

Grant Number: 5R01CA100387-03
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Project Title: Enhancing Patient-Oncologist Communication

Abstract: DESCRIPTION (provided by applicant): *Communication about cancer treatment challenges patients and physicians as they face the transition from fighting a potentially curable disease to realizing that conventional therapies are no longer effective. Patients often confront intense fear and loss, leading to greater emotional needs than at any other time during treatment. Because oncologists also struggle with this transition, they frequently, yet inadvertently, discourage patients from disclosing emotional concerns and thus miss opportunities to communicate effectively, resulting in greater patient anxiety. Unfortunately, no easily disseminable educational interventions exist to help oncologists overcome these challenges. We propose a randomized, controlled trial testing the efficacy of an interactive CD-ROM based intervention using feedback from the oncologists' own recorded encounters to improve their communication. At baseline of this five-year, two site (Duke and the University of Pittsburgh) study, we will audio record 400 outpatient encounters between oncologists (n=50) and patients with advanced cancer (n=200) as they discuss the transition to palliative care. These digitized recordings will be coded for the oncologists eliciting patients' concerns and responding to emotional content. After baseline assessment, we will randomly assign the oncologists to intervention and control arms. The intervention oncologists each will receive a personalized user-friendly CD-ROM that contains their coded conversations, packaged with related educational material. A technical advisor will encourage and facilitate their use of materials. The control group will not receive the CD-ROM or any other support. Three months later, we will conduct the post-intervention assessment by recording another 400 clinic visits between these same oncologists (intervention and control) and a new sample of patients to measure the intervention impact. Primary outcomes will be the communication behaviors emphasized in the intervention, such as responding to empathic opportunities and eliciting patient concerns. This project will expand the field of oncologist-patient communication by identifying key communication skills that may assist patients through difficult transitions and by creating an easily disseminable intervention to help oncologists implement these skills.*

Institution: DUKE UNIVERSITY
DURHAM, NC 27710
Fiscal Year: 2005
Department: MEDICINE
Project Start: 01-MAY-2003
Project End: 31-MAR-2008
ICD: NATIONAL CANCER INSTITUTE
IRG: ZRG1

A. OVERVIEW

Despite major advances in cancer treatment, the majority of patients with cancer eventually die from their disease. In fact, 40% die within 5 years of diagnosis.¹ Nearly every day, most oncologists see patients with whom they must discuss bad news and modify the goals of care to focus on palliation. Acknowledging this reality, the National Cancer Policy Board and the Institute of Medicine recently issued a report, “Improving Palliative Care for Cancer,” that highlights shortcomings in the quality of cancer care at the end of life, and identifies physician-patient communication as a key domain requiring intervention.²

Patients who experience the transition from fighting a potentially curable disease, to recognizing that conventional therapy is no longer effective, to accepting palliative care and, possibly, entering hospice face great challenges to their physical, emotional and spiritual integrity. The transition renders them emotionally vulnerable.³ How patients’ emotional needs are addressed affects their subsequent anxiety, depression and ability to cope with their illness.^{3,4}

Unfortunately, oncologists may not be prepared to discuss these transitions in a manner that meets patients’ needs.² They may see stopping anti-cancer treatment as a failure, or experience sadness at the anticipated loss of a dear patient.^{5,6} Even in the absence of such feelings, they may not possess the communication skills to convey empathy and respond to patients’ emotions. Recent physician-patient communication research has focused on the notion of the “missed empathic opportunity.”⁷ In conversations with physicians, patients frequently offer brief windows or clues into their deeper concerns.^{8,9} Physicians who respond to such clues with empathic language and further exploration are likely to uncover important information about patients and respond more appropriately to their emotional needs. Unfortunately, the majority of such clues are not acknowledged by physicians, leading to missed opportunities for relieving patient distress.^{9,10} Even when such opportunities are recognized, research from both cancer and general medical settings suggests that physicians inadvertently discourage patients from disclosing psychosocial concerns and thus miss potential opportunities to communicate effectively.¹¹⁻¹⁵ Oncologists also struggle to promote hope in patients with advanced cancer, and fear that discussing death may decrease patient hopefulness.^{16,17} As a result they frequently convey prognosis with an optimistic bias or do not give this information at all.¹⁸

Most studies have focused largely on communication between primary care physicians and patients regarding end-of-life care,¹⁹⁻²¹ and between oncologists and patients at earlier stages of treatment.^{10,22} One study from the Netherlands that observed conversations between oncologists and patients receiving palliative chemotherapy noted lack of attention to quality-of-life issues.²³ Another study from the United Kingdom (UK) noted that oncologists responded to less than half of patients’ verbal cues.²⁴ However, no one has directly observed conversations between U.S. oncologists and patients facing the transition from anti-cancer treatment to palliative care, and documented how oncologists elicit concerns, handle emotions, respond to empathic opportunities, and convey prognosis. Recent studies document the effectiveness of a three day curriculum in improving oncologist’s communication skill.^{24,25} Unfortunately, these intensive communication courses are time consuming, expensive and not likely to be embraced by many practicing oncologists. Despite the apparent need, no easily disseminable educational interventions exist to help oncologists overcome the challenges of communicating with patients at this time.

The overall goal of this project is to expand the field of oncologist-patient communication by enhancing our understanding of how oncologists and patients communicate about the transition to end-of-life care, identifying key communication skills that may assist patients through difficult transitions, and creating and testing an easily disseminable intervention to help physicians implement these skills.

Accordingly, the specific aims are to:

- AIM 1:** Audio-record conversations between oncologists and patients with advanced cancer as they discuss the transition from active cancer treatment to palliative care, and compare the quality of these audio-recorded conversations with best practices described in the literature with particular attention to communication behaviors that promote patient disclosure of concerns, use of emotion handling skills, recognition of empathic opportunities, and the conveying of prognostic information.
- AIM 2:** Develop an intervention to improve oncologists’ communication skills in these areas using an interactive CD-ROM based on the oncologists’ own recorded discussions with patients.
- AIM 3:** Assess the feasibility of this intervention and, using a randomized, controlled design, measure its effectiveness for changing physician communication behaviors and relevant patient outcomes including reduced distress and increased satisfaction.

B. BACKGROUND AND SIGNIFICANCE

B.1 Improving end-of-life care is a high national priority.

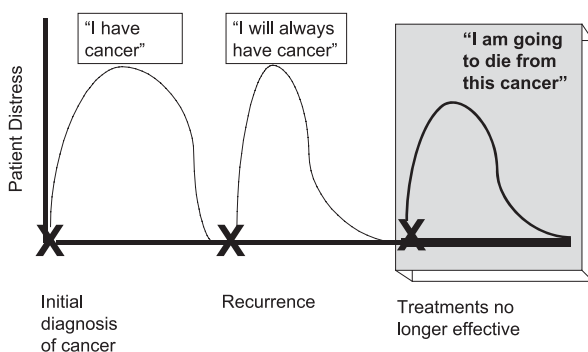
SUPPORT and other studies documented that many patients in the U.S. do not die well.²⁶⁻²⁸ They die prolonged and painful deaths, receiving unwanted, expensive, and invasive care. Up to 70% of patients with advanced cancer experience pain, frequently severe enough to impair their ability to function.^{27, 29, 30} Emotional suffering at the end of life can be profound, and anxiety and depression are commonplace in terminal cancer.³¹ Nevertheless, these symptoms are grossly under treated, perhaps because they are not recognized and acknowledged.³¹⁻³³ Death and bereavement also raise great spiritual questions, and patients may be overwhelmed as they struggle with issues related to loss of control, the meaning of their illness, uncertainty regarding the dying process, and unfulfilled goals.³⁴⁻³⁷

Recognition of these issues has raised the improvement of end-of-life care to a national priority. The Institute of Medicine has issued two reports outlining the current shortcomings in the care of dying cancer patients and proposing an agenda for the future.^{2, 38} The American Medical Association created a national program to educate physicians on end-of-life care (EPEC); the American College of Physicians developed guidelines on the topic; and the American Society of Clinical Oncology has recently increased its focus on palliative care. The Robert Wood Johnson Foundation, the Project on Death in America and other foundations have invested more than \$100 million in this effort. *The profession and the public now recognize that we must improve the care provided to cancer patients at the end of life; such efforts must address oncologist-patient communication.*

B.2 Patients with advanced, incurable cancer face a series of transitions, but the transition from active cancer treatment to palliative care seems especially challenging.

Living with cancer means experiencing life-changing transitions. Receiving the initial diagnosis changes people from “healthy” to “sick,” and forces them to confront physical and psychological challenges. If patients are cured they become “survivors” with the attendant life changes. Recurrence is reminiscent of receiving the initial bad news; however, it may portend a more serious problem, and patients who recur generally know they will be living with the specter of disease the rest of their lives. Finally, many patients reach a point when anti-cancer treatment is no longer effective, they will be asked to consider palliative care and, possibly, hospice. Each of these transitions presents patients with new challenges that require adjustment (*Figure 1*).

Figure 1. Points of transition in cancer patient



Communication with cancer patients – difficult at all stages of the continuum of care – may be most challenging as patients face the transition of their disease to a point where anti-cancer therapies are no longer effective. This transition occurs over time, as patients may first come to realize that the disease is not curable, later face decisions about experimental therapies and phase I trials, and finally, perhaps consider a referral for hospice care. At this time, patients face the threat of the ultimate loss, death, and are in an emotionally vulnerable state. Their concerns at the time of learning bad news predict future levels of anxiety and depression.^{4, 39} To make decisions about cancer treatment and palliative care, patients must understand the nature of the illness, its prognosis and the available treatment options. Emotionally, they must accommodate to a profound loss and learn to live with the illness despite a terminal prognosis.

Understanding prognosis is determined by patients’ emotional state, ability to comprehend prognostic data, and the way that oncologists discuss the data with the patient. Fearing the loss of hope, patients frequently cope by expressing denial, and may be unwilling to hear what is said.⁴⁰ Patients may be so overwhelmed by the impact of the news that they are incapable of processing the information. That is, patients are unable to systematically process messages,^{41, 42} which in turn decreases message encoding and recall. Some studies have shown that emotion affects processing; people who are in negative moods may pay more attention to how messages are given (heuristic route) than to the content of the messages (systematic route).^{43, 44} Thus when patients are experiencing high levels of negative affect, and oncologists do not ameliorate this affect, patients may be less likely to receive oncologists’ messages.

Patients also may struggle with the transition to palliative care because, for a variety of reasons, physicians systematically convey an optimistic bias to patients when discussing prognosis.⁴⁵ Physicians struggle to support hope in the patient and to support a positive outlook.^{16, 17, 45-47} In an effort to promote hope, they may give

information that is unrealistically optimistic. In turn, patients with more optimistic assessments of their own prognoses are more likely to choose aggressive therapies at the end of life, although this does not affect their life expectancy.^{48, 49}

These data suggest that, for patients to comprehend and retain information about prognosis and treatment, oncologists must attend to patients' affect. Unfortunately, such an emphasis on emotion is not the norm (*see section B.6*). ***Patients struggle during the transition from anti-cancer treatment to palliative care and require emotional support from their oncologists at this difficult time.***

B.3 Oncologists also struggle with the transition from anti-cancer treatment to palliative care.

Physicians score higher on death anxiety scales than other professional groups,⁵⁰ and find caring for terminally ill patients stressful.⁶ Medical residents with high death anxiety scores are more likely to employ dysfunctional communication strategies such as avoidance and denial.⁵¹ Their training, particularly in oncology, emphasizes prolongation of life, and the shift to palliative care may seem counter-intuitive, awkward, or even aversive. In a study of nephrologists and end-of-life decision-making, 25% admitted difficulty with advance directives if the patients' choices clashed with their own beliefs.⁵² Physicians often maintain a sense of omnipotence, and working with the dying can generate feelings of helplessness or failure.⁵³ Increased empathy may lead to a sense of confronting one's own mortality, and feelings of failure may result in avoidance or over-treatment.⁵⁴⁻⁵⁷

Given the emotional difficulties oncologists experience when interacting with patients facing the transition from anti-cancer treatment to palliative care, it is not surprising that some choose to avoid threatening topics that will provoke engaging patients' emotions.^{22, 58, 59} Oncologists and other health care providers attend selectively to the cognitive aspects of such discussions, and employ blocking behaviors that distance them from addressing the affective concerns of patients at this time.⁶⁰

Furthermore, physicians' affect impacts patients' recall of information and their emotional reaction. In one study, women were randomly assigned to view a video of an oncologist, portrayed as worried or not worried, presenting mammogram results. Those watching the "worried" physician received less information, experienced higher anxiety levels and perceived the situation as more severe compared with those watching the "non-worried" physician.⁶¹ This suggests that physicians' affect plays an important role in patients' reactions to medical information. ***Oncologists must deal with their own issues of loss, helplessness, and personal failure as they realize they are unable to save the patient's life, and this poses challenges as they communicate with patients facing the transition from anti-cancer treatment to palliative care.***

B.4 Effective communication can help patients and oncologists cope with transitions at the end of life.

One way to help both patients' and oncologists' cope with transitions from anti-cancer to palliative care is to enhance their communication. Patients assign tremendous symbolic importance to their physician and the quality of communication.⁵⁸ In non-cancer patients, communication has been shown to influence malpractice claims,⁶² patient satisfaction,⁶³ recall of information,⁶⁴ and clinical outcomes such as diabetic glucose control and functional status.^{65, 66} Among cancer patients, quality of communication affects psychological well-being, with "patient-centered" consultations leading to improved satisfaction and psychological adjustment.⁶⁷ One study of women with breast cancer found that simply adding 40 seconds of compassion into a physician-patient encounter significantly reduced patient anxiety.⁶⁸ Another showed that women with breast cancer who perceived their oncologists to be caring during the delivery of the bad news demonstrated decreased long-term distress.⁶⁹ Furthermore, palliative care requires addressing the diverse needs and preferences of patients.^{70, 71} Physicians and other health care providers must be able to assess these needs to respond to them.

Patients accrue tangible benefits when communication focuses on their emotions. The number and severity of cancer patients' concerns predict anxiety and depression.⁴ Eliciting and addressing these concerns should decrease these psychological sequelae. Such communication also may help decrease use of aggressive interventions unlikely to alter disease course and inconsistent with the patient's underlying values and goals for care. Finally, although pain and symptom management are not a focus of this proposal, it is worth noting that better communication about patient concerns is likely to also improve physical as well as psychological symptoms. Communication techniques that are more open-ended and focus on patients' emotional states are more likely to elicit patients' concerns about pain or other symptoms, which can then be treated.

