Improving Advanced Cancer Patient-Centered Care by Enabling Goals of Care Discussions
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Mount Sinai	Protocol Title:	Improving Advanced Cancer Patient-Centered Care by Enabling Goals of Care Discussions
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MSSM Protocol Template HRP-503a

Instructions:

1. *Prepare a document with the following sections. Note that, depending on the nature of your research, certain sections below may not be applicable. Indicate N/A as appropriate, explaining where possible.*
2. *For any items described in the sponsor's protocol, grant application or other source documents submitted with the application, you may reference the title and page numbers of these documents rather than cutting and pasting into this document.* ***Do NOT refer to any derived documents, such as the Sample Consent document, or other internal documents required with the submission.***
3. *If you reference page numbers, attach those pages to this protocol.*
4. *When you write a protocol, keep an electronic copy. You will need to modify this copy when making changes.*

Brief Summary of Research (250-400 words):

We propose to enable oncologist and their patients with advanced cancer to have a Goals of Care (GoC) discussion. To achieve this and ensure that we capture patients' experiences and preferences, we have recruited stakeholders representing cancer patients and providers experienced in the challenges faced by patients and their caregivers. Patient stakeholders will be invited to participate in team meetings to provide their insights to: inform our tools, study design and aid with interpretation of the findings. Our goal is to develop approaches that enable GoC discussions to occur that are effective in different practice settings. Toward that end, we have recruited a tertiary referral, community and municipal hospital in different health systems. All serve inner city populations but their structures, organizational characteristics & supports differ. We will assess the feasibility of conducting GoC discussions and explore the cultural and experiential differences in practice. We will train oncologist to conduct GoC using Oncotalk and 4 joint visits and an Oncotalk trainer-palliative care physician.

1) Objectives:

Aim 1: Describe patients' perspectives about GoC discussions & oncologists' perspectives about barriers & facilitators of GoC discussions.

Aim 2: Determine the efficacy of the innovation of joint oncologist-palliative care communication training in real life settings to improve communication skills and assess its feasibility.

Aim 3: Block randomize oncologists in a municipal, 3ary referral and community hospital to the Oncotalk- joint Pall Care-Oncologist GoC visit & assess the effects on patient perceived and experienced quality of care.

2) Background

Please refer to pages 1-2 of the protocol.

3) Setting of the Human Research

This is a multi-site study which will be conducted at Mount Sinai, Mount Sinai Beth Israel, Yale University and Kings County Hospital Center. IRB approval will be sought at respective sites.

4) Resources Available to Conduct the Human Research

Please refer to page 7 in the protocol where you will find a table with SPARCS data indicating number of patients seen at each hospital site with a metastatic cancer diagnosis code as well as sample size calculations, to which we apply rates of ineligibility and refusal.

We have submitted biosketches describing qualifications for the principal investigator and co-investigators.

The study will have a project manager and assistant project manager who will have experience in managing research grants. We will also have two research assistants for the study who will be trained in study protocols and data collection procedures.

Research conducted at the 4 hospital sites will be coordinated with MSSM's study team. The research assistants will support the work conducted at the 4 hospital sites.

Dr. Schulman-Green from Yale University will serve as our qualitative expert and will analyze the interview data. Dr. Back from the University of Washington will help support the study by consulting on the design of the OncoTalk training.

5) Study Design

a) Recruitment Methods

<u>Pre-Intervention Interviews</u>

At each site, we will work with a research assistant to identify eligible patients with advanced cancer (primary stage IV hepatobiliary, esophageal, colorectal, glioblastoma, gastric, pancreatic, melanoma, head & neck, kidney, bladder, liver or locally advanced stage IIIor IV lung) for pre-intervention interviews. We aim to recruit 30 patients across the 3 hospital sites. Patients will be selected to have varied representation across different: age groups, cancers, and number of treatments. We will also recruit Spanish & Chinese speaking patients to be able to capture cultural differences. We will require research assistants at each site with the aid of the site PI, to review pathology and the EHR record in order to identify eligible patients. Once eligible patients are identified, they will be

contacted via a letter from their treating oncologist explaining the study. Patients will be approached by the research assistant at the next upcoming visit in order to discuss the study and if interested, proceed with consent process. For those patients who agree to be involved, informed consent will be obtained in person at which point we will schedule a time for the interview. The interview may take place at the local hospitals or clinic, whichever is more convenient. The research team at Mount Sinai will consent and conduct interviews with all patients at the sites. Keeping this process with the research team at Mount Sinai allows us to maintain quality control and oversight capabilities.

