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**Study Title:** Personalized experiences to inform improved communication for patients with Life Limiting Illness

## I. Hypotheses and Specific Aims

### **R00 Phase: Proof-of-Concept Study of the Narrative Intervention**

**Specific Aim 1, Outcome Measures:** Compare the effects of the narrative intervention to usual care on the primary outcome of patients' perceptions of quality of communication and on the secondary outcomes of patients' physical function, anxiety, depression, fatigue, sleep, ability to participate in social roles/activities, pain interference and intensity, and psychosocial illness experience.

**Specific Aim 2, Process Measures:** Establish acceptability, feasibility, and usability of the narrative intervention through identification of barriers and facilitators of the narrative intervention from the perspectives of the key stakeholders—patients with serious illness and acute-care bedside nurses—through patient and nurse exit interviews; field analysis of EHR interface use and end-user usability surveys of the nurses.

#### **Impact**

The *expected outcome of the R00* phase will be completion of the preliminary testing of the narrative intervention. The immediate next steps in my program of research would be an efficacy trial (Phase III) of the narrative intervention. This proposal will continue to build my program of research working with patients with serious illness and providing the foundation for future R01 applications testing and tailoring person-centered communication interventions to improve quality of life for palliative care patients. The proposed study aligns clearly with NINR's strategic focus on palliative care science, addressing disparities, and evaluating patient-centered interventions to optimize QoL.<sup>38</sup>

## II. Background and Significance

Health care advances have extended the lifespan and cured many diseases; however, advanced health care treatments are sometimes discordant with patient preferences, values, and beliefs,<sup>1-7</sup> which can lead to insufficient symptom control, difficult patient-provider interactions, and poor psychosocial and spiritual support.<sup>6-14</sup> Further, poor patient-provider communication contributes to continued unwanted care.<sup>1-3,15</sup>

A comprehensive palliative care approach improves communication, leading to better quality of life (QoL) for patients,<sup>16</sup> yet discordant care continues in part because of knowledge gaps about patient psychological, social, and spiritual needs.<sup>4</sup> Person-centered narrative interventions can fill these knowledge gaps, yielding an increased understanding of patient psychological, social, and spiritual needs,<sup>17-28</sup> which will help providers develop tailored palliative care interventions.<sup>29-31</sup> The use of storytelling (narrative) is an effective way for patient's to communicate their cultural values and beliefs,<sup>20-31</sup> however, in the healthcare system, patients do not always have the opportunity to share these values/beliefs with providers.

In the health care setting, the electronic health record (EHR) is one of the primary modes of communication about patients, but most of this information is provider-centered.<sup>32</sup> There is a need to integrate more of the patient as person into the patient's health record. Incorporating a patient's narrative into the EHR provides an opportunity to communicate patient's cultural values/beliefs to the healthcare team and has the potential to improve patient-nurse communication. However, there is limited research on effective integration of a patient's narrative into the EHR. This proposal investigates an innovative way to integrate patient values/beliefs into the EHR through a narrative intervention. The *central hypothesis* of this proposal is that implementing a person-centered narrative intervention with hospitalized patients will result in improved patient-nurse communication and improve patient's psychological and social well-being.

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## Significance

### Importance of Person-Centered Narrative Interventions that Incorporate Cultural Values and Beliefs

Person-centered care<sup>39</sup> includes shared decision-making,<sup>40</sup> holistic patient care with respect for patient's preferences and goals,<sup>41-44</sup> attention to non-medical aspects of care,<sup>45</sup> communication,<sup>46-48</sup> knowing the patient as person,<sup>41-44</sup> and understanding culture, which influences health behaviors and the meaning of illness.<sup>17,18, 29-31</sup> Communication appears to be one critical element of person-centered care.<sup>46-48</sup> Story theory can be applied to person-centered care because of its foundation in "meaning making"<sup>24,pg.205</sup> built on intentional dialogue, creating ease, and connecting with self-in-relation.<sup>34</sup> Using the foundation of story theory, patient narratives about illness experiences<sup>34-37</sup> offer providers a view into patients' cultural attitudes<sup>29-31</sup> about their illness and patients' psychological, social, and spiritual beliefs/values. When a nurse knows more of the patient's narrative, improved quality of communication may occur<sup>46-48</sup>, which can create opportunities for culturally congruent care and lead to improved patient QoL.<sup>3, 29-31</sup> A narrative intervention implemented with patients living with serious illness can draw together the complexities and varied cultural meanings of illness experiences,<sup>35,36,49</sup> which can improve QoL and decrease suffering.<sup>19-21, 24-27</sup> Patient participation in narrative interventions has been linked to reduced pain, stress, anxiety, and fatigue, and improved psychosocial and QoL outcome measures.<sup>19-21, 24-27</sup>

