

A. SPECIFIC AIMS

The long-term goal of this research is to improve the quality of care for patients suffering from serious, life-limiting illness by improving communication between doctors and patients in the hospital setting.¹⁻³ Inadequate communication about serious illness is widespread and causes confusion about diagnoses, prognosis, and treatment options, heightens patients' anxiety, and increases their risk of receiving therapies not in accord with their wishes.⁴⁻²⁷

The literature recommends that clinicians use specific communication skills to: 1) elicit and respond to patients' informational and emotional concerns, and 2) recommend a treatment plan based on the patient's prognosis and preferences for end-of-life care.²⁸⁻³⁵ To improve communication, it is critical that we identify skills that are associated with positive patient outcomes and develop interventions to teach physicians these skills.³⁶⁻⁴⁰

Patients with life-limiting illness are frequently hospitalized in the last 6 months of their lives.^{3,41} Hospitalists now provide the majority of physician services to seriously ill hospitalized patients,⁴²⁻⁴⁴ yet communication about serious illness has not been studied in the hospitalist model. The goals of this 4-year research plan are to determine whether hospitalists' communication about serious illness meets literature-recommended standards and describe the relationship between use of recommended skills and patient outcomes. The specific aims are to:

Aim 1: Develop a cohort of patient-hospitalist interactions at the time serious illness is discussed. This dataset will link audio-recorded discussions between hospitalists and patients about serious illness, physician and patient survey data, and administrative data.

Aim 2. Describe the frequency with which the hospitalists use recommended communication skills to discuss serious illness. *Hypothesis 1:* Hospitalists will infrequently use skills to elicit and respond to informational and emotional concerns or recommend a prognosis- and preference-based treatment plan.

Aim 3. Determine the association between use of recommended communication skills and patient outcomes. *Hypothesis 2:* Patients whose hospitalists elicit and respond to concerns will have lower anxiety, fewer unaddressed concerns, and higher satisfaction and trust in the hospitalist. *Hypothesis 3:* Patients whose hospitalists recommend a prognosis- and preference-based treatment plan will be less likely to receive life-prolonging therapies, evidenced by being more likely to have a DNR order, less likely to receive care in an ICU, more likely to have discharge plans for hospice, and incurring lower hospitalization costs.

B. BACKGROUND AND SIGNIFICANCE

1. Significance

Importance of the problem: When diagnosed with a life-limiting illness, most Americans prefer medical care focused on comfort.^{4,45-48} Nonetheless, most seriously ill patients die in hospitals receiving life-prolonging treatments that are not in accord with their wishes and suffer with uncontrolled pain and other symptoms.^{3,22,47,49-52,41,48,54} Improving doctor-patient communication about serious illness in the hospital setting through rigorous research is a key strategy in improving the quality of care for patients suffering from life-limiting illness.^{12,36,53,4}

Innovative nature of the proposed research: While expert recommendations exist,²⁸⁻³⁵ there is little evidence to guide clinicians in communicating about serious illness. A few studies have shown that physician use of recommended communication skills, such as responding empathically to emotion, is associated with lower anxiety and higher satisfaction.³⁷⁻⁴⁰ Using mixed qualitative and quantitative methods, my KL2 research will take a further step to explore whether use of recommended skills changes the types of treatments patients receive.

Future directions and impact of findings: The hospitalist field has identified palliative care and communication as core competencies, yet hospitalists are inadequately trained to communicate about serious illness.^{4,55-61} Thus, in the next phase of my research, I will design

and test an intervention, using proven methods,⁶⁴⁻⁷² to increase hospitalists' use of skills that are associated with positive patient outcomes,^{29,53,62,63} thereby translating the results of my KL2 research into practice. Once it is tested, the intervention will be disseminated to hospitalists nationally, giving it the potential to impact seriously ill patients across the country.⁴²⁻⁴⁴

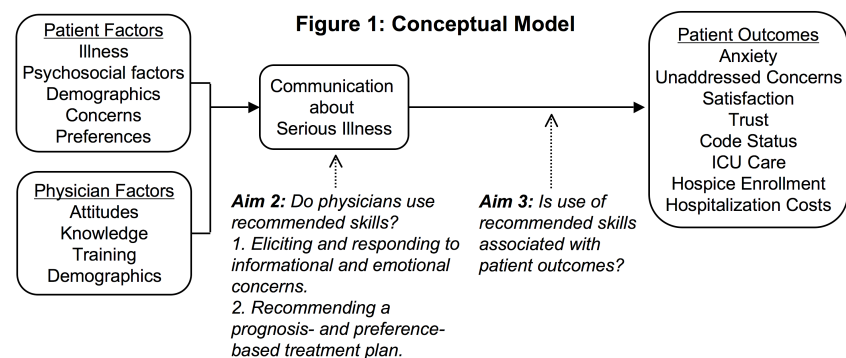
2. Background

Communication with providers about serious illness does not meet patients' needs.

