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Study Title: Personalized Experiences to Inform Improved Communication for Minorities with Life Limiting Illness

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I. Specific Aims

Comprehensive palliative care improves quality of life (QoL) for patients with life-limiting illness (LLI).[8] There is a growing population of racial and ethnic minority patients[9] with LLI in the United States who are underserved by health care in many ways, including in both access to and quality of palliative care.[9,10] Specific disparities have been reported in palliative care for minority patients,in part because of gaps in knowledge around patient-centered psychological, social, and spiritual palliative care interventions.[10] Studies also show differences by race and ethnicity in patient receipt of and preferences for life-sustaining technologies in the context of LLI.[11,12] Minority patients with LLI report a desire to discuss their care preferences with health care providers, yet do so at a much lower rate than white patients.[13,14] Even more concerning, minority patients with LLI often do not receive treatment consistent with their wishes.[15] Poor patient-provider communication contributes to the provision of aggressive care for many minority patients who do not want it.[15,16]

Patient-centered palliative care practice must be informed by the perspectives of patients living with LLI.[8] An increased understanding of psychological, social, and spiritual needs from the patient's perspective will help providers develop tailored palliative care interventions centered in patient's cultural values and beliefs.[17-19] Storytelling is an effective way to communicate cultural values and beliefs.[20,21] In the health care setting, the electronic health record (EHR) is one of the primary modes of communicating information about patients to all providers. Incorporating a patient's story into the EHR is an opportunity to more fully incorporate the patient's cultural values and beliefs into their care. Thus, integrating minority patients' stories into the EHR has the potential to improve patient-provider communication around minority patients' values and beliefs. Yet there is a lack of research about how to effectively integrate patient stories into the EHR. This proposal focuses on investigating an innovative way to integrate patient values and beliefs into the EHR through a storytelling intervention.

My *long-term goal* is to improve palliative care for minority patients with LLI by facilitating communication between patients and their health care providers. The *objectives of this grant and proposed studies* are to assess the feasibility and efficacy of a storytelling intervention designed to improve communication of values between patient and provider. The *central hypothesis* of this proposal is that implementing a patient-centered storytelling intervention with minority patients will result in improved patient-provider communication about these patients' care preferences, based on the cultural values and beliefs that underlie those preferences. The assembled mentoring team is well prepared to support the proposed research with a unique combination of skills and experience in palliative care, storytelling, mixed methods, and informatics.

K99 Phase: Storytelling Intervention Design (Define and Refine)

Specific Aim 1: Identify barriers and facilitators for the storytelling intervention from the perspectives of the key stakeholders—minority patients with LLI and acute-care bedside nurses—through patient and nurse exit interviews; and field analysis of EHR interface use and end-user surveys of the nurses.

Specific Aim 2: Conduct usability testing, applying a user-task-system-environment evaluation process to determine essential requirements for integration and use of the patient-centered story into the EHR, from the perspective of an important end user: the acute-care bedside nurse.

Impact

The proposed study aligns clearly with NINR's strategic focus on palliative care science, addressing health disparities, and evaluating patient-centered interventions to optimize QoL.[22] This proposal builds on my prior research experience with narrative analysis methodology.[2] It is *innovative* in that incorporating meaningful use of the EHR is a new approach to improving patient-provider communication. The *expected outcome of the K99* phase will be the refinement of a storytelling intervention. The *expected outcome of the R00* phase will be

completion of a proof-of-concept of the storytelling intervention. This proposal will build a program of patient-centered research with racial and ethnic minority populations and provide the foundation for future R01 applications for developing, testing, and tailoring patient-centered communication interventions.

II. Background and Significance

Palliative Care Decreases Suffering in Patients with Life-Limiting Illness. Health care advances have extended the lifespan and cured many diseases. Advanced health care technologies can also encourage aggressive, life-extending, yet sometimes non-beneficial treatments for patients with life-limiting illness (LLI), at the expense of psychosocial and spiritual support.[11,12,15] Depression, anxiety, and physical/emotional suffering have been reported by patients receiving life-extending treatments.[16] Decreased depression and improved QoL has been reported when patients receive palliative care early in the course of their illness.[23] As the population of minorities with LLI increases,[9] there is increasing need for patient-centered palliative care interventions that are consistent with patients' cultural values and beliefs. Research that improves communication between providers and patients, decreases suffering, and improves QoL for this population is an urgent need.

Importance of Addressing Racial/Ethnic Disparities in Palliative Care. Disparities between white and racial and ethnic minority patients have been reported in both access to and quality of palliative care services.[16, 24-26] Culture influences health behaviors and the meaning of illness.[17-19] Minority patients with LLI have experienced insufficient symptom control, difficult interactions with their health care providers, and lack of psychosocial and spiritual support.[16,27-31] Patient-centered communication interventions can provide better knowledge about the psychological, social, and spiritual experiences of racial and ethnic minority populations with LLI. For instance, gathering stories about a patient's illness experiences can give health care providers a view into the patient's cultural values, attitudes, beliefs, and/or preferences of care.[20, 21] Health care provided through a culturally sensitive, patient-centered framework may improve quality of communication between providers and patients.[8] Improved communication leads to care that is more consistent with patients' cultural values and beliefs.[20,21,32,33] *While research examining cross-cultural psychological, social, and spiritual experiences of patients with LLI is increasing, it remains limited in scope, quantity, and settings.*[10,13,14,25]

