons who participate in the training sessions at UT-S/PMH and OHSU. Surgeons will receive incentives only for participating in the training as the intervention requires modest effort beyond the usual care surgeons provide to patients.

Trauma provider interviews following best case/worst case tool training: No incentive is provided for those participating in the interview. *Nurse survey*: UT-S/PMH and OHSU research team members will give $5 to nurses upon completion of each QOC survey.

Moral distress survey: No incentive is provided for those participating in the moral distress survey.

Family members and patients

Family Member Participant Incentives: OHSU research team members will give family member participants $15 for completing the first survey and $10 for the second survey. Family members who complete the third survey will receive an additional $10 for a maximum incentive of $35.

UT-S/PMH research team members will give family member participants $24 for completing the first survey. Incentives given to family members at UT-SW are lower than at OHSU because UT-SW requires researchers to collect social security numbers and use ClinCards for incentives of $25 or more. To avoid burdening family members by asking for social security numbers and by including the off-putting Clincard language in their consent form, we have reduced their total incentive.

At both sites, patients will not receive any compensation for participating in this study. If the family member providing surrogate consent for a patient who lacks DMC and the study partner are *not* the same person, only the study partner will receive incentives.

Statistical Considerations

Sample Size

UT-S/PMH and OHSU research team members will sequentially recruit 50 patients in the control and 50 patients in the intervention arms. Power calculation: Based on current available publications, the standard deviation for the QOC measurement is estimated to be around 3.5. Assuming the between doctor variance accounts for 10% of the total variance, we computed power of 84% to detect a medium-large effect of 2.00 points on the QOC scale, and 96% power to detect a large effect of 2.50 QOC points. If the between doctor variance accounts for 30% of the total variance, the power to detect these effects are 92% and 99% respectively.

Analysis

Analysts at UW will test the intervention effect, QOC, in the framework of generalized linear mixed effects models[58],[59] comparing the pre-intervention with post-intervention periods with a treatment dummy variable, surgeon random effect, and site dummy variables to control for site-specific effect. We will adjust for covariates to increase the statistical precision of our treatment effect estimation. Our exploratory analyses will examine other patient endpoints such as intensity of treatment and palliative care received. We will use linear mixed effects models for continuous responses, logistic random effects models for binary responses and log-linear random effect models for count-dependent variables.

We will audio record and transcribe each focus group and interview transcript. Using qualitative content analysis,[62] three coders with distinct clinical backgrounds will analyze each transcript independently and then convene to adjudicate each coded phrase or idea using the technique of constant comparison to develop a taxonomy of consensus codes. A group process of code

adjudication will initiate higher level analysis, identifying themes and trends in the data and consolidating feedback for tool adaptation. Using the technique of member checking, tool modifications will be presented to trauma team leaders for additional comments and refinement. NVivo software, QSR International-Melbourne, will be used to catalogue the data. De-identified data from the focus groups may be shared with the Qualitative Research Group (QRG) at UW. QRG is an ICTR resource and a UW-Madison initiative. All QRG members are UW-Madison faculty or staff and only de-identified data may be shared.

Risks and Discomforts to Research Subjects

All activities of the study meet the Office of Human Research Protections (OHRP) definition of a minimal risk study. There are known potential risks for participants but the likelihood and seriousness of these risks is considered to be low and ample protections are in place to minimize the likelihood of their occurrence.

Trauma providers:

The main risk for trauma providers who participate in the training is loss of time. Providers who participate in "best case/worst case" communication tool training may find that use of the tool results in their consultations with patients and family members taking more time than their usual care practice did. There is a risk that providers may be stressed by participating in a training program and learning to use the communication tool. Providers might be stressed by knowing that family members and nurses will be completing surveys regarding the providers quality of communication. There is also a potential for psychological stress from the presence of an audio recorder during the standardized patient practices.

For focus group and post-training interview participants, there is the possibility that participants may feel anxious knowing that the discussion/interview is being audio-recorded. To address this, the information sheet will include clear instruction that participants do not have to answer any questions they do not wish to. The focus group moderator/interviewer will remind participants of this at the start of the session.

For nurses who complete the QOC survey, there is a risk that reporting on the quality of care communication provided by a trauma provider in their unit may prove stressful.

For those who complete a moral distress survey, there is a risk that these providers may find some of the questions distressing or be reluctant to answer.

