SUMMARY OF REVISIONS

Thank you for reviewing my previous submission for the Junior Faculty Career Development Award, "ICU Communication and Surrogate Psychological Health." Since my previous submission, I completed a research and clinical fellowship in Palliative Care and General Internal Medicine at the University of Pittsburgh, and am now an Assistant Professor in the Palliative Care Program and Division of Hospital Medicine at the University of California, San Francisco (UCSF). The overall goal of this career development award is to foster my development into an independent researcher focusing on communication techniques that address patients and relatives' informational and emotional concerns, thereby reducing anxiety. My move to UCSF prompted changes in this proposal that both strengthen its merit and respond to the reviewers' previous concerns.

First, my training plan takes advantage of UCSF's position as the preeminent institution for Hospital Medicine in the United States and a leader in hospital-based Palliative Care. Hospitalists provide the majority of inpatient care to seriously ill patients in the US, so the long-term goal of my research is to improve end-of-life care for hospitalized patients by improving hospitalists' communication about end-of-life issues. My NPCRC project is designed to collect preliminary data describing the relationship between hospitalist skill use in end-of-life discussions (which include, but are not limited to, discussions about patients in the intensive care unit setting) and patient or next of kin anxiety. Accordingly, I have changed the title of my submission to: "Communication and Anxiety in Seriously Ill Hospitalized Patients and their Relatives." The Division of Hospital Medicine has a strong history of mentoring junior faculty, who are now national experts in their areas of focus within Hospital Medicine. The Division is dedicated my success and to Palliative Care research, and will protect 75% of my time for research and provide the resources I need to succeed.

Second, I have assembled a team of mentors at UCSF who can help me to develop the skills I need to become an independent researcher in my chosen field. My co-mentors are Susan Folkman, PhD, my research mentor, and Steve Pantilat, MD, my career mentor. Dr. Folkman is world-renowned for her research and theory of stress and coping in terminal illness, and is a highly accomplished NIH-funded senior researcher. Dr. Pantilat has an impressive history of academic success, and is a national leader in palliative care. He has extensive experience in hospital-based palliative care program development and dissemination. Andrew Auerbach, MD, MPH, an independently funded outcomes researcher in the Division of Hospital Medicine, will guide the implementation of my project and provide focused mentoring about statistical modeling methods as a consultant. I will continue my strong relationships with James Tulsky, MD (at Duke University), and Robert Arnold, MD (at the University of Pittsburgh), my mentors from residency and fellowship, who as consultants will provide focused mentoring on the analysis of recorded medical conversations, as their specific expertise is not available at UCSF.

My responses to each of the reviewers' concerns describe how my revised proposal addresses the previous submission's shortcomings.

Comment 1 (Approach): *"However, this is an ambitious plan, perhaps overly ambitious considering the other career development projects … that she has planned."* (Reviewer #1)

I understand the reviewer's concern. In the revised proposal, I limit my career development and research activities.

1) *Career development:* I decreased the amount of coursework (from 20% time to 10% in Year 1, and from 15% to 5% in Year 2). I limited my formal coursework to two courses: qualitative analysis and multivariate modeling. I focused my career development plan on guided study and data analysis with my mentors and consultants, to teach me skills I will need for a career as an independent investigator studying hospital-based end-of-life communication. Specifically, my training plan is designed to expand my knowledge base about stress and coping, and develop hands-on experience in the analysis of recorded communication and in statistical modeling techniques to analyze multivariate, longitudinal, clustered data.
2) *Research plan:* In my previous submission, I planned to measure mental disorders 3-months after the recorded family meeting. In my revised submission, I chose to measure patient or next of kin anxiety before and immediately after the recorded discussion. Accordingly, I selected an anxiety instrument that measures transient (state) anxiety (please see Comment 5). In addition to reducing the project workload, measuring anxiety before and immediately after the encounter has a methodological advantage in that it will reduce the chance that factors other than the recorded discussion (e.g. discussions with providers, unrelated events) will impact the outcome variable. While I expect anxiety levels to increase because the discussions are stressful, when hospitalists elicit and respond to informational and emotional concerns the increase will be smaller.[1] Most importantly, my NPCRC study will establish the feasibility of enrolling patients and next of kin and recording these discussions. This will serve as pilot data for a larger study that includes post-hospitalization follow-up of patients and relatives.

Comment 2 (Approach): *"The 10% support [for a clinical research nurse salary] … seems low considering the expected responsibilities of the nurse."* (Reviewer #1)

I agree. For the revised proposal, the Division of Hospital Medicine will fund a full-time research assistant in Year 1 to enroll patients and next of kin and collect and enter data. This will allow me to focus on data analysis and career development activities.

Comment 3 (Approach): *"Of concern is that there is no discussion of ICU professionals who will assist her in making her study feasible in an ICU in which she does not work."* (Reviewer #1)

I understand and fundamentally agree with the concern; this was a limitation of my previous proposal. At UCSF, my appointment is in the Division of Hospital Medicine, and I attend on the hospitalist service. In my revised submission, I propose to study end-of-life communication on the UCSF hospitalist service, which cares for both ICU and general medical patients. This has two advantages:

1) I will conduct research on a clinical service on which I work. My hospitalist Division Chief (who is also Associate Chairman of our Department of Medicine and Chief of the Medical Service at UCSF) and faculty colleagues are supportive of the study, and have committed to participate and assist with patient and next of kin recruitment. My colleague in Pulmonary and Critical Care, Dr. Douglas White, has recorded family meetings in ICUs, 40% of which are led by hospitalists, demonstrating that audio-recording UCSF hospitalists' communication about serious illness is feasible. I have Dr. White's support in launching my research plan, and access to the infrastructure he developed to record these discussions.
2) I have the opportunity to study communication between hospitalists and seriously ill patients and their next of kin. Hospitalists are now providing the majority of care to hospitalized medical patients in the United States, and most hospitalists follow patients into ICUs (i.e. "open units").[2] At UCSF, hospitalists care for both ICU and general medical inpatients, so my study will capture discussions about patients at varying levels of acuity. In practice, physicians communicate primarily with patients when they are well enough to participate in discussions about their care, and with their next of kin when the patient is too ill to participate. By recording conversations with both patients and next of kin, my study will capture the range of communication that occurs about seriously ill hospitalized patients. My NPCRC research will allow me to develop and test a communication training intervention for hospitalists. The hospitalist professional society, the Society of Hospital Medicine, effectively promotes dissemination of information to its more than 7,000 members. The hospitalist field and its Society have identified end-of-life care and communication skills as core competencies. My work will create evidence-based guidelines about hospitalist communication at the end of life. UCSF has been an academic leader of the hospitalist movement since its inception, so I am well positioned to have an influence on hospitalist practice nationally.

Comment 4 (Career Development Plan): *"…again, her plans are ambitious." (Reviewer #1)*

I agree, please see response to Comment 1.

Comment 5 (Approach): *"Are there data to support the validity of the Major Depressive Disorder, Generalized Anxiety Disorder, Panic Disorder and Post Traumatic Stress Disorder modules of the Structured Clinical Interview for the Diagnostic and Statistical Manual Version IV when administered via telephone?"* (Reviewer #2)

In my revised plan, I will not use the Structured Clinical Interview to measure anxiety. Because I will measure anxiety before and after the patient or next of kin communicates with the hospitalist (please see Comment 1), I chose an instrument that can measure changes in anxiety from before to after the discussion and differences in hospitalist communication during the discussion. The state portion of the State Trait Anxiety Inventory (STAI-S),[3] measures transient anxious mood. It is reliable and valid in hospitalized medical patients, and is commonly used to measure immediate changes in anxiety as a result of experimental procedures.[3,4] Further, previous studies have shown that physician expressions of empathy decrease patients' STAI-S score.[1]

Comment 6 (Approach): *"It is likely that the family members may have already been involved in family meetings, or will be involved after the recorded sessions. How will this be taken into account during analysis?"* (Reviewer #2)

Please see response to Comment 1.

Comment 7 (Approach): *"The post-conference understanding of the patient's clinical situation is based on Azoulay's work. Are there data to support the validity of the instrument?"* (Reviewer #2)

I decided not to use this instrument in the revised proposal, because it was developed for ICU patients and our study will also include general medical patients. I will measure the patient's or next of kin's understanding of the illness with an instrument developed to assess awareness of terminal illness.[5,6] Responses to this measure correlate with the clarity of physician communication about prognosis and treatment choices.[5,6] I will also measure the patient's or next of kin's satisfaction with information provided by the hospitalist using items from validated measures.[7,8]

Comment 8 (Approach): *"How will the primary provider who will lead the meeting be identified?"* (Reviewer #2)

I am focusing on communication between hospitalists and seriously ill patients or their next of kin in the revised proposal. Thus, I will only record discussions in which the hospitalist plans to be the primary provider communicating with the patient or next of kin. I will initially focus my analysis on the hospitalist's communication. If I note that other providers speak frequently in the discussions, I will create decision rules to classify discussions by whether other providers played a significant role and will control for that in analysis.

Comment 9 (Career Development Plan): *"Of concern is the feasibility of conducting the proposed research in the 2 year time period…one needs to take into account the need for palliative care personnel to forge a link with ICU staff and that this process often takes time."* (Reviewer #2)

I agree, please see response to Comments 1 and 3 above.

A. SPECIFIC AIMS

My NPCRC research is a preliminary study of the association between skills that hospitalist physicians use to communicate about end-of-life issues and anxiety levels in seriously ill hospitalized patients and their next of kin. It will establish the feasibility of audio-recording end-of-life discussions between hospitalists and seriously ill hospitalized medical patients and their next of kin and collecting survey data from the patients or their next of kin. I will use the data I collect to develop an educational intervention to teach hospitalists skills for communicating with patients and their relatives about end-of-life issues, and to test the ability of this intervention to decrease anxiety in seriously ill hospitalized patients and their relatives.

Most Americans receive end-of-life care, and ultimately die, in hospitals.[9-15] Hospitalization for serious illness is very stressful for patients and their relatives, all of whom need information and emotional support to help them cope.[16-23] Studies show that providers' communication often inadequately addresses patients and relatives' informational and emotional concerns. Most of these concerns are not disclosed to physicians, and physicians' do not respond to concerns when they are disclosed.[24-36] Unaddressed informational and emotional concerns result in anxiety, which leads to decreased quality of life, morbidity and mortality, and increased health care utilization and likelihood of psychiatric disorders.[37-50]

Hospitalists provide the majority of physician care to hospitalized patients in the United States, but communication between hospitalists and seriously ill patients and their relatives has not been studied.[51,52] Studies in primary care, outpatient oncology and ICU settings have defined teachable communication skills that elicit and address patients' and relatives' informational and emotional concerns.[1,7,8,26-28,36,53-57] This literature provides a foundation to study how hospitalists communicate with seriously ill hospitalized patients and their families and for developing a communication education intervention for hospitalists. By teaching hospitalists effective communication skills, seriously ill patients and their relatives should experience less anxiety and enjoy more favorable outcomes.