A Narrative Communication Intervention Can Improve Outcomes for Minority Patients with LLI. Palliative care providers are well- positioned to support minority patients' psychosocial and spiritual well-being through narrative communication interventions. [20,21] Story theory is based on the foundation of "meaning making" [34,pg.205] and can be applied to communication between nurse and patient. The theoretical basis of story theory is built on three concepts: intentional dialogue, creating ease, and connecting with self-in-relation.[34] According to story theory, when a nurse knows more of the patient's illness story, both direct and indirect effects occur.[34] These effects provide opportunities for the type of culturally congruent care that leads to improved QoL and can lessen suffering for minority populations with LLI.[16-19] Through the method and practice of listening to minority patients' stories, cultural aspects of psychological, social, and spiritual dimensions of care for minorities with LLI can be discovered. A storytelling intervention that elicits patients' psychological, social, and spiritual experiences can contribute to culturally sensitive, patient-centered care that recognizes and brings attention to differences in patient values, preferences, and expressed needs.[8] *Addressing gaps in knowledge around the cultural values and beliefs of minority patients can lead to reduced suffering among minority patients with LLI.*

Figure 2. Culturally Sensitive Patient-Centered Palliative Care

Theoretical Framework. In this proposal's conceptual framework (see Figure 2), the palliative care approach integrates cultural beliefs and values of physiological, psychological, social, and spiritual healing.[8,17-19] Healing and suffering are on a continuum centered around the patient's social, spiritual, psychological, and physical experiences of LLI.[8]

Innovation

Storytelling Can Be a Culturally Sensitive Patient-Centered Communication Intervention. A storytelling intervention can draw together the complexities of LLI experiences and the varied cultural meanings of illness by collecting, analyzing, and sharing illness stories of minority patients living with LLI with the healthcare team.[1,35,36] Storytelling interventions have been shown to improve QoL and to decrease suffering.[34,37-40] Patient participation in storytelling interventions has been linked to reduced levels of pain, stress, anxiety, and fatigue, and to improved psychosocial and QoL outcome measures.[34,37-40] Some research has integrated narrative interventions such as life review on DVD[32,33] and digital storytelling uploaded to YouTube to be shared with families and found positive outcomes.[40] However, little is known about storytelling specifically for minority patients with LLI and whether storytelling could improve communication and thereby improve patient and family outcomes. Research is needed to understand if and how storytelling interventions can improve patient-provider communication, which may be one of the mechanisms for improving psychosocial outcomes and QoL for patients with LLI.

III. Preliminary Data

Preliminary study. My dissertation research used narrative analysis and collected African American elder illness experiences in the form of co-created stories. Through this process, the next logical step was to begin testing a storytelling intervention. In the proposed studies, I will investigate the potential effects on patient-centered communication intervention of using written meta-stories within the EHR. This proposal is to define and refine a storytelling intervention and test its mechanisms, feasibility, and effects. This research will enroll only patients from racial/ethnic minority groups, because expert input from minority patients improves the likelihood of developing a culturally sensitive intervention.[10,17-19]

Storytelling Has Never Before Been Included in the Electronic Health Record (EHR). Integrating patient stories into the EHR could benefit patients and providers who interact in increasingly technology-rich health care environments. Since the EHR is one of the primary modes of communicating health care information about the patient, the integration of minority patients' stories into the EHR has the potential to improve patient-provider communication[41] around patient-centered values and beliefs. Yet, there is a lack of research about how to integrate patients' stories into the EHR in a meaningful, efficient, and effective way.

Relevance of Research to Palliative Care Science. A program of research around patient-centered communication interventions can contribute to enhancing QoL among racial and ethnic populations of patients with LLI. At this time, to decrease the complexity of the intervention, only written stories will be tested; future studies could incorporate video or audio stories as well. These and future studies within this theoretical approach will provide input into a much-needed area of study of patient-centered communication interventions with potential to promote psychological, social, and spiritual healing for minority populations with LLI. The proposed program of research has the potential to improve communication between providers and patients, and aligns with NINR's strategic focus on resolving health disparities and promoting palliative care practices that improve QoL for patients with LLI.[22]

Relevance of Research to My Career Goals. My research career goals are guided by the Obesity-Related Behavioral Intervention Trials (ORBIT) model[6] for the development of programs of research in behavioral intervention (see Figure 1 in Candidate Goals and Objectives section). Using Riessman's narrative methods for human sciences[1] in a population of aging African American elders, for my dissertation I completed an exploratory descriptive design using a narrative analysis methodology.[2] Following my dissertation, I developed a significant research question: How can narrative interventions be used to improve communication among patients with serious illness and their providers? My in-depth study of narrative methodologies,[1,20,21,35,36,42-44] coupled with my years of palliative care nursing practice, helped me recognize the utility of narrative as an intervention to improve psychological, social, and spiritual suffering across myriad illness states and across many cultures. The phase of this training plan builds on my completed dissertation research and continues Phase I of the ORBIT model[6] in defining and refining a storytelling intervention.