Communication about serious illness has been most extensively studied in outpatient oncology and ICU settings. These studies identify 2 key deficiencies: 1) Providers do not elicit or respond to concerns. During serious illness patients face a cascade of physical and psychosocial stressors that result in multiple concerns about biomedical and psychosocial issues.^{7,73,74} Unaddressed concerns lead to anxiety, and can result in psychiatric disorders.⁷³⁻⁷⁷ Patients look to providers for information and emotional support,^{14-16,78-81} but communication with providers often does not meet these needs. Providers fail to elicit the majority of patients' concerns, are unaware of their emotional distress, and miss opportunities to provide information and emotional support.^{7-105,6,82} 2) Providers do not make treatment recommendations based on patients' prognosis and preferences. Patients make choices about life-prolonging therapies based on their perceived prognosis and treatment effectiveness,¹¹⁻¹³ and want to discuss prognosis and preferences for end-of-life care with providers.^{4,14-18,83} Unfortunately, communication about serious illness rarely includes information about prognosis, treatment effectiveness, or a discussion of patients' overarching values.^{19-21,23,24} As a result, seriously ill patients are poorly informed about prognosis^{25-27,84} and more likely to receive life-prolonging therapies.^{11-13,26223,85}

Specific skills may improve communication about serious illness. Experts recommend communication skills to meet patients needs. To elicit concerns, they recommend open-ended questions and allowing more time for patients to speak.^{6,82,86,87} To respond to informational cues such as, "I'm not sure why I'm in the hospital",⁸ they recommend the Ask-Tell-Ask technique in which each piece of information given is bracketed with a question to ensure patient understanding.²⁹ To respond to emotional cues such as, "That's one thing I have as a big fear",^{8,81,88,89} clinicians should acknowledge the emotion and encourage its expression using the mnemonic NURSE (naming, understanding, showing respect, expressing support, and exploring).^{19,29,89,90} When discussing life-prolonging therapies, clinicians should first discuss prognosis and elicit patient's values and preferences,^{4,91} then recommend a treatment plan that is tailored to the patient's prognosis and preferences.^{92,93} In outpatient and ICU settings, use of these skills is associated with lower anxiety and higher satisfaction.^{37-40,94} Interventions that increase communication between providers and families have been shown to reduce ICU length of stay and use of life-prolonging therapies.⁹⁵⁻⁹⁹ However, the specific communication skills used to accomplish these outcomes have not been described, and the relationship between communication skills and outcomes has not been studied in physician-patient dyads in the hospital. Thus, I will perform

an observational study of physicians and seriously ill hospitalized patients to further our understanding of the relationship between use of recommended skills to communicate about serious illness and anxiety, satisfaction, trust, and use of life-prolonging measures (Figure 1).



C. PRELIMINARY STUDIES

1. Audio-recording discussions between physicians and patients. As of September 2008, I have been piloting a protocol to study the process by which hospitalists develop rapport with patients (The Hospitalist Rapport Study). In this pilot, I have been recruiting all hospitalized patients who are able to communicate directly with their physician, regardless of whether they have serious, life-limiting illness, and have been audio-recording the first meeting between the hospitalist and patient. I have audio-recorded an average of 1 discussion per day. My consent rate for hospitalists is 100%, and my consent rate for patients is 77%. The procedures and preliminary data I generate will be used to plan Aim 1 of the K08 research plan, in which I will recruit only patients with serious, life-limiting illness and audio-record discussions during which hospitalists plan to discuss serious illness (bad news, code status, goals of care, prognosis, or limitation of life-sustaining medical therapies). To minimize fatigue for UCSF hospitalist physician participants, there will be a 6-month window between data collection for the Hospitalist Rapport Study and the proposed KL2 research.

Dr. White has audio-recorded 71 family meetings in the ICUs at UCSF, 40% of which are led by hospitalists. His consent rate is 95% for physicians and 70% for family members.