In my NPCRC research, I will audio-record conversations in which hospitalists plan to discuss end-of-life issues: bad news, code status, goals of care, prognosis, or limitation of life sustaining medical therapies. Because physicians communicate with relatives when patients are too ill to participate in discussions about their care, I will record conversations with the patient's next of kin when the patient is too ill to participate. At UCSF, like most hospitals in the U.S., hospitalists provide care to general medical and ICU patients,[2] so seriously ill patients in both groups will be included. Patient (or next of kin) outcomes will be assessed by survey immediately before and after the conference. The specific aims are to:

1. Describe the frequency with which hospitalists use literature-recommended skills to elicit and respond to seriously ill hospitalized patients or their next of kin's informational and emotional concerns in end-of-life discussions.
2. Describe the patients or next of kin's anxiety levels before and after the hospitalist end-of-life discussion as well as how well the hospitalist addressed their concerns, their trust in the hospitalist, and their satisfaction with the hospitalist's provision of information and emotional support.
3. Analyze the association between hospitalists' communication skill use and patients or next of kin anxiety, unaddressed concerns, trust, and satisfaction.

Hypothesis: Because I am recording stressful discussions, anxiety will increase from the pre-discussion to post-discussion measurement. However, when hospitalists use literature-recommended skills to elicit and respond to informational and emotional concerns, patients and next of kin will have a smaller increase in anxiety.

B. BACKGROUND AND SIGNIFICANCE

B.1 Improving end-of-life care in hospitals is a national priority. Most Americans receive end-of-life care in hospitals. Of Medicare beneficiaries in 2003, 70% were hospitalized during the last 6 months of their lives.[9] Half of Americans who die of chronic disease die in the hospital.[10,11] End-of-life care in hospitals is inadequate. Seriously ill hospitalized patients receive care that is inconsistent with their preferences and values, and suffer with uncontrolled physical and psychological symptoms.[12-14] Doctors communicate directly with patients who are at end of life, and also with their relatives when patients become too ill to participate in discussions about their care.[58-60] The Institute of Medicine particularly highlighted communication at the end of life as a priority for improvement.[15]

B.2 Anxiety is prevalent in seriously ill hospitalized patients and their relatives.

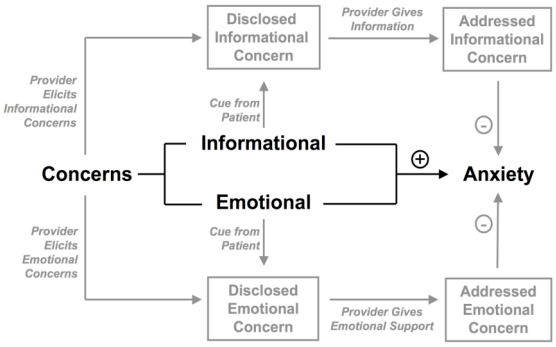
Half of seriously ill hospitalized patients report anxiety.[12] In the ICU, more than half of patients have anxiety that is moderate to severe.[61,62] Anxiety is prevalent in patients with cancer, heart disease, chronic obstructive lung disease, and end stage renal and liver disease.[44,45,63-65] It is associated with poor symptom control, decreased quality of life, morbidity, and mortality as well as distress in caregivers and higher health care utilization.[42-50] Of note, interventions aimed at supporting coping and reducing anxiety reduce mortality. For example, melanoma patients who participated in a psychiatric intervention to enhance coping and reduce distress survived longer than those who did not.[47] Relatives of seriously ill patients also have high levels of anxiety. In the ICU, 40-70% of patient relatives have symptoms of anxiety, and they develop post traumatic stress symptoms after the patient's discharge or death.[41,66-68] Three months after patient discharge, 30-80% of relatives have post-traumatic stress symptoms; relatives at highest risk for persisting symptoms are those who share in end-of-life decisions.[41]

B.3 To cope with the stress of serious illness and hospitalization, patients and their relatives need information and emotional support. Serious illness and hospitalization are stressful life events. Patients and their relatives face changes in

their hopes for the future, physical functioning, finances, and daily routines. Hospitalization creates additional stressors: acute illness, associated physical symptoms and uncertainty, altered sleep, being in a new and uncomfortable environment, and being away from home. This cascade of stressors results in multiple concerns about biomedical and psychosocial issues.[24,37,40]

Concerns have both informational and emotional components (Figure 1). Seriously ill patients and their relatives need information about their illness and how it will affect them.[16] They use this information to plan for the future and to make medical and life decisions.[17,18] They want their doctor to be honest and realistic in giving information while being sensitive to what information they are ready to hear and how it is affecting them.[18-22] Seriously ill patients and their relatives also need emotional support, and they look to physicians for it.[23] They feel emotionally supported when their doctor shows care for them as a person, by spending enough time with them, allowing them to ask questions, and listening to their concerns.[18-20]

Figure 1: Conceptual Model



B.4 Communication with providers does not address patients and relatives' informational and emotional concerns. Though patients and relatives look to health care providers for both information and emotional support, provider communication is currently inadequate in responding to their informational and emotional concerns. Providers fail to elicit the majority of concerns, and miss opportunities to respond to cues for information and emotional support.[24-30] Physicians are unaware of patients' preferences for end-of-life care.[14] Cancer patients are often unaware of their prognosis, and misunderstanding of prognosis has been linked to preferences for life prolonging therapies.[31,32] ICU patients and surrogates do not understand basic information about their medical situation, and are poorly informed about prognosis.[33,69] Audio-recordings of ICU family meetings in the United States reveal that prognosis for survival is often not discussed.[70] Even when patients express anxiety in clinical encounters,[54] providers are unaware of patient's emotional distress,[34-36] and do not respond empathically when patients and relatives express emotion.[26-30]

B.5 Unaddressed informational and emotional concerns contribute to anxiety. Unaddressed concerns lead to anxiety, and can result in psychiatric disorders.[37-40] Anxiety arises in response to threats of negative outcomes in the future.[71,72] It can result from uncertainty about what will happen in the future (epistemic uncertainty), or uncertainty about our ability to react (pragmatic uncertainty), or both.[73] Anxiety is reduced by acquiring new information to reduce epistemic uncertainty, or, if information is not available, by coping with the emotion directly. Because of the inherent uncertainly at the end of life, seriously ill patients and their relatives need both information and emotional support. Patients and relatives are more anxious when communication with providers does not address their informational and emotional concerns. For example, relatives of patients in the ICU who felt that not enough time was allowed for information or that information was not easy to understand or incomplete were more likely to have anxiety 3 months after the patients' ICU stay.[41]

B.6 Teachable communication skills that reduce anxiety have been defined in the literature. The literature recommends specific communication skills that address informational and emotional concerns (Figure 1). First, patients' and relatives' concerns must be disclosed to the provider. Certain provider behaviors have been shown to elicit these concerns: open-ended questions, allowing more time for patients to speak, and empathy.[36,53] Patients and relatives also give "cues" to providers about their concerns, for example, "I'm not sure why I'm in the hospital." [cue for information] or "That's one thing I have as a big fear." [cue for emotional support].[26-28,54] After informational and emotional concerns are disclosed, providers must respond appropriately to them. For responding to informational concerns, the Ask-Tell-Ask technique, where the provider brackets each piece of information provided with a question to check its effect on the patient, ensures that information is paced to the patient's understanding and that the provider doesn't give more information than that patient is ready for.[55] Providers give emotional support by listening and using specific language that expresses empathy and nonabandonment, for example, "Can you tell me more about what frightens you?" or "I know this is scary, I want you to know that we will work through this together".[28,56] Relatives of ICU patients were more satisfied with family meetings when the physician leading the meeting allowed more time for them to talk and expressed nonabandonment.[7,8]

Patients are less anxious when providers use these skills. For example, cancer patients whose doctor presented information clearly and gave them as much as they desired, and who talked about their feelings at their diagnosis, were less anxious a year later.[57] Breast cancer patients were more likely to feel the doctor cared about them and were less anxious when the doctor expressed empathy.[1] Empathy and nonabandonment can be expressed without significantly prolonging the time providers talk with patients; as little as 40 seconds of empathic language results in significant changes is patient's anxiety level.[1] Studies also demonstrate that ***teaching*** providers these communication skills can decrease patients' and relatives' anxiety. Primary care patients of physicians who were trained to express empathy were less anxious compared with patients of physicians who were not trained.[74] In France, a communication intervention for ICU physicians reduced post traumatic stress in relatives of patients who died in the ICU.[75]

Multiple studies with trainees and senior providers in generalist, oncology, and ICU settings document that these communication skills can be taught, are retained, and are used in clinical interactions. Significant improvement in skills is evident after only a few days of training. Training has been shown to increase providers' self-reported ability to give

information, elicit patients' values and feelings and discuss bad news.[76-80] It increases use of literature-recommended skills such as open-ended questions and empathy.[74,80-83] Providers retain these skills months later without intervening training, by self report[79] and direct observation.[74] To be effective, communication training must involve skills practice, so interventions must use clinical situations that are appropriate for the learners they target.[83,84] Communication training interventions have not been developed for hospitalists.

B.7 An evidenced-based communication skills training intervention designed for hospitalists is an effective and efficient way to improve end-of-life care in hospitals. The hospitalist model is the predominant mechanism for providing physician care to hospitalized patients. The term "hospitalist" was first used in 1996 to describe a group of physicians who focused on the care of medical inpatients.[85] The hospitalist model has become an increasingly common way of providing inpatient care; hospitalists are the most rapidly growing field in the history of American medicine.[51] Currently, 40% of U.S. hospitals have hospitalist programs, and 70% of hospitals with 200 or more beds have hospitalist programs.[52] Thus, when seriously ill patients are admitted to the hospital, hospitalists are likely to be their physicians.

The hospitalist movement represents an opportunity to improve care for hospitalized dying patients and their families.[86] By defining an expertise in inpatient clinical care and hospital systems, the hospitalist movement has improved health care utilization, performance on quality measures, and education.[87-91] The hospitalist professional society and education mechanisms effectively promote dissemination of information to hospitalist physicians across the country.[92] Incorporating end-of-life care into this defined expertise is an effective and efficient way to improve care of the dying.

