Detailed Protocol

Title: A pilot study to test the acceptability and feasibility of brief motivational interview intervention to help patients formulate their goals for medical care in the emergency department

Principal Investigator: Kei Ouchi, MD, MPH

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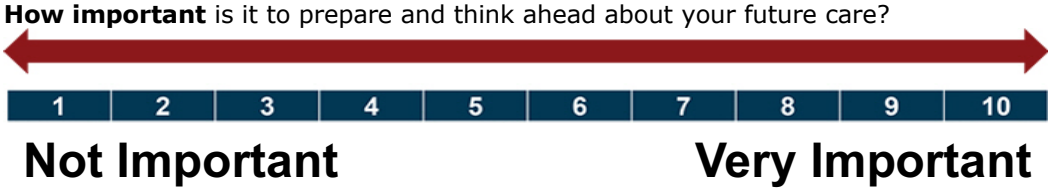
I. BACKGROUND AND SIGNIFICANCE

The majority (75%) of older adults with serious illnesses visit the ED during the last six months of life. [1] ED visits often mark an inflection point in these patients' illness trajectories, signaling a more rapid rate of decline. [2,3] Many of these patients have not formulated and communicated their goals for end-of-life care, [4] and the majority (56 to 99%) of older patients do not have advance directives available at the time of ED presentation. [5] Most of these patients have priorities other than simply to live as long as possible, [6] yet without alternative plans in place, they may receive aggressive care that does not align with their goals. [7] Therefore, the ED provides a point in time and a location to identify and empower patients who would benefit from formulating and communicating their goals for future medical care.

Emergency medicine (EM) physicians recognize this opportunity and have expressed interest in engaging older adults with serious illnesses in a discussion of their end-of-life care; [8] however, the time-pressured ED environment discourages physicians from conducting in-depth conversations with these patients. [4] There is not yet a suitable brief intervention that is acceptable in the ED environment for physicians without extensive training in serious illness communication. Lack of a feasible method to intervene in the ED constrains our current clinical practice.

We propose to close this gap with a practical method to empower them to formulate their goals for end-of-life medical care. We are currently developing and refining the BMI intervention for serious illness communication (**Table1**). The BMI method allows physicians to engage patients in thinking about the importance of addressing a chronic care issue without conducting a time-consuming, sensitive conversation in the time-pressured ED environment. The BMI methods have been demonstrated robustly to improve outcomes for ED patients with alcohol and opioid abuse by helping patients understand the obstacles to and reasons for their medical care. [9-12] We are developing a BMI intervention to engage older adults in thinking about the importance of establishing care goals.

In this protocol, we will pilot test (Part I) the intervention to demonstrate its acceptability and feasibility in the ED, then collect patient-centered outcomes (Part II) on older adults with serious illness being discharged from the ED. This study will inform the study design of a future randomized clinical trial using this intervention.

Table 1 Brief Motivational Interview ED Intervention to Facilitate Serious Illness Communication	
1) Open	I'd like to talk about what is ahead with your illness after leaving the ED. **Is that ok?**
2) Prognostic Awareness	What is your **understanding of your _____ (serious illness)?**
3) Information & Feedback Elicit (Ask) Provide (Tell) Elicit (Ask)	**Have you thought** about preparing for your care in the future? In the ED, we care for patients in the moment and **also help them prepare** for what's ahead after leaving the ED. **Preparation helps patients** and their caregivers adapt to an uncertain situation and relieve difficult decision making for caregivers. **How you think about these ideas of preparing** about the future?
4) Assess Importance Reinforce positives Ask about lower #	**How important** is it to prepare and think ahead about your future care?  You think it is __ (very / not very) important to think about this. That's great! Why did you choose that number and **not a lower one** like a 1 or a 2?
5) Worries &Strength Reflect & Summarize	What are your **worries** about planning for your future medical care? What **strengths** in your life can you turn to for support in working through these questions about the future? You are **worried** about ___, AND ___ gives you **strength** to plan for your future medical care.
6) Action Plan Make a recommendation Thank patient	Based on what you said, **a. NOT ready (1-2)** "This isn't the right time for you to think about your future care. I will recommend that your doctor asks you about this topic again at your next visit. Here is an information sheet that you may find helpful to read at home before your next visit with your doctor." **b. Somewhat ready (3-9)** "I recommend that you explore what is important to you using Prepareforyourcare.org before your next visit with your doctor." **c. Completely ready (10)** "I will work with your doctor about documenting your goals and preferences with your doctor on a medical record." Let me **write down steps** that I would recommend for you and **notify your doctor** to let him/her know about your visit to the ED and our conversation today, to help him/her know where you are in your planning process. Is that okay? Thank you for talking with me today.