## Innovation

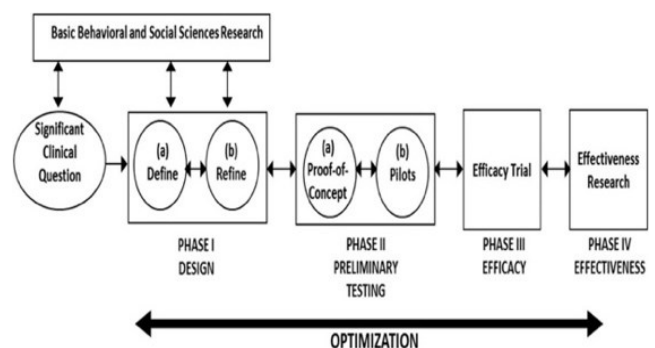
### Integration of a Person-Centered Narrative into the EHR

Some research has shared the patient's narrative with families, e.g. life review on DVD<sup>19,20</sup> or digital storytelling uploaded to YouTube, and found positive outcomes.<sup>27</sup> However, minimal research has integrated narrative interventions into the EHR in a meaningful and efficient way and tested whether the narrative intervention could improve communication between patient and nurse and impact the patient's overall well-being. There is an urgent need to investigate innovative ways to incorporate the patient's narrative into their healthcare record. In our fragmented health care systems, the lack of personhood increases suffering, thus decreasing QoL for this population.<sup>41-48</sup> The integration of a person-centered narrative intervention into the EHR could benefit patients and nurses interacting in technology-rich environments. Since the EHR is one of the primary modes of communicating health care information about the patient, the integration of patients' narratives into the EHR has the potential 1) to improve person-centered care by incorporating patient's values/beliefs, 2) to provide opportunities to enhance patient-to-nurse communication, and 3) to positively impact patient's psychosocial and spiritual well-being.

## III. Preliminary Studies/Progress Report

### Relevance of Research to My Career Goals

I have based my research program on the ORBIT model<sup>33</sup> for developing and testing behavioral intervention ( Figure 1). During my dissertation, I conducted qualitative work<sup>34</sup> that provided a rich understanding of how to form a significant clinical question: How can narrative<sup>34-36</sup> interventions be used to improve communication among patients with serious illness and their providers? Using this question, my K99 study assisted in refining and defining the narrative intervention<sup>37</sup> (Phase 1). For this R00 proposal, preliminary testing of the narrative intervention will be studied (Phase II).



## Preliminary Data

**Dissertation.** By using the ORBIT model to build a program of behavioral interventional research, my dissertation research provided insight about "identifying attitudes, norms, and values that could affect an intervention's acceptability and feasibility."<sup>33, p. 976</sup> Using Riessman's narrative methods for human sciences<sup>49</sup>, I completed an exploratory descriptive study using a narrative analysis methodology that explored the phenomenon of psycho-social-spiritual healing among African American elders with serious illness.<sup>34</sup> Second,

I examined the NIH Clinical Center Palliative Care and Pain Service's psycho-social-spiritual healing measure as a culturally appropriate instrument for African American elders with serious illness. Cognitive interview methodology, verbal probing, and think-aloud techniques<sup>50</sup> were used to gain expert input from African American elders with serious illness regarding the instrument.<sup>51</sup> This, coupled with my years of palliative care nursing practice, began a process of observing how narratives could provide a person-centered palliative care intervention. In addition, my in-depth study of narrative methodologies helped reveal the possible utility of narratives as an intervention to improve psychological, social, and spiritual suffering for patient with serious illness.<sup>17, 18, 22, 23, 28, 35, 36, 49</sup>

**K99 Phase: Define Narrative Intervention (Phase I ORBIT Model<sup>33</sup>).** The outcome of the K99 phase helped define the narrative intervention and test the preliminary feasibility and acceptability of the intervention from two key stakeholders: the hospitalized patient with serious illness (n=20) and the acute care bedside nurse (n=18).<sup>37</sup> The 20 patient participants and the 18 nurse participants found participation in the study easy and beneficial. Eighteen of 20 patient participants discussed their narrative with others, including family (n=12); friends (n=2), and health care team members (n=15). Healthcare team members included nurses (n=10); physicians (n=3), and nursing aides (n=2). Eighteen of 20 patient participants confirmed that they would be willing to participate in a similar type of intervention in the future. All eighteen nurse participants described having positive experiences. Nurses described the intervention as “eye opening” giving them a “different perspective about what their patients are going through emotionally and physically” and allowed them to “connect” to their patient.