Recruit Oncologists: We will obtain a list of oncologists who treat the aforementioned advanced cancers from the Division of Hematology and Medical Oncology at each participating hospital with the aid from each site's PIs and oncology leadership. We will recruit the eligible oncologists to participate in this study by giving Grand Rounds and presenting the project at meetings of the Oncologist Attending staff. Site PIs know and work closely with key personnel needed for this project to succeed, pathologists, radiologists, nurses, clerical & administrative personnel. We will recruit and consent oncologists who see at least 2 new advanced cancer patients per month to participate.

Patient Identification for the Intervention: At each site, we will work with a research assistant to identify eligible patients with advanced cancer (primary stage IV hepatobiliary, esophageal, colorectal, glioblastoma, gastric, pancreatic, melanoma, head & neck, kidney, bladder, castrate resistant prostate cancer, liver or locally advanced stage III or IV lung). We aim to recruit 280 patients across the 4 hospital sites. Research assistants at each site will be required to review pathology and the EHR record in order to identify eligible patients. Once eligible patients are identified, they will be contacted via a letter from their treating oncologist explaining the study. Site research assistants will identify eligible patients' upcoming oncology visits. Patients will be approached by the research assistant at that visit in order to discuss the study and if interested, proceed with the consent process. Research assistants at Mount Sinai will consent and survey patients at the sites. Keeping this process with the research team at Mount Sinai allows us to maintain quality control and oversight capabilities. Patients may be surveyed at the local hospitals, clinic or via telephone, whichever is more convenient for patients.

b) Inclusion and Exclusion Criteria

Inclusion Criteria*:* Men or women who are at least 21 years of age and diagnosed within one month with a pathologically confirmed advanced cancer who have an average of <2 y life expectancy (primary stage IV hepatobiliary, esophageal, colorectal, glioblastoma, gastric, pancreatic, melanoma, head & neck, kidney, bladder, castrate resistant prostate cancer liver or stage III or IV lung) and are being treated at one of the participating hospital sites and speak English or Spanish. Oncologists who treat at least 2 advanced cancer patients per month at a study participating hospital will be enrolled into the study.

Exclusion criteria: We will exclude patients who have seen an oncologist after undergoing first line treatment imaging as this group has a higher likelihood of having received a goals of care discussion. Men or women who do not speak English or Spanish will be excluded.

c) Number of Subjects

30 pre-intervention patient interviews; 25 oncologist interviews; 315 patients for intervention (see table with breakdown of intervention patients below). Given the high number of screen failures, we had to increase the number of consented patients to 315 to have a total of 280 eligible enrolled patients. Based on initial discussions with the oncology departments at all the sites when the grant was being developed, we expect 25 oncologists to be recruited across the 4 sites. However, this number may differ given that there is constant turnover in physicians at each of the sites and actual number of oncologists will not be determined until the study has begun.

Name of Hospital	Number of Patients
Beth Israel Mount Sinai	40
Kings County Hospital Center	27
Mount Sinai Hospital	201
Yale University	47
Total Expected to Be Enrolled	**315**

d) Study Timelines

Study patients were followed for 6 months and completed two surveys; one at baseline and one at 6 months. Over the course of the study, we enrolled 315 patients across all sites. Upon conclusion of previously collected data, we are now adding an additional intervention oncologist interview. Intervention oncologists will be consented to participate in a <1 hour interview. We expect this will take a few months to enroll 10 oncologists across all sites.

e) Study Endpoints

Primary endpoints are patient's perceptions that goals of care discussions occurred and patient's satisfaction with the discussion. Secondary outcomes include patients' perspectives about goals of care discussions & oncologists' perspectives about barriers & facilitators of goals of care discussions. We will evaluate change in oncologist's communication skills and assess feasibility of the intervention. In addition, we will assess healthcare utilization at the end of life and whether goals of care led to care in line with patient preferences.

f) Procedures Involved in the Human Research

Prior to Intervention Phase.
Prior to the intervention phase of the study, we will conduct pre-intervention interviews with oncologists and patients. To obtain experiences and perspectives on goals of care discussions, including barriers and facilitators of these discussions and the influence of organizational culture on goals of care discussions we will recruit 20 oncologists across the 4 hospital sites (Beth Israel, Kings County, Mount Sinai, Yale) for a 30 minute audiotaped interview and survey. We will briefly survey oncologists about communication skills training experience & comfort conducting goals of care discussions. In addition, we will assess all oncologists' baseline communication skills by audiotaping the visit with an advanced cancer patient after the imaging study following the first line of chemotherapy.