Patients and Family members:

There is a risk of loss of privacy for patients whose chart is reviewed while in the study. There is a risk of family members developing confusion or anxiety about questions related to the patient's care while completing follow up surveys with study staff. There is also a risk of patients or family members developing confusion or anxiety during the discussion about treatment decisions for both groups, due to the way the surgeon may describe treatment options. There is a risk of confusion about options for both the control and intervention groups as we do not know if one approach to talking to patients may cause more confusion than the other. However, our previous

studies show that patients and families have been remarkably supportive of the communication intervention, noting that it improved clarity about options and decision making, promoted better understanding of expectations, and helped them prepare for adverse events.[63] Answering questions about the physician's communication skills may make family members feel uncomfortable.

Protections against all of the above risks are described below.

Adequacy of Protection against Risks

Overall Protection Against Risks

All investigators, researchers, statisticians and collaborators with access to identifiable study data will have completed human subjects training prior to the start of the study. Dr. Schwarze will be alert for any potential harm to subjects, including breaches of confidentiality. Research coordinators at each site will report any breach of confidentiality to the site IRB and UW lead site upon its discovery. The risk of breach of confidentiality is low because only information related to the research questions will be collected. However, adequate provisions are in place to ensure that breach of confidentiality will not occur including: all hardcopy research files (including consent forms, surveys, audiotape transcripts) will be kept in a secure, locked office, all computer files will be kept on a secure, password protected computer, only the minimum amount of information that is necessary to achieve the aims of the research will be collected, excess copies of paper documents will be promptly shredded, and health information collected will not be associated with any identifying information. Only a unique participant study number will be associated with the data.

Data will be managed and protected rigorously at each study site. All hardcopy research files (including consents and surveys) will be kept in secure, locked offices and all computer research files will be kept on secure, password protected computers. Excess copies of paper documents will be shredded. Only indirectly identifiable information will be collected on study surveys and chart abstraction data collection forms. To protect participant data, electronic study data will be kept in two separate databases at each site. One spreadsheet will have a master code that includes the subject's name and an associated number which will serve as the participant identifier (ID) for study purposes. This participant ID will be kept on a password protected computer on a secure server at each institution (in a place separate from the data collection database). Only approved study personnel will have access to the identifiers. The data collection database (UW REDCap server) will have the subject's ID number only, without any identifying information. After data analysis is complete the master list that links the subject's name and study ID number will be destroyed and the data will then be stored in a de-identified state on a secure server for a minimum of 7 years post publication. 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.

Site investigators will be alert for any potential harm to subjects, including breaches of confidentiality. Any breach of confidentiality will be reported to the site IRB and UW lead site upon its discovery. The risk of breach of confidentiality is low because only information related

to the research question will be collected and adequate provisions are in place to ensure that breach of confidentiality will not occur.

For the recorded training session with standardized patients and focus groups, study staff members or outside contractors with a business associate agreement who have been approved by UW Legal Services/Privacy Officer for HIPPA compliance will perform complete transcription of the audio tape recordings from all sites. Sites will send audio recordings (from the focus groups and post-training interviews) to UW for central transcription. The audio recordings and transcripts will be shared through a secure server that only contractors and study team members have access to. Though it is unlikely any identifying information would exist on audio files of the standardized patient sessions, transcriptionists will remove any identifiers.

Plans for addressing specific risks to subject groups are noted below:

Trauma providers

Best case/worst case tool training: Trauma providers participating in training and intervention activities at UT-S/PMH and OHSU will be given the opportunity to stop study participation at any time, during both the usual care and intervention arms. This will be noted on the consent form for this research activity. They may also choose to exclude specific patients to approach for study participation. In addition, the training session will include skills that address length of time required to use the tool with patients. Trainers are available for optional, informal feedback sessions following the training, should an enrolled surgeon wish to check in regarding use of the tool.

Focus groups and post-training interviews: To address any anxiety felt by being recorded, the focus group and interview consent forms will include clear instruction that participants do not have to answer any questions they do not wish to. Participants will be reminded of this by the focus group moderator/interviewer at the start of the session. To address concerns about confidentiality, all participants will be informed that adequate provisions are in place to ensure that breach of confidentiality will not occur. We do not believe the study will place participants at risk of damage to their reputation or employment status. The purpose of the focus groups is to discuss with members of the trauma unit how they currently discuss treatment options and prognosis and how they might use the best case/worst case tool to accomplish this.

Nurse survey: Nurses who participate in QOC surveys will be reminded that they do not have to answer survey questions they prefer not to and this will be noted on their consent form as well.

Moral distress survey: Survey instructions will remind participants that they may skip any questions they do not wish to answer and that the survey is anonymous.