IV. Research Methods

Approach: Define/Refine a Storytelling Intervention (ORBIT Model Phase I)

A. ***Design and Outcomes.*** For this study, I will use an observational design[45] to define and refine the storytelling intervention, seeking input from the key stakeholders: patients (minority patients with LLI) and providers (acute-care bedside nurses). Outcomes from this study will provide the in-depth understanding necessary to refine a culturally sensitive patient-centered storytelling intervention**.**

B. *Description of Populations to be Enrolled.*

Setting/sample. This study will take place at University of Colorado hospital. The participants will be minority patients with LLI and their bedside nurses. Purposeful sampling strategies[45,46] will be used to recruit participants. The plan is to obtain consent from 24 patient participants equally divided (8 patients each) among three diagnostic groups: cancer, COPD, and heart failure. Data will also be collected from 12 nurse participants who provided care to the participating patients. The small sample size was chosen to be consistent with both qualitative data analysis techniques[45-48] and usability data analysis techniques.[46,49]

Patient eligibility criteria. Patients will be 18 years of age or older; able to read English; capable of giving informed consent; self-identifying as part of a racial or ethnic minority; and diagnosed with at least one LLI. The operational definition of LLI eligible for this study includes the following diagnoses: (1) metastatic solid cancer or inoperable lung cancer; (2) COPD with FEV1 values < 35% predicted or oxygen dependence; (3) New York Heart Association Class III or IV heart failure (CHF). The disease criteria were chosen to identify groups of patients with a median survival of about 2 years.[50–53] These diagnoses represent 3 of the major causes of death related to LLI in the United States. Due to the nature of the qualitative design and geographical location census data, a broad group of racial/ethnic groups will be eligible to participate to allow for maximum variation sampling[45] to collect acceptability data from a variety of groups.

Nurse eligibility criteria. All participating nurses will be 18 years of age or older and ~~able to read English~~, and will confirm verbally that they were involved in the care of a patient who is participating in the storytelling intervention. Bedside nurses were specifically chosen as provider participants due to amount of time they interact with inpatients and the frequency with which they interface with the EHR compared to other team members. In future R01 studies of this intervention, other members of the patient's care team will be added.

C. *Research Methods*

Patient recruitment. I will attend University of Colorado inpatient nurse staff meetings to introduce the study, identify potential units with potential patient participants and post recruitment flyers on units. Once these units are identified, I will attend nursing rounds to identify potential patients with the assistance of the nursing care team. If a potential patient is identified by a nursing care team member, that member will provide a flyer to potential participant and obtain verbal consent. Nursing care team members will notify me of patients who provide verbal consent via secure, encrypted e-mail. I will then arrange a convenient time to meet with each patient to review the study protocols, complete screening and obtain informed consent. The consent process and the storytelling intervention interview will occur in the patient's private inpatient room. Based on my dissertation research, I anticipate that this process will take 60–90 minutes of the patient's time. For the burden of time, *e*ach patient who completes the storytelling intervention interview will receive $50 in appreciation, plus an additional $50 at the time of the exit interview. If the patient is discharged from the hospital, the follow-up exit interview will be collected via telephone.

Nurse recruitment. After a patient story is added to the EHR (see Data Collection/Analysis), I will collect from the EHR the names of the nurses who cared for the patient. These nurses will be approached for consent to participate in the study, with the goal of 12 participating nurses. For the user-centered testing, an additional 6 nurses will be recruited, for a total of 18 nurse participants. Nurses will be contacted via e-mail with a recruitment flyer. After receiving verbal consent for participation via e-mail, a convenient in-person time will be coordinated for data collection for the exit interviews. Weekly follow-up e-mails will be sent if there are difficulties recruiting the 24 nurses for data collection or the 6 nurses for user-centered testing. For the burden of time, each nurse completing the study will receive $100 in appreciation.

Storytelling intervention. As principal investigator (PI), I will conduct a storytelling intervention interview with each of the patient participants. During the interview, I will prompt the participant to share their story using probing questions such as these: tell me about your illness, tell me how your illness has affected your emotions, your relationships, your spirituality. This storytelling intervention has been field tested during my prior dissertation research (see Appendix B. Storytelling Interview Guide). I will read the prompts, concurrently take field notes of the participant's

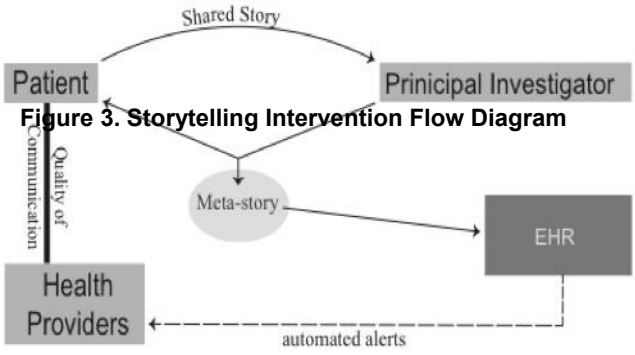

Figure 3. Storytelling Intervention Flow Diagram

responses, and audio-record the interview. The de-identified audio recording will be delivered via an encrypted e-mail to the transcriptionist. After the interview has been transcribed, I will review the transcripts for accuracy and create a 1- to 2-page meta-story[1] of the participant's responses. Criteria are that the meta-story[1] (1) is written in the first person; (2) is nonjudgmental; (3) captures the participant's voice; (4) accurately reflects the content of the interview; and (5) is nondiagnostic (not labeling). I will complete and return each meta-story to the patient participant within 48 hours. The participant and I will review the meta-story on my password-protected computer, and the participant will be encouraged to make any desired changes, facilitating co-creation of the meta-story. Once the meta-story has been approved by the participant, I will upload it to the EHR (see Appendix C. Exemplar of Meta-Story). Automated alerts, built within the EHR, will be sent to the participant's EHR-assigned nurse once the meta-story has been uploaded. To decrease complexity of the study design at the define-and-refine phase, only acute-care bedside nurses will be recruited to participate, thus acute care bedside nurses are the only providers who will receive the alert and participate in the usability testing. This workflow is depicted in Figure 3.