We will also recruit 40 patients across the 4 sites for a 45 minute audiotaped interview to gather information on patient perspectives of goals of care discussions including when discussion should take place, patient/family concerns, cultural beliefs, and preferences.

Intervention Phase
Oncologist Participation
For the intervention phase of the study, we will work with each site's PI to identify and obtain a list of oncologists treating at least 2 eligible patients per month in each participating hospital. Following oncologist engagement by site PIs and Grand Rounds presentations, we will consent interested oncologists. All participating oncologists will receive a one-hour didactic training during Oncology Grand Rounds. The session will acknowledge the changing nature of goals of care discussions and emphasize the importance of starting these discussions at the 1st visit following imaging during 1st line treatment. Oncologists will be randomized to the intervention or usual care group.

Intervention oncologists will receive a two hour basic training; first hour focuses on practicing skills of goals of care discussions; the second hour focusing on choreographing joint consultants with the Palliative Care specialist trained in Oncotalk facilitation. We will conduct a total of 4 joint patient visits over a two month accrual period for each intervention oncologist. We chose 4 sessions to allow adequate time to model and tailor feedback to the oncologist. We will pair intervention oncologists with a palliative care specialist trained in Oncotalk facilitation to ensure that role modeling and tailored feedback occur in real time and in real settings. Immediately prior to the joint consult, the palliative care specialist will review the "choreography" of that visit – which physician will cover specified elements of the GoC talk, reinforcing the 2h role play session. We envision that during the initial joint visit, the oncologist will cover the Knowledge portion and the palliative care specialist, the remainder, thus modeling how to approach the more difficult parts of the conversation. With each successive session, additional portions will be led by the oncologist so by the 4th joint consult, most, if not all the session will be led

by the oncologist with the palliative care specialist providing backup. Each joint consult will fill a 40 minute visit slot with 30 minutes of patient visit, 5 minutes pre-visit planning and 5 minute post-visit assessment & feedback. During each joint consult, the palliative care specialist will complete a checklist of skills performed. Immediately following each joint consult, the palliative care specialist will review with the oncologist the GoC areas performed, what went well, and together, plan corrective approaches for the next session. The pre- and post-visit planning & feedback times are based on prior OncoTalk feedback assessments.
At 12-months or after the OncoTalk training for intervention oncologists, all oncologists will have an audiotaped patient visit to assess changes in goals of care discussions.

Patient Participation
We will work with the research assistant at each site to identify patients using the EHR. Once eligibility has been determined, patients will be contacted via a letter from their treating oncologist explaining the study and informing them that a research team member will be contacting them. Patients will be approached by the research assistant at the next upcoming visit in order to discuss the study and if interested, proceed with consent process. This consent will be done in person. Once the patient has been consented, the research assistant will contact them over the telephone after their first imaging is done to schedule a 1 hour baseline survey immediately following their next oncologist visit (which we will ask to audiotape) or over the telephone whichever is more convenient for the patient. Baseline survey will assess whether goals of care discussion took place, their satisfaction with the discussion and whether the discussion helped them identify their preferences in care. Audiotape will confirm conduct of a goals of care discussion. The patients will be surveyed 6 months after the baseline survey either in person or over the phone. Six months later, patients (if alive) or their caregivers will be surveyed to assess whether the care received was in line with their preferences and determine hospice and health care utilization at other sites. In the event, the patient is deceased, we will call the caregiver and ask them if they are willing to participate, consent him/her and conduct survey over the phone or at a place convenient to them. We will conduct a chart review of consented patient's records to determine treatments received for their cancer.

Post-Data Collection Phase
Oncologist Participation
We will interview the same intervention oncologists that had been enrolled in the study at post-intervention using a semi-structured survey to obtain feedback about the Communication Skills Training to understand what they got from the training and whether they used the skills obtained.

g) Specimen Banking

N/A

h) Data Management and Confidentiality

We will be collecting advanced cancer patients' treatment information and physician interviews. All study personnel are instructed on proper confidentiality and data safeguarding procedures. Data will be stored on a secure password protected computer maintained by our IT specialists in the Department of Population Health Science and Policy at the Icahn School of Medicine at Mount Sinai. Any hard copy materials will be maintained in locked cabinets when they are not in use. Study subjects are assigned unique identification numbers and we will strip the files of identifiers once data analysis is complete. We will remove names, addresses and other direct identifiers from hardcopy and computer readable data after they are not necessary for patient and physician tracking, and we will use an encrypted link file for subsequent identification of patients and physicians. The research assistant will place the audio recorder in the clinic room and collect the recorder at the end of the visit. The research assistant will not be present in the room during the visit. We will ensure that all patient audio recordings do not contain any personal identifiers and they will be stored with unique identifiers for analysis purposes. Once data analysis is complete the recordings will be deleted. The recordings will be stored in a password protected computer maintained by our IT specialists in the department. We will ensure that all communication contain no confidential information and will only refer to participants using their unique study number. The Principal Investigator, Project Manager, Data Analyst, Chart Abstractor and Research Assistants will have access to the data base.

