Improving Communication Between Cancer Patients & Oncologists

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Improving Communication Between Cancer Patients and Oncologists Using Patient Feedback on Actual Conversations and the ABIM Maintenance of Certification Program.

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1.0 INTRODUCTION

1.1 Overview

Cancer patients face numerous physical and emotional challenges. Anxiety and depression can decrease quality of life and even decrease survival. High quality cancer care depends upon recognizing and responding to patients' emotional needs. Unfortunately, oncologists frequently do not respond to patients' emotional concerns.

Oncologists can learn to communicate better. The most successful teaching occurs in intensive courses with patient actors. However, these courses take time and are expensive. We created a computerized program called SCOPE, **Study of Communication in Oncologist Patient Encounters,** in which oncologists audio record conversations with real patients and then receive feedback on how well they did. Oncologists who used this program in a research study doubled how often they responded to patients' emotional concerns and increased their patients' trust.

We will take this program and add an additional feature in which real patients also listen to the conversations and give feedback to these doctors. We will then have doctors who are being recertified in oncology by the American Board of Internal Medicine use this program as part of that recertification process. We will test how well it increases their patients' satisfaction in their communication, and whether it improves their communication skills.

If successful, this intervention will represent an effective communication training program for physicians in which they improve their communication skills through direct feedback from patients. Because of the integration with the ABIM Maintenance of Certification Program, if fully adopted into that program, it could have an extraordinary impact on thousands of physicians and their patients.

1.2 Background and Rationale:

People living with cancer suffer greatly and the burden is greatest on those with advanced disease. Cancer patients experience extraordinary physical, emotional, and existential challenges, and up to 60% acknowledge difficulty coping with their illness.[1-3] Among patients with advanced disease, 25% describe their suffering as moderate to extreme.[4] Physical symptoms are the greatest source of this distress, and up to 70% of patients with advanced cancer experience pain severe enough to impair function.[5-7] Emotional suffering can be profound as well, as patients experience fear, anger, sadness or isolation. Psychological distress, particularly anxiety or depression, is common in all cancer patients, with a reported prevalence between 30-50%.[2,8-13] Psychological and emotional distress has been correlated with lower quality of life,[13-16] a desire to hasten death,[17] caregiver distress,[18-20] increased health care utilization[21-23] and shorter survival.[24-26] Facing a life threatening illness also raises questions about existence and self-integrity, and patients may be overwhelmed as they struggle with loss of control, the meaning of their illness, uncertainty regarding the future, and unfulfilled goals.[27-30] ***Cancer radically changes the lives of those it afflicts, and the accompanying psychosocial distress can lead to worse health outcomes.***

Distress affects patient decision-making. To make decisions about cancer treatment and future care, patients must understand the nature of the illness, its prognosis and the available treatment options. A

patient's emotional state, ability to comprehend prognostic data, and how oncologists discuss these data all affect the understanding of medical information. Fearing the loss of hope, patients frequently cope by psychologically denying the information's import.[31] Patients may be incapable of processing the information they hear,[32,33] which in turn decreases message encoding and recall. Emotion affects processing; people who are in negative moods may pay more attention to how messages are given than to the content of the messages.[34,35] Thus when patients are experiencing high levels of negative emotion, and oncologists do not ameliorate this affect, patients may be less likely to understand oncologists' messages. ***When patients are emotionally distressed, they cannot process information well and decision-making suffers.***

Patients feel better when they express emotional concerns and their physicians respond empathically. Disclosure of emotional concerns helps patients in two ways. First, the expression of emotional concerns is therapeutic in itself. The self-disclosure literature demonstrates a variety of positive outcomes associated with expressing personally stressful experiences.[36] Particularly after loss or trauma, expressions about stressful events result in fewer physician visits and fewer self-reported physical ailments.[37-41] In women with breast cancer, emotional expression reduced somatic symptoms and medical visits.[42] Patients assign tremendous symbolic importance to their physician and the quality of communication.[43] When oncologists respond empathically to patients' emotions, patients report higher satisfaction and better adherence.[44] One study used a standardized videotape stimulus to assess the effect of physician compassion on viewers' anxiety. They found that women with breast cancer who saw the "enhanced compassion" videotape were significantly less anxious after watching it than women in the other group.[45] Second, cancer patients with unresolved concerns are more distressed than those whose concerns are resolved.[46-49] Oncologists can only respond to patients' concerns that they hear, and 90% of patients say they want to talk to their doctors about these issues.[50,51] Oncologists can promote these discussions by asking about patients' emotional concerns. In addition, techniques such as active listening, using open-ended questions and emotional words, and responding appropriately to patients' emotional cues assist in their expression.[52] ***When oncologists encourage their distressed patients to express their concerns and then respond appropriately, they help relieve patient suffering and create an environment conducive to improved decision-making.***

Effective patient-centered communication improves multiple patient outcomes. Outside of the cancer setting, patient-centered communication has been shown to influence malpractice claims,[53] patient satisfaction,[54] recall of information,[55] and clinical outcomes such as diabetic glucose control and functional status.[56,57] Among cancer patients, quality of communication affects psychological well-being, with "patient-centered" consultations leading to improved satisfaction and psychological adjustment.[58] Empathic communication reduces patient anxiety and decreases long-term distress.[44,45] Finally, communication techniques that focus on patients' emotional states are more likely to elicit patients' concerns about pain or other symptoms, which can then be treated. ***All aspects of a patient's care are enhanced with improved communication.***

Effective communication is open, honest and patient-centered. According to Epstein and Street, "patient-centeredness" includes four core components: (1) eliciting and understanding the patient's perspective, (2) understanding the patient's psychosocial context, (3) achieving a shared understanding of the problem and its appropriate treatment in the context of the patient's preferences and values, and (4)

empowerment, by involving patients actively in decision-making.[59,60] This serves as an overall model for good communication, and many guidelines have been proposed for specific tasks such as delivering bad news, discussing disease progression and talking about palliative care.[61-67 68,69 70] ***Patient-centered communication is respectful, empathic, inclusive, and efficient, seeks to elicit patients' goals and preferences, and to match these to an individualized plan of care.***

Oncologist-patient communication often does not meet experts' standards. Unfortunately, a large literature documents that physicians generally, and oncologists specifically, often do not meet the accepted quality standards for communication.[43,51,65,71-75] Physicians rarely talk with seriously ill patients about their goals, values or even treatment decisions.[76-83] Oncologists commonly do not elicit the full range of terminally ill cancer patients' concerns, or attend to patients' affect.[84] 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.[85] As a result, cancer patients tend to disclose fewer than 50% of their concerns to oncologists and other providers.[85,86] 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.[74] In another study, only one of five oncologists' assessments of patients' distress correlated accurately with patients' self-report.[75] A study from the Netherlands of audio-recorded 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.[87] Patients' emotional functioning and fatigue were not addressed 54% and 48% of the time, respectively.

We conducted the SCOPE Trial (Study of Communication in Oncologist Patient Encounters; R01 CA100387, Tulsky, PI, Pollak, Arnold, and Farrell, Co-I's) to analyze emotion handling in patient-physician communication and to develop an intervention for physicians.[88] In the initial observational phase, we audio-recorded 398 conversations between 51 oncologists and 270 patients with advanced cancer in two cities. We found that patients disclosed emotional concerns in only 37% of these conversations, fewer than expected given the known high prevalence of distress.[89] When patients did express negative emotions (e.g., anxiety, fear), oncologists responded empathically only 27% of the time. Patients likely stop expressing their concerns when they learn they will not receive a helpful response. Several oncologist characteristics were associated with their communication style. Oncologists who used more empathic statements were younger than those who did not. Also, oncologists who responded empathically were more likely to describe themselves as socioemotional rather than technical in their orientation to medical care (80% vs. 45% respectively, p=.03). Of note, gender was related to the number of empathic opportunities; female patients seen by female oncologists had the most empathic opportunities (p=.03), suggesting that oncologist behavior (women oncologists use more empathic language) affects the expression of concerns.[89]

Oncologists' may not address patients' emotional concerns for several reasons. Constructs in social cognitive theory,[90] the transtheoretical model of behavior change,[91] and a barriers model proposed by Cabana[92] may explain oncologists' behavior. They 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 expectations), lack the confidence to address patients' emotional concerns (self-efficacy), or 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 cues[93]) and environmental factors (e.g., lack of time or resources) may deter oncologists from

addressing patients' emotional concerns. ***A significant gap exists between the idealized model of oncologist-patient communication and the reality of practice. Behavior change theories explain oncologists' communication patterns, and may be employed in interventions to improve these behaviors.***

