

R36 Protocol and Analysis Plan

Protocol #: 18-1675

Project Title: Underutilization of Hospice in Older African Americans

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I. Hypotheses and Specific Aims: The goal of this study is to determine if poor health literacy and/or insufficient knowledge of hospice care are barriers preventing African Americans from understanding what hospice care is and negatively influences their opinions of hospice care. Additionally, the study will evaluate the influence of perceived discrimination and mistrust in healthcare on hospice knowledge and attitudes and beliefs towards hospice care.

Aim 1: To evaluate the relationship between literacy, mistrust and perceived discrimination on hospice knowledge and hospice beliefs and attitudes in older African Americans.

Aim 2: To evaluate the effect of hospice decisional support materials on hospice knowledge and attitudes and beliefs about hospice in older African Americans.

II. Background and Significance:

Research demonstrates that African Americans fail to enroll in hospice services,^{1,2} even though they disproportionately suffer more aggressive forms of, and experience more disability from, the diseases most common among hospice enrollees. The increasing number of people of color living with debilitating chronic disease and the continued growth of healthcare expenditures threatens to financially overburden Medicare. By the year 2050, African Americans will comprise nearly 12% of Americans over the age of 65.³ These factors create a significant need for interventions to increase hospice utilization in aging African Americans.

There is limited research that explores the reasons driving underutilization of hospice services among African Americans. Many researchers reduce the disparity to religious and/or cultural beliefs and an inherent preference for more aggressive treatments.^{1,4-11} Although these may be legitimate barriers, another plausible barrier to hospice utilization is health literacy and a diminished or inaccurate knowledge of hospice care.

African American patients routinely report misconceptions and deficiencies in knowledge about hospice care. Patients report they do not receive information on hospice from healthcare providers^{12,13} and receive misinformation from family and friends.¹⁴ Studies suggest that White providers are less likely to provide information about hospice services or refer their African American patients to hospice.¹⁵⁻¹⁹ Other cultural barriers for African Americans include an emphasis on informal or family caregivers and family-centered decision making,^{20,21} and the importance of integrating religious and spiritual values into care plans.^{6,20-24} Hospice incorporates family-centered care models and accommodates patients' religious and spiritual beliefs, but this core piece of information may not be adequately communicated to African American patients. Inaccurate and inadequate information about hospice prevents patients from understanding the full scope and range of hospice services.^{12,14,25}

Limited knowledge about hospice and the misconceptions of hospice care are health literacy barriers which may be mitigated with a patient decision aid designed to provide accurate and unbiased information about hospice care. Patient decision aids are evidence-based interventions that promote knowledge production, patient-centered care, decisional autonomy, and reduce decisional conflict in medical decision making.²⁶ This study will test hospice decisional support materials (e.g. hospice paper decision aid and hospice video decision aid) that will potentially address knowledge and literacy barriers to hospice use among African Americans. The decisional support materials conform to the rigorous standard of the Internal Patient Decision Aid Standards (IPDAS), which is an organization that ensures the production of high-quality patient-centered decision aids.

This study hypothesizes that low health literacy correlates to low hospice knowledge. This hypothesis builds on prior work by Volandes and colleagues^{27,28} which demonstrates poor health

literacy is a stronger predictor of end of life choices than race. These studies focused specifically on end of life decisions in patients with dementia. Some scholars criticize the Volandes team's work for producing heavily biased videos that show graphic representations of end-stage disease and treatments that shock patients into choosing hospice.²⁹ The goal of the current project is to use a neutral decision aid representing the benefits and disadvantages of hospice. The content of this decision aid heavily relied on input from stakeholders such as patients, caregivers and the diverse variety of providers who care for hospice patients. The decision aid presents general information about hospice and is not disease specific, unlike Volandes' decision tools.

Additionally, this study hypothesizes that standing paradigms of discrimination perpetuate a systemic mistrust in healthcare. African Americans were systematically and intentionally excluded from healthcare and the evolution of the modern healthcare system. From pre-slavery America through the middle of the 20th century, American physicians were trained to believe African Americans were a different species.³⁰ This racist thinking allowed medical professions to abuse and experiment on African Americans with impunity.^{31,32} These practices bred and nurtured the mistrust African Americans feel towards the healthcare system and healthcare professionals, and by extension may negatively influence knowledge and perceptions of hospice care. Decision aids may help lessen mistrust and improve perceptions of hospice.

III. Preliminary Studies/Progress Report:

We conducted an extensive qualitative needs assessment and environmental scan of available hospice decision aids. Through the needs assessment we interviewed 5 patients, 20 caregivers and 27 providers (e.g. social workers, nurses, chaplains) regarding their perceptions of participating in hospice. In the preliminary analyses, we found that all participant groups describe misunderstandings and myths regarding hospice care consistent with those cited in the literature. Additionally, we learned that timing of introduction and initiating of hospice care was a major theme across all participants. Hospice is often presented as an option only when death is imminent. As a result, caregivers expressed regret for not being aware of or enrolling their loved ones in hospice earlier in the disease course.