Similarly, oncologists who are comfortable communicating with patients about the transition from anti-cancer treatment to palliative care and exploring patients' emotional concerns, are more likely to feel fulfilled in their clinical practice,^{37, 72} and physicians with improved communication skills are less likely to experience burnout.⁷³ ***Effective communication that includes attention to patient affect is fundamental to the whole patient assessment, to oncologist well-being and, therefore, to all other improvements in end-of-life cancer care.***

B.5 What is effective communication at the end of life?

Effective communication at the end of life must meet several goals. According to a recent study of dying patients, family members and health care providers these goals include: talking with patients in an honest and straightforward way, being willing to talk about dying, giving bad news sensitively, listening to patients, encouraging questions, and being receptive to when patients are ready to talk about death.⁴⁷ Patients wish for oncologists to achieve a balance between being honest and straightforward and not discouraging hope. Another study found that although patients must receive adequate information to make informed choices, they wish to receive that information in an emotionally supportive way.⁷⁴ Patients want to discuss emotional concerns, but frequently are unwilling to bring them up spontaneously and may need to be prompted.⁷⁵

These findings suggest a communication style with patients at the end of life that is informative, patient-centered rather than physician-centered,⁷⁶ and attends to patients' emotional needs. Many models have been proposed, particularly for specific tasks such as delivering bad news.⁷⁷⁻⁸³ Baile and von Gunten have described models for discussing disease progression and end-of-life decisions,^{84,85} and a consensus panel from the American College of Physicians recently outlined an approach to discussing palliative care.⁸⁶ *All of these guidelines converge on several key elements, including the skills we will evaluate and teach oncologists in this project: eliciting patient concerns, responding supportively to patient emotions, recognizing empathic opportunities, and communicating prognosis in an honest and caring fashion.*

B.6 Oncologist-patient communication about end-of-life issues often does not meet experts' standards.

Physician-patient communication research has enabled us to measure critical components of the medical encounter that reflect standards of practice.⁸⁷⁻⁸⁹ Through such research, we have learned that the delivery of bad news frequently does not meet patients' needs, or falls short of expert recommendations.^{47, 58, 81, 90-94} Physicians rarely talk with seriously ill patients about their goals, values or even treatment decisions.^{19-21, 95-99}

Maguire has shown that oncologists commonly do not elicit the full range of terminally ill cancer patients' concerns, or attend to patients' affect.¹³ Rather than using facilitative communication techniques, such as open-ended questions or empathic responses, when inquiring about psychosocial issues, they often block discussion by changing the subject or not attending to patients' emotions.²² As a result, cancer patients tend to disclose fewer than 50% of their concerns to oncologists and other providers.^{3,22} These undisclosed concerns merit attention because patients with more undisclosed concerns have adverse psychological outcomes. Others corroborate Maguire's findings that oncologists frequently overlook emotional disorders, both in ambulatory and hospitalized patients. For example, one study of 177 encounters in which oncologists gave bad news

revealed that they tended to use closed rather than open-ended questions, and infrequently asked about psychosocial concerns.⁹³ In another study, only one of five oncologists' assessments of patients' distress correlated accurately with patients' self-report.⁹⁴ Finally, a recent study from the Netherlands of audio-taped encounters between oncologists and patients receiving palliative chemotherapy observed that physicians devoted 64% of their conversation to medical/technical issues and only 23% to health-related quality of life issues.²³ Patients' emotional functioning and fatigue were not addressed 54% and 48% of the time, respectively.

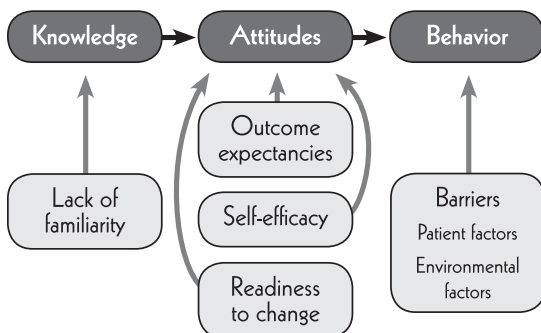
Oncologists' may be unable to address patients' emotional concerns for several reasons that correspond with constructs in social cognitive theory,¹⁰⁰ the transtheoretical model of behavior change,¹⁰¹

and a barriers model proposed by Cabana¹⁰² (Figure 2). Oncologists may be unaware that they are neglecting patients' emotional concerns, lack the skills to address patients' concerns, feel that addressing their concerns will not improve patients' well-being (outcome expectancies), lack the confidence to address patients' emotional concerns (self-efficacy), and be unmotivated to improve their communications skills (readiness to change). Also, external barriers such as patient factors (e.g., patients giving indirect rather than direct emotional cues¹⁰) and environmental factors (e.g., lack of time or resources) may deter oncologists from addressing patients' emotional concerns. *The preponderance of the literature points to a significant gap between the idealized model of oncologist-patient communication at the end of life and the reality of practice. Behavior change theories can be applied to explain oncologists' communication patterns.*

B.7 With training, physicians can improve their communication skills.

Although physicians frequently regard the ability to communicate as an inborn talent, in fact, these skills can be learned. With only one exception,¹⁰³ rigorous evaluations of communication skills teaching have shown positive

Figure 2. Conceptual model for changing physician behavior



results when interventions incorporate adult learning principles, practice, and feedback in settings supervised by trained facilitators. The American Academy on Physician and Patient (AAPP) has developed a highly regarded model for such training.¹⁰⁴ The AAPP 5-day course includes didactic learning, small group skills practice, and self-awareness sessions where participants reflect on feelings provoked by clinical situations. Participants report a significant increase in their interviewing and self-awareness skills.¹⁰⁴

Early studies documenting effective communication skills teaching involved non-oncologists. Medical house staff completing a half-day course focusing on discussion of life-sustaining treatment demonstrated an increased self-reported ability to introduce the topic, give information, and elicit patients' values and feelings.¹⁰⁵ Roter and Hall found that physicians participating in an eight-hour course used significantly more emotion-handling skills than did untrained physicians, and patients of these physicians experienced decreased distress for up to 6 months afterwards.¹⁰⁶ Examining the effect of longer courses, Levinson and Roter found that physicians completing a 2.5-day course asked more open-ended questions and more frequently asked patients' opinions than physicians enrolled in a 4.5-hour course.¹⁰⁷ Worstell reported that an interactive seminar for physicians on how to communicate better with regard to asthma led to shorter physician-patient encounters and to more favorable patient responses to physicians' actions.¹⁰⁸

Several recent studies have demonstrated short-term improvement in the communication skills of oncologists, all evaluating curricula similar to those described above. Baile conducted a series of half-day workshops focused on giving bad news and managing difficult patients.¹⁰⁹ Self-efficacy questionnaires revealed increased confidence in communicating bad news and managing problem situation cases after the workshops. Parle and Maguire conducted similar 3-day and 5-day workshops in the UK for oncology clinicians that demonstrated improved self-assessed ratings of performance in communication tasks and improvements in behaviors with standardized patients.⁸⁰ Fallowfield, also in the UK, conducted a series of 1.5 or 3 day retreats for senior oncologists,⁷² and found that oncologists' confidence ratings significantly improved after the course; 3 months later, 95% of the participants reported significant changes in their clinical practice. Most recently, Fallowfield reported on a randomized controlled trial of the 3 day training course involving 160 oncologists from across the UK.^{24, 25} She found that, in addition to favorably altering oncologists' attitudes and beliefs towards psychosocial issues, this intervention demonstrated improved communication behavior in videotaped patient interviews.²⁴ Intervention oncologists increased significantly their use of open-ended questions, expressions of empathy, and appropriate responses to patient cues or empathic opportunities. *Communication skills critical to discussions with patients facing the end of life, such as eliciting concerns, handling emotions, and demonstrating empathy, can be taught and lead to increased physician self-confidence and reduced patient distress.*

B.8 There is a need for practical, accessible, theory-based interventions.

Despite the success of communications skills training workshops, they are costly, time-intensive, and are "one-shot" options that do not allow participants to revisit or review the material. Such interventions require extensive coordination to assemble groups and facilitators, and do not allow oncologists to learn at their own time and pace. Although they may be appropriate for physicians-in-training, who can be required to attend, it is unrealistic to expect many practicing oncologists to be able to involve themselves in such efforts even if they would like to do so. In fact, only a handful of oncologists currently attend the communication courses taught by the AAPP, and even the skills workshops held at the American Society of Clinical Oncology are not well subscribed. There is a need to develop a communications training intervention that oncologists can incorporate easily into their clinical practices. Such an intervention requires an application of behavioral principles coupled with technology that can ensure ease of administration.

Further, such a self-directed intervention should accommodate multiple learning preferences to maximize use. Virtually all of the previously described training has used either role play or standardized patients. Although effective methodologies among seminar attendees, these exercises tend to be greeted with skepticism by some clinicians who prefer to discuss real-life encounters.

Using physicians' own recorded patient encounters as a training tool overcomes this objection, and allows the creation of an intervention that can be completed inexpensively at the oncologists' convenience. Just as in workshops where clinicians review their own training audio or videotapes,⁷² we expect that physicians will be more receptive to communications skills training when they can observe and reflect on their own behavior. This should increase their awareness of their deficits. Further, using oncologists' own words allows us to tailor the training rather than presenting recommendations that do not fit the oncologists' own communication styles. Moreover, using the oncologists' own words with actual patients will increase the interventions' face validity. The doctors will clearly understand the relevance and importance of the suggestions. Learning from and working with their own real-life communications should increase oncologists' skills, and eventually outcome expectancies, self-efficacy, and intention to change.

In an analogous, but different use of audio-recordings, oncologists who have experimented with giving patients audio-tapes of their clinic visits to review afterwards, have found that patients increase their knowledge about their disease,¹¹⁰ suggesting that it could be an effective learning tool for physicians as well.¹¹¹ Moreover, interactive continuing medical education and the use of reminders are rated as the best methods for changing physician behavior.¹¹² This methodology is also consistent with the Agency for Healthcare Research and Quality's recommendations on how to change physicians' behavior.¹¹³ In the setting of teaching bioethics, interactive computer-based learning has been shown to increase learner retention and satisfaction.¹¹⁴ Finally, one non-randomized trial was recently conducted in the Netherlands that used a computer-assisted instruction program to teach oncologists communication skills.¹¹⁵ Participants demonstrated improved ratings on quality of communication behaviors in videotaped encounters with real patients after completing the instructional program. Although the curriculum did not use the oncologists' own encounters as teaching tools, and the study lacked a control group thus weakening its conclusions, this trial demonstrates the utility of this approach and its feasibility in our study population. ***We hypothesize that a CD-ROM based intervention that uses oncologists' own coded audio-recordings to teach them communication skills poses an inexpensive, practical and disseminable alternative to communication workshops.***

B.9 Summary and significance

The transition from anti-cancer treatment to palliative care poses great challenges for both patients and physicians. Effective communication at this time is essential to providing optimal care at the end of life. Research demonstrates that physicians inadequately address patients' emotional reactions, and that current efforts to train physicians to communicate differently are unlikely to affect the majority of oncologists. Despite considerable data about physician and oncologist communication generally, few studies have looked rigorously at how oncologists respond to affective content specifically when discussing the transition from anti-cancer treatment to palliative care. This study would collect the largest dataset of conversations between oncologists and patients to date, and would use it as the foundation of a teaching intervention for physicians.

An intervention of this kind must be tested for effectiveness. Relevant outcomes include actual communication skills of physicians as measured by number of patient concerns elicited, appropriate responses to patients' emotions, percentage of empathic opportunities addressed, and truthful delivery of prognostic information. Patient-level outcomes include satisfaction with communication and emotional distress. If successful, this intervention would provide an inexpensive, practical and disseminable product for oncologists.

C. PRELIMINARY STUDIES

Our interdisciplinary research team brings tremendous expertise and experience to each of the key components of the proposed research: 1) evaluation of physician-patient interactions; 2) recruitment of physicians; 3) recruitment of cancer patients; 4) training physicians; and 5) development and evaluation of interventions including written self-help guides, videos, and tailored feedback with a broad array of populations. ***Together, the interdisciplinary team brings the necessary expertise needed to examine oncologist-patient interactions regarding the transition from anti-cancer treatment to palliative care, and to develop and evaluate a self-directed intervention for oncologists.***

C.1 An experienced and diverse research team

C.1.1 James A. Tulsky, MD is Associate Professor of Medicine, Associate Director of the Duke Institute on Care at the End of Life, and Director of the Program on the Medical Encounter and Palliative Care at Duke University and the Durham VA Medical Center. He is a practicing primary care internist and palliative care physician with extensive research experience analyzing audio-recorded clinical encounters and conducting communications teaching interventions with physicians. He is a highly sought after teacher who has conducted communication skills training at medical schools and professional meetings; Dr. Tulsky's pre-course at the Annual Meeting of the Society of General Internal Medicine on Communicating with Patients at the End of Life won the meeting's "Best Pre-Course" award two years in a row (1998, 1999). He has co-facilitated a week-long course on communication at the end of life for the American Academy on Physician and Patient, facilitates weeklong retreats for oncology fellows (see C.10) and is a consultant to the project, "Improving clinician-family communication in the ICU," (PI: J. Randall Curtis, MD, MPH; 5R01NR005226-02). 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 recently awarded the Presidential Early Career Award for Scientists and Engineers (PECASE) from the White House Office on Science and Technology.

C.1.2 Kathryn I. Pollak, PhD is an Assistant Research Professor in Community and Family Medicine and a member of the Duke Cancer Prevention, Detection and Control Research Program. She is a social

psychologist with experience surveying patients and physicians regarding cancer prevention and screening behaviors and health disparities. Recently, she has conducted research with family physicians and their patients in which she successfully obtained brief physician post-visit surveys from 90% of study physicians. She also has collaborated on randomized, controlled intervention trials to promote smoking cessation in which she developed print materials and counseling protocols based on the same theoretical frameworks proposed for this study (e.g., social cognitive theory). Dr. Pollak is an instructor for Duke University School of Medicine's behavior change strategies course. Most recently she has published several articles examining patient and physician perceptions of what occurs during office visits.¹¹⁶⁻¹¹⁹

C.1.3 Robert M. Arnold, MD is the Leo H. Crip Chair in Patient Care, Professor of Medicine and Chief, Section of Palliative Care and Medical Ethics at the University of Pittsburgh Medical Center. Dr. Arnold has collaborated extensively with Dr. Tulsky on research on physician-patient communication at the end of life, and developed courses to train physicians in these skills, with a particular emphasis on the affective experience of the physician. He was a Project of Death in America Faculty Scholar, is a past President of the American Society of Bioethics and Humanities, and was Program Director of the 2000 Annual Meeting of the American Academy of Hospice and Palliative Medicine.