Though communication between hospitalists and their patients and relatives has not been studied, it is likely that they, like other providers, do not use evidence-based communication skills because they lack training.[93] Preliminary evidence does show that hospitalists feel communication and end-of-life care are important. In a national survey, hospitalists rated communication with patients and relatives as the most important skill in their day-to-day work, more important even than clinical skills.[93] Because they frequently care for dying patients, hospitalists may already be more attuned to end-of-life issues than their non-hospitalist colleagues. A study of end-of-life care provided to hospitalized patients found that hospitalists were more likely than community physicians to document issues related to communication and symptom management.[94] Hospitalists care for seriously ill patients of varying acuity as general inpatients and in ICUs. As a result, they frequently communicate both with patients and their next of kin. The goal of my NPCRC research is to collect preliminary data that will inform the development of a communication skills training intervention for hospitalists. Because of the widespread use of the hospitalist model and its effective mechanisms for education and dissemination, this intervention has the potential to have a significant impact on end-of-life care for hospitalized patients.

C. INVESTIGATOR QUALIFICATIONS

C.1 Candidate. I am an internist and fellowship-trained palliative care clinician and researcher. Last year, I completed a two-year research and clinical Fellowship in Palliative Care and General Internal Medicine at the University of Pittsburgh with Dr. Robert Arnold. Subsequently, I joined the Palliative Care Program and Division of Hospital Medicine at the University of California, San Francisco (UCSF) as an Assistant Professor and clinician investigator. My area of expertise is patient-provider communication. I chose a faculty position at UCSF for the opportunity to study communication between physicians and seriously ill hospitalized patients and their families in the Division's well-established research program in hospital medicine. The goal of my research is to describe communication behaviours that address patients and relatives' informational and emotional concerns and therefore reduce anxiety. In my career as an independent investigator, I will design communication training interventions to teach providers evidence-based skills that reduce anxiety and help patients to cope with the stress of serious illness and hospitalization.

I have been involved in research since my undergraduate years at Reed College, where I received a BA and completed a thesis in Biochemistry and Cell Biology. I began college with an interest in psychology and human behaviour, and as I studied, I became more interested in analysing smaller and smaller levels, focusing first on biology and then cell biology and biochemistry. In my thesis, I investigated the intracellular signalling pathway of an autocrine growth factor on ovarian cancer cells. For me the scientific process was amazing - a means to discovering truths about the workings of the universe and of human beings that were hidden until their discovery by a researcher. I think it is this ability to describe the presently unknown that has kept me enthralled with research.

While I was in college my grandfather showed me the importance of integrating science and humanism and introduced me to palliative care. He was diagnosed with prostate cancer during my junior year and died a year later. The two of us spent hours on the phone talking about his diagnosis; it was so important to him to understand how the cancer worked and why it meant he was dying - for him this understanding was a comfort. I saw in a very personal way that my communication with him improved his quality of his life. At the end, my grandfather very much wanted to be in his own home, and we wanted to help him achieve this goal. However, we had no experiences with the practicalities of caring for someone - medications, bed baths, and bed pans - and found those things incredibly difficult. It was only with the help of a hospice team that we were able to keep him at home where he died peacefully; their knowledge and support gave us the skills and strength to fulfil my grandfather's wish.

I went to medical school at the University of California at San Diego wanting to combine my interest in discovery, the logic of science, and a desire to work with humans rather than cell cultures. During a rotation at San Diego Hospice, I found that palliative care was a way to realize all my interests and to help other families at a difficult and meaningful time the same way hospice helped ours. I continued my involvement with Palliative Care during medical school by doing elective clinical rotations at San Diego Hospice and leading a curriculum modification for the required medical student

hospice rotation. We published the evaluation of this curriculum, which showed improvement in knowledge, in *Academic Medicine.*

I completed residency in Internal Medicine at Duke University Medical Center. In addition to receiving first-rate clinical training, I met James Tulsky. Working with him and other palliative care researchers at Duke, I found kindred spirits and a career path. They also helped me develop independent research skills and interests. My personal and medical school experience with hospice showed me the potential values of end-of-life care and dying at home. However, in residency, I saw a significant number of hospice patients who were admitted to facilities at some point in their hospice course, and I became interested in why they transferred and how the transfer affected their care. I therefore designed and carried out a qualitative study of interviews with caregivers of home hospice patients who had transferred to a facility at some point in their hospice course. We published our results in the *Journal of Palliative Medicine.* We learned that though all the patients and caregivers valued care and death at home, circumstances arose that prevented this: an acute medical event, an uncontrolled symptom, imminent death, or the inability to safely provide care at home. Most interestingly to me, the caregivers did not necessarily regret the fact that the patients could not be kept at home. Satisfaction with care - at the transfer facilities and at home - was determined not by location but by interactions with health care providers: whether goals were clarified, treatment preferences followed, and care plans individualized. Methodologically, I gained experience in the grounded theory approach to qualitative analysis. Though I had heard concerns regarding its lack of reliability, I was struck by how clear our findings were after listening to the interviews. Further, I felt that our results added an important narrative understanding that a purely quantitative approach could not have elucidated. Finally, my interactions with the caregivers who were our subjects invested in me a sense of personal pride and responsibility that I had not felt in bench research; I felt that since the caregivers had invested their time in the study and had so many important things to say, that I had an obligation to convey their perspective to the best of my ability. My residency research project and work with Dr. Tulsky sparked my interest in communication, and this interest was magnified by my clinical experience in the hospital. I found communication about end-of-life issues frustrating, because I frequently felt our team and the patients and families polarizing and getting stuck in conflict about what to do. I was therefore so grateful for the communication skills I learned from Dr. Tulsky. As I used them, I saw how using specific techniques such as tending to emotions could de-escalate conflicts and help the medical team, patient and family be on the same page.

After residency, I travelled in Asia and worked as a Palliative Care Registrar (post-graduate medical trainee in Palliative Care) at the Sydney Institute of Palliative Medicine in Australia for 6 months. I sought out this position because I had the impression that Palliative Care in Australia was more sophisticated that in America. My work in Australia added an international perspective on Palliative Care and a breadth of clinical experience that I continue to value. However I mostly noticed the similarities. Patients and their families went through the same difficult decisions and experiences at the end of life. Doctors had similar problems negotiating about difficult treatment decisions and goals of care. While in Australia, I authored a chapter with Robert Arnold on Withholding and Withdrawing Life-Sustaining Therapies for the textbook Palliative Care: Core Skills and Clinical Competencies. It was an evidence-based chapter, so I had the opportunity to delve deeper into communication research. I found that most of the communication skills we recommend and teach are only beginning to be empirically studied - that many of them are based only on expert recommendations or patient and family satisfaction. During medical school and especially residency I had come to appreciate the importance of understanding the data or lack of data behind our interventions. Because of this appreciation, I felt it was urgent that we better understand how our communication influences patients and their families' health.

Thus, I set my course at the beginning of fellowship to study the health outcomes of palliative care communication. I began the two-year Fellowship in Palliative Care and General Internal Medicine at the University of Pittsburgh in summer of 2005. I chose this program because it allowed me to combine my interests in research and clinical palliative care, and for the opportunity to work with Robert Arnold, a national expert in communication theory, education, and research. I completed a Masters in Clinical Research in the K30-Funded Clinical Research Training Program, focusing on Effectiveness and Outcomes Research. For my fellowship research, I chose to study ICU patients and their families because of my strong clinical experience with seriously ill hospitalized patients and their families during residency. I focused on caregiver outcomes because my experience interviewing hospice caregivers impressed upon me the impact of our health care system and a patient's death on those who are left behind. My two primary projects were chosen to ensure I learned new skills in communication and research with seriously ill patients and relatives; they are described in detail in the Preliminary Studies section.

I was involved in multiple other scholarly projects during my fellowship, chosen both to allow me to learn more about palliative care and to develop new research skills. I honed my skills in education research and database analysis by studying survey data from the University of Pittsburgh School of Medicine about medical students' end-of-life care attitudes and knowledge. We that found students who had experience with death, either personally or during medical school, had more positive attitudes toward and better knowledge about end-of-life care. I presented this study as a poster at the Society of General Internal Medicine Annual Meeting in 2006, and am first author on the manuscript describing our findings, which we are currently preparing. In addition to the structured review of the ethical and communication issues associated with forgoing life sustaining treatment I completed for Palliative Care: Core Skills and Clinical Competencies, I contributed to another chapter, Withholding and Withdrawing Treatment for the textbook Palliative Medicine. I also wrote an evidence based review article about communication at times of transitions for *The Cancer Journal.*

During my fellowship, I also had the opportunity to develop skills in grant writing and presentation of my work. I wrote a grant on ICU relatives' mental health and decision-making preferences that was funded by the Institute for Doctor-Patient

Communication at the University of Pittsburgh (see preliminary results). I also received funding from the National Institutes of Health Clinical Research Loan Repayment Program for my fellowship research. I presented the results of my project about emotional expression in oncology patients as a poster presentation at the 16th International Congress on Care of the Terminally Ill in Montréal in 2006 and will as an oral presentation at the American Academy of Hospice and Palliative Medicine Annual Assembly in 2007. Manuscripts from my two main fellowship projects have been accepted in *Supportive Care in Cancer* and the *Journal of Critical Care*.

I have also had the opportunity to be involved with Oncotalk, an NCI-funded program run by Dr. Tony Back at the University of Washington that teaches communication skills to oncology fellows and faculty. During my fellowship, I co-taught the Oncotalk course with Dr. Arnold to the oncology fellows at the University of Pittsburgh. This year, I was chosen as one of five Junior Palliative Care faculty members to participate in the program as a simulated oncology fellow. In this role, I have gained direct experience in the teaching methods used in Oncotalk, and have built relationships with experts in communication research and palliative care colleagues from around the country. This is important to me because I will use this knowledge base and skill to develop communication skills training interventions.

I began my faculty position at UCSF in September 2007. I spend 75% of my time doing research, and 25% teaching and attending on the palliative care consult service and inpatient medical service. I have continued projects I began at the University of Pittsburgh (see Preliminary Studies section), identified research mentors at UCSF, and designed a program to study hospitalist communication (see Research Design and Methods Section).

In summary, I have had the good fortune to receive excellent mentoring, training, and research experience. I have been successful in designing and conducting research, obtaining grant funding, and publishing my work. I am committed to a career as a palliative care researcher, and feel that in this role I can improve the quality of care for seriously ill hospitalized patients and their families.

C.2 Career Development Plan. I will have 75% protected time for the activities described in this proposal (Table 1). Through this research project and the excellent mentorship team and research environment I have available to me, I will develop the skills I need to become an independent investigator in communication and anxiety in seriously ill hospitalized patients and their relatives. I have identified particular gaps in my training to date, and planned activities to fill these gaps. These skills and how I will attain them are described in 3 career development objectives correlated with the 3 study aims. The timeline of when I will accomplish the career development and study goals is shown in Figure 2.