## **IV. Research Methods**

### **Proposed Study**

#### **R00 Phase: Preliminary Testing of Narrative Intervention (Phase II ORBIT Model<sup>33</sup>)**

For Aim 1, this study will test: 1) the effects on quality of communication between patient and nurse, as measured by the patient, 2) the effect of the intervention on patient's overall biopsychosocial and spiritual well-being, as measured by the PROMIS 29 profile, and 3) the effects on patient's psychosocial illness impact, as measured by the PROMIS psychosocial illness impact. For Aim 2, this study will test acceptability, feasibility, and usability of the narrative intervention from the perspectives of the key stakeholders—patients with serious illness and acute-care bedside nurses via 1) patient and nurse exit interviews, 2) field analysis of EHR interface use, and 3) end-user usability surveys of the nurses. This study builds on knowledge from the K99 study<sup>37</sup> and will continue the optimization of the biobehavioral narrative intervention by providing the necessary preliminary data required to submit an independent R01 grant, an efficacy trial (Phase III Orbit Model).

### **A. Outcome Measure(s)**

#### **Aim1: Outcome Measures:**

**Primary outcome—Quality of Communication (QOC).**<sup>57</sup> The QOC survey assesses patients' perceptions of the quality of communication with nurses. The QOC was initially developed from qualitative interviews and focus groups with diverse set of patients, families and providers.<sup>57-59</sup> The QOC has 19 items, with scores ranging from 0 (worst) to 10 (best). Internal consistency reliability and construct validity of the QOC has been established across several illness groups,<sup>57-62</sup> and the QOC survey's responsiveness to communication interventions has been demonstrated by changes in pre- and post-intervention scores.<sup>60-62</sup>

**Secondary Outcomes. PROMIS measures.**<sup>63,64</sup> This study will use the two PROMIS measures for patient reported outcomes: 1) PROMIS- 29 profile<sup>65</sup> v2.0 form (29 items), which assesses physiological, social, and psychological outcomes. These biopsychosocial domains include physical function, anxiety, depression, fatigue, sleep, ability to participate in social roles/activities, pain interference and intensity and 2) PROMIS psychosocial illness impact<sup>66-69</sup> items assesses negative and positive aspects of the illness experience. The PROMIS positive item bank measure (8 items) assesses positive psychosocial outcomes of illness. The positive psychosocial illness impact refers to outcomes that can occur as a result of confrontation with one's mortality, such as greater life appreciation, interpersonal relationships, and personal resources. The PROMIS

negative item bank measure (8 items) assesses the direct negative psychosocial effect of illness, distinct from general emotional distress. The positive or negative items do not, however, seek to capture the impact of illness on physical or functional domains. All PROMIS measures have established reliability and validity.<sup>63,64</sup>

**Table 1. Outcome Data**

Participant	Time 1: Baseline	Time 2: 24-48 hours post baseline/narrative upload	Time 3: 24-48 hrs after Time 2	1- week Post Upload
<b>Patient</b>	1. Quality of Communication(19)* 2. PROMIS-29 Profile:v2.1(29)* 3. PROMIS Psychosocial Illness Impact a)Positive affect (8)* b) Negative affect (8)* 4. Demographics	1. Quality of communication(19)* 2. PROMIS-29 Profile:v2.1 (29)* 3. PROMIS Psychosocial Illness Impact a)Positive affect (8)* b) Negative affect (8)*	1. Quality of communication(19)* 2. PROMIS-29 Profile:v2.1 (29)* 3. PROMIS Psychosocial Illness Impact a)Positive affect (8)* b) Negative affect (8)*	
<b>Nurse</b>				System Usability Scale (10)*
<b>Pt/Nurse</b>				Exit Interviews

\*(n)= number of items in outcome measure

## B. Description of Population to be Enrolled

**Setting/Sample.** This study will be conducted at University of Colorado Hospital, the same setting of the K99 study. As in the K99 study, there will be patient participants and acute care bedside nurse participants.