C.1.4 Celette Sugg Skinner, PhD is an Associate Professor in the Department of Surgery and the Duke Cancer Prevention, Detection and Control Research Program. She is a behavioral scientist specializing in cancer communications interventions to enhance physician recommendations for mammography and genetic testing for colorectal cancer. Recently, she has developed a dual patient-physician intervention to systematically "match" patients' needs and the information and services received for screening and genetic testing, if applicable, for breast, ovarian, and colorectal cancer.

C.1.5 Maren Olsen, PhD is a Biostatistician in the Center for Health Services Research in Primary Care, Durham VA Medical Center, and an Assistant Research Professor in the Department of Biostatistics and Bioinformatics at Duke University. Her primary area of expertise is the use of random-effects models in the analysis of longitudinal data. Dr. Olsen also has considerable expertise in principled methods for incomplete, multivariate data. She is currently a co-investigator on several projects, including a randomized controlled trial with Dr. Tulsky (PI) that examines the degree to which interactive voice response improves patient-centered outcomes.

C.1.6 David Farrell, MPH is President of *People Designs*. Mr. Farrell has experience developing cancer communications interventions for varied populations. He has developed interactive CD-ROMs promoting healthy eating for Food Stamp recipients, providing child feeding information for WIC participants, and teaching usage of the USDA Food Guide Pyramid for adults and children. In addition, he worked with Dr. Skinner to develop an interactive cancer risk profile program for patients and doctors at primary care clinics. In these projects he conceptualizes the interventions, develops program interfaces and logic, develops interactive media including audio and dramatic as well as documentary video, and programs interactive software. In this project, Mr. Farrell and his staff will develop the interactive CD-ROM.

C.1.7 P. Kelly Marcom, MD is an Assistant Professor of Medicine, and a medical oncologist at Duke with extensive clinical experience, particularly in breast oncology. He has followed countless patients through the transition to palliative care, and is a key link to the practice community. Dr. Marcom will serve as the Duke oncology liaison and will help promote use of the intervention among study oncologists.

C.1.8 Keith Meador, MD, ThM, MPH is Director of the Duke Institute on Care at the End of Life and is Professor of the Practice of Pastoral Theology and Medicine in Duke University's Divinity School and Clinical Professor of Psychiatry and Behavioral Science in the School of Medicine. He brings extensive expertise in addressing patients' psychosocial and spiritual concerns, and has a research interest in the measurement of health-related spirituality.

C.1.9 Terrance Albrecht, PhD is an expert in health communications. She has vast experience conducting work in medical settings. Dr. Albrecht has experience audio- and videotaping physician-patient interactions with cancer patients. Dr. Albrecht is currently recruiting 75 physicians and 260 patients in an NCI-funded (R01 CA75003-01A3) field study to examine interaction data to determine physicians' influence on patients' decision-making regarding participation in clinical trials. She has developed many coding systems that are sensitive to the characteristics of cancer patients.

Together and separately, members of the team have conducted the following studies that create the background for the current proposal.

C.2 Audio-tape studies of physician-patient discussions regarding decisions at the end of life.

Dr. Tulsky and colleagues have studied extensively physician-patient communication regarding decision-making at the end of life. They have analyzed audio-taped encounters using quantitative and qualitative methods, and have examined patient and physician satisfaction with the discussions. First, they audio-taped conversations between medical residents and hospitalized patients about the decision to withhold cardiopulmonary resuscitation (CPR).⁹⁹ Using three independent observers and a coding instrument developed for the study, they found that physicians often did not provide sufficient information to allow patients to make an informed decision. For example, the potential outcomes of treatment were rarely discussed – only 13% of physicians mentioned the patient’s likelihood of survival after CPR. Only 10% of physicians in this study asked patients about their values or goals for care. As a corollary to this project, 115 residents from the same sample were asked whether they felt competent discussing resuscitation decisions with patients.¹²⁰ 88% of the physicians responded, and 90% of the respondents felt confident about their skills. Why this discrepancy between the physicians’ perceptions of the discussions and the recorded tapes of their performance? These house officers talk about resuscitation frequently, with an average of four patients each month, yet 33% had never been observed by a more experienced physician while performing a do-not-resuscitate (DNR) discussion, and 71% had been observed fewer than two times. Because they rarely observed others or were themselves observed, they had little opportunity to learn differently.

Drs. Tulsky and Arnold collaborated on a study of fifty-six audio-taped discussions about advance directives between attending physicians and their outpatients at five sites, in two cities.^{19, 121} They developed a combined quantitative and qualitative analytic method based on the UNIX Text Analysis computer program (codebook available at <http://hsrd.durham.med.va.gov/PMEPC/Instruments/Instruments.htm>). This study, which achieved nearly 90% physician participation, found that physicians focused advance directive discussions on scenarios that were of only limited value to future decision-making. In post-visit surveys, many patients demonstrated poor understanding of key concepts relevant to decisions about life-sustaining treatments.¹²¹ Perhaps most concerning was that even after discussing advance directives, physicians’ predictions of patients’ wishes for treatment were no better than chance. ***Both physicians-in-training and seasoned primary care physicians exhibited significant shortcomings in these conversations; the studies concluded that teaching programs might help physicians learn specific techniques to use when discussing preferences for care at the end of life.***

C.3 Audio-tapes of expert physicians demonstrate definable, teachable communication skills.

The results of previous studies raised the question of whether standards espoused in the literature for end-of-life communication were unrealistic for any physician, or whether those specifically trained in these skills might perform better. Tulsky, Arnold and colleagues observed discussions about advance directives conducted by physicians nationally recognized for their expertise in medical ethics and physician-patient communication. They enrolled eighteen experts (of twenty approached) and audio-taped up to three discussions each with the experts’ own patients.¹²² Analysis was conducted using the Roter Interactional Analysis System (RIAS), overlaid with content codes similar to those developed in the earlier community physician study. When compared with the previous study, experts spent close to twice as much time with patients and were less verbally dominant. After controlling for length of visit, expert physicians gave less information and asked fewer questions about biomedical issues, but tended toward more psychosocial and lifestyle discussion. Experts also engaged in more partnership building with their patients. ***Thus, these experts employed specific communication skills that could be identified and taught to all clinicians.***

C.4 Patients facing the end of life want a physician they can trust.

Dr. Tulsky and colleagues conducted eight focus groups with fifty- six community dwelling elderly people.¹²³ They were asked how they wanted to talk to physicians about decisions at the end of life. A qualitative content analysis revealed that patients do not dissociate the idea of talking to a physician about end-of-life planning from their concern about finding a physician they can trust to discuss their fears, goals and values. Trust, patients stated repeatedly, was built through a relationship with someone who understands their life story and its impact on health care decisions. ***Physicians who wish to communicate with patients about palliative care must demonstrate empathy to help establish trusting relationships.***

C.5 Presentation of numeric prognostic data does not affect satisfaction if physicians are empathic.

Tulsky conducted a subsequent study to test how patients interpret quantitative information about outcomes in discussing CPR. He produced two videotapes of a discussion between a patient and a physician about the use of CPR and assessed the reactions of 120 elderly patients to these different approaches using a randomized, controlled design. The videotapes were identical and only differed in the way selected information was presented. When patients were given quantitative information about outcomes (e.g., “you would have a 5%

chance of surviving CPR”) rather than purely qualitative information (e.g., “you probably wouldn’t do well”), they were significantly more likely to correctly assess the probability of survival for CPR and less likely to desire CPR.¹²⁴ Furthermore, the physicians’ use of numbers in the discussion had no effect on participants’ perceptions of the physician’s warmth or overall communication skills, which were rated highly. *These data suggest that prognostic information improves decision-making, and its reception by patients can be modified by an empathic delivery from the physician.*

C.6 Audio-tape studies of physician-patient encounters in managed care examine role of affect in responding to patients’ expectations, and demonstrate feasibility of large-scale communications studies.

Tulsky and colleagues are now completing two large studies of physician-patient communication in managed care. Their objective is to characterize negotiations between primary care providers and patients around expectations and requests for diagnostic tests, referrals, or new drug prescriptions, and to describe the relationship between provider communication style, percentage of unmet expectations and unfulfilled requests, and patient satisfaction.¹²⁵ The first of these studies was conducted in the Durham VA Medical Center primary care clinics. Study staff identified 252 patients who presented to their physicians with expectations for specific tests, referrals or treatments and audio-taped the subsequent encounters. 100% of physicians (n=18) agreed to be audio-taped in this study. The second study used a similar design, yet focused on managed care practices throughout the North Carolina Triangle region, audio-taping 200 clinic encounters with 55 physicians (70%) in 20 different practices. Analyses are underway, using coding techniques similar to those proposed for this study. *Both of these projects use digital audio technology for conversion, archiving and analysis, and demonstrate the ability, as described in C.11 below, to recruit physicians and patients for such studies.*

C.7 Identifying important issues to patients and families at the end of life.

In an effort to learn what attributes are most important at the end of life, Tulsky and colleagues conducted a series of focus groups and a national survey of seriously ill patients, recently bereaved family members, and health care providers. They found that although pain and symptom management were very important, being treated as a “whole person,” preparation for death, and achieving a sense of completion were also valued highly.⁷⁰ For some attributes, such as “coming to peace with God,” and “being mentally aware,” attitudes of patients and physicians were widely discrepant.⁷¹ *These studies highlight the importance of an individualized approach to patients at the end of life, and the value of explicitly eliciting their concerns.*

C.8 Recruitment of lung cancer patients and pregnant smokers.

Dr. Pollak recently collaborated on a feasibility study to determine whether lung cancer patients would be willing to give permission to contact their relatives or caregivers who smoke. Using techniques similar to those proposed in this application and in the literature,^{126, 127} lung cancer patients were identified from the Duke Thoracic Clinic’s automated database. Study staff sent letters to lung cancer patients who had been seen for an initial visit in the prior 3 months (N=62) to describe the study, and patients could call a toll free number to refuse participation. After a 7-day waiting period, interviewers called patients to complete a survey to enumerate their relatives who smoked. Of the patients identified, 76% (n=47) consented to complete the survey. Pollak has also developed theoretically-based tailored interventions for pregnant smokers in an NCI smoking cessation study and conducting yearly physician trainings at each of the 5 study clinics. Physicians obtained CME credit for attending the smoking cessation education sessions. Trainings have been well attended and well received. Pollak also trained and supervised counselors for this study and others. *These recruitment and intervention methodologies map to those proposed in the current study.*

C.9 Evaluation of communication skills training programs and development of computerized technology for analysis of audio-recordings.

In response to findings documenting shortcomings in discussions about end-of-life treatment decisions, Dr. Tulsky and colleagues designed the PREPARE (Program of Residency Education to Promote Awareness and Respect at the End of life) project. PREPARE is a controlled clinical trial of an educational intervention to train medical house staff in palliative care skills, with a particular focus on communicating with patients at the end of life. Participating house staff completed audio-taped interviews with four standardized patients each before and after the teaching intervention (small-group learning emphasizing role play). The study enrolled 61 physicians (85% recruitment rate) and 121 extremely ill hospitalized patients (56% recruitment rate). Audio-tapes are currently being analyzed to identify whether communication skills improved in response to the intervention.

The team developed a coding tool for this study that combines, on one screen, a digital audio playback program (Sound Forge XP) with a Microsoft Access database, and facilitates audio coding and retrieval.¹²⁸ This technology, already quite successful, is a prototype for the more sophisticated program to be developed in the

proposed project. Using personal computers equipped with a multi-media player and a 32-bit sound card, analog recordings are converted to digital “.wav” (sound) files. Individual encounters are processed using Sound Forge XP filtering tools to enhance sound quality. The processed encounters are archived on compact discs (CD) as digital data files. Once archived, Sound Forge XP and Microsoft Access are used simultaneously in a split-screen format to analyze individual encounters. Sound Forge XP plays the audio file, provides a visual image of the sound frequencies, and enables researchers to “time stamp” significant events for easy retrieval and to time specified regions of talk to one-hundredth of a second. While the recording plays, coders can complete the Access data-entry form that has been programmed to automatically perform calculations and prepare data for entry into a SAS database. Visual Basic programming was used to integrate the two programs.

For example the audio data are visualized in the upper half of the screen, as well as heard, and the coding data are entered below. After delivering the bad news, the physician may have stated “I’ll be with you throughout your illness,” and thus received a positive score for the code “make a non-abandonment statement.” Furthermore, it is time stamped with the exact location on the tape that the statement occurred.

The processing capability of Sound Forge XP greatly enhances the sound quality of poorly audible analog recordings. Visualizing the sound frequencies of an encounter enhances analysis and helps achieve higher inter-rater reliability than previously possible, achieving kappa values ≥ 0.8 . Events within encounters can be easily marked, timed, and retrieved. The user-friendly nature of such a system makes audio-tape analysis as easy as a mouse click. Processing software makes noisy clinic backgrounds and background hiss disappear. Automated data processing minimizes errors, and digital archiving makes the data portable. The technology proposed in this grant takes the level of ease and quality one step further. *The investigators’ experience with this technology, augmented by the expertise of David Farrell, gives us confidence in our ability to code audio-recordings and create the CD intervention.*

C.10 Evaluation of a communications skills training program for oncology fellows.

Drs. Tulsky and Arnold are co-investigators on a recently funded NCI R25 grant (PI: Anthony Back, MD) entitled “A Training Program for Medical Oncology Fellows on Communication near the End of Life (OncoTalk).” This project will train 200 oncology fellows in communication skills over a five year period, and employs 5 day workshops, similar to those discussed in section B.7. The first of these was held in April, 2002; Drs. Tulsky and Arnold are course facilitators, and Dr. Tulsky is also responsible for the evaluation, using audio-recorded standardized patient encounters in a format similar to the PREPARE study. At the April, 2002 retreat, we successfully piloted the Olympus DM-1 digital audio-recorders proposed for use in this project. We have also created a modular curriculum that will serve as a template for educational material used in the proposed CD-ROM (*see appendix*). Fellows attending these workshops will not participate in this proposed study. OncoTalk is an enormous opportunity to train a future generation of oncologists in communication skills, and represents a commitment from the NCI in this regard. *However, this R25 project and the labor intensive workshop model will not reach oncologists in practice who remain in need of communications skills training.*

C.11 Successful recruitment of physicians and patients.