II. SPECIFIC AIM

Test the acceptability and feasibility of our brief motivational interview intervention to facilitate advance care planning (ACP) conversation on older adults with serious co-morbid illness being discharged from the emergency department (ED) and interview the participants to understand their perception and collect patient-reported outcomes data after leaving the ED.

Hypotheses

a) ≥80% of clinicians will find it acceptable to conduct this interview in the ED for appropriate patients;

b) ≥80% of patients will find the interview respectful to patient-oriented needs;

c) ≥25% of participants will have reported completing ACP conversation with their primary outpatient clinician at one month (28 days) after leaving the ED.

Methodology

We will pilot test (Part I) the intervention to ED patients and interview 15 to 25 participants (depending on theme saturation) immediately following the intervention to explore how they perceived the intervention. After the intervention is administered, they will be asked to complete a Likert scale survey about acceptability. Additionally, we will collect pre-/post-intervention patient-centered outcome data (Part II) using a set of surveys in-person before the intervention and via phone/mail at 7±3 days, and one month (28±7 days) after the ED visit for 100 patients.

III. SUBJECT SELECTION

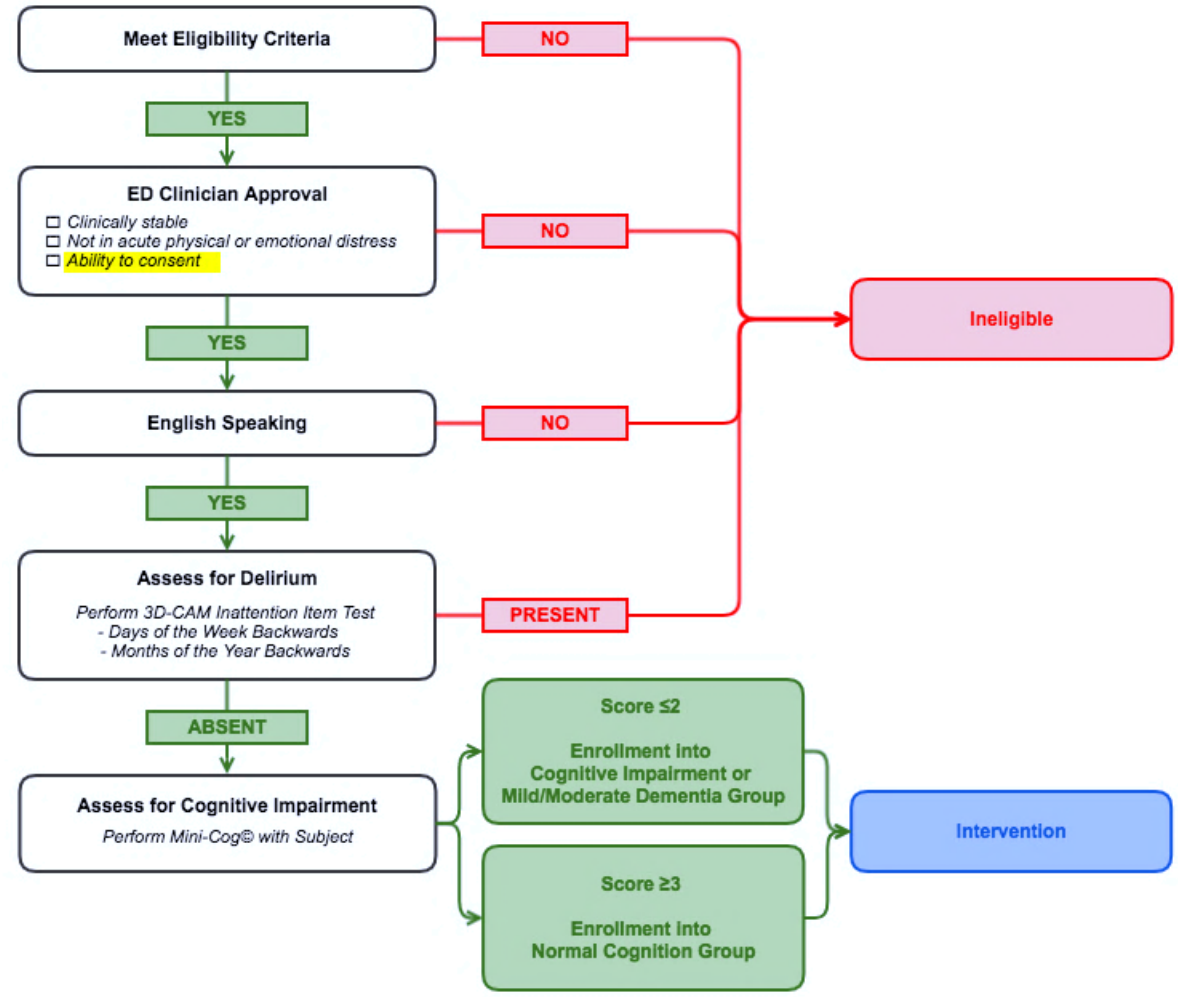
Trained RAs will recruit the subjects using the inclusion and exclusion criteria (**Table 2**). We will use convenience sampling for this study. Each morning when a trained EM physician evaluates patients in the ED or ED observation unit, the trained RAs will ask the physician to identify potential subjects based on inclusion and exclusion criteria.

Table 2 Subject Criteria

Inclusion	Exclusion