Patients and family members

UT-S/PMH and OHSU Research Coordinators will instruct trauma providers to check in with patients and family members from both the control and intervention groups after their treatment discussion to ensure that they are not confused about treatment options. During follow up surveys family members will be instructed that they do not need to answer any questions that

make them feel uncomfortable. Research staff will also remind family member participants that their participation is voluntary and they may drop from the study at any time. In cases where patients have DMC and have consented to participate in the study, they will be reminded that they may withdraw from the study at any time. Research staff at UT-S/PMH and OHSU will be trained on adverse event reporting and will encourage patient and family member participants to contact the trauma care team if they have any medical questions.

Potential Benefits to Human Subjects and Others

Trauma providers: It is possible that trauma providers who participate in the communication tool training will learn new communication skills which may subsequently improve provider satisfaction and communication with patients. Surgeons will also have an opportunity to discuss the challenges of helping patients make these difficult decisions with their colleagues and study staff during the surgeon training which may make them feel supported psychologically and professionally.

Patients and family members: Patients and family members in the control arm are not expected 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 care that better aligns with their values, benefiting their treatment experience.

Importance of the Knowledge to be Gained

Use of the "best case/worst case" communication tool could result in improved communication in the context of trauma care delivery, potentially leading to care that is better aligned with the values and goals of patients. This patient-centered approach may improve trauma care decision making and quality of life for the nearly 500,000 geriatric patients who are admitted to the hospital with a traumatic injury annually. 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.

Records to be Kept

To better protect patient information, electronic study data will be kept in two separate databases. One spreadsheet will have a master code that includes the subject's name and medical record number and an associated random number which will serve as the participant ID number. This participant ID master list will be kept on a secure departmental server at UT-S/PMH and OHSU and will never be transferred to UW. Only approved study personnel will have access to this document and investigators who will not be interacting with study participants and/or are only involved with analysis will only have access to the coded and eventually de-identified study data. Coded study survey and chart review data will be stored in a database on the UW ICTR REDCap server. The data collection database (UW ICTR REDCap) will bear the subject's ID number only, without the subjects' (patient, family member, provider) identifying information. No

identifiers will be entered into the REDCap database and only the unique participant study number will be associated with the data.

No tissue or other physical specimens will be collected for this study. The following data security measures will be taken: all research files (including consents, surveys and transcripts) 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.

Only approved study personnel at UT-S/PMH and OHSU will have access to the identifiers (personnel approved for identification and recruitment and interaction with subjects will need access to update the master code/spreadsheet). Investigators who will not be interacting with study subjects and/or who are only helping with analysis will only have access to the coded study data.

After data analysis of the questionnaires is complete and manuscripts have been accepted for publication all hard copies of research files (including the audiotapes) will be destroyed. Other research materials and data are maintained in on the secure Department of Surgery server for a minimum of 7 years post publication.

Data and Safety Monitoring Plan

This is a minimal risk study. The lead PI (Dr. Schwarze) will be alert for any potential harm to subjects, including breaches of confidentiality. All research team members will be involved in safety monitoring. Although not expected, research staff will be prepared to address any negative reactions to the conversation with the surgeon or to survey questions. All negative reactions will be reviewed to determine whether a change in protocol is necessary.

We will follow an internal Data and Safety Monitoring Plan (DSMP) for this minimal risk study. A Data Safety Monitoring Committee (DSMC) will be established with membership made up of our study staff. All research team members will be involved in safety monitoring. Although not expected, research staff will be prepared to address any negative reactions to the conversation with the surgeon or to interview and survey questions. All negative reactions will be reviewed to determine whether a change in protocol is necessary.

Prior to enrollment of the first subject, the DSMC will meet to finalize DSMP. We anticipate DSMC meetings four times; at enrollment, 3 months, 6 months, 12 months, and 18 months. Reports to the DSMC will include data quality, timeliness and participant recruitment, accrual, retention, and confidentiality of the research subjects. Notes will be taken to document the meetings. These summaries will be available for inspection when requested by any of the regulatory bodies charged with the safety of human subjects and the integrity of data including, but not limited to, the UW-Madison Health Sciences IRB. The PI will report any policy violations to the IRB immediately. The PI will also report any adverse events in compliance with the IRB policy for reporting. In addition to the DSMP, the PI will review the research study and the accrued data on a monthly basis in project meetings so as 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.

Research team members will also be involved in safety monitoring throughout the study. Although not expected, research staff will be prepared to address any negative reactions to study procedures such as survey questions. All negative reactions will be reviewed to determine whether a change in protocol is necessary. Site investigators will report any policy violations to their respective IRB immediately. Site investigators will also report any adverse events in compliance with the IRB policy for reporting. In addition to DMC review, the lead site PI will review the research study and the accrued data on a monthly basis in project meetings so as 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.

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