Between them, Tulsky and Pollak have successfully recruited over 400 physicians into eight studies. At the University of Pittsburgh, Dr. Arnold has similarly recruited over 150 physicians into a variety of studies. Recently, Pollak concluded a project examining preventive health priorities of primary care residents. Through her relationships with chief residents for Medicine, Family Practice and Obstetrics/Gynecology, she successfully recruited 100 primary care residents. This experience has provided a rich understanding of effective incentives and recruitment practices to induce study participation. In studies of physicians at Duke University and the Durham VA, at least 80% of physicians approached have consistently agreed to participate, even when asked to audio-tape their clinical encounters.

Tulsky and colleagues have successfully recruited more than 650 patients for studies of physician-patient communication. As with their experience recruiting physicians, these studies have generated a wealth of knowledge regarding effective recruiting practices, leading to a patient recruitment rate of 70% of all patients approached for audio-tape studies. *This combined experience makes us confident that we will be able to recruit the necessary sample of oncologists and their patients for this project.*

D. METHODS

D.1 Overview of Study Design

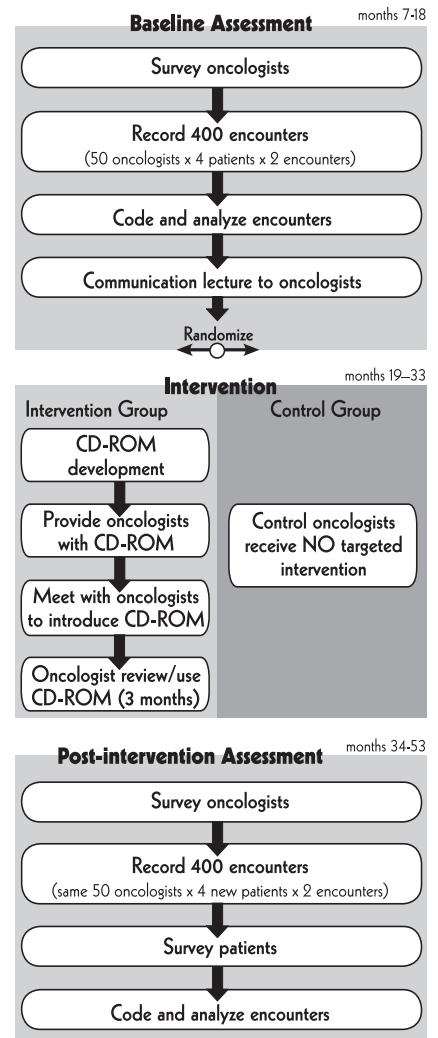
We propose a five-year, randomized, controlled trial to evaluate an intervention to improve oncologist-patient communication at the end of life (*Figure 3*). At baseline, we will audio-record oncologists and outpatients with advanced cancer as they discuss the transition from anti-cancer treatment to palliative care. We will enroll 50 oncologists in two cities, 4 patients per oncologist, and audio-record 2 visits from each pair to arrive at our total sample of 400 encounters. We will analyze the recorded visits and compare the quality of these audio-recorded conversations with best practices described in the literature with respect to how oncologists elicit patient concerns, address emotional content, recognize and respond to empathic opportunities, and discuss prognosis. At the close of the baseline assessment, we will provide a general lecture on communication skills to all participating oncologists.

After the lecture, we will randomly assign the physicians, in equal numbers, to intervention and control groups. The communication intervention will consist of a personalized, user-friendly CD-ROM that contains oncologists' own coded baseline conversations, and an interactive educational interface with reference materials and video-clips of model conversations. Specifically, the intervention will attempt to improve oncologists' skills in eliciting patients' concerns, handling emotions, recognizing empathic opportunities, and discussing prognosis. A secondary goal will be to enhance oncologists' outcome expectancies that patients will respond positively, increase their confidence that they can address patients' emotional concerns, and increase their comfort in addressing death with patients. The intervention physicians will review these CD-ROMs in a structured format over a three-month period (*see section D.7*), while the control physicians will not receive a CD-ROM or any feedback on their previous discussions.

In the post-intervention assessment, we will record another sample of 400 clinic visits between these same oncologists (in both the intervention and control groups) and a new sample of patients with similar disease attributes to those enrolled at baseline. We will analyze these visits using the same coding methodology and compare oncologists' post-intervention recordings with their baseline recordings. In addition, during the post-intervention assessment phase, we will survey patients after each clinic visit. Primary outcomes from the oncologists will be the skills emphasized on the CD-ROM, such as eliciting patient concerns, responding to empathic opportunities, and using more psychosocial rather than medical language. Proposed mediating mechanisms for these changes are oncologists' skills, outcome expectancies, and confidence for addressing patients' emotional concerns and overall comfort dealing with death. Primary outcomes from the patients are their reported levels of anxiety and depression.

We have chosen a randomized, controlled design as the strongest methodology to measure an intervention effect. The control group allows us to evaluate the presence of a confounding secular trend or maturation effect (particularly among the younger oncologists). The only significant threat to internal validity with such a trial is potential contamination between the intervention and control groups. We could assign physicians to groups based on site (Pittsburgh vs. Durham), yet this loses the benefit of randomization, and increases the risk of a confounding site effect. Our considerable experience at both sites is that there is little discussion among these physicians about their personal communication styles. It is also unlikely that oncologists will share their CDs, containing recordings of their own confidential patient conversations, with colleagues. To decrease baseline differences between groups, and emphasize the exclusive effect of the CD-ROM intervention, we will bring all participating physicians (intervention and control) together for an introductory communication lecture prior to randomization. To assess whether contamination exists, we will ask the control physicians about their contact with the intervention physicians and the intervention. ***A randomized, controlled design is the strongest methodology to determine the effect of this educational intervention.***

Figure 3. Design overview



D.2 Study Setting

Physicians and patients will be recruited from the medical and radiation oncology clinics at Duke University Medical Center (DUMC) and the Veteran's Affairs Medical Center (VAMC) in Durham, NC, as well as the University of Pittsburgh Cancer Institute (UPCI). DUMC and UPCI are NCI designated Comprehensive Cancer Centers that treat the majority of patients with cancer from their local communities and serve as regional referral centers. DUMC and VAMC include 17 medical oncologists, 10 radiation oncologists, 13 hematologists treating malignancy and 12 first and second-year medical oncology fellows. UPCI has 66 medical oncologists, 16 radiation oncologists, 41 hematologists treating malignancy and 18 fellows. In 2002 UPCI will open the Hillman Cancer Institute centralizing patient care and increasing the ability to conduct clinical research. We only need to recruit 26% of the available oncologists to achieve our targeted sample size of 50 physicians.

In 1999, the DUMC oncology clinic alone served 418 late-stage cancer patients with solid tumors – 44% lung cancer, 12% colorectal cancer, 10% breast cancer, 4% ovarian cancer, 1% prostate cancer, and 29% other sites. Most of the patients are White (81%), some are African-American (18%), few are Asian (1%) and none are Hispanic. About half are male (55%). The VAMC serves approximately 200 late-stage cancer patients each year, of whom the overwhelming majority are male, and 30% are African American. The new UPCI Hillman Center anticipates 200 patients per day with a variety of malignancies (35% breast, 26% lung, 20% colorectal, 19% prostate), and the ethnic breakdown is 90% White, 7% African-American and 3% other.

D.3 Physician Participants

All medical and radiation oncology faculty and medical oncology fellows who see patients in the participating clinics will be eligible for the study. Dr. Marcom will serve as a Co-Investigator and our key liaison with medical oncologists at Duke. In this role, he will be excluded from the study; however, he and his patients will participate in pilot-testing. At UPCI, Dr. Arnold will serve as the key liaison with the oncology staff. Although not an oncologist, he has a long history of collaboration with the cancer program, serves as Co-Director of UPCI's Palliative Care Program, and successfully recruited 10 oncologists for training and group work to become palliative care educators. We have also generated enthusiasm among key opinion leaders (*see the attached letters of support from multiple division chiefs and program directors at DUMC, VAMC and UPCI*).

We expect DUMC, VAMC and UPCI clinicians to participate in the study as a supportive gesture to their colleagues and for the intrinsic value of learning about their own communication skills. Yet, to enhance oncologist recruitment, we have inserted multiple incentives and inducements. During each phase of the study (baseline, intervention and post-intervention), participating oncologists will receive, at two different time intervals, \$25 gift certificates to a local gourmet food store. They will all receive \$100 in compensation for attending the communication skills lecture after the baseline data has been collected. This is competitive with program fees offered by pharmaceutical manufacturers. In addition, they will receive continuing medical education (CME) credits for attending the introductory lecture, and for the time spent learning with the CD-ROM. We will also provide each oncologist in the intervention group, as a gift, a pair of high-quality headphones for use when reviewing their audio-recorded conversations which, in addition to serving as a recruitment tool, will emphasize and ensure patient confidentiality. Given our previous experience (*see section C.11*) of achieving extraordinarily high physician participation rates in audio-recording studies, ***we are extremely confident of our ability to collect audio-recordings in the baseline and post-intervention phases of the study. We are including multiple inducements of gifts, CME credits, and active encouragement from key administrators and clinical leaders.***

D.4 Patient Participants

Eligibility criteria for patients will be identical in the baseline and post-intervention assessment phases. Our goal is to identify patients with advanced disease and no realistic expectation of cure according to their oncologists, who are considering stopping anti-cancer therapy and receiving only palliative care. We want to enroll patients just prior to discussions with their oncologists about these options. Therefore, biweekly, we will present participating physicians with a list of upcoming clinic visits and ask them to identify those patients whom they “would not be surprised might die within six months.” We prefer using the physician's assessment of prognosis over objective criteria such as disease stage, weight loss or performance status because physician prognostic estimates are more predictive of decision-making than objective data.⁴⁵ The question about “surprise,” rather than direct prognosis (“who would you expect to be dead in six months?”) is a more inclusive criterion that decreases the optimistic bias.¹²⁹ Eligible patients must: 1) speak English; 2) receive primary oncology care at DUMC, VAMC or UPCI, defined as at least two visits to the clinic during the past year and a future scheduled appointment; 3) be receiving treatment for any malignancy; and 4) have access to a telephone. We will exclude patients who are: 1) incompetent for interview (documented diagnosis of active psychosis or

dementia) or unable to provide informed consent as assessed by the interviewer; 2) seen primarily by non-physician providers (e.g., nurse practitioners, physician assistants) or medical residents; or 3) hearing impaired or have a speech disorder. Patients will not be compensated for participation in the study, but will receive free valet parking on the day of their audio-recorded visit.

D.5 Recruitment of Minority Patients

African-Americans comprise approximately 18% of cancer patients at Duke, 30% at the VA, and 7% at UPCI. We expect that the ethnic composition of our study population will be representative of this population. To facilitate minority recruitment, we will employ at least one African-American research assistant at the Durham site and aim to match the race of the research assistant and the patient. In our prior communication studies in the VA and North Carolina Triangle practices we have achieved that goal and recruited 30% and 23% African-American patients respectively. Recruitment rates for African-American patients have not been significantly different from those of White patients.

D.6 Data Collection

The different phases of the study are outlined in Figure 3. The recruitment, audio-recording and survey protocol will be standardized across baseline and post-intervention assessment phases to ensure comparability of the samples. At the beginning of the study, participating oncologists will provide informed consent and complete a short survey. Drs. Marcom and Arnold will hand deliver the surveys, and oncologists will return them to the research staff. A research assistant will follow-up in one week to ensure the surveys are returned.

During data collection phases, trained research assistants will conduct a biweekly review of patient appointment lists for the upcoming month in each clinic, and ask participating oncologists to identify eligible patients according to the criteria listed above. Identified patients will receive a letter from the project leader inviting them to participate in a study about patient-physician communication that will include audio-recording of visits. Patients who do not wish to be contacted about the study may call a toll-free number to refuse. If patients do not respond, a research assistant will contact them by telephone several days prior to their clinic visit, explain the study in detail, and obtain verbal consent for participation. Patients will be informed that we are studying cancer treatment decision-making; however, we will not specifically mention that our focus is on end of life. Based on our prior experience of more than 700 patients approached in other audio-recording studies, we anticipate a refusal rate of approximately 30%. On the day of the clinic visit, the research assistant will meet patients shortly before they see their oncologists, obtain written informed consent and administer a brief survey. In the baseline data collection, the patients will only be interviewed prior to the visit and asked to complete questions on demographics. In the post-intervention data collection phase, the pre-visit survey will also include questions on quality of life, affect, and social support. At that time, the research assistant will arrange a time to telephone the patient within one week of the visit to conduct a ten-minute post-visit survey (only during the post-intervention data collection phase). The patient will be given an appointment card reminder of this upcoming call. We expect to audio-record two visits with each patient (*see below*), and on subsequent visits, the research assistant will briefly meet the patient, remind them of the study, note their continued willingness to participate and arrange the follow-up call. Just before the patient enters the exam room, the research assistant will place the audio recorder and cylindrical conference microphone (0.5" x 2") in an unobtrusive location, turn it on and leave the room. When the visit is completed, the research assistant will retrieve the audio recorder and give the oncologist a very brief (30 second) self-administered survey that assesses content of the visit to determine, among other things, whether the discussion of ending anti-cancer treatment occurred.

In our past studies, we have been able to record clinic visits with minimal disruption to patient flow. Because physicians will be aware of the audio-recording, there is the possibility that they will modify their behavior during the encounters. The issue of performance bias in response to audio-recording has been addressed by several investigators. Korsch and colleagues found no difference in patient report of physician behavior, or patient satisfaction or compliance when audio-taped and non-taped visits were compared.¹³⁰ Inui similarly concluded that the presence of a tape recorder did not effect physician-patient communication in any systematic manner.⁸⁷ Although it is true that we may capture "best behavior," we can conclude if we identify shortcomings, these might be even more strongly pronounced in unobserved practice. Furthermore, if such behavior were to occur, it should be equally present in both study groups.

We aim to audio-record two visits for each oncologist-patient pair (n=200) in each data collection phase of the study. We recognize that discussions of treatment limitation, and even referral to hospice, occur over time, and we are more likely to capture the actual issues being discussed if we observe multiple encounters. In addition, physicians are more likely to exhibit a consistent communication style over time. We anticipate that some patients will become too ill to return to clinic, thus leading to only one audio-recording for some pairs.