Table 1: Percent Activity during NPCRC Funding

Career Development Activities	Year 1	Year 2
Research	50%	55%
Coursework	10%	5%
Directed Readings	10%	10%
Seminars, Meetings	5%	5%
Subtotal	75%	75%
Other Activities		
Clinical	20%	20%
Teaching	5%	5%
Subtotal	25%	25%

1. Study Aim: Describe the frequency with which hospitalists use literature-recommended skills to elicit and respond to seriously ill hospitalized patients or their next of kin's informational and emotional concerns in end-of-life discussions.

Career Development Objective: Learn to code medical conversations using combined qualitative and quantitative methods.

The cornerstone of studying medical communication is the ability to analyze medical conversations. This is done through two primary methods: qualitative and quantitative. Qualitative methods are useful for developing insight into the process and content of communication.[95] Quantitative measures of communication are essential because they allow communication behaviors to be used as predictors for health outcome measures.[96,97] I have preliminary experience with codebook development and use from my fellowship projects, however lack the skills to independently design, test, and apply a codebook. I will obtain these skills through coursework as well as guided study and analysis with Drs. Arnold and Tulsky, who are national experts in the field of health communication. They will guide my study of codebook development[95,98,99] and will assist me in codebook development and coding of the recorded communication in the research portion of the project. As part of my meetings with them, I will write a review paper summarizing the different techniques used to analyze communication and their strengths and weaknesses. I will meet with Drs. Arnold and Tulsky by telephone on an at least monthly basis for the duration of the award and will communicate by email as necessary. I will visit them at their institutions one week per year for the duration of the award. I will take the course *Qualitative Research Methods* through UCSF's Clinical and Translational Science Institute (CTSI). My Co-Mentors will also provide their expertise, from stress and coping and palliative care perspectives, in the qualitative analysis of the audio-recordings.

2. Study Aim: Describe the patients or next of kin's anxiety levels before and after the hospitalist end-of-life discussion as well as how well the hospitalist addressed their concerns, their trust in the hospitalist, and their satisfaction with the hospitalist's provision of information and emotional support.

Career Development Objective: Increase my understanding of coping and anxiety theory and research methods in seriously ill patients and their family members.

The goal of my research is to understand how, through communication, health care providers can help patients and their families to cope with the stress of serious illness and hospitalization. To do this, I must first understand the processes and determinants of stress and coping. Dr. Folkman is an expert in stress and coping research and theory, and is internationally recognized for her contributions to the field. She will guide my career development for this objective through directed readings. The readings will focus on current models of stress and coping and their strengths and weaknesses. We will study the various ways that researchers have described coping and measured anxiety, and will review the literature about techniques to decrease anxiety and enhance coping. Finally, we will work together to develop a model of stress and

coping in the hospital, and how providers can minimize stress and enhance coping. Dr. Pantilat will provide input from his position as an expert in hospital-based palliative care. I will summarize what I have learned in an article describing our model and its implications.

3. Study Aim: Analyze the association between hospitalists' communication skill use and patients or next of kin anxiety, unaddressed concerns, trust, and satisfaction.

Career Development Objective: Gain experience with statistical modeling techniques to measure health-related outcomes in hospitalized patients and their relatives.

For this study and my future research, I will need to lead analyses that describe associations between quantitatively coded communication and health outcomes. Though I completed coursework in linear and logistic regression for my Master's in Clinical Research, I lack hands-on experience in statistical modelling. I will achieve this direct experience through guided analysis of my study data with Dr. Auerbach and through analysis of his data when a larger dataset is required for my learning. I will learn about and work with techniques such as regression methods for the analysis of cohort data, including the generalized linear model and generalized estimating equations (with emphasis on logistic and Poisson regression), and Cox regressions with time-dependent covariates. I will take the course *Biostatistical Methods for Clinical Research III* through UCSF's Clinical and Translational Sciences Institute, which covers multivariable statistical analysis including analysis of repeated measures and clustered data. I will also have the expertise of the statisticians at the CTSI who will assist me with statistical analysis and design of future studies.

University Seminars: I will attend and present my work at the weekly Hospitalist meeting, the bi-weekly Palliative Care meeting, and the monthly Hospital Medicine research in progress meeting. These seminars will allow me to develop skills in presenting research and will provide me with the opportunity to receive feedback from experienced faculty from different disciplines. I will also participate in seminars offered through the Clinical and Translational Sciences Institute. For example, as I prepare my K series grant application, I will participate in the *Grant Writing Workshop on Mentored Career Development Awards.*

National meetings: As my work relates to the fields of palliative care, health communication, and hospital medicine, I will submit my work for presentation at meetings of those professional societies: American Academy of Hospice and Palliative Medicine, American Academy on Communication in Healthcare, and Society of Hospital Medicine.

Figure 2. Timeline

	Year 1 NPCRC Funding								Year 2 NPCRC Funding															
	2008								2009												2010			
	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J
Study Activities																										
IRB submission																										
Study organization																										
Record discussions																										
Develop + test codebook																										
Code discussions																										
Career Development																										
Anxiety and coping																										
Coding communication																										
Modeling + analysis																										
Publication + Funding																										
K-23 preparation																										
Analysis + manuscript prep																										

C.3 Mentorship Team. I have been fortunate to develop a mentorship team comprised of national experts in stress and coping, communication, and research in the hospital (see letters of support). All members of the team have extraordinary dedication to their fields and to the success of young investigators.

Mentor: Susan Folkman, Ph.D., Director of the Osher Center for Integrative Medicine and Osher Foundation Distinguished Professor of Integrative Medicine at UCSF. She is internationally recognized for her theoretical and empirical contributions to the field of psychological stress and coping. Her work since 1988 has focused on stress and coping in the context of HIV disease and other chronic illness, especially on issues having to do with caregiving and bereavement. Dr. Folkman received her PhD from the University of California at Berkeley in 1979, where she remained as a research psychologist until coming to UCSF in 1988. Since 1990, she has also been Professor of Medicine at UCSF, and from 1994 until 2001 she was Co-Director of the UCSF Center for AIDS Prevention Studies (CAPS). In 1997, she was awarded an honorary doctorate from the University of Utrecht, The Netherlands, for her contributions to coping theory and research. Her research has been supported by grants from the National Institute of Mental Health (NIMH), the National Institute of Nursing Research (NINR), and the National Center for Complementary and Alternative Medicine (NCCAM). From 2000-2004 she served on the NIH/NIMH National Advisory Mental Health Council. She was a member of the Institute of Medicine panel on CAM use in the US, and from 2004-2007 was Chair of the Consortium of Academic Health Centers for Integrative Medicine. She is a Fellow of the American Psychological Association and the American Psychological Society and has chaired or been a member of various NIH proposal review committees, served on Institute of Medicine and NIH workgroups, and was co-chair of the American Psychological Association task force on ethics in research with human participants. She has mentored many junior faculty researchers in the area of stress, coping, and chronic illness, with NIH-funded K and other types of awards. In 2000, she received the UCSF/AIDS Research Institute George Sarlo Award for Excellence in Mentoring. As my primary research mentor, Dr. Folkman will meet bi-weekly, or

more frequently as needed, so that she can supervise my training in stress and coping research, and guide me regarding project design and analysis as well as career development. Drs. Folkman, Pantilat, and I will meet together on a quarterly basis to coordinate my mentoring.

Co-Mentor: Steve Pantilat, M.D., F.A.C.P., Professor of Clinical Medicine in the Department of Medicine at the University of California, San Francisco. He is an expert in the provision of Palliative Care in the hospital setting and on communication about end-of-life issues in seriously ill hospitalized patients and relatives. He directs UCSF's Palliative Care Service and Palliative Care Leadership Center, one of 6 prestigious programs funded by the Robert Wood Johnson Foundation to teach teams from hospitals across the country how to establish palliative care programs in their institutions. Dr. Pantilat has been a leader of hospitalist movement since its inception, serving as one of the first eight presidents of the Society of Hospital Medicine. He was a Soros Foundation Project on Death in America Faculty Scholar, and a recipient of a K-23, Mentored Patient-Oriented Research Career Development Award from the National Institute on Aging. Dr. Pantilat's research focuses on improving end-of-life care in hospitals and on palliative care education. He has published and lectured widely in the areas of hospitalist care, inpatient-outpatient physician communication, and palliative care. He is currently involved in several projects focused on end-of-life care including evaluating a palliative care curriculum for medicine residents and hospitalist trainees at UCSF, evaluating a palliative care inpatient consultation service, and determining the prevalence of palliative care services in California. Dr. Pantilat, along with colleagues at UCSF, is a co-editor of an ongoing series in JAMA focused on improving end-of-life care titled "Perspectives on Care at the Close of Life." He has mentored many junior faculty members over the course of his Palliative Care leadership at UCSF. As a Co-Mentor, Dr. Pantilat will be my career mentor and provide specific expertise in hospital-based palliative care. He will advise me in the analysis of the recorded conversations and the development of a model of stress and coping in terminal illness in the hospital. We will meet every 2 weeks, or more frequently as required.

Consultant: Andrew Auerbach, M.D., M.P.H., Associate Professor of Medicine in Residence at UCSF. His area of expertise is assessments of patient outcomes in different systems of care, with a special interest in the hospitalist model. He received clinical research training at Harvard, and joined the UCSF in 1998 as the first clinician-researcher to focus on the hospitalist model. Dr. Auerbach was the UCSF PI for a multicenter study of Hospitalist systems, and currently is PI for studies examining associations between Hospitalist practice characteristics and patient outcomes, as well as the relationships between surgical volume, care quality, and patient outcomes. He is Associate Director of the UCSF General Internal Medicine Research Fellowship, teaches research methods, and mentors junior research faculty in the Division of General Medicine and Hospital Medicine. His role in my project will be to lead my research and career development activities related to outcomes research, specifically multivariable modeling. We will meet on a monthly basis, or more frequently if necessary.

Consultant: Robert Arnold, M.D., Professor of Medicine, Director of the Institute on Doctor-Patient Communication, and Chief of the Section of Palliative Care and Medical Ethics at the University of Pittsburgh. He is an accomplished researcher and educator regarding patient-provider communication and death and dying. Dr. Arnold was a Soros Foundation Faculty Scholar on the Project on Death in America who focused on teaching physician leaders how to teach other physicians to better communicate regarding ethical, psychosocial, and existential issues at the end of life. He is currently a co-principal investigator on a National Cancer Institute-funded grant to develop a structured curriculum on doctor-patient communication for oncology fellows and to explore the barriers to communication, and received funding from the National Palliative Care Research Center to develop an educational intervention to improve critical care medicine fellows' communication skills. Dr. Arnold was my research mentor during my fellowship. He will continue to advise me on overall project design and career development, and advise research and career development of coding recorded conversations. I will have telephone conversations on an at least monthly basis, and I have Division funds for yearly travel to Pittsburgh.