1. ≥65 years of age **AND** ≥1 Serious illness* ***OR*** ED clinician would not be surprised if patient died in the next 12 months 2. English-speaking 3. Capacity to consent	1. Acute physical or emotional distress 2. Determined by EM physician not to be appropriate 3. Clearly documented goals for medical care** *(Unless the treating clinician recommends that the patient needs the intervention)* 4. Delirium (assessed using 3D-CAM Inattention Item) 5. Already enrolled in this study 6. Unable/unwilling to schedule follow-up outcome assessment survey
*New York Heart Association stage 3 or 4 heart failure, oxygen-dependent chronic obstructive lung disease, chronic kidney disease on dialysis, or metastatic cancer	**MOLST, medical order for life sustaining treatment.

IV. SUBJECT ENROLLMENT

Picture 1. Study Flowchart



There are two subject types in this study – ED clinicians and ED patients. ED clinicians (attending physicians and physician assistants) will be recruited to train in and administer the proposed intervention on ED patients. After the intervention is administered, they will be asked to complete a Likert scale survey about acceptability. Clinicians will be asked to participate voluntarily. The PI will make an announcement at the faculty / physician assistant meetings and hand out the study information sheet. ED patients will be recruited to be interviewed after the intervention to learn their perception of the intervention. Upon identification of the potential subject, the trained RAs will approach the potential subject to explain the study and ask about their willingness to participate. Once the eligible subject agrees to participate, the PI or co-investigator (licensed physician assistants or physicians) will consent the patient to enroll. After the trained RAs explain the study, the subjects will have time to think about the enrollment until the PI or co-investigator