Training can improve clinician communication. Although physicians frequently regard the ability to communicate as an inborn talent, these skills can be learned. With one exception,[94] rigorous evaluations of communication skills teaching have shown positive results when interventions incorporate adult learning principles, practice, and feedback in settings supervised by trained facilitators. The American Academy on Physician and Patient (AAPP) first developed the model for such training with a 5-day course that included didactic learning, small group skills practice, and self-awareness sessions where participants reflected on feelings provoked by clinical situations. Participants reported a significant increase in their interviewing and self-awareness skills.[95] 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.[96] Examining the effect of course length, 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 half day course.[97] Worstell reported that a similarly designed 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.[98]

This training model has been used in oncology as well. Baile conducted a series of half-day workshops focused on giving bad news and managing difficult patients[99] and found increased confidence in communicating bad news and managing problem situation cases after the workshops. Parle and Maguire conducted multi-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.[64] Fallowfield, also in the UK, conducted a randomized controlled trial of a 3-day training course involving 160 oncologists from across the country.[100,101] She found that, in addition to favorably altering oncologists' attitudes and beliefs towards psychosocial issues, the course resulted in improved communication behavior in videotaped patient interviews.[101] Intervention oncologists increased significantly their use of open-ended questions, expressions of empathy, and appropriate responses to patient cues or empathic opportunities. These changes persisted for at least twelve months.[102]

Members of our team have developed several programs to train physicians to recognize better patients' psychological distress and to respond empathically. An eight- hour communication skills course for medical house staff improved their ability to deliver bad news and respond to emotional cues in standardized patient evaluations.[103] We have created the leading communication skills training program for oncologists, OncoTalk, originally designed as an intensive four-day communication retreat for oncology fellows.[104] Based on small group learning using role play and feedback, we demonstrated significant improvement in fellows' empathic communication behaviors.[105] In fact, changes were so profound that the trained fellows were easily identified by blinded raters. Perhaps most importantly, participants found it transformed their practice, and the model has been replicated across the U.S. and overseas. ***Communication skills such as eliciting concerns, handling emotions, and demonstrating empathy, can be taught and lead to increased physician self-confidence and reduced patient distress.***

Face-to-face courses are the gold standard for training physicians, yet have significant limitations. Well designed communications skills training workshops are effective in changing physician behavior, yet they are costly, and time-intensive. Such interventions require extensive coordination to assemble groups, facilitators and simulated patients. Although they may be appropriate for physicians in training who can be required to attend, it is unrealistic to expect many practicing oncologists to take the time from their busy practices to undergo such training. ***Practicing clinicians need a more flexible model to fit communication skills training into their busy lives.***

The SCOPE program – a widely disseminable online alternative to the face-to-face course. We recognized this need for alternative evidence-based educational venues that are easily accessible, not disruptive to clinical practice, inexpensive, and brief. We developed SCOPE, a computerized, interactive, tailored program that teaches oncologists basic communication skills and allows them to review their own audio-recorded encounters and provides suggestions on how to respond better to patients' negative emotions. SCOPE uses the principles found to be effective in face-to-face retreats and incorporates them into an online tool that can be efficiently used in the privacy of an oncologists' home or office.[106] In SCOPE, oncologists learn basic skills and observe them in exemplar video and then have the opportunity to practice and receive feedback ***on their own conversations***. Furthermore, employing the Social Cognitive Theory model described above,[90,92] SCOPE addresses oncologists' self-efficacy and outcome expectations, and provides ongoing coaching and encouragement to overcome barriers to learning and adopting new skills.

The original SCOPE program was comprised of five modules: (1) *Principles of Effective Communication*; (2) *Recognizing Empathic Opportunities*; (3) *Responding to Empathic Opportunities; (4) Conveying Prognosis*; and (5) *Answering Difficult Questions*. A final module summarized main points from the intervention. Each module was designed to be viewed in 10-15 minutes and followed a similar format. First, barriers to learning the material were addressed. Then, the new communication skill was introduced, and demonstrated in one or two video clips. Important teaching points were summarized and, finally, users were asked to review selected excerpts from their own previously recorded conversations. These excerpts were accompanied by tailored feedback (e.g., "Great job, try to use more statements like that!" or "Next time, you may want to try saying…."). Oncologists were then asked to commit to using a new skill with their patients in the future, and they were sent email reminders of this commitment prior to their next clinic sessions.

In a randomized, controlled trial, we tested SCOPE's efficacy with 48 oncologists and 264 patients.[107] The program was well accepted. Twenty-one of 24 in the intervention group reported using the CD-ROM with a median usage time of 64 minutes. More importantly, 92% of the oncologists reported changing their clinical practice as a result of what they learned in SCOPE.[106] Oncologists in the intervention arm used more empathic statements (RR =1.9; 95% CI, 1.1, 3.3; p=0.02) and were more likely to respond to negative emotions empathically (OR = 2.1; 95% CI, 1.1, 4.2; p=0.03) compared to control arm oncologist. Most importantly, patients of intervention oncologists reported higher trust compared with patients of control oncologists (estimated mean difference = 0.1; 95% CI, 0.0, 0.2; p=0.04).[107] After one hour of training with the SCOPE program, oncologists improved their skills and increased their patients' trust, findings almost as robust as seen in multi-day workshops. ***The SCOPE program, an innovative, computerized approach to teaching communication skills based on the same principles as face-to-face courses, can achieve similar results to these courses, yet be integrated into the everyday practice of a***

busy oncologist. SCOPE offers an inexpensive, practical and disseminable alternative to communication workshops.

The Enhanced SCOPE Program – Capturing the patient's voice in the medical encounter. In the SCOPE program, medical visits between oncologists and patients are recorded, uploaded to a server, and using an application called ENCOUNTER, are coded by trained research assistants for the specific behaviors of interest (e.g., patient expressions of negative emotion, empathic responses by oncologists, etc). These results are then given back to the oncologists, together with tailored feedback on specific examples.

For this project we have created the Enhanced SCOPE Program. Rather than having the coding done only by research assistants, we will involve patients in the feedback process. The recorded encounters will also be reviewed by trained patient advisors (not the oncologists' own patients) who will listen to the recordings and directly insert their own "subjective" feedback. Physicians rarely are given the opportunity to hear what patients truly think about their communication style. ***The Enhanced SCOPE Program provides oncologists with both objective coded feedback and a sense of how real patients react to their communication, thus "using the patient's voice" to improve the medical encounter.***

The American Board of Internal Medicine (ABIM) Maintenance of Certification Program – A model for integrating Enhanced SCOPE into clinical practice. All ABIM board-certified medical specialists (certified within the past 25 years) are required to enroll and complete the Maintenance of Certification (MOC) program requirements if they wish to retain this important credential. The framework and evidence for the MOC program are well-established.[108,109] A physician's association with the MOC program occurs over a number of years and involves completing a series of steps including educational modules and an exam. An important and unique component of this program is the Practice Improvement Module (PIM), in which recertifying physicians conduct a quality improvement exercise using patients and data from their own practices. There are a number of different PIM's to choose from and, currently, one of these is a communication module. Physicians who select this module ask a sample of their patients to complete the Clinicians and Groups-Consumer Assessment of Healthcare Providers and Systems (CG-CAHPS) satisfaction survey, receive a report of the survey results as feedback, and then design and complete a performance improvement plan based on these results. When they are done with their performance improvement plan, CAHPS surveys are collected again from a different sample of patients. The MOC program offers a unique opportunity to integrate the Enhanced SCOPE program into a process already familiar to (and required of) board certified internists and subspecialists. As an alternative to the current communication PIM, physicians could audio record conversations with their patients using their smart phone (the app is already developed), these conversations would be coded and reviewed by the patient advisors, and the physicians would then work through the SCOPE modules, including receiving feedback on their conversations. We have engaged in a strong partnership with ABIM around researching this idea that allows us to take advantage of the powerful ABIM MOC platform.

This collaboration meets the longstanding goal of ABIM to be able to truly evaluate and improve communication quality, and the intervention can be widely disseminated that could transform patients' experiences with their physicians.