Consultant: James Tulsky, M.D., Professor of Medicine, and Director of the Center for Palliative Care at Duke University. Dr. Tulsky was a Project on Death in America Faculty Scholar, a Robert Wood Johnson Generalist Physician Faculty Scholar, the recipient of a VA Health Services Research Career Development Award, and was awarded the Presidential Early Career Award for Scientists and Engineers (PECASE) from the White House Office on Science and Technology. He is PI of an NCI funded study of Communication in Outpatient Oncology Encounters after which the codebook used for this research will be modeled. He has extensive research experience analyzing audio-recorded clinical encounters and conducting communication teaching interventions with physicians. He has co-facilitated a week-long course on communication at the end of life for the American Academy on Communication in Health Care, facilitates weeklong retreats for oncology fellows and is a consultant to the project, "Improving clinician-family communication in the ICU," (PI: J. Randall Curtis, MD, MPH). Dr. Tulsky was my research mentor during my residency, and during my fellowship I worked with him on a sub-project of his study of Outpatient Oncology Encounters. He will continue to guide my career development and research about project design and coding recorded conversations. Dr. Tulsky and I will have telephone conversations on an at least monthly basis, and I have Division funds for yearly travel to Durham.

C.4 Environment and Institutional Commitment. Since September 2007, I have been an Assistant Professor in the Palliative Care Program and Division of Hospital Medicine at the University of California, San Francisco (UCSF). UCSF provides an excellent environment for my career development and research, as described below. The letters from Dr. Talmadge King, Chair, Department of Medicine, Dr. Robert Wachter, Chief, Division of Hospital Medicine, and my Co-Mentors, Drs. Susan Folkman and Steve Pantilat affirm the institutional commitment to my project and career. I will have 75% protected time for research for the duration of the award. I have funds available through the Division for data

analysis and a full time research assistant in Year 1 for enrollment and data collection. Data management and statistical support will be provided by through the Biostatistics, Research Ethics, And Design Program in UCSF's Clinical and Translational Science Institute (CTSI). The Division of Hospital Medicine will fund travel for yearly site visits with grant consultants, and provides discretionary funds to cover travel to national meetings and for educational resources.

The UCSF School of Medicine is ranked 4th in NIH funding. The Division of Hospital Medicine has been an academic leader of the hospitalist field since it began. Dr. Wachter, the current Division Chief, coined the term hospitalist in 1996. The UCSF group was the first to publish a peer-reviewed paper about the positive impact of the hospitalist model on clinical care. UCSF has continued to be an academic leader of the hospitalist movement, studying its effect on outcomes, quality of care, and safety. The Division has a history of success in mentoring junior faculty, who are now leaders in their areas of research within hospital medicine. Members of the Division have been successful in receiving grant funding for career development awards and R01 grants from the NIH, in addition to funding from private foundations. I will have access to clinical research infrastructure that has been established within the School of Medicine and the Division. Relevant to my current research, I will collaborate with Dr. Andrew Auerbach, who is currently conducting outcomes research in the hospitalist service, and with Dr. Douglas White, a colleague of in the Division of Critical Care Medicine, who has been audio-recording and coding family meetings in the ICU.

The Palliative Care Program was founded and continues to thrive within the Division. UCSF is a National Palliative Care Leadership Center, offering expertise and training to other programs. The Moffitt-Long hospital consult service, on which I attend, offers palliative care consultation service and inpatient palliative care. In addition to providing clinical services, the Program is active in research about its effect on symptom control and health care utilization, and leads education about palliative care for medical students, residents, and attendings.

The NIH-funded CTSI is of particular relevance to my training. UCSF is one of the first 12 institutions to be part of the NIH's national clinical and translational science consortium, which has a charter to transform clinical and translational research. Within the CTSI, I have access to resources for Research Design, Biostatistics, Ethics, Data Management and Analysis. The CTSI offers coursework and workshops, and runs the K-12 career development award program.

UCSF also provides resources for the dissemination of my NPCRC research. The goal of my NPCRC research plan is to provide data to develop and test a communication skills training intervention for hospitalists. For this, I will work with the UCSF Clinical Skills Center, which performs training and evaluation with standardized patients, and has the resources and experience for all stages of educational intervention development and evaluation. For testing this intervention, the Division has both national and local ties with academic and community hospitalist programs that will facilitate the testing of my intervention at these sites.

D. PRELIMINARY STUDIES

My fellowship research projects have prepared me to conduct this project, giving me experience with analysis of medical communication and conducting research in the hospital with family members of seriously ill patients.

D.1 Analyzing recorded medical conversations. In order to gain skills analyzing medical conversations and to develop insight into the methods of evaluating communication skills training interventions, I chose to become involved in the Studying Communication in Oncology Patient Encounters (SCOPE) project.[96] SCOPE is a multi-center NIH-funded randomized controlled trial of a novel CD-ROM educational intervention for oncologists. Dr. James Tulsky, my residency mentor, is the PI, and Dr. Robert Arnold, my fellowship mentor, is co-PI. The randomized controlled trial I plan to evaluate my educational intervention will be modeled after SCOPE. Patients whose visits were recorded were identified through oncologists enrolled in the study. Patients were approached if their oncologists said they would not be surprised if they were admitted to an ICU or died within 1 year. In the pre-intervention phase of the study, 415 visits that 281 patients with advanced cancer made to their oncologists at 3 US Cancer Centers were audio-recorded to determine the frequency with which oncologists used evidence-based communication skills before the intervention. An evidence-based code-book[30,54] was developed to code specific oncologist skills including eliciting and responding to informational and emotional concerns.

My sub-project within SCOPE was to describe how patients with advanced cancer verbally express negative emotion to their oncologists. Cancer patients have high levels of distress, yet oncologists often do not recognize patients' concerns. The goals of this project was to present a guide for clinicians to identify distress in their own patients. Using qualitative methodology, we coded for verbal expressions of negative emotion, identified words patients used to express emotion, and categorized emotions by type and content. To reliably identify instances of negative emotional expression and code each by type and topic, we developed a standardized, explicit coding process.[95,99] Based on previous work,[26-28] we defined negative emotional expression as any instance where a patient used words to describe a negative emotional state in the past, present, or future, for example, "I'm *anxious* about this test" or "I was feeling *depressed.*"

We found that patients verbally expressed negative emotion in 17% of the visits.[54] The most commonly used words were: "concern," "scared," "worried," "depressed," and "nervous." Types of emotion expressed were: anxiety (46%), fear (25%), depression (12%), anger (9%), and other (8%). Topics about which emotion was expressed were: symptoms and functional concerns (66%), medical diagnoses and treatments (54%), social issues (14%), and the health care system (9%). Though all patients had terminal cancer, expressed negative emotion overtly related to death and dying only 2% of the time.

Because anxiety and fear are related to the possibility or threat of a negative event,[71,72] the fact that these were the predominant emotions expressed indicates that patients were concerned about the future and uncertainty (e.g., prognosis).

Oncologists could lessen this anxiety and fear by giving information and expressing empathy.[73] Further, the fact that only 17% of visits contained a direct expression of distress is concerning given the high rates of reported distress in cancer patients.[63] In a separate analysis of the recordings, oncologists responded empathically to patients' expressions of emotion less than 1/3 of the time.[30] Because past research has shown that physician behaviors influence patients' disclosure of concerns and distress,[53,100] we hypothesized that patients might have disclosed more concerns if their oncologists had expressed empathy more frequently. The SCOPE intervention should increase the oncologists' use of evidence-based communication skills. Thus, this hypothesis can be tested in the post-intervention phase.

D.2 Anxiety and decision-making preference in relatives of ICU patients. Because my career focus is anxiety and communication about serious illness in the hospital, I designed my primary fellowship project to gain experience in this area. I designed and conducted a preliminary study to assess symptoms of anxiety and depression in relatives of ICU patients. I chose to study decision-making preference because its relationship with anxiety in ICU relatives had not been investigated.

The design was a cohort study of relatives of ICU patients in a quaternary care teaching hospital, the University of Pittsburgh Medical Center. We recruited adult relatives of 50 patients from medical, cardiac, neurologic, surgical, trauma, cardiothoracic, and transplant ICUs (total 11 units, 150 beds) whose attending physician anticipated an ICU stay of more than 2 days. For each patient, we enrolled the relative who was identified by the patient's family and medical team as the primary decision maker. While the patient was in the ICU, we administered the Hospital Anxiety and Depression Scale (HADS)[101] to measure symptoms of anxiety and depression and the Control Preference Scale[102] to assess relatives' preferences for involvement in decisions about patients' medical care. Because we were curious about the long-term effects of the relative's experience in the ICU, we followed them for 6 months after the initial interview, conducting interviews at 1 and 6 months by telephone. At the 1-month interview, we conducted in-depth interviews with each relative, to gain insight into their experiences in the ICU, their experiences with decision-making, and how they felt the experience and decisions they made affected them. At the 1 and 6 month interviews we re-administered the HADS, and at the 6-month interview we administered the Impact of Event Scale (IES)[103] to assess post traumatic stress symptoms and the Inventory of Complicated Grief (ICG).[104]

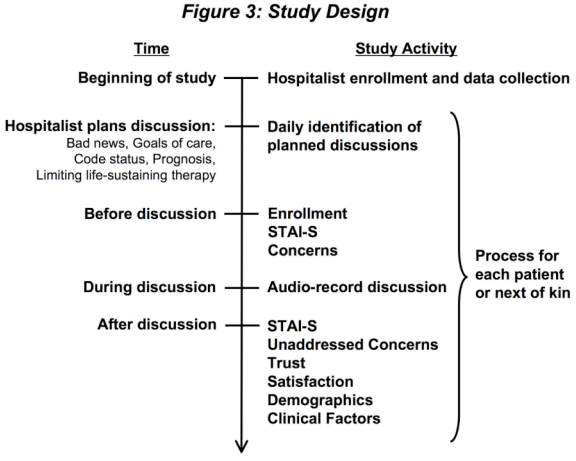
Our consent rate was 63%. We conducted 39 (78% retention) 1-month and 34 (68% retention) 6-month interviews. While the patient was in the hospital, 42% (n=21) of relatives had symptoms of anxiety and 16% (n=8) had symptoms of depression.[105] All relatives wanted some role in decisions and most (58%, n=28) preferred to have equal responsibility to the doctor; 25% (n=12) preferred to have more responsibility than the doctor, and 17% (n=8) preferred that the doctor have more responsibility. Of relatives who preferred to have less responsibility, 88% had symptoms of anxiety and 50% had symptoms of depression, $p<0.007$ and $p<0.026$ compared with other relatives. We are currently analyzing the 1 and 6 month HADS, IES, and ICG and performing a qualitative analysis[106] of the semi-structured interviews. These analyses will provide insight into the stressors relatives of seriously ill patients experience in the hospital, and how providers can help them to cope with the experience.