D. Data Collection/Analysis.

Specific Aim 1: Barriers and facilitators. Two weeks after the meta-story is added to the EHR, both patient and nurse will be contacted for exit interviews to collect information about barriers and facilitators of the intervention (see Appendix D. Exit Interview Guide). The transcribed exit interviews will be entered into ATLAS.ti (a qualitative data management/analysis program). An interpretive approach will inform the understanding of the patients' and nurses' perspectives related to barriers and facilitators. Open coding, which allows codes to form patterns as they emerge from the transcripts, will be used for the thematic analysis.[1,54] An inductive approach to coding, through the use of the participant's actual words, will be used for up to 3 transcripts.[54] Once the initial codes are chosen, the transcripts will be read again through an iterative process defined as "a movement back and forth through" data coding for creating thematic analyses.[54(p86)] As PI, I will complete the preliminary coding for each transcript. Then the research team, which includes my primary mentor, Dr. Doorenbos, and my co-mentor, Dr. Meek, will review my preliminary codes. Once the first 3 transcripts are coded, the research team will analyze the preliminary codes across the remainder of the transcripts. Throughout the entire analytical process, the codes will be refined and defined more clearly. At each of the monthly research team meetings, codes can be expanded or similar codes collapsed into larger codes[1] as part of the iterative process for arriving at the final themes. To ensure the rigor of the data analysis, Sandelowski's criteria for trustworthiness (credibility, applicability, consistency, and neutrality)[55,56] will be used.

Specific Aim 2: Usability testing.[57-61] Usability is defined as the relationship between humans and computers. Usability testing focuses on evaluating process measures based on four major components: user (nurse), task (utilization of meta-story by nurse), system (meta-story in EHR), and environment (inpatient nurse's station).[60] The user-task-system-environment framework of process measures[60] will be incorporated into the usability testing to determine barriers and facilitators from the perspective of the bedside nurse and to help determine the essential requirements for integrating the patient-centered storytelling intervention into the EHR by evaluating information flow, use of information, and system functionality. The process measures collected to determine usability will include the following: field observations of the end user (the nurse); chart review/log analysis of the nurse's use of the patient's story; time/cost analysis of the collection of the story, which includes transcribing the story, writing and co-creating the meta-story, uploading the final meta-story into the EHR, and exit interviews for both patient and nurse participants. In addition, time log analyses will be completed. These analyses will include recording the uses of the meta-story by all providers, not just the acute-care bedside nurse, to evaluate if other providers accessed the meta-story, how many times, and for what length of time the meta-story was accessed. These exploratory analyses will inform the design of future studies and how they can incorporate other types of providers as participants.

For user-centered testing, I will recruit 6 nurses to test the workflow processes. The participating nurses will (1) provide content expertise of the workflow processes, and (2) put the storytelling intervention through in-house usability testing to check the "strength" of the EHR features as well as the level of user-friendliness. The goal is to make using the storytelling intervention as intuitive as possible. Prior research shows that testing with 5 participants identifies 85% of usability issues.[57-59] Testing will assess ease of use, relevance and appeal, efficiency, error frequency and severity, and subjective satisfaction with the presentation of the meta-story in the EHR. Following the session, the participants will be debriefed and asked to complete a questionnaire modeled after the System Usability Scale (SUS),[61] which asks them to rank their experience and satisfaction

with specific elements (such as where the meta-story is labeled and presented in the EHR, technical difficulties, use of the material, trust in the material, and ability to navigate within the EHR).

Expected Outcomes. The expected outcomes of the phase will be the completed design of a patient-centered storytelling intervention. Understanding of the patterns of barriers and facilitators of the storytelling experience from the perspectives of the key stakeholders, and evaluating the usability of the EHR integration, will inform the development of the intervention.

Table 1. Timeline for the Design of Storytelling Intervention (ORBIT Model Phase I)

	YR 1				YR 2				YR 3	
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2
Obtain IRB approval for study										
Finalize study protocols										
Begin recruitment										
Complete recruitment										
Data analysis										
Prepare R00 phase re-application										
Dissemination										
Submit IRB for R00 phase										

E. Potential Problems and Alternative Strategies.

Patient burden. Thinking and conversing about end-of-life preferences and overall QoL may initially distress some patients and families. Some patients may decide not to participate because these issues are too difficult to deal with in the context of their illness. I have expertise from prior research experience in collecting patients' stories, and I will use strategies to conduct the conversations with a minimum of associated distress/anxiety to avoid increasing suffering. Participants' distress will be evaluated throughout the intervention, from initial audio-recording to integration of the meta-story into the EHR. A referral plan is in place for appropriate follow-up services as needed for any increased level of participant distress. If distress occurs, the participant can withdraw. To evaluate acceptability and feasibility, withdrawal data will be collected in a protocol log and discussed at research meetings; adjustments to the protocol will be completed as necessary.

F. Protection of Human Subjects

Risks to Human Subjects

a. ***Human Subjects: Involvement, Characteristics, and Design***

A purposive sample of patient-nurse dyads will be enrolled in this study. Participants in this study are minority patients with life limiting illness (cancer, COPD, or heart failure) and their health care nurses. We expect to enroll 24 minority patients with life limiting illness and 18 nurses who are directly involved in the care of the patient. The principal investigator (PI) will enroll all participants after each of them voluntarily decide to become a participant.