2.0 AIMS

The overarching goal of this project is to improve communication between oncologists and their patients by ensuring that the patient's voice is heard in the medical encounter. Thus, we hope to improve the experience for patients living with cancer. We seek to accomplish this goal by providing oncologists communication skills training that includes feedback on their own audio-recorded conversations. The feedback will come from two sources: 1) Professional research assistant coders who will identify objective learning opportunities based on specific coding criteria and 2) Trained patient reviewers who will listen to the recordings and offer their own, subjective feedback at key moments in the encounters. We will address the following specific aims:

Aim 1: Identify barriers to implementing the ENHANCED SCOPE app. & website in participating oncology practices. Barriers include: oncologist enrollment, patient enrollment and transmission of data.

Aim 2: Compare the effect of the Enhanced SCOPE program to the standard communication Practice Improvement Module (PIM) on patient satisfaction with oncologist communication as measured by the CG-CAHPS survey.

Aim 3: Compare the effect of the Enhanced SCOPE program to the standard communication PIM on oncologist communication behaviors, including their use of empathic responses to patient emotional concerns, as coded from audio-recorded medical encounters.

3.0 RESEARCH SUBJECT SELECTION

The study will involve the recruitment and consent of three types of subjects: (1) board-certified oncologists who practice in any setting in the United States and have a smartphone; (2) patients receiving care from these oncologists who are willing to complete an anonymous survey; and, (3) patients receiving care from these oncologists who are willing to be audio recorded.

Inclusion criteria: Eligible patients who will be recorded will have metastatic cancer, (those patients who take the survey can have cancer of any stage) be at least 18 years of age, speak and read English, and receive oncology care from an enrolled oncologist. Patients who meet criteria will be introduced to the study by their enrolled oncologist during a clinic visit. There is no requirement related to life expectancy.

Eligible caregivers who will be recorded are those present in the room with the enrolled oncologist and the patient participant receiving oncology care during the audio-recorded clinic visit. Caregivers will be introduced to the study by an enrolled oncologist alongside a recruited patient.

All participating oncologists who are enrolled in the ABIM MOC program, complete Practice Characteristics Survey, complete baseline patient surveys of at least 25 patients and who audio record 4 patient interactions will be eligible for randomization to study conditions.

Exclusion criteria: Oncologists who do not speak English to their patients, patients who do not speak English, oncologists who do not have enough patients with advanced cancer. DFCI oncologists are excluded from this study; this includes DFCI satellite sites, non-DFCI DF/HCC sites, and other non-DF/HCC sites that are under the DFCI IRB.

DF/HCC Standard Operating Procedure for Human Subject Research Titled Subject Protocol Registration (SOP #: REGIST-101) must be followed. This project has been granted decentralized

registration where study staff as opposed to the Office of Data Quality staff will be registering participants in OnCore.

4.0 RESEARCH SUBJECT ENTRY

First, we will enroll oncologists through the American Board of Internal Medicine (ABIM) Maintenance of Certification (MOC) program. All oncologists involved with the MOC program are eligible for the study and will self-refer through the ABIM website, which will house a description of the study and invite participation. Additionally, ABIM will contact oncologists enrolled in the MOC program by email to announce the offering of the Enhanced SCOPE program. Oncologists interested in participation may review detailed information about the study on the website and contact a study representative at Dana Farber Cancer Institute or ABIM with questions. Oncologists who express interest will be invited to register and assigned an individual sign-in code. They will enter the online Communication Practice Improvement Module (PIM) using their code, read and sign an electronic consent form, and complete the registration process. Once enrolled, the oncologist will recruit 25 patients from their practice to complete anonymous CAHPS satisfaction surveys. Any patient who is seeing or has seen the oncologist at any time will qualify as a participant in this study. They can be an existing patient or someone who is seeing the doctor for the first time. Because the CAHPS survey is entirely anonymous and no PHI will be disclosed, formal written informed consent will not be required for the patients completing the surveys. Language at the introduction of the survey will describe the research, be clear that participation is voluntary, and state that survey completion implies consent.

After 25 patients have completed the surveys, oncologists will then identify potentially eligible patients from their practice to audio record one clinic visit each (using a secure smartphone application). Doctors will be informed about the importance of privacy while using their smartphones, and will be given information explaining how to keep their recordings private and secure. The security measures are as follows:

As a participant in the SCOPE study, the oncologist will audio record up to 10 conversations they have with their patients. SCOPE follows strict procedures to ensure the privacy and security of these audio recordings, and it is the oncologists' responsibility to do the same. They will follow these guidelines for using the recorder app:

1. Keep your phone secure:

- Use only your personal phone, not a shared phone or device.
- Set your phone's built-in locking feature to require a passcode, fingerprint, or other identification method each time the phone is used.
- Choose a hard-to-guess passcode and change it periodically and whenever you think it may have been compromised.
- Set your phone to automatically lock after a period of inactivity.
- Keep your phone up-to-date with the latest operating system.

2. Keep your recorder app passcode secure:

- You will be required to set a passcode the first time you use the recorder app, and then enter the passcode each time you subsequently use the app.
- Choose a passcode that is not easily guessed.
- Do not share your passcode with others or write it down.
- If you suspect your passcode has been compromised, change it immediately.

3. Use the recording app securely:

- Quit or switch out of the app when not in use, it will lock automatically when you do this.
- Use the app's lock function when you need to leave the app running unattended.
- Be aware of the physical environment in which you use the app. If you listen to a recording, make sure it cannot be heard by others.

A total of 4 patient visits (with different patients) will be recorded prior to oncologist randomization and, after oncologists have completed the Enhanced SCOPE intervention or the control Communication Module, they will audio-record another 4 patient visits (with different patients from the pre-intervention). For those oncologists enrolled in the SCOPE intervention, an additional 2 patients will be recorded during the intervention period to provide them with additional feedback on their communication as they undergo the training. These 2 extra recordings per SCOPE oncologist will be used solely for feedback purposes and will not be included in the analysis at the end of the study.

Oncologists will identify potential patients for audio-recorded visits and introduce them to the study, however they will not be the ones to obtain informed consent. Rather, the oncologist will download and print from the ABIM website a handout with a full written description of the study and give that to the patient. This handout will include a phone number connecting the patient to study staff. Oncologists will be reminded that their patients may feel obligated to participate because they are being asked by their treating physician, and will be asked to reassure the patient that their participation is entirely voluntary. If patients wish to proceed, they will then call the DFCI study staff who will introduce the study and discuss the basic elements of informed consent with the patient, including the nature of the research study, risks, benefits and alternatives to participating. Study staff will describe what PHI may be disclosed, to whom it will be disclosed, and the use of the information. Study staff will also make clear to the patient that participation is entirely voluntary and may be withdrawn at any time and that the decision not to participate will not affect their care, now or in the future. Patients will be encouraged to ask questions during the consent process or in the future should they arise later. After expressing their willingness to participate, the patients will be sent a link via text or email to an electronic informed consent and HIPAA authorization form. Study staff will confirm the receipt of consent, notify the oncologist, and after that point, the visit may be audio-recorded.

If a caregiver is present, the physician may print and download from the ABIM website a handout similar to that given to the patient, including a full written description of the study. At the beginning of the patient consent process, patients are asked if a caregiver or family member will accompany them during the recorded appointment. If a caregiver will be present, they are passed the phone and talked through the caregiver consent by study staff. If multiple caregivers are present, they will be talked through the caregiver consent at the same time or separately if preferred. All caregivers will have the opportunity to ask questions during the consent process or in the future should they arise later. After expressing their willingness to participate, the caregiver(s) will be sent a link via text or email to an

electronic informed consent. All caregivers will utilize the same link and physician ID, but will login to the consent form using separate caregiver ID numbers given to them by study staff during the consent call. All caregivers present in the room at the time of recording must sign the consent form before the visit may be audio-recorded.

In the case of a patient or caregiver who does not have a phone with text and internet capabilities or is struggling to complete the electronic consent process virtually, we will provide to the physician two options. A physician can request an iPad with a return envelope addressed to study staff at Dana-Farber. This iPad will be pre-programmed with the links to both the patient and caregiver consent. Or, a physical copy of the consent form will be included with the handout containing the phone number connecting the patient or caregiver to study staff. If they wish to proceed, they will then call study staff via the phone number found on the handout. A member of the study staff will introduce the study and discuss the basic elements of informed consent with them, including the nature of the research study, risks, benefits, and alternatives to participating. In the case of consenting a patient, study staff will describe what PHI may be disclosed, to whom it will be disclosed, and the use of the information. Study staff will also make clear to the patient that participation is entirely voluntary and may be withdrawn at any time and that the decision not to participate will not affect their care, now or in the future. Patients and caregivers will be encouraged to ask questions during the consent process or in the future should they arise later. After expressing their willingness to participate, study staff will ask the patient or caregiver to complete the electronic consent on the iPad provided to the physician or sign and date the physical copy of the consent form and hand it back to their physician. The physician will then fax the signed consent form to study staff who will in turn sign and date the consent form. Study staff will fax the completed consent form back to the physician who will give it to the consented patient or caregiver for their records. After that point, the visit may be audio recorded.