**Patient participants.** Patient participants (N = 80) will include those from two illness groups: heart failure and end-stage renal disease. The sample size was chosen to be consistent with pilot and usability studies.<sup>53,54</sup>

**Patient Eligibility Criteria.** Patients will be age 18 or older, able to speak/read English, capable of giving informed consent, and be diagnosed with at least one serious illness. The operational definition of serious illness for this study will include the following: 1) New York Heart Class III or IV heart failure, and/or 2) dialysis dependent renal failure. These illnesses were chosen based on successful recruitment during the K99 phase,<sup>37</sup> and the disease criteria were chosen to identify groups of patients with a median survival of about 2 years.<sup>55, 56</sup>

**Nurse Participants.** The nurse participants (N=80) will be the acute care nurse who is caring for the patient.

**Nurse Eligibility criteria.** Nurses will be age 18 or older, able to read English, and able to confirm verbally that they were involved in the care of the enrolled patient.

## C. Study Design and Research Methods.

**Design.** This study will use a mixed methods design.<sup>52</sup> The quantitative data will include the patient-reported outcomes on effects of the narrative intervention and will inform potential effect size for the later efficacy trial. The qualitative data will include: 1) patient and nurse exit interviews for triangulation of the quantitative findings and 2) patient’s illness narratives. At this phase of biobehavioral interventional development,<sup>33</sup> both the quantitative and qualitative data give necessary information about acceptability, feasibility, usability for optimization of the narrative intervention.

### Expected Outcomes

The expected outcomes of the R00 phase will be to conduct and complete preliminary testing of the narrative intervention (Phase II). This study will test the effects on QOC and patient reported outcome data and this study will continue to collect data on acceptability from the key stakeholders for evaluation of barriers and facilitators.

**Table 2. Timeline for the R00: Narrative Intervention Study (Phase II ORBIT Model: Proof of Concept Study)**

	YEAR 1	YEAR 2	YEAR 3
Obtain IRB approval			
Review/finalize procedures			

Recruit and randomize pts				
Collect baseline data				
Conduct intervention				
Data analysis: Quantitative				
Data analysis: Qualitative				
Dissemination				
Prepare R01 Submission				

**Recruitment.**

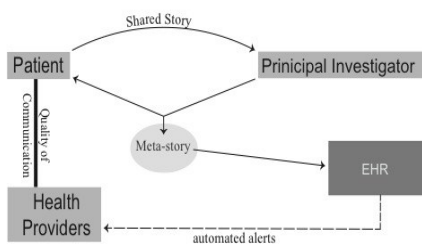
*Patient recruitment.* Recruitment rounds will be completed on three units at the University of Colorado Hospital: cardiac progressive care, cardiac-medical, and dialysis. A research team member will round at least weekly to meet with the charge nurses for identification of potential patients. At the hospital, charge nurses will identify potential participants based on eligibility criteria. If any patients are identified, the research team member will deliver a flyer regarding the study to potential patients and describe study protocols and obtain verbal agreement taking precautions to notify the potential participant that participation in the study is totally voluntary and will not affect care. If a patient volunteers at that time, or at later time by notifying a nursing care team member, the research team member will then arrange a convenient time to meet with potential patients to obtain HIPAA and informed consent. At these initial meetings with the potential participant, the PI will complete the official screening, describe the study, review the informed consent, and discuss risks/benefits with the participant.

If a potential patient is identified, then a research team member will introduce the study to the patient by reviewing the patient recruitment flyer and the informed consent. When a patient agrees to enroll, the informed consent will be completed with the patient, and the patient’s baseline measures will be collected. Each patient will receive \$25 after completing the baseline measures and \$25 at completion of data collection.

*Nurse recruitment.* After a patient is enrolled, the research team will collect from the EHR the names of the nurses who cared for the enrolled patients. These nurses will be approached for consent to participate in the study, with the goal of 80 participating nurses for collection of exit interviews. For the nurses who patients were randomized to the intervention, additionally, these 40 nurses will complete the user-centered testing which consists of nurse participant completion of the system usability scale questionnaire and providing any feedback to PI on ease of use, relevance and appeal, efficiency and subjective satisfaction of the nurse’s use of the patient’s story. Nurses will be contacted via e-mail or in-person with a recruitment flyer. After receiving verbal consent for participation via e-mail or in-person, a convenient in-person time will be coordinated for obtaining consent and subsequent data collection for the exit interviews and/or user centered testing. Each nurse will receive \$25 after completing the exit interview.

Weekly follow-up e-mails x 3 times will be sent if there are difficulties recruiting the 80 nurses for exit interviews or the 40 nurses for user-centered testing. If after these three e-mails, the nurse does not enroll, then the research team will attempt to recruit another nurse who attended the patient. Patient participants will not be withdrawn from the study even if a patient participant’s nurse is not enrolled.