Patients. Each patient participant will engage in two audio-recorded interviews lasting approximately 60-90 minutes. For the first interview, through a narrative analysis framework, the patients will answer open-ended questions related to their illness experiences and how their illness has impacted their emotions, relationships and spirituality. (See Appendix A-Storytelling Interview Guide). For the second interview, the patient will answer exit interview questions to capture their experience of the storytelling intervention. For the patient interviews, the location will include their private inpatient room or private conference room in the facility. If the patient is discharged prior to the second exit interview, the exit interview may take place over the telephone. (See Appendix B-Exit Interview Guide).

Nurses. The nurses will be interviewed once. This interview will capture exit interview data related to the storytelling intervention. The participant and nurse will be interviewed at separate times. For the nurse interview, the PI will coordinate a convenient and private place to conduct the interview which might include nurse's office or private conference in the facility. (See Appendix B- Exit Interview Guide). For the usability testing, the PI will coordinate a convenient time between at the nurse's convenience to conduct the user-task-system-environment evaluations.

The following characteristics will determine the eligibility for patient participants and nurse participants. Eligibility criteria will first be determined by the patient participant, who must be:

(1) Over age age 18

(2) Able to speak English

(3) Be capable of giving informed consent

(4) Self identify as being a racial/ethnic minority and

(5) Have one of the following LLI: cancer, COPD, or heart failure.

Eligibility criteria for the nurses are that they be:

(1) Nurses will be at least age 18

(2) Able to read, speak and write English

(3) Confirm verbally that they were involved in the care of the patient who received the storytelling intervention.

Data collection activities for patient participants include completing the storytelling intervention via a 60-90 minute audio-recorded interview and completing an exit interview via a 60-90 minute audio-recorded interview. Data collection activities for the 12 nurse participants will include completing a 60-90 minute exit interview via an audio recorded interview. For the usability testing, data collection will include testing of the EHR interface with the bedside nurses and completion of a short questionnaire at the end of the hour session.

Setting: The participants will be recruited through the University of Colorado hospital.

b. ***Sources of Materials***

Data for this proposed project will only be collected by the PI. Materials include audio-recordings of interviews, field notes, and correspondence (i.e., memos, emails) with research team members. A total of 60 audio-recorded interviews will be collected; 24 interviews for the storytelling intervention; 24 for the patient exit interviews, 12 for the nurse exit interviews. Safeguards for protecting anonymity of participants will include creating a master list of names with corresponding numbers assigned to participants at the time of the screening by the PI. Once assigned, the corresponding numbers will then be used to de-identify the remainder of participants' personal information and each participant's interview transcript. Only de-identified transcripts of interviews will be available for the remainder of the research team for analysis and interpretation processes.

All data will stored electronically on password-protected servers, folders and files, and only study staff and the investigators will have access to these study-related electronic files. Weekly assessment data will be entered into separate electronic databases directly by study staff from the paper or phone interview data collection. To obtain the patient's medical records data, we will create and maintain a separate, password-protected file of a data matching key with the names, medical record numbers, dates of admission, and study ID number for each participant. We will request electronic data for the enrolled participants from the staff who maintain the clinical data bases and match the data to the study ID number. Once all data have been matched and we have a complete set with only study identifiers (names and medical records numbers will be deleted), we will destroy the key linking study identifiers to personal identifiers for the enrolled patients. This will happen no later than the end of the study period.

The digital audio files and transcripts of the qualitative interviews will be reviewed and edited to remove all identifying information (such as names, places, or specific unique details of the patient or nurse). Original recordings and transcript files will be destroyed when the final usable set of transcripts is complete, also no later than the end of the study period.

c. ***Potential Risks***

There are minimal risks to participants who elect to participate in these studies.

Physical. Participants could become fatigued during the 60-90 minutes storytelling interview process; the 30-45 minutes exit interview process and/or outcome measures data collection procedures. In this event, the researcher will encourage rest periods or if necessary reschedule a return visit to complete the interview. For the burden of time, each patient will receive $50 in appreciation for completing the Storytelling intervention and

then again at the time of the exit interview. For the burden of time, each nurse will receive $100 in appreciation for completing the study.

Psychological. For the patient participants, there is minor/moderate/severe risk for psychological distress due to the sensitive topics of life limiting illness. We will assure that participants understand both orally and in writing that they are free to decline participation in any of all study activities at any time, including declining to answer specific questions, refusing participation in the intervention, requests to speak off the record, or complete withdrawal from the study. If any of the interview or psychometric assessment data reveal increased participant distress, dissatisfaction or any adverse event, the data collection will cease. If the participant exhibits any verbal or non-verbal distress, the PI will allow the participant to stop the interview, reschedule for return visit to complete interview, or allow participant to withdraw consent. If moderate distress is exhibited, the researcher will assist in referring participant for emotional support either through family, friends, or medical nurses for follow-up related to the participant's distress. If severe distress, such as suicidal ideation is noted, the researcher will immediately refer for further work-up and care. The PI will carry a list of contact phone numbers for such referrals. If any moderate or severe distress is noted, this will be reported immediately to the primary mentor and co-mentor for help in determining if the event meets criteria for a reportable adverse event. If deemed serious adverse event, the IRB will be notified and the participant's involvement in the research study will be discontinued. Participants will be able to contact the PI to discuss any concerns or questions at any time during their participation in the study. We anticipate these to be rare events, given the nature of the data collection procedures.