In the case that study staff are present at the physician's clinic at the time of consenting, study staff will talk the patient or caregiver through the consent process in person. They will then hand the patient or caregiver an iPad with the appropriate electronic consent form pulled up or a physical copy of the consent form and ask them to complete it. Once the consent has been completed, the visit may be audio recorded.

5.0 STUDY DESIGN AND METHODS

5.1 Design/Study Type:

Interventional: Randomized controlled trial

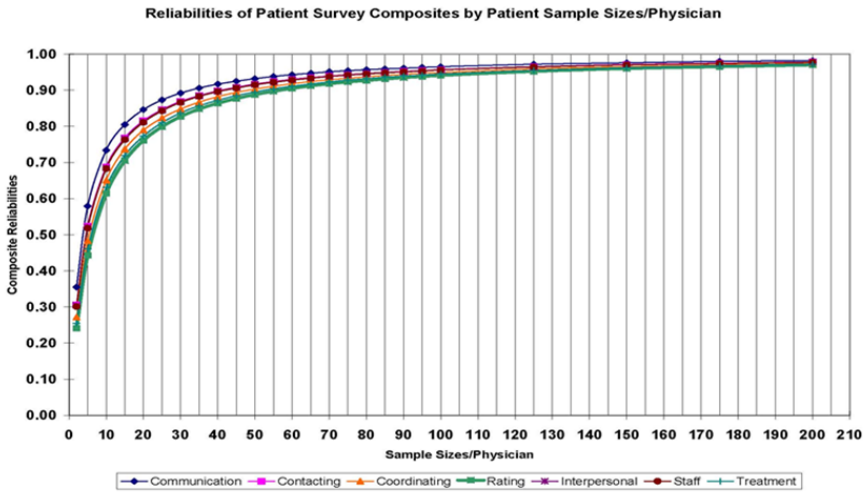
5.2 Selection of Instruments:

CG-CAHPS survey: Patient satisfaction with communication – the primary outcome of this trial is the effect of the enhanced SCOPE program on patient satisfaction with communication, as measured by the CG-CAHPS survey.[111,112] This well validated 48-item measure overseen by the Agency for Health Research and Quality and endorsed by the National Quality Forum measures patient experience with an outpatient health care provider over the past twelve months. The CG-CAHPS survey is comprised of questions that encompass 3 major composites (access to care, doctor communication, and courtesy of staff) and two global rating items. All composites have been shown to yield acceptable individual level internal consistency reliabilities (Cronbach's alpha >= 0.77), as well as practice level reliabilities

(Cronbach's alpha >=0.75). In addition, all composites were significantly correlated (P<0.01) with the global rating items, demonstrating construct validity of the measures. These studies were used in the SCOPE study. It should take about 15 minutes for the patients to complete the survey.

Based on prior work at the American Board of Internal Medicine, the Intercluster Correlation Coefficient (ICC) is used as a reliability index for measures collected within physician practices such as patient ratings or quality measures of care. The ICC measures the stability of patient ratings based on the average ratings of the patient samples within physicians. This reliability measure increases with sample size, as does the precision of the average ratings. The ABIM employs a very high standard of reliability for high-stakes assessments (e.g., certification examinations) of 0.85, so has in the past used a survey sample size of 35, which provides reliabilities that range from 0.85 to 0.91 (Figure 1). For the purpose of this study and in an effort to recruit somewhat fewer patients, we are willing to accept a slightly lower (yet still outstanding) reliability of approximately 0.80. As seen in Figure 1, this can be achieved with a sample size of 25, and we will use this for the study.

Figure 1



Oncologist surveys – oncologists will complete brief surveys at baseline (demographics) and after completion of the practice improvement module (feedback on the module). These data will be collected directly online through the portal of the Enhanced SCOPE website. This survey was used in the SCOPE study and it should take about 5 minutes to complete. For continuous and ordinal variables (e.g., age, years in practice) comparisons will use the Wilcoxon rank-sum test. For categorical variables (e.g., sex, race, practice setting) comparisons will use Chi-square tests. These hypothesis tests are intended for data monitoring and quality control.

The relevant scale used from CAHPS that is treated as continuous is derived the Provider Communications composite in our study. The communications composite consists of six items relating to frequency of events during interactions between the provider and the patient from the patient's perspective. Each of these items are rated on a 1 to 6 scale (never to always) so the raw score is the sum of these ratings. The score range in this case is 6 to 36. The communications items will also be scaled using a graded response item response model, the latent variable scores will have a mean of 50 and a standard deviation of 10. These scaled scores will be treated as continuous variables with an expected range between 20 and 80, with standard errors of approximately ± 2 points.

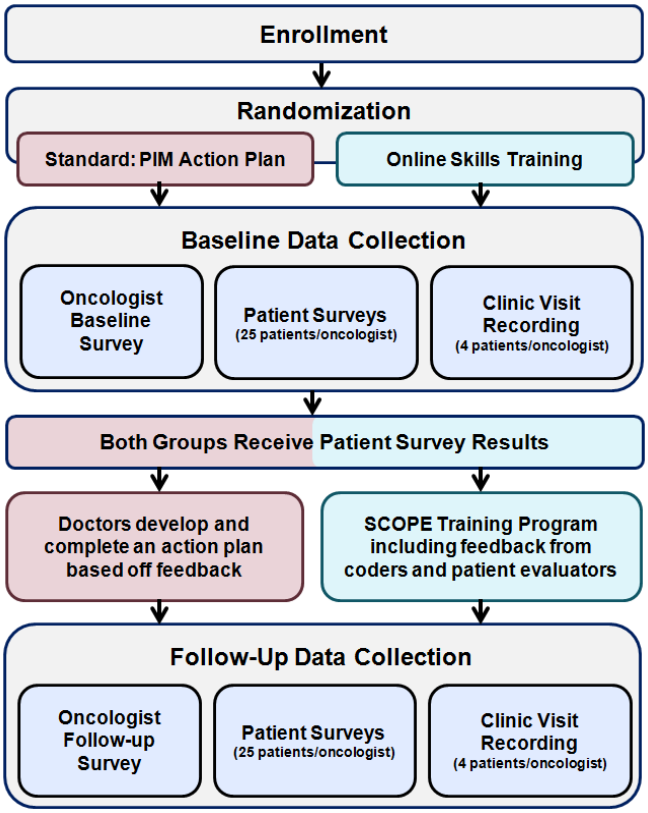
5.3 Description of Intervention

The primary objective of the Enhanced SCOPE program is to teach oncologists to recognize the role of emotion in discussions with cancer patients, to increase their self-efficacy for addressing affective concerns, and to provide them with the skills for doing so. Oncologists are most likely to achieve competency in these areas when, in addition to didactic training, they can also observe their own conversation and receive feedback on their interactions. The Enhanced SCOPE program itself is an online web application that can be viewed from any computer with internet connectivity.

We will be conducting a randomized controlled trial to test the impact on patient satisfaction and medical visit quality of a communication skills teaching intervention for oncologists that is integrated into the American Board of Internal Medicine (ABIM) Maintenance Of Certification (MOC) process. Oncologists who choose to enroll in this pilot Practice Improvement Module (PIM) will, as described above, complete a baseline questionnaire, send out satisfaction surveys to a sample of their patients, and then audio record (using a smartphone application) four clinic visits with four different patients. Oncologists who are assigned to the control arm will receive the results of the patient surveys and be asked to conduct a quality improvement activity that responds to the survey feedback (the current "standard" communication PIM). They will be offered several resources for upgrading their communication skills and asked to describe their study plan and the success in its completion. Physicians randomized to the control arm will be given the opportunity to conduct the SCOPE training after study completion. Oncologists assigned to the intervention arm will receive the survey feedback ***as well as*** the enhanced SCOPE program which provides an online interactive didactic learning platform and provides tailored feedback on their own audio-recorded encounters. The feedback will come from two sources: 1) Professional research assistant coders who will identify objective learning opportunities based on specific coding criteria (e.g., empathic opportunities, use of open-ended questions) and 2) Trained patient reviewers who will listen to the recordings and offer their own, subjective feedback at key moments in the encounters. These patient reviewers will be drawn from our stakeholder partners and are active patient advocates. They will be treated as members of the research team, paid for the reviews, and are not patients of the study physicians. After completing the SCOPE online module, intervention group oncologists will audio-record two more clinic visits and receive another round of tailored feedback as a "booster." One month after completing the intervention or control arm processes, oncologists in both arms will audio record another four clinic encounters and collect another batch of 25 satisfaction surveys from a new sample of patients. Outcomes will be patient satisfaction measures in the survey, and communication quality, as measured by objective coding from the recorded encounters.