D.7 Intervention

After completing baseline assessment and coding the conversations, we will develop a CD-ROM educational program and deliver it to oncologists in the intervention group. The CD will be individualized for each oncologist, containing coded baseline conversations (*see section D.9*). Users will work through an entertaining, user-friendly communication skills program that contains their own audio-recordings. They will observe examples of particular skills they have done well or poorly, such as responding to patients' expressions of affect. These examples on the CD will link to modules that discuss the skills and provide video-clip examples of good and bad practices. Three months after physicians receive the CD-ROM, the post-intervention assessment will begin, and oncologists in both intervention and control groups will each provide another sample of audio-recorded encounters.

D.7.1 Conceptual Model for the Intervention: The overarching conceptual model for the intervention is based on the social cognitive theory¹⁰⁰, the transtheoretical model of behavior change,¹⁰¹ Cabana and colleagues' physician barriers model,¹⁰² and the elaboration likelihood model.⁴² Similar to other behavior change interventions, this intervention will attempt to improve oncologists' communication behaviors by increasing their knowledge and skills, and improving their outcome expectancies, self-efficacy and stage of readiness to change. The following assumptions will guide intervention development: 1) oncologists may find discussing the transition from anti-cancer treatment to palliative care difficult due to the emotional content; 2) oncologists may lack the knowledge, skills, and self-efficacy to respond appropriately to patients' concerns, and may be unaware of how their communication behaviors impact patients' mental health; 3) when oncologists do not respond appropriately, patients may feel anxious or depressed; 4) when patients are anxious or depressed, they cannot process information well; 5) oncologists can learn how to respond to patients' concerns; 6) oncologists also can learn to recognize "clues" or "empathic opportunities" and feel more confident about their ability to communicate; and 7) patients will feel less negative affect when oncologists have elicited and addressed their concerns (*Figure 4*).

D.7.2 CD-ROM Design: The CD-ROM will be created as a user-friendly, self-contained learning tool (*Figure 5*). The oncologists will insert it in their computers (PC or Mac-compatible), click on an icon, enter their unique ID (for confidentiality of patient information) and launch the program. The program will direct them through a series of learning modules (*see section D.7.3*), in which they will be selectively given coded segments of their audio-recordings to review. They also will have the option to listen to their recordings in their entirety. The CD-ROM will contain audio files of all their recorded conversations (n=8); clicking on a conversation will open that file and show all of the codes that were assigned to the conversation. Clicking on one of the coded segments will play that segment aloud and open a window that provides information about the particular communication skill being examined. This window will include didactic information with references, and video clips of sample conversations. As the oncologist uses the program, whether working through the modules formally or listening to segments of conversations, the program will create a tracer file on the users' hard drive. This will contain information about which modules or recordings were opened and completed, and time spent with the program. If the user is connected to the internet, this information will be automatically uploaded to a study website that will record the data. If the user is not connected, it will be uploaded the next time they are on-line.

Figure 4. Theoretical mediation model

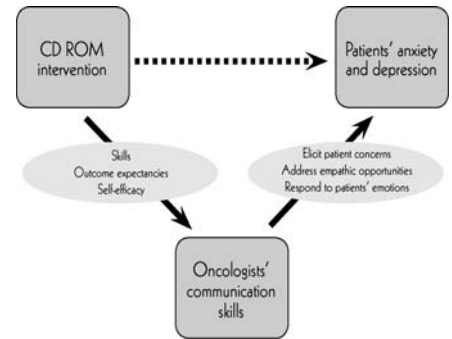
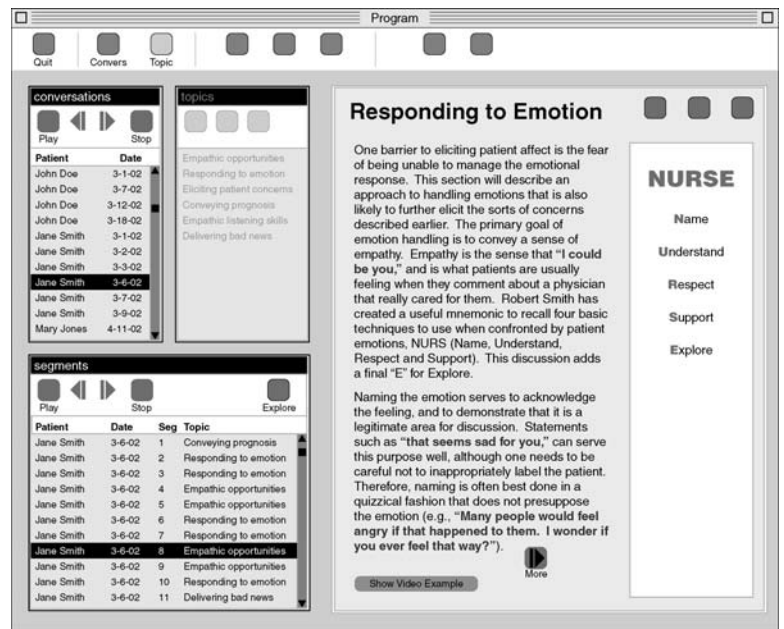


Figure 5. Sample intervention CD-ROM screen shot



D.7.3 Intervention Modules: The intervention's primary objectives are to raise awareness of emotional content in discussions about palliative care, to increase oncologists' self-efficacy for addressing affective concerns, and to provide them with the skills for doing so. We believe that oncologists will achieve these goals best when exposed to their own conversations. Listening to themselves communicate effectively in some situations should raise oncologists' self-efficacy that they can communicate effectively in most situations. Further, oncologists will see how patients respond to their communication techniques. When patients respond positively, oncologists should have improved outcome expectancies that patients will feel better in response to effective communication.

The intervention will be comprised of four modules that build sequentially upon one another. The module topics will be: 1) principles of effective communication; 2) responding to patients' emotions; 3) recognizing and responding to empathic opportunities; and 4) conveying prognosis. Although designed to be reviewed sequentially, each module can be used independent of the other modules, and each will contain information from the recorded encounters to demonstrate principles of communication. Our proposed mediating mechanisms (outcome expectancies, self-efficacy, and skills) will be addressed in each of the modules. The skills taught in the modules will be similar to those currently used in OncoTalk (see section C.10), a communication skills training program for oncology fellows, for which Drs. Tulsky and Arnold are co-investigators and small group facilitators (see Appendix for OncoTalk curriculum). **Although the modules will identify oncologists' communication weaknesses and emphasize areas for improvement, the overall "tone" of the CD-ROM will be one that stresses the difficulty of these conversations, that shortcomings are ubiquitous among physicians, and that praises and encourages positive behaviors when identified.**

D.7.3.1 Module 1: Principles of effective communication. The purpose of the first module is to define the principles of effective communication that encourage elicitation of patients' concerns, and provide exemplars of these basic tenets. Specific topics to be addressed include using open-ended questions, reflective listening, silence, psychosocial talk vs. medical talk, and empathic statements. The specific technique of "Ask-Tell-Ask" (see OncoTalk modules) will be emphasized. In addition to acquiring these skills, oncologists will learn common concerns of patients with advanced cancer, and the importance of eliciting patients' concerns.³⁹ Furthermore, their own audio-recorded visits will be coded for each of these skills. When oncologists click on a coded section of their encounters, a window will appear that presents information about the coded skill and how the patient responded. In these, as well as simulated video-clip examples, they will observe how some communication approaches are likely to encourage patients to open up while others block them from disclosing concerns. For example, using open-ended, rather than closed-ended, questions is more likely to reveal patients' emotional concerns.

D.7.3.2 Module 2: Responding to patients' emotions. This module will expand on the basic principles presented in Module 1 and address, in greater depth, the specific challenge of handling emotions. The acronym NURSE ("Name," "Understand," "Respect," "Support," "Explore") will serve as the organizing framework for this presentation.^{78, 131, 132} Examples of these "emotion handling skills" include: Naming ("I wonder if you are feeling angry"); Understanding ("I can certainly see why you would feel angry"); Respect ("I respect your decision to stop treatment at this time," or alternatively, "I am so impressed with how well you've dealt with this illness the past three years"); Support ("I will be there with you throughout this illness, no matter what you decide"); and Explore ("Tell me more about your anger"). As oncologists review their conversations on-screen, patients' emotional statements will be identified, as will the specific skills used to respond. Oncologists will see how these skills build upon the previous module (e.g., naming emotions is a form of reflective listening).

D.7.3.3 Module 3: Recognizing and responding to empathic opportunities. Patients are frequently not forthcoming with their psychosocial concerns, and give only subtle "clues" or "cues" that they are upset.⁸⁻¹⁰ Suchman and colleagues have described a model in which patients make statements that present "empathic opportunities." Physicians then respond with either "empathic continuers," that acknowledge the statement and pursue more psychosocial exploration, or "empathic terminators," in which the physician blocks further psychosocial communication.^{7, 60} Oncologists must learn how to recognize these empathic opportunities and respond appropriately.

Oncologists' conversations will be coded for empathic opportunities. When they identify these coded segments, oncologists can listen to their responses to the concern. Another window will appear that will pose several questions to the oncologist such as: "How did you respond to that opportunity? Did you express empathy toward the patient? Did you give the patient a medical explanation? Did you move onto another topic? Did you ask an open-ended question to explore reasons why they are feeling

upset?” After they answer, they will be shown how their actual response was coded. If they had an accurate response, the computer will praise them. If they gave an answer that was different from the code assigned to their response, a window will appear that informs them of the discrepancy between the code and their perception of their response. If the response was not appropriate (e.g., gave a medical explanation), oncologists will be reminded of elements in Module 1 where a psychosocial response might have been more appropriate.

Another objective of Module 3 is to increase oncologists’ confidence that they can recognize and address empathic opportunities. To increase self-efficacy, we will code discussions for good responses and when they click on these coded segments, oncologists will be told they responded to the patient’s emotional concern appropriately. When repeated in subsequent segments they will be told, “This is the second time you helped the patient feel better by responding appropriately.” The number will change to match the number of opportunities in which they performed the target behavior.

In the segments coded with a less-than-optimal response, they will be prompted to think about what made this situation different from when they responded well. Potential options might include, “I was not paying attention,” “I did not understand what the patient meant,” or “I really wanted to convey some information to the patient.” Such options represent external, changeable reasons under the oncologists’ control. These contrast with internal, permanent attributions which oncologists may feel they cannot change (e.g., “I am not the kind of person who is good at dealing with feelings”). When they select an option, they will receive a response intended to increase their self-efficacy. At the end of Module 3, a total count of empathic opportunities addressed will appear on the screen and an encouraging message will read, “You have done well. Out of X opportunities, you addressed the patient’s concerns X times. Although there is still room for you to improve, you are well on your way to communicating better with your patients.” After completing this Module, oncologists will be sent a thank you letter and \$25 gift certificate.

D.7.3.4 Module 4: Conveying prognosis. Physicians frequently do not convey prognosis accurately to patients because they fear the information will reduce their hope and harm them.^{45,133} Conversations will be coded for the delivery of prognostic data. When oncologists click on the coded section, they will be asked whether they disclosed the accurate prognosis to the patient, and if not, why they chose to give an inaccurate prognosis. Sample options might be, “I didn’t want to think I had failed with this patient,” “I didn’t want to believe that this patient was going to die,” “I didn’t want my patient to lose hope,” and “I didn’t want my patient to lose faith in me as a physician.” After the oncologist clicks any of the options, another window will come up to bring up counter arguments to those thoughts. Sample phrases might be, “The patient is probably very grateful for the work you have done and knows you tried your best,” “Unfortunately many patients will die no matter how hard you try. Although this is very difficult, the patient is better off from being under your care,” or “Sometimes patients want to know when they need to get their things in order and prepare to die. Withholding prognostic information might impede them from doing this.” Additionally, the module will stress the need to accompany discussions of prognosis with attention to patient affect. Upon completion of the fourth module, the physician will be congratulated.

D.7.4 Intervention Administration: After the personalized CD-ROM’s have been prepared, they will be distributed to groups of five intervention oncologists at small scheduled luncheons. In Durham, these luncheons will be attended by Dr. Marcom and Dr. Tulsky, in Pittsburgh, Dr. Arnold will serve this introductory role. In both sites, a “technical advisor” will also be introduced, who will provide ongoing support for the CD-ROM intervention. This person will be a Masters trained psychologist, who is thoroughly familiar with the software, and undergoes specific training for the intervention from Dr. Pollak. The CD-ROM will be accompanied by a cover letter signed by the Medical Oncology division chief or Radiation Oncology department chair, as appropriate, encouraging its use. To ensure oncologists use the CD-ROM, Dr. Tulsky (Durham) or Dr. Arnold (Pittsburgh) will make appointments to meet with each oncologist one-on-one to provide additional assistance in using the intervention. They will demonstrate the program using a CD-ROM of their own discussions, deliberately pointing out areas needing improvement. It is hoped that by exposing their own shortcomings, they will decrease some resistance by oncologists to listening to their own recordings. Again, it will be emphasized that these discussions are very difficult and that most physicians have received little prior training in these skills. Further, to encourage continued use of the CD-ROM, the technical advisors at each site will call oncologists monthly to see if they have any further questions about the CD-ROM, and offer to visit. During these calls, the advisor will offer to hear about specific cases and help the oncologist work through possible communication responses. Although time spent with oncologists in this way may be viewed as

educational, we consider the intervention to be the CD-ROM, and the efforts of Drs. Tulsky, Marcom and Arnold, as well as the technical advisor, as merely encouragement to use the intervention. As oncologists work through the CD-ROM modules, the application will create a tracer file on the oncologists' hard drive that documents which modules have been reviewed, and how much time has been spent with each module. If the computer is connected to the internet, this file will be automatically uploaded to a study website, thus maintaining a record of actual usage. Another purpose for these records is to establish some measure of the intervention penetration. Once we receive the file which indicates oncologists have completed a section of the CD-ROM, we will send thank you letters, sometimes accompanied by a \$25 gift certificate to a local gourmet food store. The oncologists will be notified in the study consent form about this monitoring and about the rewards for completing sections of the CD-ROM. Not being connected to the Internet during usage and other user-controlled technical issues will prevent some data from being transferred to the study team. If we do not receive an electronic file indicating completion within 3 weeks after their appointment with Dr. Tulsky or Dr. Arnold, the technical advisor will contact oncologists to remind them to use the program or to make sure they are connected to the internet the next time they review their CD-ROM. They will also receive a letter accompanied by the \$25 gift certificate to use the norm of reciprocity to encourage oncologists to use the program. If we still do not receive the data, we will make every effort to identify configuration issues and other technical reasons for its loss. Furthermore, with permission, we will also request to manually retrieve it from users' computers. Using such aggressive measures, we anticipate that data loss will be minimal. Additional incentives to promote continued participation will include gifts of food and candy to the physicians in clinic, ongoing email reminders, CME credits for participation, and a pair of high-quality headphones for reviewing the audio-recordings.