(licensed physician assistants or physicians) physically arrives in the ED. The PI or co-investigator (licensed physician assistants or physicians) will review all study elements again with the subjects to ensure understanding of the study. After obtaining verbal consent and providing the study fact sheet to the subject, the trained RAs will use validated tools to assess delirium (3D-CAM Inattention Item) and cognitive impairment (MiniCog™) to further determine subject's eligibility for enrollment. Assessments will be administered with the subject. Based on the results of these assessments, the patient may be deemed ineligible (if delirium is present) or enrolled into either the Normal Cognition Group OR Cognitive Impairment or Mild/Moderate Dementia Group (see Picture 1). Screening subjects for cognitive impairment is deemed necessary to provide deeper understanding into whether subjects will such condition would require more assistance in engaging in conversation about the importance of establishing goals of care. Patient with severe dementia will be excluded because they lack the capacity to consent ealier on this enrollment algorithm. Upon enrollment, the trained physician responsible for the care of the patient will administer the intervention. When a trained physician is not on duty in the ED or ED observation unit, the PI or trained clinician will administer the intervention.

There will be no other methods of recruiting for this study. Subjects assigned to any group will receive the same intervention and follow-up procedures.

V. STUDY PROCEDURES

There will be two distict parts of the study: acceptability study (Part I) using qualitative interviews to explore the patient's perception of the intervention and quantitative assessment of clinician's acceptability rating, and feasibiltiy study to measure patient-reported outcomes (Part II) after leaving the ED for future randomized clinical trial. The timing of proposed data collection is shown on Table 3.

Table 3. Timing of Proposed Data Collection and Instruments

Study Part	Subjects	Screening Assessments/ Group Assignment	Pre-Intervention	Post-Intervention	7-Day Follow-Up (7 ± 3 Days)	One-Month Follow-Up (28 ± 7 Days)
Part 1	Clinicians			Acceptability Survey		
	Patients			Qualitative Interview		
Part 2	Patients	- 3D-CAM[a] - MiniCog™[b]	- ACP-E[c] - QUAL-E[d]		- 4 Questions[e] - IES-R[f]	- 4 Questions - ACP-E - QUAL-E

a. 3D-CAM : 3-minute diagnostic assessment for Confusion Assessment Method (CAM)-defined delirium
b. MiniCog™ : 3-minute instrument for the detection of cognitive impairment in older adults
c. ACP-E : The Advance Care Planning (ACP) Engagement survey
d. QUAL-E : The Quality of Live at the End of Life (QUAL-E) scale
e. 4 Questions : Four open-ended questions to assess subjects' decision to speak with their doctors and family members
f. IES-R : The Impact of Event Scale – Revised

Part I: Acceptability Study

We will conduct in-depth, semi-structured interviews to understand patient's perception of the intervention after its administration by a trained ED clinician. We anticipate to interview 15 to 25 patients, until thematic saturation of their perception is reached. Further, we will assess clinician acceptability by administering a Likert scale survey.

Measurements

Patient Perception Assessment: The PI and the trained RA will conduct the semi-structured interviews. The following domains will be explored: beliefs about formulating and communicating goals of care, experience of the ED intervention, and attitude towards further patient education about how to formulate goals of care. Both the administration of BMI intervention by a clinician and subsequent qualitative interview of the participants will be video-recorded to ensure fidelity of the intervention administration and accurate capturing of their inputs.

Clinician Acceptability Assessment: Immediately after the clinician completes the encounter, we will ask to fill out an in-person survey to rate acceptability (Likert scale, 1 – not acceptable, 2 – somewhat unacceptable, 3 – neutral, 4 – somewhat acceptable, and 5 – acceptable).