2. Coding audio-recorded communication. I will base the codebook I develop in Aim 2 on my and Dr. White's previous work. From my fellowship research, I am familiar with a codebook developed to describe oncologists' use of recommended skills for communicating about serious illness.¹⁰⁰ Dr. Tulsky and colleagues developed a standardized, explicit coding process,^{10,81,101-103} based on previous studies of doctor-patient communication in outpatient oncology and primary care settings.^{8,88} The final codebook was evaluated by calculating inter-rater reliability between 2 independent coders who coded 15% of the 415 pre-intervention audio-recordings. The codes I plan to use from this codebook (response to emotional cues and discussion of prognosis) had Cohen's kappas of 0.65-0.79, indicating substantial agreement.^{10,81,103-105} Dr. White created a similar codebook for his ICU studies of physicians' discussion of about prognosis, expression of empathy, and decision making.^{23,40,106} In Aim 2, I will create codes to describe response to informational cues and recommending a prognosis- and preference-based treatment plan, and will evaluate the reliability of the entire codebook in hospitalist-patient discussions about serious illness.

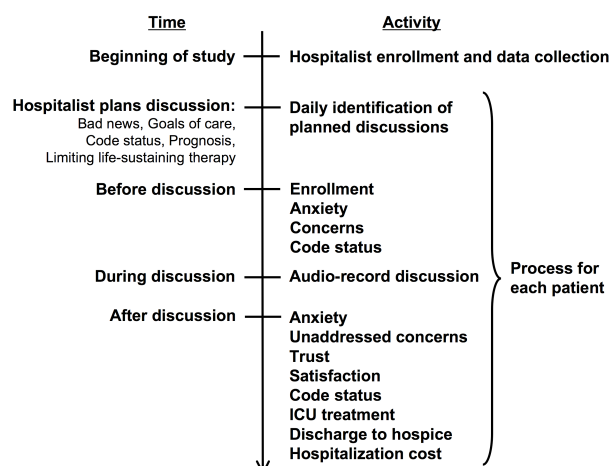
3. Association between goals-of-care discussions, resource use, and patient outcomes.

Dr. Auerbach studied the relationship between documentation of a goals-of-care discussion within 24 hours of hospital admission and patient outcomes, using data from the Multicenter Hospitalist Study.^{107,108} Of the 17,097 patients who participated in the study, a goals-of-care discussion was documented in 1776 (10.3%). Factors most powerfully associated with documenting a discussion were preadmission documentation of code status (odds ratios 3.22-11.32 compared with no preexisting documentation) and patients' site of enrollment (odds ratios 1.74-5.14). Dr. Auerbach and I are preparing a manuscript describing the association between documenting a goals-of-care discussion and outcomes in patients who survived to hospital discharge. Early results suggest that documenting a discussion is not associated with hospital length of stay, costs, satisfaction with care, or feeling rapport with the physician. There was a very broad range of frequency of care discussions across sites, so we are undertaking analyses to examine whether differences in outcomes exist within particular subgroups of patients or physicians. It may be that documentation of a discussion and outcomes are only associated for patients who died in the hospital; I will study this in a tutorial to learn multivariate modeling methods in my career development plan (Objective 3). However, this dataset is limited in that it only includes information about documentation of discussions at the time of admission and does not characterize the quality of communication. It may be that outcomes were not affected because physicians did not use recommended skills. My KL2 research plan is designed to test this hypothesis.

D. RESEARCH DESIGN AND METHODS

1. Overview of Study Design (Figure 2): I will audio-record discussions between hospitalists and patients with serious, life-limiting illness about bad news, goals of care, code status, prognosis, or limiting life-prolonging therapies and develop an explicit and reliable coding scheme to analyze the frequency with which hospitalists 1) elicit and respond to informational and emotional concerns, and 2) recommend a prognosis- and preference-based treatment plan. I will use surveys of patients and hospitalists, the patient's medical record, and administrative data to assess outcomes: anxiety, unaddressed concerns, trust, satisfaction, code status, ICU treatment, discharge to hospice, and hospitalization cost. I plan to collect data from 80 patients (4 per hospitalist).

Figure 2: Study Design



2. Subjects: *Physicians* will be eligible if they: 1) attend on the medical service at Moffitt-Long Hospital, and 2) hold a faculty appointment in UCSF Division of Hospital Medicine. I will exclude physicians who: 1) have not completed their clinical training, or 2) do not hold a faculty appointment in the Division of Hospital Medicine. Currently, 32 physicians would be eligible.