**Figure 2. Narrative Intervention Flow Diagram**



**Narrative Intervention group.** The intervention in this study is a co-created narrative whereby patients share their illness narrative with a research team member through an open-ended, audio-recorded interview about their illness. During the interview, patients are prompted to share their narrative through probing questions or statements such as: tell me about your illness; tell me how your illness has affected your emotions, your relationships, and your spirituality. These probing questions have been field tested during my dissertation research and K99 study. As the patient responds, the research team member takes field notes and audio-records the interview.

The audio-recorded interview is then transcribed verbatim, and the research team member will create a one- to two-page meta-narrative.<sup>49</sup> Criteria are that the patient’s narrative is: 1) written in the patient’s first-person voice; 2) nonjudgmental; 3) captures the patient’s voice; 4) accurately reflects the content of the interview; 5) is Instructions – How to complete the COMIRB protocol template (Social) CF-184, Effective 4-26-2010

non-diagnostic (not labeling).<sup>49</sup> The co-created patient narrative is then returned to the patient within 48 hours, and the patient reads his/her written narrative. At that member checking<sup>49</sup> follow-up session, the patient is encouraged to make any desired changes, which facilitates co-creation of the patient's narrative.<sup>49</sup> Once the narrative is approved by the patient, the patient's narrative will be uploaded to the EHR. Once the narrative is uploaded into the EHR, the assigned nurse will be alerted that the patient's narrative is ready to be read. The workflow diagram is depicted in Fig 2.

**Usual care group.** The intervention group will be compared to a usual care group of participants: hospitalized patients who meet the same eligibility criteria as the narrative intervention group. Because there are few interventions in place to increase communication among patients and nurses, the use of a usual care patient group is the most appropriate comparison.

**Randomization.** Randomization to the narrative intervention or usual care will occur at the patient level. The random allocation sequence will be computer generated using random block sizes, an allocation ratio of 1:1, and stratification by illness group. The project statistician will generate the allocation sequence using SAS software and the allocation sequence will be uploaded for study use into REDCap. Upon study completion, baseline characteristics between intervention and control patients will be compared using independent samples t-tests (continuous measures) and chi-square tests (categorical measures). Though balance is assumed, statistical adjustment will be used in outcome analyses in the event of pre-treatment differences between conditions.

**Data collection.** All survey and demographic data will be captured using electronic surveys through REDCap on password-protected iPads/laptops.

**Demographics.** At baseline, age, gender, race/ethnicity, education in years, income level, religion/spirituality preference, and clinical details to identify co-morbidities and severity of illness will be collected for all participating patients. This demographic detail will allow description of outcome means and standard deviations in key patient subgroups, including groups defined by patient race/ethnicity and specific chronic illnesses of heart disease or end-stage renal disease.

**Measures.** For Aim 1, the primary and secondary outcome measures will be collected at three time points from all patient participants. (Table 1). The purpose of these times periods are to collect the outcome measures consistently for usual care and intervention participants. This is based on knowledge gained during the K99 study regarding time to complete the narrative intervention. In the K99 study, for the narrative intervention, on average it took 24 hours post narrative interview to upload the patient's narrative into the EHR.

**Exit Interviews and Usability Scale.** For Aim 2, the patient and nurse exit interviews and system usability surveys from the nurses will be collected approximately 1-week post intervention. (Table 1).

**Sample Size and Power Analysis.** Sample size estimates were generated to determine power to detect a time by treatment interaction within the proposed repeated measures design. Assuming two-sided alpha = 0.05, a sample size of 80 patients will provide 80% power to detect an effect size associated with treatment effects on changes over time as small as  $f=.14$  (Cohen's  $d = 0.28$ ). This represents a small, clinically relevant effect, but more importantly will provide stable measures of outcome means and standard deviations over time for use in the planned R01 efficacy trial. Modern missing data techniques<sup>70</sup> will be used if patients drop out before all follow-up data is obtained. To minimize concerns for attrition, the time between baseline and follow-up data collection is small. Nonetheless, if patients are lost to follow-up, even if a high level of attrition (e.g., 20%) will allow for the detection of a small effect size of  $f=.16$ .