We concluded first that enrollment and retention of relatives of ICU patients in a research study is feasible. Second, relatives had levels of anxiety and depression that were higher than those of the general population, and similar to those of seriously ill patients.[107] Third, we found that relatives who preferred to have less responsibility in decisions were more likely to be anxious and depressed. We hypothesize that relatives who preferred to be less involved in decision-making experienced a mismatch between their preference and their actual role in decision-making, because of the emphasis on autonomy in the American medical system.[108] Mismatch between preferences and actual role in decision-making has been correlated with anxiety in cancer patients.[109,110] Without further studies, however, we cannot tell whether the decision-making mismatch caused the anxiety or whether their anxiety led them to prefer less responsibility in decisions. In either case, our results underscore the importance of eliciting and accommodating surrogates' decision-making preferences, and communicating with empathy.[29,111] Once I establish a research program in end-of-life communication on the hospitalist service at UCSF, I will conduct studies of the impact of decision-making preference on anxiety in patients and their relatives.

E. RESEARCH DESIGN AND METHODS

E.1 Overview of Study Design. This is a preliminary study designed to assess feasibility and generate effect sizes that will be used to design and test a communication skills training intervention. Figure 3 outlines the design. I will audio-record discussions that hospitalists have about bad news, goals of care, code status, prognosis, or limiting life-sustaining therapies with seriously ill hospitalized patients or their next of kin. Before the discussion, I will obtain consent from the patient or next of kin, assess their level of anxiety with the state portion of the State Trait Anxiety Inventory (STAI-S),[3,4] and record their concerns.[25] I will then audio-record the discussion and analyze the frequency with which hospitalists use communication skills to assess and meet informational and emotional concerns: eliciting concerns and responding to cues.[25-28,53,112] After the discussion, the patient or next of kin will complete the STAI-S and a survey to assess how well the hospitalist addressed their concerns, the degree to which they trust the

Figure 3: Study Design



hospitalist,[113,114] how well the hospitalist provided information and emotional support,[1,7,8,41] and demographic and clinical factors. I plan to audio-record 50 discussions during the first 12 months of NPCRC funding. A timeline of reserach activities is included in Figure 2 in the Career Development Plan section.

E.2 Study Setting. I will recruit hospitalist physicians and seriously ill patients or their next of kin from the inpatient medical service at UCSF's Moffitt-Long Hospital, an academic tertiary care referral center and community hospital for the surrounding neighborhoods. The hospitalist service provides physician care for all of the approximately 4000 medical patients who are admitted to Moffitt-Long each year. A significant number of these patients have serious life-limiting illness. Five percent die during their admission, 10% require prolonged hospitalization (≥14 days), 13% require ICU care during their hospital stay, and 30% have functional impairment requiring skilled nursing care at discharge. The Intensive Care Units (ICUs) at Moffitt-Long are "open", i.e. hospitalists have primary responsibility for all medical patients in the ICU. Thus, our study will include both general medical and ICU patients.

E.3 Participants. Study participants will be hospitalist physicians who attend on the inpatient medical service at Moffitt-Long Hospital and seriously ill patients or their next of kin with whom a hospitalist plans to discuss end-of-life issues. I chose to study communication between both patients and their next of kin because this most accurately reflects inpatient medical practice. Though patients and their family members often have different informational and emotional concerns, I hypothesize that the process by which physicians assess and respond to these concerns should be the same for patients and their next of kin. Similarly, the physician's ability to address information and emotional concerns should impact anxiety in both patients and their next of kin. I will only include patients and relatives who are 18 years or older.

E.3.a Hospitalist physicians. I will recruit all 36 physicians from the UCSF Division of Hospital Medicine who attend on the Moffitt-Long service. All of these physicians completed residency training in Internal Medicine and specialize in the provision of inpatient medical care. They are supportive of this study, and have committed to participating and assisting with patient and next of kin recruitment. Seven attending physicians attend on the service per month. To ensure variability in hospitalist skill, I will record no more than three discussions per hospitalist. The hospitalists deliver care as the attending physician supervising a team of medical students and Internal Medicine interns and residents. Though trainees lead some discussions, I will only record discussions that the attending physicians lead because I am interested in the skills of physicians who have completed their training.

E.3.b Seriously ill patients. To identify seriously ill patients, hospitalists will be asked to identify patients on their service whose death or admission to the ICU during the next year "would not be a surprise." UCSF hospitalists estimate that half of their patients on the Moffitt-Long service fit this definition. This method has been used successfully to capture communication about the transition from curative to palliative care in oncology patients.[96] As physicians generally overestimate survival,[115] it is likely to accurately identify seriously ill hospitalized patients. The hospitalist will also be asked whether he or she plans to communicate primarily with the patient or his or her next of kin. If the hospitalist plans to communicate primarily with the patient, the patient will be recruited to participate in the study. I will only record one discussion per patient or next of kin.

E.3.c Patient's next of kin. If the patient is unable to participate in a discussion of his or her care, and the hospitalist plans to communicate primarily with the patient's next of kin, the next of kin will be recruited to participate in the study. For study purposes, the next of kin will be the family member with whom the hospitalist plans to have the discussion. If multiple family members plan to participate in the discussion, the hospitalist will identify who they consider to be the next of kin. One of the goals of our study is to describe with whom hospitalists have discussions about end-of-life issues. Thus, I will recruit patients and next of kin sequentially and will not attempt to record a pre-set number of conversations with each.

E.3.d Eligible discussions. I will record discussions between participating hospitalist physicians and seriously ill patients or their next of kin where the hospitalist anticipates discussing breaking bad news, goals of care, code status, prognosis, or limiting life-sustaining therapies.[112] Discussions between hospitalists and patients or next of kin whose primary language is not English will be recorded if a translator is present. A colleague of mine in Pulmonary and Critical Care at UCSF, Dr. Douglas White, has audio-recorded 56 family meetings about ICU patients at Moffitt Long. Forty percent of these meetings are lead by hospitalists, and his consent rate is 72%. On average, he has been able to record 3.7 meetings per month. I should be able to record a similar number of conversations: though Dr. White is recording meetings led by other physicians in addition to hospitalists, I will record discussions on the general medical wards in addition to the ICU. If Dr. White's study is still underway when I begin recording, we will coordinate so we do not duplicate recruitment. My hospitalist colleagues estimate that they lead 1-5 (average 3) discussions per week while on the Moffitt Long service. Assuming a consent rate of 50-70%,[26,96,112] I will be able to record my goal of 50 discussions in 12 months.

E.4 Recruitment and Data Collection. To minimize the time between anxiety measurement and discussion recording, I aim to recruit and complete data collection for each patient or next of kin participant within 12-hours. On the Moffitt Long service, hospitalists arrange discussions about breaking bad news, goals of care, code status, prognosis, or limiting life-sustaining therapies each morning for the afternoon. We will identify and enroll eligible patients and next of kin and administer a pre-discussion survey in the morning. In the afternoon, we will record discussions and administer post-discussion surveys immediately afterward. Dr. Douglas White successfully used this protocol to record ICU family meetings with hospitalists on the Moffitt Long service. My hospitalist colleagues and I can attest to its feasibility.

E.4.a Hospitalist physicians. I will recruit attending hospitalist physicians as a group at the beginning of the study. At that time, a 15-minute survey will be administered to collect physicians' demographics, education, and attitudes about communication with seriously ill patients and their relatives.

E.4.b Identification of anticipated discussions. When the participating physicians are attending on the inpatient medical service, a research assistant or I will contact them each morning to ask whether they anticipate leading discussions about breaking bad news, goals of care, code status, prognosis, or limiting life-sustaining therapies with either seriously ill patients or their next of kin that afternoon.

E.4.c Patient and next of kin recruitment. A research assistant or I will meet with the patients and next of kin identified by the hospitalists each morning to explain the study and enroll them. We will enroll patients and next of kin sequentially until we reach my goal of 50 recordings. For use in planning future studies, I will record the consent rate and the reason patients and next of kin do not consent.

E.4.d Pre-discussion survey. Patients and next of kin who consent to participate in the study will complete the STAI-S and list their concerns immediately after they are enrolled. This survey will take approximately 10 minutes to complete. The pre-discussion survey will be administered not more than 24 hours before the recorded discussion, though I expect that for most patients and next of kin it will be administered no more than 8 hours before the discussion. For planning future studies, I will record the numbers of hours before the recorded discussion that the pre-discussion survey was administered. I plan to collect most of our survey information from patients and next of kin in the post-discussion survey so that the study enrollment and pre-discussion survey does not delay the planned discussion with the hospitalist.

E.4.e Audio-recording of discussions. A research assistant or I will record the discussions with digital recorders. Details of the recording analysis are below. Recorders are have been used in multiple studies of communication regarding end-of-life care topics in outpatient and ICU settings.[26,96,112] Dr. White has successfully recorded family meetings in his study of ICU communication at Moffitt-Long Hospital. When done unobtrusively, taping clinical encounters does not affect patient satisfaction with the encounter or physician behavior.[116-118]

E.4.f Post-discussion survey. Immediately following the discussion with the hospitalist, the patient or next of kin will complete an approximately 20 minute survey to assess 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,[113,114] their satisfaction with the information and emotional support provided by the hospitalist during the discussion,[1,7,8,41] and demographic and clinical factors. In the event that I am unable to administer the post-discussion survey immediately after the recorded encounter, I will attempt to administer it at a later time. If I am unable to administer the post-discussion survey within 24 hours after the recorded discussion, I will consider that patient or next of kin's post-discussion survey missing. For planning future studies, I will track the amount of time between the recorded discussion and the post-discussion survey for each patient or next of kin.

E.5 Measurements. (Table 2) The primary study measures are the communication behaviors displayed by the hospitalist in the audio-recorded discussion and the patient or next of kin's level of anxiety after the discussion, adjusted for their pre-discussion anxiety.