D.8 Dissemination Plan

This project will produce a wealth of knowledge about oncologist-patient communication during the transition from anti-cancer treatment to palliative care. ***The audio-recorded conversations from the baseline and post-intervention assessment phases will constitute the largest database ever assembled of end-of-life communication between oncologists and cancer patients.*** We will learn a tremendous amount about physician communication patterns that, when published in the medical literature, will contribute to other educational projects and clinical improvements. Furthermore, we will be able to immediately incorporate what we learn in our baseline data collection into the ongoing NCI sponsored OncoTalk oncology fellow training program.

If the CD-ROM intervention is effective in changing physicians' behaviors, we will work to redevelop the technology for commercial use and to disseminate it widely. First, the American Board of Internal Medicine has expressed enthusiastic interest in the technology, for use in both assessment of skills as well as education (*see letter of support*). This technology could become the standard for assessing communication competency of practicing oncologists and other physicians. Second, the CD-ROM technology lends itself easily to becoming a continuing education tool that could be marketed to physicians by a variety of organizations (e.g., the American Society of Clinical Oncology) or private firms. It creates a practical way for physicians to learn communication skills from their own practices. In addition, David Farrell, President of *People Designs*, plans to submit a Small Business Innovation Research (SBIR) proposal to offer this technology to other oncologists and physicians who want to improve their communication skills. Partnering with a small business increases the probability that this product will be disseminated after the trial is complete.

D.9 Measurements

The primary measures for this study will be the actual communication behaviors employed by the physicians and observed in the audio-recorded conversations. Other primary measures are patients' anxiety and depression. Secondary measures will be contained in the patient and physician survey responses. The timing of the measures are detailed in Table 1. First we will present the primary measures for the oncologists (D.9.1) and patients (D.9.2). Then we will describe the secondary measures for the oncologists (D.9.3) and patients (D.9.4).

D.9.1 Primary measures from audio-recorded encounters: Encounters will be digitally recorded to audio ".dss" files and transferred directly to the coding workstation as described in the Data Management section below. All coding will be conducted directly with the audio files, rather than transcriptions. Analysis in this manner saves time and money, preserves inflection, volume and other attributes of conversation that assist in coding. We will develop a codebook through an iterative process.¹⁹ First, we will create coding categories for each of the communication skills we are studying in this proposal. These are adapted from the literature review summarized in section B, and are grouped by communication task:

D.9.1.1 Elicitation of concerns and general communication skills

- *Number of patient concerns elicited* – using the Concerns Checklist³ to define concerns, we will count the total number of concerns stated by the patient during each encounter.
- *Open-ended/closed-ended questions* – each question asked by the oncologist will be coded as open- or closed-ended and a ratio will be calculated.⁹⁴
- *Physician time/Patient time* – the ratio of physician to patient speaking time will be calculated as a measure of speaker dominance.
- *Summarizing/educated guesses* – these include statements such as “what I hear you saying is that you’ve been more upset with your family this past month – is that correct?”¹³ Such statements facilitate disclosure of concerns.
- *Leading questions* – these include statements such as “you’re chemotherapy’s been going well, hasn’t it?”¹³ Such statements inhibit disclosure of concerns.

D.9.1.2 Responding to emotion

- *NURSE*^{78, 131} – using this construct (*see section D.7.3.2*) all physician statements will be coded appropriately if they contain one of these specific “emotion-handling” skills: naming, understanding, showing respect, expressing support, exploring. A summary score will be calculated for each conversation of the total number of NURSE skills used.

D.9.1.3 Empathic opportunities

- *Empathic opportunities and responses* – patient and physician statements will be coded, when appropriate, as empathic opportunities, positive responses and missed opportunities according to Suchman’s criteria modified by Levinson, and examples from Butow.^{7,9,10} We will create an empathic opportunity score of the ratio of positive responses to empathic opportunities.

D.9.1.4 Conveying prognosis

- *Discussion of prognosis* – no standard coding exists for this construct. We will identify all instances in which physicians mention prognostic information and assign it to categories related to its specificity (e.g., “30% of patients with your cancer are still alive in one year,” vs. “Things should continue to go well”).

Each coding item will be created in such a way that it is coded as either present or absent (e.g., oncologist named the patient’s emotion “It seems like you’re feeling sad”). After developing a draft of the codebook, the team will code a sample of the audio-recordings to identify problems and formulate coding rules. The codebook will then be converted to the computerized interface, a Microsoft Access data entry form that requires the rater to proceed systematically through the checklist while using Sound Edit 16 to simultaneously play and visualize the encounter using a split screen format.¹²⁸ At each item, the rater is asked to check yes/no, to use Sound Edit tools to enter a time stamp, and/or to transcribe a physician’s exact words.

We will establish reliability of the coding system by calculating an inter-rater reliability coefficient (kappa statistic) for each of the codes. Codes will be assigned to individual spoken segments, and code reliability will be based at that level. Only codes with a kappa ≥ 0.6 will be included in the final version. When the coding system is completed, the computerized interface will be finalized. Two raters will code independently all of the audio-recordings. To protect against rater drift and decay, continuous monitoring of inter-rater reliability will occur throughout the entire coding period. Coding disagreements will be resolved by conference of the two raters, and persistent disagreements will be resolved by the entire team.

The actual coding will be completed in two “passes” of the audio-recording, one completed immediately after the other. The first time the rater reviews the recording he or she will only enter codes from the concerns and emotions categories (D.9.1.1 and D.9.1.2). During the second pass empathic opportunity and prognosis codes will be entered (D.9.1.3 and D.9.1.4). Dividing the reference coding in this way increases inter-rater reliability. After all codes are entered, the rater clicks the “check” button at the end of the data entry form which initiates pre-programmed calculations (such as ratio of physician to patient talk), applies decision rules that assign a numeric value to each communication behavior being evaluated, and calculates summary scores of certain domains. These data, summarizing the result of the communication analysis, may be treated as usual quantitative data for all subsequent analyses.

The coding procedures are practical from a resources perspective. Based on our previous experience, we anticipate the coding time for a typical visit will range from two to three times the length of the visit – thus on average, no more than one hour for a 20-minute medical visit.

D.9.2 Primary measures from patients' surveys: During both data collection periods, patients will be asked to complete a survey prior to the first visit to report their demographic information. During the post-intervention assessment phase, they will also report their affect in the pre-visit survey. In the post-visit survey within one week after each visit, in which patients will be asked to report their affect, rating of communication with the oncologist, satisfaction with care, quality of life and social support.

D.9.2.1 Affect: Patients will be asked 14 items to describe their current emotional state using the Profile of Mood States (POMS).^{134, 135} Sample items include “jittery” “nervous” “distressed” and “upset” (1=Not at all and 5=Very much). Two subscales, one for anxiety and one for depression, are assessed. This measure has been found to be reliable in a sample of cancer patients ($\alpha=.91$).

D.9.3 Secondary measures from oncologists: At baseline, oncologists will be asked to complete a survey that measures their knowledge, outcome expectancies, confidence, and comfort level for addressing patients' emotional concerns. During both the baseline and post-intervention assessments, after each visit, oncologists will be asked to complete a very brief post-visit questionnaire to assess, along with other issues, whether stopping chemotherapy was discussed. After 25% of visits, oncologists will also be asked to rate their affect. After the intervention is completed (3 months), all oncologists will fill out a final survey that assesses the same constructs that were included on the pre-intervention survey (*see Table 1 for timing of measures*).

D.9.3.1 Demographics: At baseline, oncologists will be asked to report their age, race, gender, years in practice, and hours spent seeing patients.

D.9.3.2 Content of visit: In the brief post-visit survey, oncologists will be asked what issues were discussed during the visit. Items such as “treatment side effects,” “hospice referral,” “stopping chemotherapy,” and “quality of life” will be included in the checklist. Oncologists can check boxes marked “other” to fill in any options not presented.

D.9.3.3 Knowledge of appropriate response to patients' emotions: Oncologists will be asked to read a case scenario that describes a cancer patient learning he is ending conventional treatment. This scenario will be adapted from a measure used in a workshop to improve oncologists' communication skills. The scenario will have 8 parts and, in each part, the patient will present an empathic opportunity. Oncologists will be asked to choose the most appropriate response from among 5 options.⁷³ For the post-intervention survey, oncologists will be given a different scenario.

D.9.3.4 Outcome expectancies: A 23-item Communication Outcomes questionnaire will assess possible outcomes as a result of communication behaviors. A sample item reads, “Your patient will become uncontrollably upset if you ask about his or her feelings” (1=Not at all likely to 5=Extremely likely). This scale has been shown to be reliable and valid.⁸⁰

D.9.3.5 Confidence: Oncologists will be asked to answer 7 items to rate their confidence for addressing patients' concerns. Sample items read, “On a scale from 0 (not at all confident) to 100 (totally confident), please rate how successful you think you would be in... ‘Initiate a discussion about a patient's concerns’ and ‘Move patient to discuss other concerns.’”⁷³

D.9.3.6 Comfort dealing with death: A 34-item scale (The Attitudes on Death instrument) will assess oncologists' attitudes toward caring for dying patients. Originally developed by Drs. Susan Block and Robert Arnold, this instrument is currently being used in the Harvard Palliative Care Program. A sample item reads, “Caring for patients who are dying is depressing” (1=Never and 5=Always). This scale has been validated in a study on physicians' emotional reactions to their patient's death and is also being used in a national survey of medical students' experience regarding end-of-life care.

D.9.3.7 Affect: After 25% of visits, oncologists will be asked to complete the POMS, as described above.¹³⁴

D.9.4 Secondary measures from patients:

D.9.4.1 Demographics: At baseline, patients will be asked to report their age, race, marital status, education, and income.

D.9.4.2 Self-rating of communication with oncologist: Patients will be asked to answer 4 items to rate the quality of communication with their oncologist.¹³⁶ A sample item reads, “When you are talking with your doctor about the kinds of treatment you want if you get very sick do you feel that your doctor cares about you as a person?” (no, probably yes, yes). This scale is reliable and valid ($\alpha = .81$).

D.9.4.3 Satisfaction with care: Patients will be asked 10 items from the Visit-Specific Satisfaction Questionnaire related to the care they received from the oncologist.^{137, 138} The items measure personal communication and physician aspects of the care. A sample item reads, “How would you rate the skill of your provider?” (1=Poor and 5=Excellent). The scale has high internal consistency ($\alpha = .94$).

D.9.4.4 Quality of Life (Physical and emotional well-being subscales of the FACT-G, 13 items).¹³⁹ Examples of questions included in FACT-G subscales are: *Physical well-being* ($\alpha = .82$) - “I have trouble meeting the needs of my family (1=Not at all and 5=Very much) and *Emotional well-being* ($\alpha = .74$) - “I am losing hope in the fight against my illness” with the same response categories.^{134, 135}

D.9.4.5 Social support (3-items from the Interpersonal Support Evaluation List (ISEL)).¹⁴⁰ A sample item is, “In the past 30 days, how often has someone made you feel loved and wanted” (1=Never and 5=Very Often, $\alpha = .84$). Social support may mediate the impact of an oncologists’ communication behavior with the patient.

Table 1. Description and timing of measures

D.9.5 Process Measures: To assess intervention dose, at the post-intervention survey, oncologists will be asked to report which Modules they had completed. We will check their responses against our electronic files. They also will be asked to report the amount of time spent reviewing each Module, when they reviewed the CD-ROM, and when they re-reviewed it (if applicable). They will be asked to rate the helpfulness, utility, and ease of the CD-ROM on an 11-point scale (0=Not at all helpful (useful, easy to use) and 10=Very helpful (useful, easy to use) and asked how likely they would be to recommend the program to a colleague (1=Not at all likely and 5=Extremely likely).

D.9.6 Length of Surveys: The oncologists’ baseline survey will include 77 questions, and their post-intervention survey will include 72 questions. The oncologists’ post-visit questionnaire will include 1 questions, and for 25% of the sample, 11 additional questions (to measure immediate affect). The patient’s baseline survey will include 6 questions, and their post-visit questionnaire will include 38 questions.

D.10 Analysis

D.10.1 Descriptive Analyses: Continuously measured variables collected from each phase will first be described and explored using means, medians, standard deviations, histograms, and box plots. Particular attention will be paid to identification of outliers or influential observations as well as departures from standard Gaussian assumptions (e.g., normality). When non-normality occurs (e.g. skewed distributions), appropriate transformations will be applied prior to testing hypotheses using parametric statistical tests based on normality. Discrete survey data will be described with frequency tables and examined using categorical data analysis techniques. To understand trends and variability in the data, descriptive analyses of the patients will be performed within oncologist, within phase of the study (across oncologists), and within each phase/oncologist combination. The primary outcome measures from the audio-recorded conversations are primarily measured as counts and will be described with frequency tables and bar plots.

Primary outcomes	Instrument	Timing
Oncologists’ skills		
Elicitation of concerns	Coded audio-recordings	During visit
General communication	Coded audio-recordings	During visit
Responding to emotion	Coded audio-recordings	During visit
Empathic opportunities	Coded audio-recordings	During visit
Conveying prognosis	Coded audio-recordings	During visit
Patients’ affect		
Anxiety*	Profile of Mood States	Post-visit
Depression*	Profile of Mood States	Post-visit
Secondary outcomes		
Oncologist measures		
Demographic characteristics	Pre-visit questionnaire	Baseline
Skills	Case scenarios	Baseline and post-intervention
Outcome expectancies	Communication Outcomes	Baseline and post-intervention
Confidence	Confidence in Skills	Baseline and post-intervention
Comfort dealing with death	Attitudes on Death	Baseline and post-intervention
Content of visit	Checklist of topics	Post-visit
Affect (only 25% of visits)	Profile of Mood States	Post-visit
Patient measures		
Demographic characteristics	Pre-visit questionnaire	Pre-visit
Quality of life*	FACT-G	Post-visit
Social support*	Adapted ISEL	Post-visit
Self-rating of communication*	Quality of communication	Post-visit
Satisfaction with care*	Satisfaction survey	Post-visit
Process measures (oncologists)		
Dose of intervention*	# Modules completed/time spent	Post-intervention
Self-rated utility of intervention*	Helpfulness, ease of CD-ROM	Post-intervention
*only assessed post-intervention		

D10.2 Primary Analyses:

Hypothesis 1: In the post-intervention assessment, oncologists in the intervention group will elicit a greater number of concerns than oncologists in the control group.