Social. One primary concern is the possible perception of coercion due to participant recruitment occurring in health care settings. We will attempt to avoid perception of coercion by emphasizing the voluntary nature of participation and the ability of the participants (patient or nurse) to withdraw at any time without penalty. Participants could feel pressured to participate in the proposed project. The researcher will arrange with the participants a private location with only researcher and participant present for collection of the interview. Once in this private setting, the PI will remind them that participation is voluntary and that they may withdraw from the project at any time without any penalty or prejudice.

Adequacy of Protection Against Risks

a. ***Recruitment and Informed Consent***

The PI will be solely responsible for screening, consenting and collecting all the interviews. The participants will have the opportunity to decline at anytime throughout the study. The PI will recruit, through convenience sampling, minority patients with life limiting illness. Study participants will be recruited through University of Colorado Hospital. The PI will meet round at least weekly on identified units and as needed with nursing care team members nurses at the hospital and provide updates on recruitment needs till recruitment is complete.

At the hospital, nurses will identify potential participants based on diagnoses and ethnicity. If any patients are identified, a nurse will deliver a flyer regarding the study to potential patients to obtain verbal consent taking precautions to notify the potential participant that participation in the study is totally voluntary and will not affect care. Once verbal consent is obtained, nursing team members will notify the PI of potential patients via secure encrypted e-mail. The PI will then arrange a convenient time to meet with potential patients to review the study protocols and obtain informed consent. At these initial meetings of the participant, the PI will complete the official screening, describe the study, review the informed consent, and discuss risks/benefits with the participant. If at this initial meeting, participant volunteers and meets inclusion/exclusion criteria, the PI and participant will sign the informed consent. After the informed consent is signed.

Recruitment will include the use of flyers being given to the nursing team members and posted in the medical-surgical units. The PI will ensure continual availability of flyers for the key recruitment stakeholders. These flyers will include a brief description of the study, inclusion criteria, and multiple avenues for contacting the PI, such as by e-mail or or phone. The PI will also communicate weekly with the nursing care teams to identify any potential concerns with the recruitment procedures. The PI will be present at nurse staff meetings) to answer questions in person for the key stakeholders. In addition, this presence within the staff meetings will also act as a reminder to care team members about the study and updates on the recruitment needs for the

study. (See letters of support by Dr. Thomas Flaig and Laurie Blumberg-Romero, UC Health Research Administration).

The written consent forms will inform patients and nurses about their own participation in study activities, including randomization, participation in the intervention, and data collection and the risks and benefits of participation. The consent form for the patient participants will also include a section describing the possibility of being selected to participate in the optional qualitative exit interviews to be scheduled after the intervention. Patients and nurses will receive

b. ***Protections Against Risk***

Prior to any data collection, institutional Review Board approval will be obtained from University of Colorado Institutional Review Board (COMIRB).

Physical. Participants could become fatigued during the 60-120 minutes interview process. In this event, the researcher will encourage rest periods or if necessary reschedule a return visit to complete the interview.

Confidentiality. Although there is a rare risk for breach of confidentiality, the PI will maintain confidentiality of proposed study materials by assigning each participant a unique study ID number and use this unique identifier throughout the entire study. At the signing of the consent, the PI will assign a numerical identifier. In addition, immediately after transcription of participant interviews, the PI and/or study staff will remove any identifiable names of person or place. To protect against any breaches of confidentiality, we will maintain strict data security procedures. A hard copy of the master list of these unique identified numbers and the will be kept in a locked cabinet in the PI's office at the University of Colorado, College of Nursing. The master full length transcripts, the meta-story and all audio-files will be kept on the PI's password protected computer only and uploaded to the secure server at University of Colorado. The PI will review the meta-story with the participant on the password protected computer. During this review, the patient will be allowed to make changes to the meta-story prior to uploading the meta-story into the electronic health record. If additional changes are required, these changes will be completed in person with the participant at this time of the review. When completed, the PI will upload the meta-story into the patient's protected electronic health via the University of Colorado Hospital secure network.

We will maintain strict data security procedures. All offices and laboratories on the University of Colorado-Anschutz Medical Center have wired and wireless connectivity to institutional networks and are supported by the UC-AMC Information Technologies department. The UC-AMC Information Technologies department infrastructure staff maintains, updates, and troubleshoots these services in order to provide 24/7 high availability. After-hours support is available by pager.

The PI and her local nursing mentor, Dr. Meek store all research data on central servers that are managed by the University information technology department. Servers and other sensitive equipment are located in secure, climate-controlled server rooms on the UC-AMC. All electronic information systems that contain federal data are protected from unauthorized access by strong password security protocols. Network security is in compliance with University of Colorado Human Subjects Division, HIPAA, and FERPA standards. All electronic information systems that contain federal data are protected from unauthorized access by strong password security protocols. Network security is in compliance with University of Colorado Human Subjects Division, HIPAA, and FERPA standards. Personal computers are networked by either high-capacity wired or secure wireless connections. The potential for breach of confidentiality is being addressed through the maintenance of a secure "log-on" system on the secure computer server dedicated to this project. Interview audiotapes will be transcribed and stored on the secure computer server. It is necessary to capture participant information in order to pay participants for their participation. Identifying information for participants (e.g., name, address, and telephone number) may be required for the telephone contacts made by research staff. This information will be kept in a logbook stored in a computer file that is protected by a secure log-on system; only research team members who require that information will have log-on access to the identifying information. These security precautions will be explained in the consent form.