## **D. Description, Risks, and Justification of Procedures and Data Collection Tools.**

### **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 patients with serious illness (heart failure or end-stage renal disease) and their acute care nurses. We expect to enroll 80 patients with serious illness (40 for the intervention group and 40 for the usual care control group) and 80

nurses who are directly involved in the care of the patient. The research team members 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. 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. This interview will last approximately 60-90 minutes. For the second interview, the patient will answer exit interview questions about their experience with the narrative intervention. This interview will last approximately 30 minutes. For the first 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.

*Nurses.* The nurses will be interviewed once. This interview will collect exit interview data related to the narrative intervention. The participant and nurse will be interviewed at separate times. For the nurse interview, the PI will coordinate a convenient time and private place to conduct the interview, which might include nurse's office, private conference in the facility, or take place on the telephone. In addition, the PI will collect the nurse's system usability scale responses during the exit interview for the usability testing.

*Patients:* For both randomized (narrative intervention) and control (usual care) groups, the involvement of patients includes participation in pre- and post-intervention data collection activities.

Intervention group: Data collection activities for patients include completing demographic and outcomes measures at baseline (enrollment). Then, they will have outcome measures collected immediately after narrative upload into the EHR (approximately 24 hours after narrative is collected), and 24-48 hours post narrative upload into the EHR. For the narrative intervention group, a one-time audio recorded interview (60-90 minutes) with the research team member will occur once baseline measures have been collected. In addition, the intervention participants will participate in a second audio-recorded audio exit interview (30 minutes) and will collect information on acceptability and feasibility of intervention. This interview will be collected in the private location of the patient's hospital room or may be collected and recorded over the telephone if patient has been discharged from the hospital.

Usual care group: Data collection activities for these patients include completing demographic and outcomes measures only at baseline (at enrollment), and again 24-48 hours after enrollment.

*Outcome Measures:* The estimated time for completion of the 64 items on the questionnaires is approximately 30 minutes. The following questionnaires are included as the outcome measures: Quality of Communication (QOC) which consists of 19 items; PROMIS-29 Profile v.2.1 of 29 items each; and PROMIS Psychosocial Illness Impact {Negative and Positive} Short-Form 8a which consist of 16 items.

*Nurses:* Data collection activities for the nurse participants will include completing a 30 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 30 minute exit interview.

Data collection activities for intervention patient participants include:

1. Completing baseline outcomes measures and demographic information, approximately 30 minutes
2. Completing the narrative intervention via a 60-90-minute audio-recorded interview
3. Completing outcome measures after narrative upload
4. Completing outcome measures 24-48 hours after narrative upload
5. Completing an exit interview via a 30-minute audio-recorded interview.

Data collection activities for the nurse participants will include completing a 30-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 30-minute exit interview.

The participants will be recruited through the University of Colorado Hospital.

b. *Sources of Materials*

*Qualitative Data.* For this proposed project, data will only be collected by the research team. Materials include audio recordings of interviews, field notes, and correspondence (i.e., memos, emails) with research

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team members. A total of 240 audio-recorded interviews will be collected—80 interviews for the narrative intervention, 80 for the patient exit interviews, 80 for the nurse exit interviews.

**Quantitative Data.** All patients (intervention and usual care group) will complete a questionnaire at baseline, immediately post narrative upload in the EHR, and 24-48 hours post narrative upload. All survey data will be captured using electronic surveys through REDCap on password-protected iPads/laptops. After each participant's baseline data is collected by the professional research assistant, the participant will be randomized to be included in either the narrative intervention or usual care group. This randomization will occur with the randomization computer-generated algorithm. After the participant is randomized, a unique study identifier for all enrolled participants will be created for a de-identified data set.

Steps of de-identification:

1. The research team will assign the patient participant a de-identified code (i.e. P1) after consent is signed. This code will be the identifier throughout the study to link the narrative interview, the REDcap surveys, and the exit interview.
2. The research team will assign the nurse participant a de-identified code (i.e. N1) that corresponds numerically with the patient participant code.
3. For the REDCap survey data:
  - a. When each participant is added to the REDcap database, the research team will add this assigned de-identified code as the participant identifier.
  - b. Since the participant needs to take the survey three times, at the time of adding the de-identified code, the exact number of times they should take the survey will be added.