Hypothesis 2: In the post-intervention assessment, oncologists in the intervention group will use a greater number of emotion-handling skills than oncologists in the control group.

Hypothesis 3: In the post-intervention assessment, oncologists in the intervention group will have a higher empathic opportunity score than oncologists in the control group.

As described in Section D.9 (Measurements), multiple outcomes will be measured by coding the audio-recordings in both the baseline and post-intervention assessments. A primary goal of the intervention is to modify the behavior of intervention group oncologists so they are more likely to elicit a greater number of concerns, employ a greater number of emotion-handling skills, and recognize and respond to empathic opportunities in conversations with their patients.

In both the baseline and post-intervention assessments of the proposed study, 50 oncologists (25 in the intervention group and 25 in the control group) will have audio-recorded conversations with 4 patients each at 2 visits. In the primary analyses for the first three hypotheses, the two visits per patient will be treated as one contiguous visit. For example, if Dr. Smith elicited two concerns in the first visit with patient A and elicited one concern in the second visit with patient A, the number of concerns elicited for Dr. Smith seeing patient A would be three. There are several reasons for this decision. First, we do not expect that all outcomes will happen at each visit, but we do expect to see most outcomes across multiple conversations between the oncologist and his or her patient – particularly in the post-intervention phase of the study. Also, treating multiple conversations as one unit more accurately reflects the continuous nature of care oncologists give their patients.

Because the first two primary outcomes are measured as counts within a specific unit of time (*number of concerns and number of emotion-handling skills*), it is natural to think of them arising from a Poisson process. In most situations, a Poisson regression or log-linear model would be most appropriate for this type of data.¹⁴¹ One basic assumption of a Poisson regression is that observations are independent. In the proposed study design, however, patients are nested within physicians. That is, outcomes from conversations of patients with the same oncologist may be more similar than outcomes from conversations of patients with different oncologists. In contrast to the standard Poisson regression model, a mixed-effects Poisson regression takes into account that observations within a cluster (oncologist) may be more correlated than observations between clusters.¹⁴²

Let Y_{ij} equal the number of concerns elicited by oncologist i in visits with patient j ($Y_{ij} = 0, 1, 2, \dots$). Under a mixed-effects Poisson regression, the expected number of concerns, λ_{ij} , is modeled: $\log(\lambda_{ij}) = X_{ij}\beta + Z_{ij}b_i$ where X_{ij} is the covariate vector for the fixed regression parameters, β , and Z_{ij} is the design matrix for the random effects, b_i . The distribution of the random effects is assumed to be normal with mean μ_b and variance σ_b^2 . Finally, given β and b , Y_{ij} is assumed to be Poisson with mean and variance equal to λ_{ij} .

The first primary hypothesis will be tested using the model: $\log(\lambda_{ij}) = \beta_0 + \beta_1*(post) + \beta_2*(int) + \beta_3*(post)*(int) + b_i$ where λ_{ij} is the expected number of concerns elicited. *Post* is the patient-level indicator variable that is equal to 0 if patient j is in the pre-intervention phase of the study and is equal to 1 if patient j is in the post-intervention phase of the study. *Int* is the oncologist-level indicator variable that is equal to 0 if oncologist i is in the control group and is equal to 1 if oncologist i is in the intervention group. If the estimate for β_3 is positive and significantly different from zero, this provides evidence that intervention-group oncologists have a higher number of expected concerns in the post-intervention assessment as compared to control-group oncologists. The model and test are similar for the second hypothesis, but instead, λ_{ij} represents the expected number of emotion handling skills. PROC NL MIXED in SAS 8.2 (SAS Inc., Cary, NC) will be used to fit the mixed-effects Poisson regression models.

The outcome for the third primary hypothesis is the empathic opportunity score – a ratio of positive responses to empathic opportunities. This score is a proportion that ranges from 0 to 1 and will be treated as a continuous outcome in the analysis models. If most of the observed scores are either close to 0 or 1, they will be transformed via an arcsin transformation at the modeling stage.¹⁴³ This will insure that expected values remain between 0 and 1. We will use a linear mixed effects model to test the intervention effect on empathic opportunity score.¹⁴⁴ Again, patients are clustered within oncologist, so patients' scores within a particular oncologist may not independent. For patient j clustered within oncologist i , a

linear mixed effects model for the empathic opportunity score (Y_{ij}) is written: $Y_{ij} = \beta_0 + \beta_1*(post) + \beta_2*(int) + \beta_3*(post)*(int) + b_i + e_{ij}$ where *post* and *int* are the same indicator variables as defined above. If the estimate for β_3 is positive and significantly different from zero, this provides evidence that intervention-group oncologists responded to more empathic opportunities in the post-intervention assessment as compared to control-group oncologists. The random intercept, b_i , is normally distributed and allows for variation in the intercept across clusters of patients. Finally, e_{ij} is independent of b_i and normally distributed; it represents the within-patient measurement error. PROC MIXED in SAS 8.2 (SAS Inc., Cary, NC) will be used to fit the linear mixed-effects models.

In addition to the overall intervention effect, we also plan to examine the process measures as potential covariates. These measures may be particularly important because the primary outcomes are addressed in separate modules of the intervention. To assess if intervention dose is important, the number and type of modules completed will be entered as a covariate. For example, it is expected that oncologists who complete all four modules will elicit more patient concerns than oncologists who complete less than all four of the modules. We also expect that oncologists who complete the first module will elicit more concerns in the post-intervention assessment than oncologists who do not complete the first module. Time spent on the modules and ease of use will also help to differentiate the impact of different facets of the process of the intervention. Tests of these measures may also provide insight into how the intervention could be translated to practical use.

Hypothesis 4: Patients with oncologists in the intervention group will have lower anxiety and depression (measured by POMS) than patients with oncologists in the control group.

The POMS will be administered to patients at baseline and after each visit in the post-intervention phase of the study. The anxiety and depression subscales of the POMS are continuous measures. Of primary interest is to compare the post-visit assessments between patients with oncologists in the intervention group and those with oncologists in the control group. Because each patient has two visits and the same oncologist sees several patients, measurements of anxiety and depression at each visit will not be independent. Hierarchical linear models¹⁴⁵ are an appropriate and flexible analytic tool for continuous, clustered data such as these. Using hierarchical linear models allows the analyst to include unbalanced data (e.g., a different number of visits per patient or a different number of patients per oncologist) and both fixed and random effects at each level of clustering. The hierarchical linear model for the fourth hypothesis can be written: $Y_{ijk} = \beta_0 + \beta_1*(int) + \beta_2*X_{ijk} + b_{ij} + c_i + e_{ijk}$ where Y_{ijk} is the post-visit anxiety or depression score and X_{ijk} is the pre-visit anxiety or depression score for patient j with oncologist i at visit k . Including the pre-visit score helps to adjust for the regression to the mean artifact.¹⁴⁶ As with the primary hypotheses, *int* is an indicator variable that is equal to 1 for those patients seen by intervention-group oncologists. If β_1 is negative and significantly different than zero, this provides evidence that patients seen by intervention-group oncologists are less anxious or depressed as compared to patients seen by control-group oncologists.

The oncologist-level random effect is denoted by c_i and takes into account that outcomes on patients seen by the same oncologist may be more similar than patients seen by different oncologists. b_{ij} represents the patient-level random effect and takes into account that outcomes on multiple visits within a patient may be more similar than visits across patients. Both random effects and the residual error (e_{ijk}) are assumed to be independent and normally distributed. PROC MIXED in SAS 8.2 (SAS Inc., Cary, NC) will be used to fit the hierarchical linear models.

If there is a significant intervention effect (i.e., if β_1 is significantly different from zero in the above model), then we also plan to examine whether oncologist behaviors mediate the impact of the intervention on patients' anxiety and depression (*see Figure 4*).¹⁴⁷ Three additional steps are required to show mediation. First, the intervention must be linked to the mediator (e.g., oncologists' emotion-handling skills). Then, the association of the intervention and mediator also must be significant (e.g., oncologists' emotion-handling skills associated with patients' anxiety). If these previous steps have significant results, the final step is to fit a hierarchical linear model that specifies patients' anxiety as the outcome and oncologists' emotional-handling skills as the mediator of the effect of the intervention. If the effect of the intervention is reduced (i.e., β_1 is not significantly different from zero) when oncologists' emotion-handling skills is included, then this particular behavior mediates the impact of the intervention on patients' anxiety.

D.10.3 Secondary Analyses: Additional outcomes to be obtained from the audio-recorded conversations include the number of educated guesses, the number of leading questions, the ratio of open-ended/closed-ended questions, and the ratio of physician time/patient time. The first two outcomes are both measured

as counts and will be analyzed using a mixed-effects Poisson regression as described for primary hypotheses 1 and 2. The remaining two outcomes are ratios and will be treated as continuous variables. Similar to the third primary hypothesis, a linear mixed-effects model will be used to analyze these two outcomes as well. Unlike the empathic opportunity score, however, these two ratios may be greater than one, so an arcsin transformation is not necessary or appropriate.

The secondary oncologist-level measures will be obtained via survey prior to baseline assessment and immediately after the intervention is complete. Skills for addressing patients' emotional concerns, outcome expectancies, confidence, and comfort dealing with death are scored measures and will be treated as continuous variables in analytic models. ANCOVA models with the baseline score as a covariate will be used to analyze these measures. In addition, outcome expectancies, confidence, and comfort dealing with death may be used as oncologist-level covariates in the primary outcome models.

The patient-level secondary measures will all be obtained via survey in the post-intervention assessment. As described in section D.9.4.4, Quality of Life (QOL) will be measured at each visit using the FACT-G. Similar to the affect measures, QOL is a continuous outcome and will be analyzed using a hierarchical linear model as described for the fourth primary hypothesis. The remaining patient-level measures (social support, satisfaction with care, and self-rating of communication with oncologists) will mainly be used for descriptive analyses and will serve as covariates in additional, exploratory models of the primary outcomes.

D.10.4 Missing data: The survey data may contain missing values in any of the oncologist-level and patient-level variables due to drop-out, a missed interim assessment, or item non-response. In addition, we have experienced occasional audio-recorder mechanical failure (although less likely with using a back-up recorder simultaneously), and, rarely, physicians or patients have chosen to turn-off the recorder in the middle of the visit.

Given a thorough understanding of the missing data mechanism, it is possible to use all of the available information in analysis, rather than only using participants with completely observed information. Because mixed models allow for unbalanced or incomplete data, all patients and oncologists with partial data on the outcome variables will be included in the analyses.

For other types of analyses or if data are missing on predictor variables, we can specify a joint, multivariate normal model for the incomplete and complete observations, as explained by Schafer¹⁴⁸ and Little and Rubin.¹⁴⁹ Under this imputation model, the missing data mechanism can depend on observed values but not unobserved values (also known as missing at random, as defined by Rubin).¹⁵⁰ Using the software NORM,¹⁵¹ we will specify an imputation model and create $m=10$ imputed data sets. Each of these data sets will be fit under the same analysis model, and the m -sets of parameter estimates and standard errors will be combined using Rubin's¹⁵² rules for multiple imputation. Multiple imputation is unique in that it explicitly adjusts for the uncertainty involved in imputing a missing value.

D.10.5 Qualitative analysis: In addition to the primary quantitative analyses described above, we will also conduct a qualitative analysis on a sample of the audio-recordings for two reasons. First, such an analysis will serve as a validation check on the quantitative coding, to ensure that the conclusions drawn seem reasonable and within context. Second, the qualitative analysis will allow us to explore other themes and patterns that may escape the content code analysis and to generate hypotheses for further research. The coding database we will create for this study will allow us to index and catalogue relevant segments by noting the audio-recording counter position at the beginning and end of the section for later transcription and analysis. The qualitative coding itself will follow a typical grounded theory approach.¹⁵³

D.11 Sample size and power considerations

In the proposed study, we plan to enroll 50 oncologists where 25 will be in the control group and 25 will be in the intervention group. During the post-intervention assessment, four patients from each oncologist will be enrolled for 200 patients total. In this section, we present power estimates based on the post-intervention sample size of 50 oncologists and 200 patients.

As stated in the analysis section, the first two primary hypotheses will be tested using a mixed-effects Poisson model. Generic power and sample size techniques are not available for this type of analytic model, but they can be well approximated with techniques derived from generalized estimating equation (GEE) procedures.¹⁵⁴ GEE procedures are semi-parametric and simply require specification of the expected mean structure and the correlation structure.

In a Poisson regression framework, it is natural to specify the mean structure as the ratio of the rates expected under the alternative hypothesis versus the null hypothesis ($R = \lambda_1/\lambda_0$). Based on work by Heaven and Maguire,³⁹ we expect 2 concerns elicited by the control-group oncologists. Given an expected rate of statements in the control group of $\lambda_0=2.0$, and if the expected rate of statements in the intervention group is $\lambda_1=3.0$, then $R=1.5$. Outcomes from conversations of patients with the same oncologist may be more similar than outcomes from conversations of patients with different oncologists. In the power estimates, this similarity is taken into account by specifying a within-physician correlation (ϕ). An exchangeable correlation structure was used.

Table 2. Power estimates for number of “concerns” and “emotion-handling skills”

λ_1	R	ϕ	Power	ϕ	Power
2.7	1.35	0.1	0.8	0.3	0.65
3.0	1.5	0.1	0.95	0.3	0.90
3.4	1.7	0.1	0.99	0.3	0.99

Table 2 presents power estimates for the proposed number of patients and oncologists, a type-I error of 0.05, varying values of R, and small ($\phi = 0.1$) and moderate ($\phi = 0.3$) within-physician correlations. With 100 patients in each group (25 oncologists with 4 patients per oncologist) and a Type-I error rate of 0.05, we will have approximately 80% power to detect $R=1.35$ given a control-group rate of 2.0. Similarly, we will have 95% power to detect $R=1.5$ given a control-group rate of 2.0.