Psychological. There is minor/moderate risk for psychological distress due to the sensitive topics as part of illness stories and the psychological, social and spiritual impacts of life limiting illnesses. If the participant exhibits any verbal or non-verbal distress, the researcher will allow the participant to stop the interview, reschedule for return visit to complete interview, or allow participant to withdraw consent. If moderate distress

is exhibited, the researcher will help refer them for emotional support either through family, friends, or medical practitioners for follow-up related to the participant's distress. A referral list of appropriate services and/or nurses has been compiled and will be kept with the PI when conducting interviews. If the participant exhibits any verbal or non-verbal distress, the PI will allow the participant to stop the interview, reschedule for return visit to complete interview, or allow participant to withdraw consent. If moderate distress is exhibited, the researcher will assist in referring participant for emotional support either through family, friends, or medical nurses for follow-up related to the participant's distress. If any moderate or severe distress is noted, this will be reported immediately to the primary mentor and co-mentor for help in determining if the event meets criteria for a reportable serious adverse event (SAE). If a potential SAE occurs related to the study intervention, the IRB within 24 hours of occurrence and the participant's involvement in the research study will be discontinued. Participants will be able to contact the PI to discuss any concerns or questions at any time during their participation in the study. We anticipate these to be rare events, given the nature of the data collection procedures.

Social. Participants could feel pressured to participate in the proposed project. Thus, the researcher will arrange with the participant, a private time with only researcher and participant present, for collection of the interview. Once in this private setting, the PI will remind them that participation is voluntary and that they may withdraw from the project at any time without any penalty or prejudice. At no time will participants be coerced to participate and the PI will remind them that they may refuse to participate at anytime during the proposed study.

Potential Benefits of the Proposed Research to Human Subjects and Others

There are no known potential benefits for the participants. However, research has shown that allowing patients to narrate stories about their serious illness has improved well being for this patient population. The risks to the participants are minimal in comparison to the potential for generation of new knowledge about patient-centered palliative care storytelling interventions for minority patients living with life limiting illness. We have outlined procedures to minimize the risks to participant, which are primarily psychological in nature. These procedures include reiterating the voluntary nature of the study and the participant's ability to withdraw consent at anytime throughout study, having available appropriate referral contact information for supportive personnel for any moderate/severe psychological distress, and takings steps to ensure data security.

G. Importance of the Knowledge to be Gained

The proposed work will contribute significantly to the science in the area of culturally sensitive, patient centered palliative care interventions. As this proposed study aligns clearly with NINR's strategic focus on PC/EOL science of resolving health disparities, of benefiting clinical practice while improving QOL for patient with life limiting illnesses, the impact of this proposed study supports research exploring interventions for optimizing QOL across different care settings and cultural contexts.

Data Sharing Plan

The proposed research for the this study phase will include data from 24 minority adult patients with life limiting illness and 18 nurses. The final data set will include self-reported demographic and behavioral data from self-report, questionnaires, and interviews. The final data set will be stripped of individual identifiers prior to release for sharing. Furthermore, the data and associated documentation will be made available to users only under a data-sharing agreement that provides for (a) a commitment to using the data only for research purposes and not to identify any individual patient; (b) a commitment to securing the data using appropriate computer technology; and (c) a commitment to destroying or returning the data after analyses are completed. Such a data-use agreement will be executed through the PI. The database of demographic and patient reported outcomes and de-identified transcripts will only be accessed via our secure website.

We will maintain strict data security procedures. All offices and laboratories on the University of Colorado-Anschutz Medical Center have wired and wireless connectivity to institutional networks and are supported by the UC-AMC Information Technologies department. The PI and her local nursing mentor, Dr. Meek store all research data on central servers that are managed by the University information technology department. Servers and other sensitive equipment are located in secure, climate-controlled server rooms on the UC-AMC. All electronic information systems that contain federal data are protected from unauthorized access by strong password security protocols. Network security is in compliance with University of Colorado Human Subjects Division, HIPAA, and FERPA standards. Personal computers are networked by either high-capacity wired or secure wireless connections. The potential for breach of confidentiality is being addressed through the maintenance of a secure "log-on" system on the secure computer server dedicated to this project. Interview audiotapes will be transcribed and stored on the secure computer server. It is necessary to capture participant information in order to pay participants for their participation. Identifying information for participants (e.g., name, address, and telephone number) may be required for the telephone contacts made by research staff. This information will be kept in a logbook stored in a computer file that is protected by a secure log-on system; only research team members who require that information will have log-on access to the identifying information. These security precautions will be explained in the consent form.

Data and Safety Monitoring Plan(DSMP)

Monitoring for data integrity and safety will be the responsibility of the PI, the mentor team and the Institutional Review Board of the institution. The following items will be part of the DSMP: safety of participants, reporting of any adverse events, validity and integrity of the data, enrollment rate relative to expectations, retentions of participants, adherence to study protocols, and data completeness.

a. Monitoring entity

The study is low risk; therefore we do not anticipate any serious adverse events. The PI will be collecting all data sources and provide oversight for the de-identification of the data management. The PI will review all data collection forms on an ongoing basis for: data completeness, data accuracy and protocol compliance. Reviews of the rate of subject accrual and compliance with inclusion and exclusion criteria will occur monthly throughout the entire data collection phases to ensure that a sufficient number of patient participants are being enrolled and they they meet eligibility criteria and the targeted ethnic diversity goals outlined in the grant proposal.