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 narrative interview process; the 30 minute exit interview process and/or outcome measures data collection procedures. In this event, the research team member will encourage rest periods or, if necessary, reschedule a return visit to complete the interview. For the burden of time, each patient participant will receive \$25 in appreciation for completing the narrative intervention and then another \$25 at the time of the exit interview. For the burden of time, each nurse participant will receive \$25 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 serious illness. We will assure that participants understand both orally and in writing that they are free to decline participation in any and 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 research team member 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 research team member will assist in referring participant to emotional support either through family, friends, or the healthcare team for follow-up related to the participant's distress. If severe distress, such as noting suicidal ideation, the research team member will immediately refer patient for further work-up and care. The research team member 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 PI 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. Patient or nurse participants will be able to contact the PI to discuss any concerns or questions at any time during their participation in the study. In a previous study using this methodology, none of these adverse events occurred. Therefore, we anticipate these risks 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 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 research team members will arrange with the participants a private location with only research team member and participant present for collection of the interview. Once in this private setting, the research team member will remind them that participation is voluntary and that they may withdraw from the project at any time without any penalty or prejudice.

*Breach of confidentiality.* 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.

## **Adequacy of Protection Against Risks**

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

The research team members will recruit, through convenience sampling, patients with serious illness. Study participants will be recruited through University of Colorado Hospital. The research team members will meet weekly and as needed with nursing staff at the hospital and provide updates on recruitment needs until recruitment is complete. At the hospital, the research team member will meet with the charge nurse to identify any potential participants based on diagnoses. If any patients are identified, a research team member 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 voluntary and will not affect care. Once verbal consent is obtained, the research team member, will arrange a convenient time to meet with potential patients to review the study protocols and obtain informed consent. At these initial meetings with the participant, the research team member will complete the official screening, describe the study, review the informed consent, and discuss risks/benefits with the participant. If participant volunteers and meets inclusion/exclusion criteria at this meeting, then the research team member and participant will sign the informed consent.

Recruitment will include the use of flyers given to the nursing staff on the hospital units. The research team members 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 phone. The research team members will also communicate weekly with the nurse managers on each of the hospital units to identify any potential concerns with the recruitment procedures. This weekly presence within the nurse managers and nursing staff will also act as a reminder to nursing staff on the hospital units about the study and updates on the recruitment needs for the study.

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. Only the research team members will be responsible for screening, consenting, and collecting all the interviews. The study participants will have the opportunity to decline at anytime throughout the study.

### **b. Protections Against Risk**

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

*Physical.* Participants could become fatigued during the 60-90minutes interview process. In this event, the research team member will encourage rest periods or if necessary reschedule a return visit to complete the interview.

*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 serious illnesses. If the participant exhibits any verbal or non-verbal distress, the research team member 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 has been compiled and will be kept with the research team member when conducting interviews. If the participant exhibits any verbal or non-verbal distress, the research team member 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 research team member 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 PI 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 will be notified 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 research team members will remind them that they may refuse to participate at any time during the proposed study.

*Confidentiality.* Although there is a rare risk for breach of confidentiality, the research team member 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 consents, the research team member will assign a unique numerical identifier, for example: Patient participant 1 = P1 and Nurse Participant 1= N1).

Steps of de-identification:

1. The research team will assign the patient participant a de-identified code (i.e. P1) after consent is signed. This code will be the identifier throughout the study to link the narrative interview, the REDcap surveys, and the exit interview.
2. The research team will assign the nurse participant a de-identified code (i.e. N1) that corresponds numerically with the patient participant code.
3. For the REDCap survey data:
  - a. When each participant is added to the REDcap database, the research team will add this assigned de-identified code as the participant identifier.
  - b. Since the participant needs to take the survey three times, at the time of adding the de-identified code, the exact number of times they should take the survey will be added.

In addition, immediately after transcription of participant interviews, the research team member will remove any identifiable names of person or place. 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 and the research assistant's password protected computer only and uploaded to the secure server at University of Colorado. The research team members will review the meta-narrative with the participant on the password-protected computer. During this review, the patient will be allowed to make changes to the meta-narrative prior to uploading the meta-narrative 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 research team member will upload the meta-narrative 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 availability. After-hours support is available by pager.

The PI stores 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 collect 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.

All data will be 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.

### **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 narrative interventions for patients living with serious illness. We have outlined procedures to minimize the risks to participants, 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 taking steps to ensure data security.