Outcome Our primary outcome for the patient perception assessment of the study is to identify a recurring theme that illustrates the patient perception of the intervention. Our primary outcome for the physician assessment of the study is the proportion of administering clinicians who found the rating to be somewhat acceptable (4) or acceptable (5). Secondary outcomes are the time to administer the intervention and how often the 4 intervention components are appropriately completed.

Part II: Feasibility Study

We will collect pre-/post-intervention data to demonstrate the intervention's feasibility to improve patient-reported outcomes using a set of surveys. We will measure patient-reported outcomes before the intervention (in-person), as well as 7 (±3) days, and one month (28±7 days) after leaving the ED. After the collection of 10 IES-R surveys (as part of the 7-Day Follow-Up), the investigator will analyze the impact of the intervention. If the IES-R is proven insignificant ($p > 0.05$), collection of this assessment and all 7 (±3) day follow-up procedures will be discontinued. At this point, the one month (28±7 days) follow-up procedures will instead be completed after 3 weeks of the intervention (21±7 days).

Participants will be provided with a certificate of completion (see attached) and a compensation of $5 at the time of enrollment.

Post-Intervention Outcome Surveys:

Participants will have three ways to complete the outcome survey: i. over the phone; ii. by mailed survey with a return postage; or iii. in-person by a research assistant at the next doctor's appointment on campus at BWH/BWFH (we will ask permission to look through their medical records for future scheduled hospital visits). At the time of enrollment, we will ask the participants which option is most feasible for them.

We will exclude the subjects if they are unable/unwilling to schedule follow-up outcome assessments in the reasonable time.

In addition, we will send a "Thank You" postcard (see attached) and a total of $10 to all participants at the time of outcome survey (a total compensation of the entire study is $15). For patients who choose to complete the follow-up survey over the phone with a research assistant, verbal consent will be obtained to audio-record the conversation prior to administration of the questionnaires. If the patient elects to complete the surveys by mail, we will place a reminder call/voicemail at the 7-day and 1-month follow-up timepoints. In addition, we will obtain verbal consent to send email and text message reminders to subjects to complete the assessments. We will assess the proportion of participating older adults who self-reported having spoken to their primary outpatient physician and/or caregivers about their goals for end-of-life medical care following the intervention. We will use validated instruments to measure quality of life (QUAL-E), [13] ACP engagement behavior (ACP Engagement Survey), [14] and potential subjective distress caused by the intervention (a potentially traumatic event). [15]

Measurements

After obtaining verbal consent, but prior to enrolling the subject, several validated instruments will be used to assess delirium and cognitive impairment. Before all enrollment procedures, a trained RA will administer the 3D-CAM Inattention Item to assess delirium. In the absence of delirium, the trained RA will administer the MiniCog™ to the subject. Based on the results of these assessments, the patient may be deemed ineligible (if delirium is present) or enrolled into either the Normal Cognition Group OR Cognitive Impairment or Mild/Moderate Dementia Group (see Picture 1). We will train the research assistants to administer these tools by 30-minute didactic on the concepts of delirium, cognitive impairment, and dementia, as well as bedside practice administration with the PI until competency is demonstrated (PI will self-record the responses next to the research assistant administering the instrument and compare the results. We will repeat this process with new patient volunteers until there is no discrepancy). In case of equivocal findings on these assessments administered by research assistants, physician backup will be available.

Prior to the screening assessments, study staff will offer a personal sound amplifier as a hearing-assistive device to subjects who, in the opinion of the study staff, will benefit from its use, e.g., subjects with hearing impairment issue. From our experience, given that the setting is in the busy and noisy ED, the subjects sometimes have difficulties following our instructions or answering our questions. Therefore, we believe that the hearing aids will help them respond to our prompts/instructions more appropriately.