i) Provisions to Monitor the Data to Ensure the Safety of subjects

We will follow the basic DSMP procedures.

j) Withdrawal of Subjects

This study involves chart review, communication of GoC training for oncologists, oncologist and patient interviews and surveys. No treatment will be administered to study subjects. If participants ask to withdraw from the study, we will only use the information that has already been collected.

6) Risks to Subjects

This study involves training, interviews and surveys. Minimal risk is involved. The only foreseeable risk is that questions asked during the interview might make the patients or oncologists uncomfortable. We will reiterate that they can refuse to answer any questions they wish. Patients who appear psychologically distressed will be promptly reported to Drs. Smith and Bickell.

7) Provisions for Research Related Injury

None- N/A

8) Potential Benefits to Subjects

There is no direct benefit for participants for taking part in the study.

9) Provisions to Protect the Privacy Interests of Subjects

We will only reach out to patients after initial contact is made by their oncologist via a letter. We will speak with the patients when they appear at their scheduled appointment to discuss the study and if interested initiate consent process. We will ensure that all communication among the study team contain no confidential information and will only refer to participants using their unique study number.

10) Economic Impact on Subjects

There are no costs directly associated with participation in this study.

11) Payment to Subjects

In this research study, oncologists were given a $50 incentive for interviews, pre-intervention patients received $40, and intervention study patients received $80 for their participation in the study.

12) Consent Process

We propose to obtain standard written consent from the participants across all sites. Consent will be obtained by the research team at Icahn School of Medicine at Mount Sinai. We will be following the informed consent process for research as indicated in SOP HRP-090. We will consent Spanish & Chinese speaking patients using the Spanish & Chinese approved standard consent forms as appropriate. In the event that the subject is deceased and their caregiver will be interviewed instead, we will attempt to set up an in-person meeting with the caregiver. If consent and the interview must take place by telephone, we will contact the caregiver and arrange to send them a copy of the caregiver consent form, either by email or post. After he or she has had a chance to review the consent form, the informed consent process will take place over the telephone. The signed consent form will be mailed back to the study team by the caregiver.

<u>Waiver or Alteration of the Consent Process for Review of Pathology Reports and Electronic Health Record in Preparation for Research</u>

We request a waiver of informed consent to identify eligible patients via electronic health record and scheduling systems. Once eligibility is determined we will consent patients into the study. The use of PHI will be minimal and will only be used to identify eligible

cases and to mail a letter from their oncologists informing them of the study. We will not collect patient data without their consent.

There is no reliable alternative method to identify patients in real-time who have recently been diagnosed with an advanced cancer. Without access to pathology and imaging reports and the electronic health record, we will not be able to determine patients' true diagnosis & stage and the optimal moment at which patients are eligible to have goals of care discussions. Before collecting additional information, patients will be asked to give consent and HIPAA authorization. We cannot initiate this consent process unless we first identify patients by reviewing pathology reports and the electronic health record.

13) Process to Document Consent in Writing

Consent will be obtained using standard PPHS consent forms.

14) Vulnerable Populations

Include	*Exclude*	*Vulnerable Population Type*
	X	*Adults unable to consent*
	X	*Individuals who are not yet adults (e.g. infants, children, teenagers)*
	X	*Wards of the State (e.g. foster children)*
X		*Pregnant women*
	X	*Prisoners*

Pregnant women may be eligible to participate.

15) Multi-Site Human Research (Coordinating Center)

Ichan School of Medicine at Mount Sinai is the prime institution for this proposal. The PI will monitor data collection and management to ensure data quality and adherence to the study protocol across all sites. Any unanticipated problems will be discussed between the site principal investigators and the principal investigator at Mount Sinai. Any protocol modifications at a site will be discussed with the principal investigator prior to submission.

16) Community-Based Participatory Research

N/A

17) Sharing of Results with Subjects

Results from the study will be shared with the surviving patients and oncologists participating in the study.

18) IRB Review History

We are currently working on IRB submissions to the participating sites.

19) Control of Drugs, Biologics, or Devices

Note: The IDS has its own forms that must be completed and a review process that must be followed before the IDS representative will sign off on Appendix B for submission to the PPHS.

N/A