The outcome for the third primary hypothesis is the empathic opportunity score. GEE procedures based on a Gaussian identity link can be used to estimate power for mean differences in clustered data. Based on work by Levinson,⁹ the expected score is approximately 0.3 (i.e., oncologists respond positively to approximately 30% of empathic opportunities). A conservative estimate of the standard deviation can be derived from the standard error of the difference in proportions after an arcsine transformation. This standard deviation is the square root of $(1/N_1 + 1/N_2)$ where $N_1 = N_2 = 25$. We assume an exchangeable correlation structure with small and moderate correlations. Given a control group rate of 0.3, Table 3 shows power estimates for detecting a mean difference (Δ_e) in empathic opportunity score between the control and intervention groups. All estimates assume a Type-I error rate of 0.05 and a SD equal to 0.28 in both groups. With a small within-physician correlation, we will have 80% power to detect a group difference score of 0.13. With a moderate correlation, we will have 80% power to detect a difference score of 0.15.

Table 3: Power estimates for empathic opportunity score

Δ_e	ϕ	Power	ϕ	Power
0.13	0.1	0.8	0.3	0.7
0.15	0.1	0.9	0.3	0.8
0.17	0.1	0.95	0.3	0.85

Table 4: Power estimates for anxiety and depression subscales

Δ_d	ϕ	Power	ϕ	Power
4.0	0.1	0.8	0.3	0.70
4.5	0.1	0.90	0.3	0.80
5.0	0.1	0.95	0.3	0.85

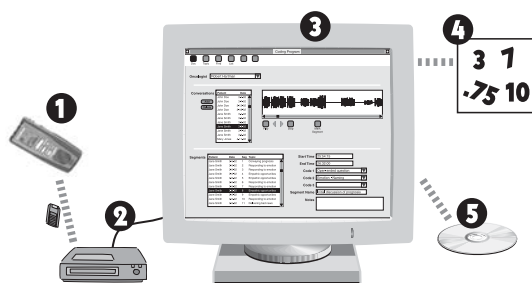
The anxiety and depression subscales of the POMS are the patient-level outcomes for the final primary hypothesis. GEE procedures can be used to estimate power for these continuous, clustered outcomes as well. In previous literature, the mean depression score among cancer patients was 10.2 (SD=8.72). We again assume an exchangeable correlation structure with small and moderate correlations. Table 4 shows power estimates for detecting a mean difference in depression (Δ_d) between the control and intervention groups. Note that all estimates assume a Type-I error rate of 0.05 and an equivalent SD in both groups. With a small within-physician correlation, we will have

80% power to detect a mean group difference change of 4.0 on the depression subscale. With a moderate correlation, we will have 80% power to detect a change of 4.5 between the two groups.

D.12 Data management and quality control

Discussions will be recorded directly on Olympus DM-1 Smart Card digital audio recorders and formatted as digital “.dss” sound files. After rapid conversion to .aiff format, sound files will be trimmed in length and processed to improve sound quality using Sound Edit 16 tools including smooth/enhance (to minimize hiss), noise gate, and the graphic equalizer. Finally, the sound files are backed up on a hard drive and archived on CD (see Figure 6)

Figure 6. Data management system



1. Encounters are recorded to .dss digital audio files using digital recorders.
2. Audio files are copied to the coding workstation and enhanced for audio clarity.
3. Audio files are imported into the coding program, and two coders code each encounter while listening to and visualizing the encounter.
4. The coding program applies decision rules to coded encounters and calculates a score for each encounter.
5. Audio files and coding program data are irregularly archived to CD-ROM.

The interviewers will enter patient response data directly into survey forms on the Palm Pilot, a hand-held personal digital assistant (PDA). All data will be transferred daily from the Palm Pilot into a central Microsoft Access database. This averts the need for external paper records. Survey forms will be created using “Satellite Forms,” a software development product by Puma Technology. Satellite Forms makes it possible to use the Palm Pilot as a hand-held CADI (computer-assisted data input) system. Microsoft Access is a flexible relational database that is SAS compatible and allows easy implementation of survey forms in a user-friendly environment. All general data management will be done in the Access database and then transferred to SAS for analysis at the completion of data collection.

The Masters level statistician and the programmer will develop the Access database, data entry and verification forms, and Palm Pilot forms. The database will be constructed so that the follow-up information is easily appended onto existing records. Monthly reports detailing the accrual and frequency of demographics will be generated and the study progress monitored. These procedures make it possible to begin data analysis soon after the data collection phase is complete. Dr. Tulsky has used Palm Pilots in three other studies with great success and has found them to be an exceptionally efficient, easy and accurate way to collect data.

D.13 Limitations and strengths

This study has several limitations. There is a risk of contamination between intervention and control groups, as discussed in section D.1. Further, there may be a concern that oncologists will not complete the intervention. To monitor this possibility, the trial will assess which components oncologists use, their evaluation of the ease and helpfulness of the intervention, and how their intensity of use of the intervention impacts their communication skills. This study also has several major strengths. This study addresses an important issue that potentially can improve the quality of life for people at the end of life. Using oncologists’ own conversations to tailor the intervention improves the applicability of the intervention. 800 audio-recorded visits with cancer patients at the end of life will result in the largest database ever collected of oncologist-patient conversations. Finally, the interdisciplinary study team is highly experienced and is very confident that it can accomplish the study goals.

Table 5. Timeline

Activities	MONTH											
	J	F	M	A	M	J	J	A	S	O	N	D
Year 1												
Recruit oncologists		X	X									
Pilot test audio recording protocol			X	X	X							
Develop coding system				X	X	X	X	X	X	X	X	X
Baseline patient recruitment						X	X	X	X	X	X	X
Baseline data collection						X	X	X	X	X	X	X
Year 2												
Develop coding system	X	X	X									
Baseline patient recruitment	X	X	X	X	X							
Baseline data collection	X	X	X	X	X							
Code baseline recordings				X	X	X	X	X	X	X	X	X
Develop intervention						X	X	X	X	X	X	X
Year 3												
Analysis and manuscript preparation	X	X	X	X	X	X						
Develop intervention	X	X	X	X	X	X						
Produce CD-ROMs						X						
Deliver intervention						X	X	X				
Post-intervention patient recruitment									X	X	X	X
Year 4												
Post-intervention patient recruitment	X	X	X	X	X	X	X	X	X			
Post-intervention data collection	X	X	X	X	X	X	X	X	X	X		
Code post-intervention recordings										X	X	X
Year 5												
Code post-intervention recordings	X	X	X	X	X							
Analysis and manuscript preparation					X	X	X	X	X	X	X	X
Implement plans for dissemination						X	X	X	X	X	X	X

E. HUMAN SUBJECTS

E.1 Inclusion of women plan

By targeting lung, breast, colon, prostate, and ovarian cancers, we anticipate recruiting equal numbers of female and male patients. In past studies, 45% of women have comprised the recruited sample.

E.2 Inclusion of minorities plan

African Americans comprise approximately 18% of cancer patients at Duke, 30% at the VA and 7% at UPCI. We expect that the ethnic composition of our patient study population will reflect this distribution. The current racial make-up of the oncologists at the Duke, VA and UPCI Medical Centers is >80% White.

	American Indian or Alaskan Native	Asian or Pacific Islander	Black, not of Hispanic origin	Hispanic	White, not of Hispanic origin	Other or Unknown	Total
Female		5	41	2	147		195
Male		6	37	2	210		255
Total		11	78	4	357		450

E.3 Inclusion of children plan

Children will not be included in this study.

E.4 Study Recruitment Population

E.4.1 Timing of Assessment and Tracking: Oncologists and oncology fellows will be assessed at baseline and approximately two years later. The surveys will occur weeks prior to audiorecording. The intervention will be disseminated several months after the initial baseline assessment; oncologists will be given 3 months to review the CD-ROM. Patients will be surveyed in person 30 minutes prior to their visit and again within the following week (over the phone).

E.4.2 Consent Procedures: Patients will be asked to read and sign the study consent form prior to their visit with the oncologist. The consent form will include sections detailing that: 1) the purpose of the study is to audio-record visit to look at patient-physician communication; 2) medical care will not be affected if they choose not to participate in the study; 3) patients will be responsible for the costs of their clinical care; and 4) they can discontinue participation in the study at any time. Oncologists will be recruited through our liaisons, Dr. Marcom and Dr. Arnold. They will encourage oncologist participation in the study and will provide consent forms to the oncologists. We expect the clinicians to participate in the study as a supportive gesture and for the value of learning about their own communication skills. However, the oncologists may opt not to participate with no repercussions.

E.4.3 Potential Risks and Benefits: After receiving the individualized CD-ROM with coded conversations, oncologists will learn how to communicate more effectively with their patients. For the patients, this study offers no potential risks or benefits as their participation is observational in nature.

E.4.4 Data Collection: Data will be collected by trained research assistants in-person or over the phone. Data will be collected on Palm Pilots in person or via Computer Assisted Telephone Interview on the phone. The data will be downloaded into password protected electronic files. All participants (patients and oncologists) will be assigned a code number that will be the sole identifier on all study data forms. The names, addresses, telephone numbers that correspond to study identifiers will be stored in a separate secured file. Access to this file will be limited to study personnel. The research assistant will sign a statement of confidentiality indicating that all participant information is not to be discussed outside of the research setting.

Research assistants will collect audio data by turning on the digital recorder and leaving it in an unobtrusive location in the exam room. These data will be coded, using a standardized coding protocol, directly from the original digital recorders in order to preserve inflection, volume and other attributes of conversation that assist in coding. Information will be transferred to CD-ROM. Prior to and after coding, digital files will be stored in a password protected directories which only the research assistant and project manager will have access.

E.5 Measures

The primary measures for this study will be the communication behaviors employed by the oncologists and observed in the audio-recorded conversations (number of patient concerns elicited, open-endedness of question, ratio of oncologist-to-patient speaking time, summarization, and leading questions). Encounters will be coded to determine the use of the NURSE construct (see Section D.7.3.2) to determine the use of “emotion-handling” skills. Empathic opportunities and responses will be coded to evaluate the ratio of positive responses to empathic opportunities. The frequency of prognostic information will be recorded as well.

Other primary measures are patients’ anxiety and depression that will be measured from patient’s survey using the Profile of Mood States (POMS).

The secondary measures from oncologist surveys include content of the visit, outcome expectancies, confidence, comfort level for addressing patients’ emotional concerns affected and self-concept. Content of the visit will be assessed via checklist (includes items such as “treatment side effects” and “quality of life”).

The secondary measures from patients include demographics, self-rating of communication with oncologist, satisfaction with care, quality of life, social support, affect, self-concept, and presence of a confidant.

Intervention dose will be assessed by asking oncologists which Modules they completed, how much time they spent, and when they reviewed and re-reviewed the CD-ROM. This information will be compared against our electronic files.

E.6 Data Safety Monitoring Plan

This project tests an educational intervention to improve oncologist-patient communication at the end of life. There are two types of research participants in this study, patients and oncologists. Patient participants will be recruited from clinic appointment logs. From these logs, physicians will identify patients they “would not be surprised might die within six months.” Additionally, patients must speak English, receive primary oncology care at Duke University Medical Center (DUMC), VA Medical Center (VAMC), or the University of Pittsburgh (UPCI), will be receiving treatment for malignancy, and have a telephone. Physician participants will be recruited from the DUMC, VAMC and UPCI - all medical and radiation oncologists as well as oncology fellows are eligible for participation. Oncologists are the sole targets of the behavioral intervention.

E.6.1 Potential adverse events: Potential adverse events (AE) for this project are all non-medical in nature. Oncologist participants may feel psychological distress or anxiety after receiving feedback about their oncologist-patient interactions. By listening to the interactions more than once, they also may re-experience the negative emotions associated with end of life visits. Patient participants may experience mild anxiety when answering survey questions about quality of life, support, etc. Because the end-of-life interactions will be recorded onto CD-ROM, there is also a slight possibility that someone other than the patient's oncologist might obtain the CD-ROMs. To protect the patients' privacy, all CD-ROMs will be password protected with a unique username and password chosen by their oncologist.

E.6.2 Monitoring Safety Of Participants: There are several ongoing mechanisms for monitoring the occurrence of adverse events. The project manager oversees day-to-day monitoring of the study activities. This monitoring is facilitated by: (1) a toll-free number provided to participants upon entry into the study to report concerns related to study participation; (2) bi-weekly meetings with project staff and investigators to discuss study progress, reactions to the intervention, and any adverse events; and (3) direct supervision of the research assistants (RAs). To address patients' and physicians' psychological distress, the RA and project manager have a referral list of phone numbers for local mental health service organizations.

E.6.3 Plans for assurance compliance regarding AE reporting: The investigator is required to report adverse events to the Institutional Review Board (IRB) on an annual basis. Every research project conducted at Duke University Medical Center is required to have yearly departmental and IRB review. For any cancer-related projects such as this, the Cancer Protocol Committee also reviews and must approve the protocol and consent form on an annual basis. Additionally, all AEs are reported as part of the progress reports in the non-competitive and competitive renewals.

E.6.4 Plans for assuring that action resulting in suspension of trial is reported: The Principal Investigator is responsible for contacting the NIH grant program director in the event that any action resulting in temporary or permanent suspension of the trial occurs. Because this trial does not involve any investigational medication, the action would be limited to an IRB- or investigator- initiated suspension.

E.6.5 Plans for assuring data accuracy and protocol compliance: The research assistant will mark some data obtained during surveys on paper records. To assure data accuracy, this information is double-keyed by two different trained research assistants into a password-protected database that is transferred to the data manager on a bi-weekly basis. The data manager processes the database to search for errors and generate basic reports for dissemination at regular meetings. Protocol compliance is monitored at the bi-weekly project staff meetings. In addition, investigators will meet weekly, and eventually monthly, with research assistants to train and ensure adherence to the intended protocol.

F. VERTEBRATE ANIMALS

None

G. LITERATURE CITED

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H. CONSULTANTS/CONTRACTUAL AGREEMENTS**H.1 University of Pittsburgh**

As detailed in the budget, this grant includes a contractual agreement with the University of Pittsburgh to pay Dr. Robert Arnold, a research assistant and a technical advisor to be a second site for data collection and the intervention.

H.2 People Designs

As detailed in the budget under “other,” this grant includes a contractual agreement with People Designs who will help develop and produce the CD-ROM intervention.

I. CONSULTANTS**I.1 Terrance Albrecht, Ph.D.**

Dr. Albrecht is a Professor in the College of Medicine at the University of South Florida and is an expert in health communications and patient-provider interactions with cancer patients. In year 1, she will provide guidance in developing the coding system for interactions with cancer patients. In year 2, she will provide expertise in the analyses of the coded data. In year 5, she will participate in developing plans for dissemination.