We will measure the proportion of patients who self-report having had the conversation with their outpatient physician. We will also use QUAL-E, a validated instrument to measure quality of life of patients with a range of diseases (cancer, congestive heart failure, chronic obstructive pulmonary disease, and end-stage renal disease). [13] This instrument is particularly suited to measuring the quality of life of patients who may or may not have acknowledged the terminal nature of their disease, but who, nevertheless, are dealing with end-of-life issues. In addition, we will use the ACP Engagement Survey, a validated instrument developed based on Social and Behavior Change Theory, and it measures the full range of self-reported

processes involved in ACP (e.g. changes in knowledge, contemplation, self-efficacy and readiness) as well as actions associated with ACP behavior. [14] To evaluate whether the ED intervention itself increases patient stress, we will also measure posttraumatic stress disorder symptoms using the Impact of Event Scale – Revised (IES-R). [15] IES-R is a validated scale to assess subjective distress caused by traumatic events. The trained RAs will administer these instruments (see *Appendix*) immediately before the intervention, and again by phone one month (28±7 days) after leaving the ED. IES-R will only be used for the 7-day (7±3 days) follow-up phone call. After the collection of 10 IES-R surveys, the investigator will analyze the impact of the intervention. If the IES-R is proven insignificant ($p > 0.05$), collection of this assessment and all 7 (±3) day follow-up procedures will be discontinued. At this point, the one month (28±7 days) follow-up procedures will instead be completed after 3 weeks of the intervention (21±7 days). During each follow-up, we will ask participants open-ended questions about their decisions to speak with their primary care physicians and family members (please refer to the 7-day and 1-month questionnaires). The subject can opt to complete the post-intervention surveys by mail. Return postage will be provided.

Outcomes

The primary outcome is the proportion of patients self-reporting having spoken to their primary outpatient physician regarding their preferences for end-of-life medical care one month after leaving the ED. The secondary outcomes are quality of life, ACP behavior change, posttraumatic stress disorder symptoms, proportion of subjects with documented ACP conversation on medical records one month after leaving the ED. We will also track the rate of patients being lost-to-follow-up to aid in appropriate design of a future randomized clinical trial.

VI. BIOSTATISTICAL ANALYSIS

Variables to be collected

We will collect demographic information of our subjects from the electronic health records, including age, gender, prior ACP documentation, co-morbid medical conditions, and ED diagnosis. Both the administration of BMI intervention by a clinician and subsequent qualitative interview of the participants will be video-recorded to ensure fidelity of the intervention administration and accurate capturing of their inputs. We will also administer the validated survey instruments (ACP Engagement Survey, QUAL-E, IES-R) and self-reported completion of ACP conversation one month after leaving the ED.

Study Endpoint

Part I – Acceptability Study

The study will conclude when 15 to 25 participants are enrolled and thematic saturation of the qualitative analysis is reached.

Part II – Feasibility Study

The study will conclude when 100 participants are enrolled and one month post intervention data is collected over the phone.

Statistical Methods

Part I Analysis

We will employ a modified phenomenological approach to code for themes that illustrate patient's perception of the intervention. We selected phenomenology as our qualitative research strategy since it is particularly suited to explore how individuals experienced our intervention. The PI and the trained RA will immerse themselves in the text by reading and re-reading for content, quality, and patterns. During this time, the audit trail of notes will be kept by individual coders to be reviewed in a subsequent discussion group. After independent coding of 5 initial transcripts, the PI and the trained RA will determine the standard labeling for common patient perception themes; and these will be organized into a code book. We will iteratively re-organize the code book until the consensus is reached among the coders. If there are disagreements between the coders on a particular theme, we will employ a third coder to aid in judgment of the codes. The coders are purposefully not blinded to the study questions because they need to decide what is pertinent to answer the study question at hand. The coders will use the code book to independently code the remaining transcripts. We will use Nvivo software to organize and manage our data. The study will conclude when new themes no longer emerge (thematic saturation is reached), based on agreement between the coders. If not, we will continue to recruit more subjects until thematic saturation is reached. The themes will be categorized and coders will decide with group consensus which quotes will be included as the representative quotes in the final manuscript. If there are disagreements, an additional researcher from the ED will be asked to review the quotes and themes.