For physicians struggling to begin or progress through the study, we will offer individual site visits by members of our study staff to encourage and support the physician as they take on this project. During these visits study staff will meet with physician office staff to help distribute and collect patient surveys and to set up processes to make this easier going forward. They will also consult with the physicians to trouble shoot any barriers to audio recording conversations. This opportunity will only be offered to physicians who have already enrolled in the study and agreed to participate. We will send an email to all participating physicians introducing the new offer and providing contact information for study staff for those interested in taking advantage of this opportunity. We will require permission from the physician before planning a visit. Participating physicians are not required to accept a visit from study staff.

Enrollment: N(Oncologists)= 120, N(Patients)= 900, N(Caregivers)= 900. In the study we plan to enroll up to 120 oncologists, with a goal of achieving a final sample size of at least 100 after attrition. 50 oncologists will be randomly assigned to each study arm. Each oncologist will collect 50 patient surveys (25 before and 25 after the intervention) for a total of 5,000 surveyed patients. These surveys are anonymous and the patients will not be required to sign a consent form, therefore they will not be included in the overall patient enrollment numbers above. In addition, all oncologists will audio-record 8 conversations (800 enrolled patients) and intervention group oncologists will record an additional 2 encounters (100 patients) for a total of 900. The majority of cancer patients are accompanied by at least one caregiver, requiring the addition of a caregiver cohort. These caregivers serve a role similar to the audio recorded patients in this study, but are not the focus of the study and their presence is not relevant to the study aims. Prior to releasing all the participants for the study, we will release a vanguard of 6 participants to conduct pilot testing to make sure that all components of the research design are working correctly, including data collection, audio uploads and the online intervention. Barring any complications affecting participation, these pilot participants will be included in the formal study, are a part of the sample size calculation, and their data will be a part of the main analyses. As they are part of the overall research project and must provide consent, these pilot participants are included in the physician enrollment numbers above.



In addition to testing the feasibility of all the components of the study, this pilot will also provide preliminary estimates of the Intracluster Correlation Coefficient (ICC) per measure, response frequencies for survey items, standardized mean differences in the patient survey composites, and estimates of group rate ratios of the number of empathic responses per number of empathic opportunities. These data will be used to re-evaluate our initial values used powering the study and to revise any procedures that will improve the quality of the information collected.

Below, we describe the components and technical processes of the SCOPE intervention. All technical and design work related to app and website development will be performed by People Designs, Inc., the Durham based firm led by David Farrell, MPH. They developed SCOPE, the AVA audio coding software, and a number of other applications used in projects with Drs. Tulsky, Pollak, Arnold, and Back.

Educational Content - SCOPE is comprised of five modules that build sequentially upon one another: 1) Principles of effective communication; 2) Recognizing empathic opportunities; 3) Responding to empathic opportunities; 4) Conveying prognosis; and 5) Responding to difficult questions. The principles and mnemonics taught in these modules are derived from the OncoTalk communication skills training program.[104,105] Although the SCOPE program identifies oncologists' opportunities for

improvement, the overall "tone" of the program is positive and supportive. It uses the language of motivational interviewing, stresses how difficult these conversations are for clinicians, states that shortcomings are ubiquitous among physicians, and praises and encourages positive behaviors when identified. Each module includes an introduction to the topic, teaches several concrete skills with video demonstrations, provides audio clip examples from the oncologists' own conversations of when they used the skills and opportunities where they could have used the skills if they did not, and offers tailored audio feedback encouraging more use of positive behaviors, less use of unhelpful ones, and alternative approaches to employ when missed opportunities are detected. In addition to the objective coded data and examples, oncologists will also receive examples with feedback selected by the trained patient reviewers. Finally, each module concludes with action steps to which the oncologist commits, and about which they will receive an email reminder in the near future.

Oncologist-Patient Encounter Audio Recording - Oncologists will audio record their patient encounters using a smartphone application specifically developed for this purpose. Upon enrollment, providers will receive an email message with links to install the smartphone app. The app is compatible with both iOS (iPhone) and Android operating systems. Possession of a compatible smartphone will be a criterion for study enrollment. Prior to recording, oncologists will identify potential patients and provide them with a flyer prompting them to call study staff at DFCI. Patients will call study staff who will then explain the study to patients and provide a website link via text message directing them to an electronic consent and HIPAA authorization form that they will then sign. To record an encounter, the physician simply launches this easy-to-use app and taps "record." At the end of the recording, physicians tap a "stop" button and can choose to immediately upload the recording to the "cloud" review platform, or to upload it later (e.g., if they don't have a current internet connection). Delivery status of each recording is prominently noted and the physician will be reminded later to upload the recording. Participating oncologists will be given detailed instructions in using the app (although it is quite simple and intuitive), reminded that all data transfer is HIPAA compliant, and that study staff will be available by phone and email to provide technical support as needed**.**

Professional "Manualized" Coding - Study staff will code recorded encounters using the AVA software program developed by our team and used previously in over 20 related studies to code over 6,000 provider-patient encounters. Using AVA, coding is performed directly on the audio recordings, preserving subtleties and context that would be lost through transcript-based coding alone. Coders identify segments within each recording and apply codes to each segment, with related sub-codes being applied to each code as appropriate. For example, a patient utterance such as "I'm so scared" would be coded as an "empathic opportunity," and a subsequent drop-box would allow it to be coded as a direct (rather than indirect) example of this. The coding rules are highly detailed, and our experience from the prior SCOPE studies as well as from numerous other project in our shop is that we can train coders to achieve high inter-rater reliability with kappa scores greater than 0.8 for most codes. After the two coders are trained, each will code approximately half of the conversations. In addition, they will both code approximately 15% of the encounters to make sure there is no coder drift. This technique results in very rich data that provides a view into specific provider communication at multiple points in each encounter.

Trained Patient Review - Patient reviewers: We believe that the most powerful example of engagement in this research is the patient clinic visit audio recording review with their feedback being given to the oncologists. This allows the patient's voice to be heard directly by the clinician. These reviews will be conducted by our Patient Research Team Members, our Patient Advisory Council

Members, as well as other patients who we will recruit with the assistance of our remarkable patient partners. These reviewers will evaluate recorded encounters using a smartphone app developed specifically for the project. Reviewers will be notified by study staff when an encounter assigned to the reviewer is ready for review. After launching the app and logging into the platform, the reviewer will be presented with a list of assigned encounters that have not already been completed. Once an encounter is opened, an audio playback interface will allow users to play, pause and seek through the recording. At any point during playback, the reviewer will be able to pause and insert a comment as a voice memo (spoken by the reviewer) or typed message. Upon completion, the reviewer will be able to inspect and modify inserted comments and ultimately mark the review as complete. The app will be designed to be immediately intuitive and to walk the reviewer through the review process. Reviewers will be trained in usage of the app and study staff will be available to provide technical support through email and phone. Each conversation will be reviewed by one patient reviewer. Prior to conducting any reviews, Dr. Pollak, a national expert and trainer in motivational interviewing, will train all patient reviewers. The purpose of this training will be to help reviewers understand how to frame their comments in behavioral language that is likely to be better understood and internalized by the oncologists (e.g., "I liked the way you said, 'That must be tough' – it showed that you really heard what the patient was saying" rather than, "You sounded really caring there."). While the patient perspective is essential and we need to retain their "voice" in this feedback, we are also aware that diffuse or overwhelmingly negative feedback is likely to trigger resistance, thus making the patient reviews counterproductive. We are certain that we can strike the proper balance with the very high quality patient partners we have recruited to this study.