Patients will be eligible if they: 1) are admitted to the medical service at Moffitt-Long Hospital under the care of a participating hospitalist, 2) have a life-limiting illness, 3) the hospitalist would not be surprised by the patient's death or admission to the ICU during the succeeding 6 months,^{24,100} and 4) the hospitalist anticipates discussing bad news, goals of care, code status, prognosis, or limiting life-prolonging therapies.¹⁰⁹ I will exclude patients who are unable to communicate directly with the hospitalist because: 1) they have altered mental status or confusion, 2) their English fluency is not sufficient to communicate without a translator, 3) they are unable to communicate verbally for another reason (e.g., speech disorder, endotracheal intubation), or 4) they are unable to give full informed consent to the study. Patients who are less than 18 years of age are not admitted to the medical service. Approximately 4000 patients are admitted to the medical service at Moffitt-Long Hospital each year. Hospitalists estimate that they would have 1-5 (average 3) eligible patients per week.

3. Subject recruitment and enrollment: *Physicians* will be enrolled as a group at the beginning of the study via email and presentations at weekly Division meetings. ***Patients:*** Hospitalists arrange discussions about breaking bad news, goals of care, code status, prognosis, or limiting life-sustaining therapies each morning for the afternoon. When the participating physicians are attending on the medical service, they will be contacted each morning to identify eligible patients. A research assistant or I will then meet with the identified patients to explain the study and to enroll them.

4. Study procedures: *Physician enrollment survey:* 15-minute survey including demographics, education, and attitudes about communication with seriously ill patients. ***Patient pre-discussion survey:*** 15-minute survey including anxiety and concerns administered the morning before the audio-recorded discussion. ***Audio-recording discussions about serious illness:*** I will use 2 recorders per discussion to obviate technical problems. No research personnel will be present during the discussion; recorders will be placed in the meeting location before the discussion and removed after it is complete. ***Patient post-discussion survey:*** 15-minute survey, completed immediately following the discussion, including anxiety, the degree to which the hospitalist addressed the concerns they identified on the pre-discussion survey, the

degree to which they trust the hospitalist, and their satisfaction with the information and emotional support provided by the hospitalist during the discussion. **Physician post-discussion survey:** 3-minute survey, completed immediately following the discussion, including the patient's functional status, primary diagnosis, and admission diagnosis. **Data from the patient's medical record:** use to assess code status, ICU length of stay, hospital length of stay, and plan for discharge to hospice. **Administrative data:** used to assess cost of the hospitalization, after the patient's discharge or death, using the Transition Systems, Incorporated (Boston, Massachusetts) cost-accounting system to access abstracted chart data.¹¹⁰⁻¹¹²

5. Measurements (summarized in the table on the following page)

Predictor Variables are the hospitalists' use of recommended communication skills. Audio-recorded discussions will be transcribed. A codebook will be developed based on the communication literature (see Background) and my and Dr. White's previous work (see Preliminary Studies), and refined using an iterative process.^{19,101} Two coders will participate in the code-development process, and only codes with kappa statistics >0.6 will be retained in the final codebook.^{104,105} The following primary codes are planned for each discussion: 1) The number of **Concerns elicited** by the hospitalist.^{8,88} 2) **Response to informational cues**, calculated as the proportion of patient informational cues, for example, "I don't know much about the different treatments,"⁸ to which the hospitalist responds positively, defined as providing reasonable coverage of the topic identified in the cue.⁸ 3) **Response to emotional Cues**, calculated as the proportion of patient emotional cues, for example, "I'm worried about my leg pain,"⁸¹ to which the hospitalist responds positively, defined as expressing understanding of the emotion and encourage its expression.^{8,10,19,88,89} 4) **Recommends a prognosis- and preference-based treatment plan**, coded as positive if the physician discusses the patient's prognosis, elicits the patient's preferences for end-of-life care, and gives a treatment recommendation based on the patients' prognosis and preferences.^{29,33,91,93}