Table 2: Outcome Measures

Primary Outcomes	Instrument	Time Collected
Hospitalist Communication Skills		
Eliciting informational concerns	Coded audio-recordings	During discussion
Eliciting emotional concerns	Coded audio-recordings	During discussion
Response to information cues	Coded audio-recordings	During discussion
Response to emotional cues	Coded audio-recordings	During discussion
Anxiety - Patient or Next of Kin	STAI-S	Before + after discussion
Secondary Outcomes		
Patient or Next of Kin		
Unaddressed concerns	Survey	Before + after discussion
Trust	1-item survey	After discussion
Satisfaction	6-items survey	After discussion
Demographics	Survey	After discussion
Clinical factors	Survey	Before discussion
Hospitalist		
Demographics	Survey	At enrollment
Education	Survey	At enrollment
Attitudes	Survey	At enrollment

E.5.a Primary measures from audio-recorded conferences. Conferences will be audio-recorded digitally. Recording and storage procedures are described in the data management section below. Though I will only record discussions in which the hospitalist plans to be the primary provider communicating with the patient or next of kin, I will note whether other providers are speaking frequently in the discussions. If I find that they are, I will create decision rules to classify discussions by whether other providers played a significant role or not and will control for that in analysis.

A codebook will be developed using an iterative process.[98,99] Two coders will participate in the code-development process, and only codes with kappa statistics >0.6 will be retained in the final codebook.[30,54,98] Twenty-percent of the conversations will be coded by two coders using the final codebook and kappa statistics will be calculated for all codes. I will code the audio-recordings directly using software developed by Dr. Tulsky and colleagues to code communication between oncologists and cancer patients in the SCOPE trial.[96] I am familiar with this software because I used it in my subproject of SCOPE.[54] Coding audio files directly has the advantage of preserving information that might be lost in transcription (e.g., tone of voice, sighs, crying) and also saves time and money by obviating the need for transcription. The coding interface has been used with ease and good reliability to code 400+ recorded oncology patient encounters. The codebook will be based on the codebook developed for Dr. Tulsky's study and the communication literature (see Background and Significance). The planned codes, organized by skill category, are shown below.

E.5.a.1 Eliciting Concerns. Patients with unaddressed concerns are more distressed than those whose concerns are resolved.[37-40] Patients do not disclose most of their concerns to providers.[24,25,53] The following codes will be developed to measure the frequency with which hospitalists use skills that increase disclosure of informational and emotional concerns:

Number and type of concerns elicited – Disclosure of concerns has been shown to decrease anxiety.[24,40] Disclosed concerns will be categorized as informational or emotional; past studies have found that physicians attend better to informational than to emotional concerns.[26,27]

Open- and closed-ended questions – Open-ended questions increase disclosure of concerns.[24,40,53,100] Questions asked by the hospitalist will be coded as open- or closed-ended and the ratio calculated for each discussion.[34] Questions will also be categorized by whether the hospitalist asks about informational or emotional topics. Past studies have shown that physicians were more likely to discuss bio-medical than emotional issues.[119]

Hospitalist / patient or next of kin speech time – Lower percentage of provider speech time increases disclosure of concerns and has been correlated with satisfaction in ICU family conferences.[7,53,100]

Total discussion time – It would also follow that total time of the discussion might impact disclosure of concerns, thus, I will include it as a variable.

E.5.a.2 Responding to Informational Cues. Clarity and completeness of information is correlated with anxiety in oncology patients and relatives of ICU patients.[41,57] The following codes will be developed to measure how the hospitalists respond to informational cues:

Informational cues from patient or next of kin – Instances where patients or next of kin give cues for information will be coded. For example, "I really don't know much about the different treatments".[26]

Hospitalist response to informational cues – Responses to informational cues will be coded as positive if they provide information about the topic identified in the cue and provide reasonable coverage of the issue.[26] The ratio of informational cues to positive hospitalist responses will be the measure of response to emotion.

E.5.a.3 Responding to Emotional Cues. Empathic responses to emotion have been shown to decrease anxiety.[1,74] The following codes will be developed to measure how the hospitalists respond to emotional cues:

Emotional cues from patient or next of kin – Instances where patients or next of kin directly state emotions they are experiencing or have experienced in the past will be coded. For example, "I'm *worried* about my dad's leg," "I was so *angry* that that test wasn't done."[54] These statements are called empathic opportunities or emotional cues, because they present an opportunity for the provider to express emotional support.[26-28,96]

Hospitalist response to emotional cues – Hospitalist responses to each instance of emotional expression by patients or next of kin will be coded as positive or negative.[26-28,96] Positive responses are empathic; they express understanding of the emotion and encourage its expression. The mnemonic NURSE has been used to describe these statements: naming, understanding, showing respect, expressing support, and exploring.[98] The response is coded as negative when it does not acknowledge the emotion and inhibits further disclosure about it: inappropriate humor, changing the subject, inadequately acknowledging the emotion.[27] The ratio of emotional cues to positive hospitalist responses will be the measure of response to emotion.

E.5.b Primary patient or next of kin measures. The primary outcome measure will be the patient or next of kin's level of anxiety after the discussion with the hospitalist, adjusted for their pre-discussion level of anxiety. I will use the State portion of the State Trait Anxiety Inventory (STAI-S), a 20-item 1-domain instrument that reliably measures state (temporary) anxiety. I chose the STAI-S because it is responsive to moment-to-moment changes in the feeling of anxiety, and will thus be sensitive to changes in patients and next of kin anxiety level as a result of the discussion with the hospitalist. The STAI-S has been used to detect changes in anxiety as a result of physicians' verbal expressions of empathy.[1] It is reliable and valid in hospitalized medical patients.[3,4] Test-retest reliability for the STAI-S ranges between 0.16-0.62, consistent with its purpose to measure a transient state; alpha coefficients are 0.90 and higher.[3,4] The outcome of the STAI-S is a continuous variable ranging between 20-80, with higher scores indicating higher anxiety. To contextualize the scores, percentiles are available for medical in patients.[4,120] I will administer the STAI-S before and after the encounter with the hospitalist. The outcome variable will be the post-encounter STAI-S score, adjusted for the pre-encounter score.

E.5.c Secondary patient or next of kin measures.

Demographic characteristics. In the post-discussion survey, I will collect the study subject's (patient or next of kin) demographic information: age, gender, education, income, religion, race, and ethnicity. If the study subject is the patient's next of kin, I will record their relationship to the patient.

Clinical factors. In the post-discussion survey, I will collect: whether the patient has a current or past psychiatric diagnosis and the patient or next of kin's perception of the patient's health at the time of the discussion (relatively healthy, seriously but not terminally ill, or seriously and terminally ill).[6] Responses to this measure correlate with the clarity of physician communication about prognosis and treatment choices.[5,6] If the patient is terminally ill, I will ask how long this fact has been known. If the study subject is the next of kin, I will ask whether the next of kin has a current or past psychiatric diagnosis using an item in the post-discussion survey. I will record the patient's acuity (floor vs. ICU) at the time of the recorded discussion, and will collect the following information from the hospitalist: reason for hospital admission, primary life-limiting diagnosis, length of hospitalization, and whether the patient has been in the ICU at any time during their hospitalization.

Unaddressed concerns. Patients with unaddressed concerns are more distressed than those whose concerns are resolved.[37-40] Concerns will be assessed before the discussion by asking the patient or next of kin to list them on the pre-discussion survey. The prompt will be an open-ended question: "What problems and concerns do you want to talk about with the

doctor today?"[25] In the post-discussion survey, patients or next of kin will be asked, for each concern they identified on the pre-discussion survey, 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 primary care patients, trust in the physician predicts adherence to treatments, and satisfaction with their physician.[113,114] In the post-discussion survey, I will administer 1-item from an instrument validated in primary care patients to assess the patient or next of kin's trust in the hospitalist: "All things considered, how much do you trust this doctor?"[113,114] Patients or next of kin will be asked to rank their responses on a 1-10 scale: 0=Not at all to 10=Completely. This 1-item instrument has been used to assess cancer patient's trust in their oncologists.[96] I chose a 1-item instrument to limit subject burden and because I felt that longer instruments, which were developed for primary care populations, were not appropriate for hospitalists, who may only have a few interactions with the patient and next of kin.

Satisfaction with information and emotional support. In the post-discussion survey, I will evaluate the patient or next of kin's satisfaction with the information and emotional support provided by the hospitalist during the recorded discussion. I have chosen 6 items that in past studies correlated with either physician communication or patient or relative anxiety (Table 3). They were chosen to address the areas of interest in my conceptual model: eliciting and responding to informational and emotional concerns. I chose to use these 6-items instead of more general measures of communication,[113] or the compete instruments from which these items were taken. I had two reasons for this: 1) I wanted to assess specifically the patient or next of kin's perception of our areas of interest, and 2) I felt these items were most appropriate for evaluating the communication with a hospitalist, who may only have a few interactions with the patient and next of kin. Patients or next of kin will respond to each item on a 1-10 scale: 0=Not at all to 10=Completely.

Table 3: Items to assess satisfaction with information and emotional support

1. Enough time was allowed for information.[40]
2. The information was easy to understand.[40]
3. The information covered all the points of interest to me.[40]
4. This doctor listened to what I had to say.[6,7]
5. I felt this doctor cared about me.[1]
6. Overall, how well did talking with this doctor meet your needs?[6,7]

Relatives of ICU patients who disagreed with items 1-3 were more likely to have post traumatic stress symptoms 3 months after patients' death or discharge from the ICU.[41] The way ICU physicians communicated in family meetings correlated with the relatives' response to items 4 and 6.[7,8] Physician expression of verbal empathy correlates with agreement with item 5.[1]

E.5.d Secondary hospitalist measures. At enrollment I will collect from the hospitalists: age, gender, race, ethnicity, post-graduate year, subspecialty training, history of communication training, perceived importance of communicating with seriously ill patients and their family members, and perceived need for communication training.

E.6 Analysis

E.6.a 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. 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. As I will have up to three recordings from the same hospitalist, analyses of the discussion within each hospitalist will be conducted. I will perform separate analyses for patients and next of kin participants. The primary outcomes of the audio-recorded discussions are measured as counts or proportions and will be described with frequency tables and bar plots.

E.6.b Analysis plan by study aim.

Aim 1. Describe the frequency with which hospitalists use literature-recommended skills to elicit and respond to seriously ill hospitalized patients or their next of kin's informational and emotional concerns in end-of-life discussions.

In the codebook development process and in final coding, kappa statistics will be calculated to measure agreement between the two coders.[121] Only codes with kappa >0.6 will be retained in the final codebook, and kappa statistics will be reported for all final codes.[30,54] I will perform descriptive statistics for each code in the final codebook. Code variables will be expressed as frequency counts or proportions within each recorded discussion (e.g. the number of concerns elicited by the hospitalist, or the proportion of information cues to which the hospitalist responded positively). I will investigate associations between these measures and factors such as patient or next of kin demographics, patient clinical factors, and hospitalist demographics, education, and attitudes. Analyses will be based on Poisson regression models, and associations summarized by relative rates. Because of the small sample size, the number of simultaneous covariates in models will be limited to 1-2. As each hospitalist may lead up to three discussions, I will use generalized estimating equation (GEE) methods to account for potential within-hospitalist correlation between responses.