Coders and patient reviewers will be contracted by DFCI. They will receive privacy and security training and will follow all DFCI policies and procedures related to accessing study data and maintaining privacy and security. Recordings and other data will not be transferred to the coders and patient reviewers. They will access recordings only through the AVA web-based coding program, using an encrypted SSL connection. Their access to data will be limited to the recordings themselves and non-personally-identifying ID's used to refer to the recordings. All professional staff coders and patient evaluators will be HSP certified. Patient evaluators will be logged into a database by DFCI staff. Staff will ensure that each evaluator has completed the HSP training. All training certificates will be stored in the Regulatory Binder.

Coded Data Review and Recorded Example Selection - Study staff will be notified when coding (by professional coders and patients) has been completed for each encounter. Data from manualized coding will be inspected by Dr. Pollak who may reject, accept, or modify specific coding. Based on prior experience managing similar review processes, initial encounters will require regular checking and discussion with reviewers and coders. This will serve as a quality improvement step that leads to better review and coding over time, ultimately resulting in very little need for checking these data prior to their usage in the online training. There will be no more than two examples given for each skill taught. Similarly, staff will examine patient reviewer comments and where necessary clarify these through discussion with the reviewer. Specific comments may be edited to better reflect reviewer intentions, and voice memos may be converted to text when a voice memo needs to be adjusted. Up to three patient reviewer comments per encounter will be selected for presentation to the oncologist. We have found in prior work that too much feedback can be overwhelming and physicians are most likely to act on small amounts of focused feedback.

Online Provider Training – After all of an oncologist's recorded encounters have been collected and coded, the data will be transferred to an individually tailored web/mobile-based training program. A

SCOPE program account will be created for the oncologist who will be notified via email. The program will include all of the components described in the "Educational Content section", including individual feedback on providers' own recorded encounters. For the manualized coding, each coded oncologist behavior will match with a feedback response from a sample library of choices. For example, when an oncologist misses an empathic opportunity, we will provide a sample empathic response. Oncologists will receive patient reviewer comments either in writing or verbally, along with clips from the encounters to which those comments are directed. Feedback will reward providers for demonstrated skills and identify deficiencies with concrete suggestions to improve communication in those areas.

The training program will be designed for use on multiple platforms, including computers, tablets, and smartphones. The interface will be intuitive, with emphasis on quick digestion of content. Physicians can work through modules in a linear fashion or follow their own preferred trajectory using a menu system. They will be encouraged to visit all content, and completion will be clearly indicated through a progress meter and map showing completed and incomplete sections. Past experience suggests most users will complete the intervention in a single setting, but users will have the opportunity to complete it over multiple sessions and to return to already completed content at any time. The training program will track usage at the page/screen level, allowing for detailed analysis of each provider's dose and usage trajectory. An administration panel will allow research staff to track physician usage.

Study Feasibility: We believe this program is feasible because of the resources we have to conduct the trial. Both interventions the SCOPE program and the Subspecialty Communications Practice Improvement Module (PIM) have been field-tested. SCOPE was evaluated in a previous randomized trial (107) and the Subspecialty Communications has been operational in the Maintenance of Certification (MOC) program at the ABIM for more than 10 years. We have an adequate pool of oncologists and their patients to participate in the study. As of 19 April 2016, there are over 6,600 practicing oncologists enrolled in the MOC program. ABIM made arrangements with its platform service provider to dedicate sufficient computer storage and data collection via web-based and IVR systems to accommodate 150 physician participants and at least 10,500 patient surveys. This will be more than adequate to cover the trial of 120 oncology practices. Finally, the incentives of 40 MOC points out of the required 100 points for to maintain certification, 40 CME credits, and a small payment of $75 per physician should enhance our ability to accrue physician participants for the study.

5.4 Data Collection

Four types of data will be collected in this study: oncologist surveys, patient surveys, oncology visit audio recordings, and Enhanced SCOPE program usage data

Oncologist surveys – oncologists will complete brief surveys at baseline (demographics) and after completion of the practice improvement module (feedback on the module). These data will be collected directly online through the Enhanced SCOPE website, described below and will be stored on the SCOPE server. All oncologists, whether assigned to the intervention or control arm, will navigate the study via this site. Survey data do not contain PHI or other patient data. These data will be transferred securely to ABIM for analysis together with the other data.

Patient surveys – the only survey data collected from patients is from the anonymous CAHPS surveys administered through ABIM. Patients will be identified by their oncologists and given a copy of the survey that on the cover sheet offers two different options through which to complete the survey. One option is automated interactive voice response (IVR), in which the patient calls a toll-free telephone number and enters an identification number for their oncologist, and is directed through a survey by a computerized system. The second option is to complete the survey via an anonymous online portal, for which the patient is given the URL and the oncologist identification number. These data, too, will reside only at ABIM. The surveys are linked to the oncologist, but otherwise have no identifiable data or protected health information. We are requesting a waiver of written consent to collect the anonymous survey data via CG-CAHPS from patients who receive care from participating oncologists. We believe this is the best way to protect patient confidentiality, as the only linkage between the survey data and the patients would be the informed consent document. This way, the data remains truly anonymous. Patients will not have the option of completing surveys on paper, thereby eliminating opportunity for loss or disclosure of hard-copy data.

Oncology visit audio recordings – the clinic visit recordings will be collected via the AVA application as described below and will reside on the AVA servers. Through review and coding of these recordings using the AVA application, additional "code" data will be generated and will be stored on the same AVA servers. These code data do not contain PHI or PII and are stored separately from the audio recordings. The code data includes data collected from both the patient and from the caregiver(s) during the audio recorded clinic visit. The data extracted from the recordings is dependent on the oncologists, their responses, and their communication. The coded data are not differentiated into "patient" and "caregiver" data; all codes are categorized only by oncologist. Therefore, all data collected from the patient or from the caregiver(s) during one audio recorded visit will be considered one set of data. The code data (without recordings), will be transferred securely to ABIM for analysis together with the other data. Portions of the visit recordings will be available for oncologists to review as part of their usage of the Enhanced SCOPE website, with each oncologists having access only to their recordings (the recordings of their own clinical encounters). These partial recordings will be stored on the SCOPE server.

SCOPE program usage – the Enhanced SCOPE website will track oncologist usage, generating common usage data including login times and content viewed, and will be stored on the SCOPE server. Usage data do not contain PHI or other patient data. Usage data, will be transferred securely to ABIM for analysis together with the other data.

Long-term storage of Data

Data stored on the SCOPE server and AVA servers will reside there only for the periods they are required to be there for study usage. Data will be securely removed from these servers on a per-item basis (as users complete the study their data will be removed, rather than waiting for all users to complete the study). Removed data will be securely transferred to DFCI servers for long-term storage.

The Enhanced SCOPE Website

The Enhanced Scope website is custom website developed for the study. The website and associated data will be hosted on a HIPAA-compliant server managed by Armor (armor.com), a HITRUST-certified HIPAA hosting and data management provider.

The AVA Application

The AVA application is a commercial product that will be licensed by the study for use to collect and code audio recordings. AVA includes a SaaS web application that is used to manage and code audio recordings, generate reports, explore recordings and data, and compile data for further analysis. AVA also includes an iOS recording app that transfers recordings directly to the AVA servers (instead of using a general purpose audio recorder app). AVA and associated data are hosted on HIPAA-compliant servers managed by Armor (armor.com), a HITRUST-certified HIPAA hosting and data management provider.

5.5 Description of Study Process

5.51 Instrument Administration:

All instruments in this intervention will be self-administered. [PLEASE SEE SECTION 5.4 "DATA COLLECTION" for further details about the surveys and recordings.]

Once oncologists have enrolled, they have 1-2 weeks to complete a baseline questionnaire, request satisfaction surveys from a "convenience sample" of 25 of their patients, and then audio record (using a smartphone application) four clinic visits with four different patients. Within 2-4 weeks the oncologists will receive their survey feedback and will be randomized into control and intervention arms. Those doctors who are randomized into the control group will have 6 weeks to conduct a quality improvement activity that responds to the feedback (the current "standard" communication PIM). Oncologists assigned to the intervention arm will have 2 weeks to complete the enhanced SCOPE program that provides feedback on their audio-recorded encounters via a web based interactive program. Oncologists in the SCOPE arm will record an additional two clinic visits to receive a "booster" of feedback after the online training. One month after reviewing their feedback, oncologists in both arms will audio record another 4 encounters and request satisfaction surveys from a new sample of patients.

5.52 Intervention Administration:

The ABIM provides electronic information to potential oncologists and those doctors self-select to join the project. Oncologists enroll, consent online, choose their own patients, then proceed with the intervention at their own pace with the use of the online function and smartphone applications. Doctors continue with this process until they finish their section, the intervention lasts the length of the study. All technical and design work related to smart phone application and website development will be performed by People Designs, Inc., the Durham based firm led by David Farrell, MPH. Data from manualized coding will be inspected by Drs. Tulsky and Pollak and these doctors will also train patient reviewers to code the audio recordings.