Patient Outcome Variables: **Anxiety** assessed by survey before and after the discussion with the hospitalist using the State portion of the State Trait Anxiety Inventory (STAI-S), a 20-item instrument that measures temporary anxiety. It has been used to detect changes in anxiety as a result of physicians' verbal expressions of empathy,³⁷ and is reliable and valid in hospitalized medical patients.¹¹³⁻¹¹⁵ The outcome will be a continuous variable, the post-discussion STAI-S score, adjusted for the pre-discussion score. **Concerns** assessed before the discussion by asking the patient to list "What problems and concerns do you want to talk about with the doctor today?"¹¹⁶ In the post-discussion survey, patients will, for each concern listed on their pre-discussion survey, rate how well the hospitalist addressed it: not at all, somewhat, or completely. Concerns that the hospitalist did not address at all will be counted as unaddressed. **Trust** In the post-discussion survey, patients will rank, on a 1-10 scale, "All things considered, how much do you trust this doctor?"^{100,117,118} **Satisfaction with information and emotional support** After the discussion, patients will rate their agreement on a 1-10 scale with 6 items (see Table) that were associated with physician communication or patient or relative anxiety in past studies,^{37-39,77} and address the areas of interest in my conceptual model. **Code status** will be described as either do-not-resuscitate (DNR) or not-DNR. Patients will be categorized by whether and how their code status changed between 2 assessments: before the audio-recorded discussion and on the day of discharge or death. **ICU length of stay** will be transformed into a categorical

Items to assess satisfaction
1. Enough time was allowed for information. ⁷⁷
2. The information was easy to understand. ⁷⁷
3. The information covered all the points of interest to me. ⁷⁷
4. This doctor listened to what I had to say. ^{38,39}
5. I felt this doctor cared about me. ³⁷
6. Overall, how well did talking with this doctor meet your needs? ^{38,39}

variable, whether or not the patient entered the ICU during their hospital stay, for analysis. **Discharge to hospice** will be a categorical variable, and will be positive if the patient's medical record indicates a plan for discharge to hospice (including home, inpatient facility, or associated with a nursing home). **Hospitalization cost** will be a continuous variable.

Patient covariates Demographic characteristics, symptoms (pain, nausea, etc),¹¹⁹⁻¹²² psychiatric illness (past and current), diagnoses (terminal and admission), functional status,^{123,124} perceived prognosis,^{12,13} and preferences for life-prolonging therapies.¹²⁵⁻¹²⁷

Physician covariates: Demographic characteristics, education, attitudes about communication.

6. Data quality and management:

All study subjects will be assigned unique study identifiers that will appear on all data collection instruments, recordings, documents, and files. Personal information needed for tracking and informed consent will be stored separately. Each discussion will be digitally audio-record with 2 Olympus DS-40 recorders with stereo microphones. The digital .wma files will be downloaded, encrypted, sent to a professional service for transcription, and stored on a secure server. All identifying data will be removed during the transcription process. The transcripts and codes will be managed using the Atlas.ti software package. Survey data will be collected on paper and double

entered through a Microsoft Access data entry interface. All paper study documents (e.g., signed consent forms and completed surveys) will be kept in a locked drawer in a locked office. Electronic data will be stored on a password-protected computer and backed-up on a secure server. Statistical analysis will be performed using SAS, SPSS, and Stata as appropriate.

7. Analysis

Descriptive analysis: Continuously distributed variables will be summarized with measures of central tendency (mean, median) and variability (standard deviation) as well as graphical representations (histograms, box plots). Normality will be tested, and outliers identified.

Study Measures		
Variable	Source	Time Collected
Predictor Variables: Hospitalist Communication Skills		
Primary		
Response to emotional cues	Coded audio-recordings	During discussion
Secondary		
Concerns elicited	Coded audio-recordings	During discussion
Response to informational cues	Coded audio-recordings	During discussion
Recommends a prognosis- and preference-based treatment plan	Coded audio-recordings	During discussion
Patient Outcome Variables		
Primary		
Anxiety	Patient survey	Before + after discussion
Secondary		
Concerns	Patient survey	Before + after discussion
Trust	Patient survey	After discussion
Satisfaction	Patient survey	After discussion
Code status	Medical record	Before discussion + at discharge
ICU length of stay	Medical record	During hospitalization
Discharge to hospice	Medical record	At discharge
Hospitalization cost	Administrative data	After hospitalization
Covariates		
Patient		
Demographics	Patient survey	Before discussion
Symptoms	Patient survey	Before discussion
Psychiatric illness	Patient survey	Before discussion
Diagnoses	Physician survey	After discussion
Functional status	Physician survey	After discussion
Perceived prognosis	Patient survey	Before + after discussion
Preferences for life-prolonging therapies	Patient survey	Before + after discussion
Physician		
Demographics	Physician survey	At enrollment
Education	Physician survey	At enrollment
Attitudes	Physician survey	At enrollment

Transformations will be used as appropriate prior to using parametric statistical tests. Categorical variables will be summarized with frequency tables and associations evaluated using appropriate measures and tests.