### **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. Further, there is a plan in place for referral to appropriate follow-up services as needed. During the K99 phase, no participants required referrals, and no participants reported feeling that the intervention was too burdensome

**Nonresponse bias and recruitment and attrition.**<sup>56,79</sup> Patients who participate may differ from those who decline. Data on response rates will be collected and non-respondent characteristics will be examined to estimate the magnitude of any potential nonresponse bias. To decrease concerns about attrition, the study design calls for only a one-week period from enrollment to follow-up data collection. In addition, as described above, we will use an intention-to-treat analysis<sup>80</sup> and modern missing data approaches<sup>70</sup>. During the K99, all enrolled patient participants completed data collection, and only 2 nurse participants were recruitment failures. One nurse participant unenrolled because of a personal family emergency. The other nurse, an outside temporary agency RN, was unable to be contacted. If we cannot recruit a nurse, the patient's data will still be included in outcome and process analyses, which will inform study procedures in the larger trial.

**Blinding and contamination of intervention effects.** Although the R00 study will use computer-randomized assignment to the intervention and usual care groups, given the patient-centered intervention and patient-reported outcomes, it will not be feasible to blind participants (patients or nurses).<sup>81</sup> Future studies could have an active control and blinded outcome assessment to help address this limitation. In the proposed R00 study, it is possible that the nurses may naturally demonstrate improved communication based on their knowledge of the study. To address this possible contamination, future studies could use a cluster randomized design with clinics or healthcare institutions, rather than patients, as the unit of randomization.

## F. Data Analysis Plan.

**Aim 1 Analysis Plan.** Statistical analyses will be performed with the use of SAS software, version 9.4. In preliminary analyses, data will be screened for errors and outliers; appropriate transformations will be made for non-normal outcomes. Baseline demographics will be summarized using standard descriptive statistics. The pattern of participant dropout will be examined to ensure a reasonable equal distribution of participants lost to follow-up between groups and based on baseline characteristics. Maximum likelihood techniques will include participants with incomplete data without need for imputation. In addition, we will conduct sensitivity analyses to examine the effect of departures from key assumptions made in the main analysis and to help determine effects of missing data. Using an intent-to-treat approach, primary and secondary outcomes will be analyzed with linear mixed models using SAS Proc Mixed to compare the two groups (narrative intervention versus usual care) over the assessment period. Separate models will be estimated for each of the primary and secondary outcomes, though relationships among outcomes will also be assessed. Mixed models will specify intervention group and time as fixed effects and subject as a random effect. Pairwise comparisons testing group effects at each time point are proposed to disentangle the effects of intervention process versus change in quality of communication between patient and nurse. All statistical analyses will be done in consultation with the project statistician, Dr. Schmiedege.

### Aim 2: Process Measures:

**Barriers and facilitators.** The patient and nurse will be contacted for exit interviews. These will be collected 5-7 days after the meta-narrative is added to the EHR. The transcribed exit interviews will be entered into ATLAS.ti, and 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.<sup>49,71</sup> An inductive approach to coding, through the use of the participant's actual words, will be used for up to three transcripts.<sup>71</sup> 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.<sup>71(p86)</sup> As PI, I will complete the preliminary coding for each transcript then the research team will review my preliminary codes. Once the first three 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. At each of the monthly research team meetings, codes can be expanded or collapsed<sup>49</sup> as part of the iterative process. To ensure the rigor of the data analysis, Sandelowski's criteria for trustworthiness<sup>72,73</sup> will be used.

**Usability testing.**<sup>74-78</sup> Following the exit interview, the nurse participants will be asked to complete the System Usability Scale (SUS),<sup>78</sup> which asks them to rank their experience and satisfaction with specific elements. Usability is defined as the relationship between humans and computers. Usability testing focuses on evaluating Instructions – How to complete the COMIRB protocol template (Social)

process measures based on four major components: user (nurse), task (utilization of meta-narrative by nurse), system (meta-narrative in EHR), and environment (inpatient nurse's station).<sup>76</sup> The user-task-system-environment framework of process measures<sup>76</sup> 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 narrative intervention into the EHR by evaluating information flow, use of information, and system functionality. The process measures collected to determine usability will include: 1) field observations of the end user: the nurse; 2) chart review/log analysis of the

### **G. Summarize 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 to benefit clinical practice while improving quality of life for patient with serious illnesses, the impact of this proposed study supports research exploring interventions for optimizing quality of life.

### **Future Directions**

The K99 and R00 studies provide the developmental steps to optimize a biobehavioral intervention, providing the preliminary data required to submit an independent R01 grant in year 3 of the R00 phase. For the next steps in my research trajectory, this R01 submission will be a Phase III efficacy study of a patient-centered palliative care narrative intervention, consistent with the ORBIT model of biobehavioral intervention development. With my strong background in palliative care, both as a clinician and narrative biobehavioral intervention researcher, I will be positioned to continue building a program of research based on narrative approaches for patients living with serious illness.

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