5.53 Special Concerns

The risks in this study are minimal and non-medical in nature. The primary risk is loss of confidentiality. To minimize the likelihood of a breach, we will collect only electronic data and anonymous data when possible. Also, mobile recording devices/applications will be designed with security measures in mind. Only the minimum amount of PHI necessary will be collected from study subjects, including oncologists and patients, and all data will be transmitted via secure, institutionally approved methods.

5.54 Compensation

Physicians will be incentivized to participate by receiving 40 MOC points (twice what is usually awarded for completing a Practice Improvement Module), 40 CME credits, and a $75 credit toward their MOC fee.

5.6 Adverse Reactions and Their Management

5.61 Reporting Adverse or Unanticipated Events

The PI will monitor and report Adverse Events (AEs) to the Dana Farber Office of Sponsored Research.

5.62 Anticipated Reactions

This study presents minimal risk to participants.

5.63 Reaction Management

Ongoing mechanisms for monitoring the occurrence of AEs include: (1) day-today oversight of study activities by the project manager; (2) a toll-free number participants may use to contact study personnel at Dana Farber; and regular team meetings and check-ins with project staff and investigators. Additionally, all research staff will be Human Subjects certified.

6.0 STATISTICAL ANALYSIS

6.1 Primary and secondary Aims:

The overarching goal of this project is to improve communication between oncologists and their patients, and thus improve the experience for patients living with cancer. We hope to accomplish this goal by providing oncologists communication skills training that includes feedback on their own audio-recorded conversations. We hope to accomplish the following specific aims:

Aim 1: Identify barriers to implementing the ENHANCED SCOPE app. & website in participating oncology practices. Barriers include: oncologist enrollment, patient enrollment and transmission of data.

Aim2*:* Compare the effect of the Enhanced SCOPE program to the standard Communication Practice Improvement Module (PIM) on patient satisfaction with their oncologist's communication as measured by the CG -CAHPS.

Aim 3*:* Compare the effect of the Enhanced SCOPE program to the standard PIM on oncologist communication behaviors, including their use of empathic responses to patients' emotional concerns, as coded from audio- recorded medical encounters.

6.2 Sample size and statistical power or precision associated with the sample size

We considered several outcomes for power calculations to determine study sample sizes, number of physicians and number of patients within physician practices. All power calculations were completed using the PASS© power analysis [116]The study assumptions for the power calculations follow:

- Intervention: SCOPE (Studying Communication in Oncologist–Patient Encounters) program
- Active control: Subspecialty Communications Practice Improvement Module program
- Type I error rate ≤ □ = .05, two-tailed test
- Power to detect minimally important difference in means, rates or odds ratios ≥ (1-β) = .8
- Analyses will involve random effects models comparing intervention and control groups with respect to mean differences, the odds ratios, or rate ratios.
- Sample allocations between treatment groups will be 1:1
- Mean differences in continuous variables (e.g. mean patient satisfaction with communication score) will be assessed using a random effects, ANCOVA with covariates [117, 118, 119]Minimally important differences between groups (in standardized units SD) reviewed included: .20 SD and .25 SD. The assumed values for minimally important differences for continuous variables is based on effect sizes determined from previous research of the Duke investigators [107]and ABIM investigators [120]

  We planned on meaningful effect sizes to be somewhere between .21 and .25 typical of effect sizes we have observed in ABIM studies and representative of the expected effect sizes we observe from continuing medical education programs. In a systematic review of the effect sizes of CME program a 2009 Cochrane Collaboration review of 30 randomized trials investigating the effects of CME on professional practice and healthcare outcomes (versus no CME), the median risk difference (RD) was 6% (IQR: 1.8% to 15.9%). Assuming equal sample sizes and a baseline

risk of 70%, a standardized difference effect size equivalent to a 6% RD is approximately .14 (0.4 to .33) SD.

- Odds ratios for categorical or ordinal variables (e.g. groups differences between items or rating scales from CAHPS survey) will be assessed using a random effects logistic regression [121]These minimally important effect sizes between groups reviewed for power calculations included 2.0 and 2.5 and were based in previous research by Duke investigators [107]Based on estimates from previous Communications PIM performance at the ABIM, we assumed Physician performance from the PIM would be about .7 for binomial variables.

- Between group rate ratios of the number of empathic responses per number of empathic opportunities will be assessed using a random effects Poisson regression [122]Minimally important rate ratios based on previous research of Duke investigators [107]reviewed included: 2.0 and 2.5. Assumed the Poisson regression fits the data so the over-dispersion parameter for the regressions was fixed at 1.0 with a baseline empathic response rate of .4 per every one oncologist to patient conversation.

- The data will have clustered structure with patient responses or physician conversations nested within oncologists. The expected intra-cluster correlation (ICC) is .1. The assumed value of the ICC is based on the observed average intra-cluster correlations from patients samples of CG-CAHPS surveys of physicians completing the Subspecialty Communications Practice Improvement Module program at the ABIM and is consistent with ICC values reported nationally for the CG-CAHPS 3. [127].

- Cluster sizes reviewed include 4 for analyses of outcomes from physician audio recording Possion and 25 per physician for analysis of outcomes from patient responses to CG-CAHPS composites.

- It is expected that there we be no more than a 16% loss to follow-up among participating physicians over the duration of the study so an initial sample of 120 would ensure 100 oncologists remaining for the duration of the study. The most likely reasons for dropouts expected include physicians not completing the data collection requirements before randomization or failing to complete in the communication improvement activities of the study arms.

Based on these assumptions, we determined that 100 physicians with 4 patient audio recordings at baseline (before randomization) and post-intervention and 25 patient responses to the CG-CAHPS surveys at baseline and post-intervention were suitable for our study objectives. Table 1 shows the twelve study scenarios that we determined sample size requirements. One hundred physicians (50 per study arm) met or exceeded sample size requirements each of the study outcomes reviewed. The proposed study size: 100 physicians, 8-10 physician-patient audio recordings depending on the arm in which they are enrolled and 50 patient surveys seemed manageable for a proposed 18 months of data collection.

Table 1. Physicians and Patients Required to Detect Selected Effect Sizes with at least 80% Power at $\alpha = .05$

	Model	Effect Size	Rho	Cluster Size	α, 2-tail	1 - β	Per Group # Physicians	Per Group # Patients	Total # Physicians	Total # Patients
1	Mean Difference	0.21 SD (1.0)	0.1	25	.05	0.80	**50***	2,500	100	5,000
2	Mean Difference	0.250 SD (1.0)	0.1	25	.05	0.81	**36***	1,800	100	3,600
3	Poisson Reg.	Rate (2.0)	0.1	4	.05	0.8	25	100	50	**200***
4	Poisson Reg.	Rate (2.5)	0.1	4	.05	0.8	14	56	28	**112***
5	Logistic Reg.	OR (2.0)	0.1	4	.05	0.72	50	200	100	**400***
6	Logistic Reg.	OR (2.5)	0.1	4	.05	0.8	37	148	74	**296***
7	Logistic Reg.	OR (2.0)	0.1	25	.05	0.8	26	650	52	**1300***
8	Logistic Reg.	OR (2.5)	0.1	25	.05	0.8	16	400	32	**800***

*Bolded number determined from power calculations

6.3 Stratification factors and intervention allocation plan for randomized studies:

All participating oncologists who are enrolled in the ABIM MOC program, complete Practice Characteristics Survey, complete baseline patient surveys of at least 25 patients and who audio record 4 patient interactions will be eligible for randomization to study conditions. The randomization of physicians will occur at the ABIM. The responsible statistician at ABIM will use a computer program for randomization. The randomization process will involve stratifying participants by gender and time interval blocks (about 12/month) as they enter the project. Because of the administration time required to score the baseline audio recordings, physicians will be assigned in time blocks to accommodate the flow of work. Total expected time to accrue physician participants is about 16-18 months.

6.4 Stratification factors and their impact on design:

At Baseline, participating oncologists will complete a background questionnaire covering the flowing topics:

- Oncologist demographics: At baseline, oncologists will be asked their age, gender, race, ethnicity and religion.

- Oncologist experience: At baseline, oncologists will be asked the number of years they have been in practice and the number of hours they spend in direct patient care.