Aim 1: Develop a cohort of patient-hospitalist interactions at the time serious illness is discussed. I will describe the consent rate for hospitalists, the number of discussions identified per hospitalist, and the percent of patients who consent to participate as well as the elapsed time between surveys and audio-recording and rates of missing data.

Aim 2. Describe the frequency with which the hospitalists use recommended communication skills to discuss serious illness. Hypothesis 1: Hospitalists will infrequently use skills to elicit and respond to informational and emotional concerns or recommend a prognosis- and preference-based treatment plan. I will perform descriptive statistics for each code, and investigate associations between these measures and patient and physician covariates using Poisson regression models and summarizing associations by relative rates. I will use linear mixed models (LMM) for continuous outcomes and generalized estimating equations (GEE) for categorical outcomes to account for within-hospitalist correlation.

Aim 3. Determine the association between use of recommended communication skills and patient outcomes. Hypothesis 2: Patients whose hospitalists elicit and respond to concerns will have lower anxiety, fewer unaddressed concerns, and higher satisfaction and trust in the hospitalist. Because I am recording stressful discussions, I expect anxiety to increase from the pre- to post-discussion measurement.³⁷ When hospitalists use literature-recommended skills to elicit and respond to concerns, I hypothesize that patients will have a smaller increase in anxiety. The change in the STAI-S will be calculated for each patient and used as the outcome variable in analyses for association with the primary study predictor variable, the proportion of emotional cues to which the hospitalist responded positively. Parallel analyses will be performed with the other predictors and outcomes. Analyses will be based on analysis of variance and covariance regression models, with results summarized using regression coefficients and associated 95% confidence intervals, and hospitalist-level clustering handled using LMM and GEE methods. Hypothesis 3: Patients whose hospitalists recommend a prognosis- and preference-based treatment plan will be less likely to receive life-prolonging therapies, evidenced by being more likely to have a DNR order, less likely to receive care in an ICU, more likely to have discharge plans for hospice, and incurring lower hospitalization costs. Using the procedures described above for Hypothesis 2, I will analyze for association between the dichotomous predictor variable recommends a prognosis- and preference-based treatment plan, the patient and hospitalist covariates, and each of these outcome variables. Hospitalization cost is continuous and likely to be skewed; I will handle this in analysis by using gamma modeling or transformations.

Sample size: A goal of this study is to gain information on key variables, associations, and effect sizes to inform the design of larger studies. In the absence of preliminary data on key variables, a formal assessment of statistical power to test hypotheses is not possible. I provide basic calculations for our primary objective, the relationship between hospitalists' response to emotional cues and patient anxiety level, to illustrate the effect size that will be detectable from our proposed sample size of 80. Using a two tailed t-test to compare patients to whom the hospitalist responded positively compared with those to whom the hospitalist responded negatively, with sample size of 80 and 80% power while setting $\alpha = 0.05$, we would be able to detect a mean difference of 10 points in the individual specific changes between pre- and post-encounter STAI-S. This is comparable to previously documented effects of acknowledging emotions on STAI-S scores.³⁷ This calculation does not take into account design effects related to clustering within hospitalist, which, depending on the degree of skill variance within hospitalist, would affect our power. Assessing this design effect is a goal of this study, so that I can anticipate its magnitude in future, larger studies.

Missing data: I aim to collect all of the audio-recorded and patient survey data within 12 hours. If clinical activities or other issues prevent the recording of the discussion within 24 hours of the pre-discussion survey or the administration of the post-discussion survey within 24 hours of the recorded discussion, I will consider that data missing. I will track missing data rates and reasons for planning future studies.