We have developed a data and safety monitoring plan, which is outlined below. The plan includes routine monitoring of adverse events by the PI, mentors and advisors. The Data and Safety Monitoring members, main purpose will be to (1) perform periodic reviews of accumulated study data and evaluate them for participant safety, participant recruitment, study conduct and progress, and efficacy; and (2) make recommendations to the PI concerning the continuation, modification, or termination of the trial. The Data and Safety Monitoring members will consist of mentors. The Data and Safety Monitoring reviews will take place by the PI at the monthly meetings with the primary and co-mentor. The primary and co-mentor will serve as the Independent monitors of the DSMP

Procedures

Monitoring study safety. For this study, serious adverse events (SAEs) are not anticipated due to the nature of the intervention. The studies safety will be monitored monthly with the PI and the primary and co-mentors or on an as -needed basis if an SAE does occur. At the monthly meetings, an audit of a random selection of approximately 5% of cases will be reviewed for: compliance with IRB requirements, conformance with informed consent requirements, verification of source documents and investigator compliance with study protocols. The one potential SAE is psychological distress. If this potential SAE occurs related to the study intervention, the SAE will be reported to the mentor and advisory committee and the IRB within 24 hours of occurrence. Study progress and safety will be reviewed monthly. Progress reports, including patient recruitment, retention/attrition, and adverse events will be provided to the mentor and co-mentors.

Identification of adverse events. The PI will be responsible for monitoring the internal review of adverse events. Adverse events will be identified by the PI and discussed further with the mentor and advisors to determine whether the event qualifies for reporting to the IRB as a SAE. Those events that do qualify will be reported to the IRB at both facilities. The PI will facilitate any required items per either sites standard policy/procedures of reporting any SAE. To help ensure consistency in reporting, adverse vents and safety alerts will be tracked using a standardized form that records the date of the event, that records the date of the event, attribution of the event (e.g., intervention-related or external situation, such as a death in the family), resolution of the event (whether resolved or controlled), and date of resolution. The format of the form has been validated in my primary mentor's previous work and an exemplar is shown in Table 1.

Table 1: Adverse Event Reporting Form with Sample Text Entries

Event	Date	Severity	Attribution	Operational definition	Resolution
Sample entry:					
Suicidal behavior	XXX	Serious	Not intervention-related/ assessed at baseline	Any risk or attempt to inflict serious bodily harm to self that may result in death	Referral to mental health practitioner Event is ultimately resolved when the mental health practitioner determines that there is no further risk

In handling adverse events, the PI will follow the general principles devised for developing a safety plan for behavioral trials. Namely:

(1) Adverse events queries should include domains plausibly affected by the interventions being tested. A primary question in defining adverse events in behavioral trials pertains to potential risks or negative events that can occur as a result of a specific intervention or of study procedures. Behavioral intervention research also needs to address behavioral, psychological, legal, economic, and social events, as these domains could be affected by the intervention being tested. To understand the adverse events or unexpected problems that can occur as a result of a behavioral intervention, it is important to monitor what the process of change will entail. These changes can be inherent to the mechanism of action of intervention under study. For example, addressing one's serious illness may increase the risk of suicidal thoughts or behavior. The PI will keep detailed field notes about each interaction with participants.

(2) Monitoring should attempt to assess relationships between intervention and adverse events.

(3) Systematic monitoring is essential to identifying unexpected events. In addition to immediately addressing a potential adverse event, the research team will discuss the following: all active cases in

depth during the monthly research team meetings, any potential adverse events, safety alerts, or other concerns.

(4) Effective monitoring is a shared responsibility that includes multiple stakeholders, namely the PI, the mentorship team which makes up the DSMB, and the IRB.

All events will be discussed on a monthly basis during scheduled mentorship meetings and any adjustments to the intervention or study protocol will be negotiated and agreed upon by the PI and the mentors. One measure of adverse events will be the number of any referrals made for moderate or severe distress. We will investigate the reasons for these referrals, determine whether there is any relation between the need for referral and the intervention or data collection activities, and make adjustments to the intervention or study protocol as needed.

Procedures to Ensure Compliance with the Monitoring Plan. Research team meetings are scheduled monthly during the study to ensure consistent review of any concerns/issues. However, meetings will also will be done on an as-needed basis for any SAE that may occur. In addition, an assessment of external factors or new developments reported in the literature relevant to this study will be reviewed annually.

The investigator will be responsible for the conduct of this study, overseeing participant safety, executing the data and safety monitoring (DSM) plan, and complying with all reporting requirements to local and federal authorities. This oversight will be accomplished through additional oversight from the Data and Safety Monitoring Committee (DSMC) at the University of Colorado Cancer Center (CU Cancer Center). The DSMC is responsible for ensuring data quality and study participant safety for all trials at the CU Cancer Center. A summary of the DSMC's activities is as follows:

- Conduct of internal audits
- Has the authority to close and/or suspend studies for safety or conduct issues
- May submit recommendations for corrective actions to the CU Cancer Center's Executive Committee

Study audits conducted by the DSMC will consist of a review of the regulatory documents, consent forms, and source data verification. Documentation of the audit conducted by the DSMC will then need to be submitted to the IRB of record at the time of the IRB's continuing review of this trial.

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