- Oncologist communication training: At baseline, physicians will be asked about prior communication skills training they have received in medical school, residency, fellowship and practice.

- Oncologist socioemotional orientation: At baseline, physicians will be asked 2 items that assess whether they are more inclined toward the social and emotional aspects of patient care or more inclined toward the technological and scientific aspects.[129] In the SCOPE Trial, these were found to be strong predictors of physician likelihood to use empathic responses. Because participating oncologists are enrolled in the ABIM MOC program, administrative data from ABIM records will be used to supplement information from the questionnaire particularly training and certification performance. ABIM records may also serve to validate responses to the study questionnaire or serve as imputation sources in the event of incomplete responses.

The questionnaire data will be used to assess whether certain training, demographic, or personal characteristics serve as moderating variables to the treatment effects. Many to these variables will serve as covariates in the ANCOVA analyses or if there are complex interactions observed, the analyses may include blocking respondents using one or more of these variables interactions.

6.5 Early stopping rules, if appropriate:

NA, there are no plans for early stopping of the study.

6.6 Definition of and allowance in design for unevaluable/ineligible participants:

Unevaluable participants will include those physicians who do not complete the baseline data collection requirements before randomization. These individuals will not be allowed to participate in the trial. Individuals who do not complete both the baseline and re-measurement portions of the study are not eligible to receive the 40 MOC points towards their certification status nor will they receive the $75 monetary incentive to participate or the 40 CME credits. Records of data collected from physicians who completed all baseline requirements and were randomized to a study arm but failed to complete the re-measurement portion will still be used in the analyses as incomplete records. Missing data models will be used to adjust for these incomplete records.

6.7 Analysis plan:

The study design for analyses purposes is what Murray [124] refers to as a cross-sectional, nested Pretest-Posttest Control Group Design. The analyses of the primary outcomes, average, patient communication and trust scores will be achieved using a linear mixed model with patient responses nested within physicians. The test for the main intervention of SCOPE versus Communication PIM is evaluated by comparing the variation among the time by intervention against the variation of the time by physician

interaction. Since there are only two times and two interventions the test is reduced to a t-test comparing the differences between post-intervention mean and baseline mean for the score intervention to the same difference for the Communication PIM. The advantage to this design when assumptions are met is that it allows for adjustment of any pretest and post-intervention differences between groups reducing sources of bias that may exist. The cost is some loss in power so we chose to use a larger physician sample of at least 100. Table 2 below shows the expected mean squares table for an unadjusted nested, cross-sectional, Pretest-Posttest Control Group design used in the study. The only difference in the expected means squares shown in Table 2 and those from an adjusted (baseline or post-intervention) analyses is the reduction in the degrees freedom from the either the group level covariates or patient level covariates along with the effects of the covariates removed from the mean squares.

The analyses of the secondary outcome, oncologists' empathic response to patient and caregiver expressions of negative emotions, a rate variable, proceeds in the same manner as the primary outcome. The difference between the two analyses is that the general linear model for the average score outcome uses a normal error linear model while the linear model for the secondary rate function follows an Poisson distribution with a log link function, thus the error terms for the two analyses have different distributions but the same data analyses design.

The differences we are measuring are the treatment arm differences in physician post-test scores controlling for pre-test scores that is, the differences between post-intervention mean and baseline mean for the SCOPE intervention to the same difference for the Communication PIM while partialling out the effects of relevant covariates. We compare test for effect 1 (Intervention, shown in Table 2) to that for test of 4 (time by intervention shown in Table 2)

Table 2. Expected Mean Squares for an Unadjusted Analysis of Data from SCOPE Versus Communication PIM Study

Source of Variation	**Df**	**E(MS)**	**MS**
Intervention (Scope vs. PIM): I	2-1	$\sigma^2_e + mt\sigma^2_{P:i} + mtp\sigma^2_e$	MS_I
Physicians: P	2*(50-1)	$\sigma^2_e + mt\sigma^2_{P:I}$	$MS_{P:I}$
Time, 1=baseline, 2= post-intervention: T	2-1	$\sigma^2_e + m\sigma^2_{TP:I} + mPI\sigma^2_T$	MS_T
T*I	1*1	$\sigma^2_e + m\sigma^2_{TP:i} + MP\sigma^2_{TI}$	MS_{TI}
T*P:I	1*2*(50-1)	$\sigma^2_e + m\sigma^2_{TP:I}$	$MS_{TP:I}$
Patient Observation: T*P:I (8 obs./physician): m **or**	2*50*2*(4-1)	σ^2_e	MS_e
Patient Observation: T*P:I (35 obs./physician): m	2*50*2*(25-1)	σ^2_e	MS_e
Note: df= degrees of freedom, E(MS) = expected mean square, MS = mean square			

There are several assumptions that apply to the models discussed [124]. First, variables adjusted in the analyses are assumed to have a straight-line relationship with the outcome measures. This assumption may be assessed by visual inspection of scatter plots of the covariates against the outcome measures. If

nonlinear trends are suspected then adding nonlinear terms to the analyses models and checking for significance of the coefficients for the terms may be used. Another assumption of the model is that the error terms follow either a normal distribution for the primary outcome or a Poisson distribution for the secondary outcomes. Model residuals can be examine using quantile to quantile plots comparing the actual residuals to expected residuals from the appropriate standard distributions. Third, regression slopes for the covariates are assumed to be homogenous across the study conditions. This may be assessed by introducing covariate by outcome interaction terms into the models and testing the significance of the terms. Fourth, covariates are assumed to be homogeneous across physician groups within conditions. This too may be assessed by testing for the significance of a physician by covariate interaction. Finally, the models assume that the outcomes have no effect on the covariates. There is no good way to assess this possibility. We must be careful to pick covariates that are related to the outcome but are not likely to be affected by the interventions such as demographic characteristics like gender. Finally, because many the assumptions of these models are assessed by adding additional terms, the model fit statistics such as the likelihood ratio test or the Akaike's and Schwarz's criteria statistics. The fit statistics of the various models may be plotted as a function the number of model parameters to suggest whether adding these terms for assumption testing is reasonable. All analyses will be conducted using the SAS® statistical software, version 9.4

6.8 Handling of missing data in the analysis:

Missing data either incomplete responses (items missing) or absent responses (dropouts or missing records) reduce the efficiency of the studies and may introduce biases into the analyses. Little and Rubin [125] describe a hierarchy of missing data mechanisms including missing completely at random (MCAR), missing at random (MAR), and not missing at random (NMAR). When data are MCAR then the records even those with missing values can be considered a random sample of the complete data [126]. Thus, a complete case analyses of only observations that all data elements would give you accurate estimates of the target population. General linear models and generalized linear models are valid assessment tools in the MCAR case [126, 127]. With MAR data, complete case analyses is invalid however, missing data may be imputed from the observed data even from records with incomplete responses. Valid inference for MAR can only occur in generalized linear models or generalized mixed linear models if the models are correctly specified otherwise the inferences will be biased [126, 127]. When data are NMAR, then the mechanism for missing data must be included in the model but unfortunately the missing mechanism is usually not known so and would have to be simulated [126]. There is no way to correctly analyze NMAR data unless the missing mechanism is included the analytical model.

For our purposes we will assume that missing data are MAR and use multiple imputation methods such as Markov chain Monte Carlo method which creates a series of plausible values for the missing data [127]. The data are combined and estimates for inference are made. The benefit of imputation is that a set or reasonable values are substituted for the missing one. The cost of imputation is that the error terms for estimates such as differences between interventions are increased thereby reducing the power of the statistical tests. For sensitivity analyses, we plan to compare results from three basic analyses: 1) complete case analyses (assumes MCAR is true), 2) multiple imputation by MCMC of all missing values, and 3) multiple imputation by MCMC to create a monotonic missing patterns in the data so that different imputation models may be tried to see how study results vary under different imputation models [125]. If after close inspection of the data, the research team suspects that a NMAR mechanism may be at work,

we will test the hypothesized NMAR assumption through simulation to evaluate how results might change.

6.9 Multiple Testing for Subgroup and Exploratory Analysis

Hypothesis tests of the differences between study interventions primary and secondary outcomes will be tested using a two, tailed significance test with the Type I error rate set at .05. For subgroup and exploratory analysis adjustments for multiple testing should be made. We intend to adjust for multiple testing by controlling the proportion of hypotheses falsely rejected among all rejected hypotheses, the false discovery rate, using Benjamini and Hochberg's linear step-up method [128].

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