Part II Analysis

We will calculate descriptive statistics of the patient-reported outcomes before and after the intervention. We will use one sample binomial exact test of proportions for categorical outcomes (e.g. proportion of patients reporting ACP conversations with their physicians), and Wilcoxon signed ranks test for ordinal outcomes (e.g. QUAL-E) at baseline and one month. We will use a p-value of 0.05 as the significance threshold.

Sample Size

Part I:

We propose to enroll 10 to 25 subjects in Part I. In prior qualitative studies, this is the general number that a study like this takes to reach thematic saturation. We may enroll more than 25 subjects if we find that thematic saturation has not reached. We will submit an amendment to change the enrollment number should that occur.

Part II:

We propose to enroll 100 subjects in Part II. A recent meta-analysis of advance directive documentation studies demonstrated improvement in ACP completion rate ranging from 2 to 44% with an intervention. [16] We assume that the baseline rate of ACP completion rate is <10% to be conservative. Based on prior similar studies, we assume our intervention will result in 25% increase in the rate of conversation above 10%. A sample of 100 subjects will afford us 97% power (two-tailed alpha of 0.05) to detect a difference of the conversation completion rates of 10% before the intervention versus 30% after the intervention. Power is also expected to be strong

for the ACP behavioral change scale outcomes (our secondary outcome, similar preliminary data demonstrated a pre-to-post improvement of 0.5 SD). [17] With a conservative assumption, we will have 85–98% power with our sample size.

VII. RISKS AND DISCOMFORTS

There is no risks and discomforts associated with procedures, drugs, devices, or radiation in this study.

Psychosocial Risks (Uncommon)

The participants will be introduced or re-initiated on the topic of ACP. Some patients with serious illness do not wish to discuss ACP because they feel uncomfortable with the topic. This potential discomfort, however, is a part of the routine practice of EM. Many ED clinicians discuss ACP with patients routinely, and the study does not add additional discomfort that is different from the routine clinical practice. Further, PI is trained in serious illness communication and will be available to manage patients' anxiety and other emotions as needed.

VIII. POTENTIAL BENEFITS

Potential Benefits to Participating Individuals

It is our hope that the proposed intervention will empower patients to engage in ACP discussions with their primary outpatient clinician ≥25% of the time one month after the ED visit. Further, this intervention may also improve other patient-reported outcomes without causing significant harm.

Potential Benefits to Society

We hope that our intervention will allow EM clinicians to reach many older adults with serious illness presenting to the ED and guide them to formulate their goals for medical care. Such intervention will allow clinicians to align the future medical care towards end of life to match patients' values and preferences.

IX. MONITORING AND QUALITY ASSURANCE

The PI will be solely responsible for monitoring of safety, adverse events, protocol deviations, and outcomes. The data safety will be monitored by the PI on weekly basis, who is solely responsible for determining whether the research should be altered or stopped. The PI will be aware of every patient who is recruited and enrolled in the study. All data obtained in this study (video-recorded interviews of the participants and responses to the surveys by both clinicians and participants) will be stored in a secure Partners shared drive of the PI. As soon as the opportunity is available, the obtained data will be anonymized and removed of personal health information. All participants and clinicians will be de-identified and assigned research subject IDs (e.g. clinician 1). Only the study staff will have access to information that can link the subject IDs with the personal health information, which will be saved in the secure shared drive.

The PI will be aware of every subject enrolled in this study. Therefore, he is able to monitor for adverse events, such as unexpected emotional distress, and address them clinically using his clinical communication skills. Further, the PI will inform the IRB of any adverse events using standard procedures.

As stated earlier, the PI will be solely responsible for the adherence to the IRB-approved protocol. The PI will be checking the adherence on every enrollment (especially because he will physically be there).

X. REFERENCES

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