Aim 2. Describe the patients or next of kin's anxiety levels before and after the hospitalist end-of-life discussion as well as how well the hospitalist addressed their concerns, their trust in the hospitalist, and their satisfaction with the hospitalist's provision of information and emotional support.

I anticipate that patient or next of kin anxiety will increase after these discussions, because they are about difficult topics.[1] The primary outcome will be a continuous variable, the difference between the post-discussion and pre-discussion STAI-S scores. This measure of change will be calculated for each participant. I will describe its central tendency and variance, and will perform analyses for association with the following co-factors: whether the study subject was the patient or next of kin, patient or next of kin demographics, and patient clinical factors. Parallel analyses will be performed for the other outcomes. Analyses will be based on analysis of variance and covariance regression models, possibly using transformed

versions of the outcomes, with results summarized using regression coefficients and associated 95% confidence intervals, and hospitalist-level clustering handled using GEE methods. As described for Aim 1, the small sample size will limit the number of covariates that can be considered in a given model.

Aim 3. Analyze the association between hospitalists' communication skill use and patients or next of kin anxiety, unaddressed concerns, trust, and satisfaction.

Hypothesis: Because I am recording stressful discussions, anxiety will increase from the pre-discussion to post-discussion measurement. However, when hospitalists use literature-recommended skills to elicit and respond to informational and emotional concerns, patients and next of kin will have a smaller increase in anxiety.

I will measure the association between each of the communication codes and the STAI-S change scores described above for Aim 2. Analyses will be based on regression methods as described for Aim 2, with covariates based on measures of hospitalist communication skill.

E.6.c Secondary hypotheses. I will test the following hypotheses in parallel analyses:

Hypothesis 1: *Use of skills by hospitalists to elicit concerns and respond to informational and emotional cues will be associated with fewer unaddressed concerns in patients and next of kin after the discussion.*

Hypothesis 2: *Eliciting concerns and responding to informational and emotional cues will be associated with higher trust in the hospitalist.*

Hypothesis 3: *Responding to informational cues will be associated with higher patient and next of kin satisfaction with information provided (satisfaction items 1-3,6).*

Hypothesis 4: *Responding to emotional cues will be associated with higher patient and next of kin satisfaction with emotional support (satisfaction items 4-6).*

E.6.d Missing data. I do not expect a high rate of missing data because I plan to collect all of my data within 24 hours. In the event that 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 the discussion or post-discussion survey missing. As this is a preliminary study to assess feasibility, I will track missing data rates and reasons for planning future studies.

E.6.e Qualitative analysis. In addition to coding the recorded discussions as described above, I will perform a qualitative analysis based on a grounded theory approach.[99,106] This will allow us to describe the discussion between the hospitalists and patients or next of kin and develop insight into that process. It will also serve to confirm and provide depth to our quantitative analysis and provide hypotheses for future studies.

E.7 Sample size and power considerations. As this is a preliminary study, our goal is to refine the study design, gain information on key variables and associations, and generate effect sizes to inform the design of future studies. In the absence of preliminary data on key variables, a formal assessment of statistical power to test hypotheses is not possible. However, I provide basic calculations for one of our primary objectives to illustrate the range of effect sizes that may be detectable from our proposed sample size of 50. The power calculation is based on Aim 3, the association between communication skill use in the recorded discussions and the patient or next of kin's level of anxiety after the discussion. For communication skill use, I have chosen response to emotional cues, because of the skills I am evaluating, its association with anxiety is the mostly strongly documented in past studies.[1,74] In primary care and oncology studies, patients gave an average of one emotional cue per conversation (range 0-10), and physicians responded to 30% of these cues.[26,27,30] If our findings are similar, I could classify conversations based on whether the hospitalists did or did not respond to the patient or next of kin's emotional cue(s). Using a two tailed t-test to compare patients and next of kin to whom the hospitalist responded empathically compared with those to whom the hospitalist did not respond empathically, with sample size of 50 and 80% power while setting $\alpha = 0.05$, I would be able to detect a mean difference of 8 points in the individual specific changes between pre-discussion and post-discussion STAI-S. This result assumes that there will be approximately equal numbers of individuals in the two groups, and that standard deviation for the individual STAI-S change scores will be 10 points in both groups. This is comparable to previously documented effects of empathy on STAI-S scores, and corresponds to 20-percentile points in the mid range of the STAI-S.[1]

E.8 Data management and quality control. The Principal Investigator will oversee all aspects of data management. In the first two months of the study, an operations manual will be developed to standardize all procedures and staff training in areas such as recruitment, measurement, assessment, and data entry, management, and security. I will create procedures to monitor enrollment and track follow-up rates and data entry. Discussions will be digitally audio-record using Olympus DM-10 recorders with conference microphones. The digital recordings are saved in the recorder as .wav files. The files will be downloaded and stored on a password-protected computer and will be backed up on CDs which will be stored in a locked file cabinet in a locked room. For analysis, the .wav files will be up-loaded into the secure password protected website that was developed and used in the SCOPE study.[96] After coding is complete, the program will generate frequency counts and proportions as appropriate for each code. Survey data will be collected on paper and double entered in by a research assistant through a Microsoft Access data entry interface. Most study data will be electronic, and will be stored on a password-protected computer and backed-up on the secure UCSF server. Only select research team members will have access. All paper documents related to the study (e.g., signed consent forms) will be kept in a locked drawer in a locked office. Analysis will be performed using SAS, SPSS, and Stata as appropriate. All study subjects (hospitalists, patients, and next of kin) will be assigned unique study identifiers that will appear on all data collection instruments,

recordings, documents, and files used in the analysis and manuscript preparation. Personal information needed for tracking and informed consent will be stored separately with only limited team members having access to that data. No personal information concerning study participants will be released without their written consent.

E.9 Limitations and strengths.

Our study has several limitations. First, it is a preliminary study, so I will not be able to create stable multivariate regression models to describe the relationship between communication and anxiety while controlling for other factors that also contribute to anxiety in seriously ill hospitalized patients and their relatives. I have attempted to include significant co-factors in our data collection, so that I can determine univariate correlations between these co-factors, communication, and anxiety and use these data to estimate effect sizes for our next study. My K award will be sufficiently powered to build a stable model including communication, anxiety, and co-factors. Second, I will only measure anxiety before and after the discussion with the hospitalist. It is unclear how changes in the STAI-S score immediately after the discussion will predict changes in anxiety and overall functioning after the hospitalization. If I find that communication skills decrease anxiety immediately after the discussion, then it will be important to see whether this effect persists. Also, I am only beginning to understand how specific communication skills affect anxiety. For example, it may be that disclosure of emotions increases anxiety in the short term but decreases it in the long term.[122,123] If so, hospitalist use of skills that increase disclosure of emotions would cause an increase in anxiety immediately after the discussion, but a decrease later. I would only capture this dual response with post-hospitalization follow-up data. In future studies I will collect post-hospitalization follow-up data, and will use the Structured Clinical Interview for the Diagnostic and Statistical Manual[124] to assess actually psychiatric diagnoses in addition to symptoms of anxiety. Third, the fact that I am performing this study in an academic setting will limit the immediate generalizability of our findings. Trainees in addition to the hospitalists will care for the patients and next of kin in our study. I have attempted to limit the effect of other communication on our measure of anxiety by collecting the STAI-S immediately after the discussion I am recording. However, I will need to replicate our findings in non-academic settings. Fourth, because past studies have documented that patients and relatives infrequently express emotion in discussions with physicians, and the physicians respond empathically to these expressions even less frequently,[26,27,29,30] I may fail to detect an effect of communication on anxiety due to low frequency of emotional cues. Because patient and relative disclosure of emotion is influenced by how physicians communicate,[30,53,54] it may be that I need to train hospitalists in order to see frequent enough use of communication skills to detect an effect on anxiety. Even if this is the case, it will not affect the utility of the results, because I will have established the feasibility of recording these discussions and collecting survey data from seriously ill hospitalized patients and their next of kin. The primary goal of this project is to collect data that I will use to design and test a communication intervention. Past studies demonstrate that teaching physicians communication skills decreased patient and relative anxiety.[74,75] Finally, the Hawthorne effect,[125] that providers will act differently because they are being observed, is a consideration in all studies of health communication. It is true that providers may be on their "best-behavior" in our recordings, however studies have shown that physician behavior is not significantly altered by recording.[118] Further, past studies have shown that providers generally do not use skills recommended by the literature even when recorded.[26,27,29,30,98] Thus, although hospitalists may exhibit their best communication ability in the recordings, this fact does not adversely impact the study aims.

My study also has a number of strengths. First, it is addresses an important area within medical communication in a population with a high symptom burden: seriously ill hospitalized patients and their families. Second, it lays the groundwork for linking communication behaviors to mental health outcomes. Most recommendations in medical communication are based on expert opinion and patient or family satisfaction measures,[78,111,126,127] and the relationship of these to health outcomes is unclear.[128,129] Third, it leads directly to a communication intervention. Because communication has repeatedly been shown to be teachable, and effective models for teaching communication skills have been developed,[74,75,82,83] teaching communication skills is an effective, economical way to improve quality of life for patients and their families at the end of life. Finally, it is the first study to focus on communication between hospitalists and seriously ill patients and their relatives. Because hospitalists are the primary physicians caring for seriously ill hospitalized patient and their families at the end of life, integrating education about end-of-life communication into established mechanisms for dissemination of information within the hospitalist specialty will have a significant national impact.

F. FUTURE CAREER AND DIRECTIONS

My goal is to become an independent investigator and expert in end-of-life communication in the hospital setting. My approach is to describe communication skills that improve outcomes of seriously ill hospitalized patients and their families, and develop training interventions to teach providers these skills. Through my NPCRC research and career development activities, I will develop an understanding of hospitalists' communication skill level, and how communication about end-of-life issues affects patients and their families. I will use this understanding to design a communication skills training intervention using simulated patients. This intervention will be modeled after Oncotalk, an NCI-funded communication skills training intervention for oncologists that has demonstrated efficacy to improve communication skills.[83] I am experienced with the Oncotalk teaching methods and have mentor relationships with the Oncotalk investigators, who are experts in education about communication at the end of life. The data I collect during my NPCRC funding will establish feasibility and provide effect sizes, both of which I will use to design a controlled trial of the intervention to test its ability to decrease anxiety in patients and their families. This trial will be modeled after the Studying Communication in Oncology Patient Encounters trial, in which I have been involved.[96] I will apply for a K-23 award in June 2009, during which I will develop and pilot the intervention. I will then apply for an R01 award to perform a multicenter trial of the intervention, in both community and academic settings.

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