8. Limitations and Strengths

The proposed research has several limitations. First, I am only studying outcomes of patients with whom hospitalists discuss serious illness. As evidenced by our and other's past research, many patients who are admitted to the hospital do not discuss their goals of care with a physician. I hypothesize that the intervention that I will design based on this data will increase the frequency with which hospitalists discuss serious illness by increasing their self-efficacy to have the discussions; I will test this hypothesis in my research following this award. Second, I am likely to capture hospitalists' best communication, because the discussions will be planned ahead of time, selected by the physician, and audio-recorded.¹²⁸ This bias is unlikely to negatively impact the study aims, because most physicians are under-trained so do not have the ability to use recommended skills, even when they are trying to perform at their best.^{8-10,19,88,129} Third, I may be unable to detect an association between use of recommended skills and outcomes because hospitalists may use recommended skills at a very low frequency and the sample size is small, limiting our ability to adjust for other factors that influence the outcomes. I will still have established procedures and collected data to generate effect sizes to plan the randomized trial of the intervention I design based on this research. Ideally, I will tailor the intervention to focus on skills that are associated with positive patient outcomes. If I find no association between the evaluated skills and patient outcomes, I will develop the intervention to increase hospitalists' use of skills that experts recommend. Fourth, my observational study and intervention focus on physicians' use of communication skills, because inadequate training of physicians is a key barrier to improving communication about serious illness.^{4,29,53,62,63} However, improving physician skills alone may not be enough to improve care for patients with serious illness, as comprehensive approaches which address social as well as organizational and economic barriers in addition to individual professional factors are often needed to effectively change medical practice.^{130,131} I my future career development, I will learn about these various factors, and they will be a focus of my future research.

The significant strengths of this research plan are in its ability to expand the evidence-base of an under-researched and critical area of need: doctor-patient communication about serious illness in the hospital setting.^{41,48,54} It will result in a theory- and evidence-based intervention, informed by past work in communication skills training.⁶⁴⁻⁷² It has the potential to improve the quality of care for patients with life-limiting illness at a national level, given that hospitalists care for the majority of seriously ill hospitalized patients in the United States.⁴²⁻⁴⁴

10. Timeline of Research Activities:

My mentors and I have designed the following timeline so as to feasibly complete the proposed activities in the time allotted.

Aim	Research Activity	Year 1	Year 2	Year 3	Year 4
1	Develop data collection procedures	■			
	Collect data	■	■		
	Manuscript preparation (methods)		■		
2	Develop and test codebook		■		
	Code audio-recorded discussions		■	■	
	Analysis and manuscript preparation			■	
3	Statistical modeling and analysis			■	
	Manuscript preparation				■
	Prepare R01 application				■

E. HUMAN SUBJECTS

This study has not yet received approval by the Institutional Review Board at UCSF. I will obtain just in time approval upon the funding of this award. The involvement of human subjects in the proposed research, the risks of the research to the subjects, and the benefits to society are outlined below.

1. Risks to the Subjects

a. Human Subjects Involvement and Characteristics: The proposed research involves physicians and patients as human subjects; 20 physicians and 80 patients will be recruited. All subjects will be recruited from UCSF's Moffitt-Long Hospital.

Physicians will be eligible to participate if they: 1) attend on the medical service at Moffitt-Long Hospital, and 2) hold a faculty appointment in UCSF Division of Hospital Medicine. I will exclude physicians who: 1) have not completed their clinical training, or 2) do not hold a faculty appointment in the Division of Hospital Medicine. It is anticipated that physicians will be age 30-65 years and will be in good health status.

Patients will be eligible to participate if they: 1) are admitted to the medical service at Moffitt-Long Hospital under the care of a participating hospitalist, 2) have a life-limiting illness, 3) the attending hospitalist would not be surprised by the patient's death or admission to the ICU during the succeeding 6 months, and 4) the hospitalist anticipates discussing bad news, goals of care, code status, prognosis, or limiting life-prolonging therapies. I will exclude patients who are unable to communicate directly with the hospitalist because: 1) they have acute or chronic altered mental status or confusion, 2) their English fluency is not sufficient to communicate without a translator, 3) they are unable to communicate verbally for another reason (e.g., speech disorder, endotracheal intubation), or 4) are unable to give full informed consent to the study. Eligible patients are anticipated to be age 18-99 years (patients who are less than 18 years of age are not admitted to the medical service).

No special classes of subjects, such as fetuses, neonates, pregnant women, children, prisoners, institutionalized individuals, or other vulnerable populations will be potential subjects.

b. Sources of Materials: Research material will be obtained from the human subjects via surveys completed by the patient and physician participants, audio-recordings of discussions of serious illness between physician and patient participants, and review of participating patients' medical chart and administrative data. Patient surveys will measure anxiety, unaddressed concerns, trust in the physician, satisfaction with the physician's communication, demographic factors, symptoms, past and present psychiatric illness, perception of prognosis, and preferences for life-prolonging therapies. Physician surveys will measure patient diagnoses and functional status and physician demographic factors, training history, and attitudes about communication. Audio-recordings will be used to measure physicians' use of recommended skills for communicating about serious illness (eliciting and responding to information and emotional cues and recommending a prognosis- and preference-based treatment plan). Patients' medical chart and administrative data will be reviewed to assess code status, ICU treatment during hospitalization, plans for discharge to hospice, and hospitalization costs.

All study subjects will be assigned unique study identifiers that will appear on all data collection instruments, recordings, documents, and files. Personal information needed for tracking and informed consent will be stored separately; only study personnel will have access to this information and the study data.

c. Potential Risks: Participation in the study poses no physical risks to physicians or patients. The surveys are designed to be low burden for both the physicians and patients. It is possible that physicians or patients could experience emotional distress as a result of their discussions being audio-recorded. We feel this is unlikely, as multiple studies have documented that audio-recording of doctor-patient communication is well tolerated by physicians and patients alike.⁸⁻

^{10,19,88,129} There is some risk of loss of confidentiality. There is minimal risk to reputation, insurability or other social risk as a consequence of a subject's loss of confidentiality. The study investigators will not be recording any information in the patient's chart. The data being collected is unlikely to pose a social risk or risk to reputation in the event of loss of privacy for either patient or physician participants.

2. Adequacy of Protection against Risks

a. Recruitment and Informed Consent: Written informed consent will be obtained from physician and patient subjects. Physicians will be notified of the study via email and presentations at weekly Division meetings. If physicians agree to hear about the study, the Candidate will meet in person with eligible physicians to explain the study procedures, risks, and benefits and obtain written informed consent if they agree to participate. The Candidate or a research assistant will then approach eligible patients, identified by the participating physicians, in their hospital room about the study. If patients agree to hear about the study, the Candidate or a research assistant will explain the study procedures, risks, and benefits and obtain written informed consent if they agree to participate.

b. Protection Against Risk: When they are notified of the study, physicians and patients will be given the opportunity to decline to hear more about it. Those who decline will not be contacted again about it. At enrollment, subjects will be reminded that they can stop their participation in the study at any time or skip any part of the study in which they do not wish to participate. The surveys have been designed to be of minimal burden. Where possible, will use chart review to gather information. To minimize risk of confidentiality, all study subjects will be assigned unique study identifiers that will appear on all data collection instruments, recordings, documents, and files. Personal information needed for tracking and informed consent will be stored separately. All paper study documents (e.g., signed consent forms and completed surveys) will be kept in a locked drawer in a locked office and electronic data will be stored on a password-protected computer and backed-up on a secure server. Only study personnel will have access to study data. Audio-files will be encrypted, and all identifying information will be removed during transcription. We will not approach patients about the study if their involvement might interfere with their medical care, and will ensure that their participation does not interfere with their receipt of medical care.

The Candidate is a board-certified internist and palliative care physician and has extensive experience in dealing with distraught hospitalized patients. In the event that a subject experiences significant emotional distress, the study investigator will be available to talk with the subject and assess whether further intervention is necessary. All study personnel will have the contact information for the patient's medical team as well as the inpatient medical social worker, who will be available to assist in the event that patients become emotionally distressed during the study.

3. Potential Benefits of the Proposed Research to the Subjects and Others

Physicians and patients who participate will not benefit from participating in the study. The risks of this study are minimal to both the physicians and patient participants, and the investigators will make every effort to ensure the participants do not experience distress or other adverse effects as a result of the study.

4. Importance of the Knowledge to be Gained

The potential benefits of the study to society are great, because they will lead to improvements in an important yet under-researched field: doctor-patient communication about serious illness in the hospital. Specific skills will be identified that, when used by physicians to communicate about serious illness, improve patient outcomes. This information will be used to generate guidelines to help physicians communicate about serious illness in the hospital setting and disseminated to hospital-based physicians nationally. The information will also be used to

develop an intervention to 1) increase physicians' use of skills, and 2) improve patient outcomes. The intervention will then be disseminated on a national level, to address the inadequate training of hospital-based physicians in communication about serious illness.

4.G Inclusion of Women and Minorities: We will not exclude women or minorities from participating in this study, either as physicians or patients. We will enroll physicians for the UCSF Division of Hospital Medicine. We will collect data on gender, ethnicity, and race for all participants. In our preliminary study of hospitalist-patient communication, 47% of physicians are female, and 5% are Hispanic. Their racial distribution is: 63% White, 26% Asian, and 11% Other.

We will enroll patients from the inpatient medical service at Moffitt Long Hospital. On average, 51% of these patients are female and 8% are Hispanic. Their racial distribution is: 51% White, 20% Asian, 17% African-American, and 12% Other.

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