People from varying different backgrounds, races/ethnicity and cultures participated in the qualitative needs assessment. Overwhelmingly participants from diverse race and ethnic backgrounds felt a hospice decision aid would facilitate end of life discussions within their communities. Study participants felt any hospice PtDA should focus on providing clear and accurate information about hospice care to help them navigate the ubiquitous misunderstanding and misperceptions of hospice care. Participants advocated for a neutral balanced tool that clearly explained the pros and cons of hospice, detailed the eligibility requirements and accurately described the payment mechanisms for hospice care.

Our environmental scan found only 7 PtDAs that mentioned hospice as a potential secondary treatment option for people with illnesses such as end stage heart failure, cancer or kidney disease. The PtDAs did not describe the eligibility criteria hospice, the services provided by hospice and failed to provide resources for patients interested in hospice care. These PtDAs inadequately explain the nuances of hospice care as a primary treatment option and have limited reach to only specific populations. Further, these PtDAs fail to acknowledge the complexity of end-of-life decision making.³³

We then brought in 20 laypersons into our lab to conduct an organic web search for information regarding hospice and to participate in a semi-structured interview regarding their perceptions of the available information. Many of the online resources that the participants found were promotional materials from specific hospices or other special interest groups, thus the participants found these materials confusing and biased. Further, the online resources failed to provide clear information on cost, enrollment, and lacked the desired patient and caregiver testimonials. Surprisingly almost all participants went to sites such as yelp to get narrative descriptions of hospices.³³

IV. Research Methods

A. Outcome Measure(s):

Overview: The goal of this study is to test whether or not hospice decisional support materials can improve hospice knowledge and attitudes and beliefs towards hospice in older African Americans.

Primary Outcomes: There are three primary outcomes for the study which are change in hospice knowledge measured by the Hospice Knowledge Survey, change in opinions attitudes about hospice care measured by the Hospice Beliefs and Attitudes Scale (HBAS) and decision self-efficacy will be measured the Decision Self-Efficacy Scale. These scales utilize a scoring scheme in which a higher score indicates more knowledge and a more positive view of hospice, and more decision self-efficacy, respectively.

Description of surveys for primary outcomes:

- Knowledge of Hospice Test: The Knowledge of Hospice Test is a 23-item scale with true/false questions.^{34,35} The Cronbach's alpha coefficient for the scale is 0.75 showing good internal reliability.
- Decision Self-efficacy: Is an 11-item instrument that one's self-confidence in decision making. This scale is a validated scale with a Cronbach's alpha of 0.92 and correlates with DCS subscale of being informed ($r=0.47$). Based on our prior study of a decision aid in palliative care, we hypothesize that one of the strongest effects of a decision aid might be to increase self-efficacy of the decision making.³⁶
- Hospice Beliefs and Attitude Scale (HBAS): The HBAS is an 8-item scale developed to measure beliefs and attitudes towards hospice care.¹² It has a Cronbach's $\alpha = .74$ for the scale, indicating a good degree of internal reliability.
- Demographic Form-a brief demographic form to record SES, age, sex and comorbidities such as diabetes, heart disease, and cancer.

Description of qualitative writing sample:

- Hospice knowledge will be qualitatively assessed prior to randomization at the baseline visit to better understand the misconceptions associated with hospice care. Matsuyama et al³⁷ described a brief qualitative assessment in which participants are asked to describe "what is hospice" in their words. Participants will provide their answers on paper. These brief writings will be analyzed using thematic content analysis.

B. Description of Population to be Enrolled:

The target population are African American adults who are 65 years of age or older. Participants must be English speaking and self-identify as African American.

C. Study Design and Research Methods

Study Design: The study employs a two phase pre-/post-test intervention design or a small pilot randomized control trial (RCT), utilizing a one-to-one randomization scheme. Participants will be randomized into groups after completing the baseline assessments. Pilot RCTs are used to test the acceptance of a new intervention, as well as the feasibility of implementing a new intervention.³⁸ The proposed study aims to test the efficacy of a paper and video decision aid for hospice care. The intervention group will receive both decision aids and the control group will receive no intervention. All participants will receive the intervention materials at the conclusion of the study regardless of intervention group.

Study Setting: Recruitment will take place at community organizations serving older African Americans and the outpatient primary care clinics for both UHealth and Denver Health.

Recruitment: The target enrollment is 150 total (75 per arm) participants.

- Community Organizations-will consist of passive recruitment via flyers, listservs, electronic mailing mechanisms and advertisements in newsletters and newspapers.

- **Outpatient Clinics-** potential patients will be identified through weekly chart reviews. The study team will communicate with the outpatient physician by his/her preferred communication method (e.g. email, phone) to determine whether the patients are appropriate to be approached. If eligible and appropriate, a research team member will approach the patient and introduce the study following their clinical encounter. Flyers will also be hung in treatment rooms and common areas of each clinic. Reasons for non-approach will be recorded.
 - **Email/Mailings-**We will also review medical records for potentially eligible patients and send them either an email or letter via US mail describing the study and asking them to contact the study team if they are interested in participating.

Research Methods: This will be a 1:1 intervention:control randomization scheme.

- **Baseline Visit (Aim 1)-** All participants will complete the baseline measurements: brief writing exercise, the Hospice Knowledge Scale, Hospice Beliefs and Attitudes Scale (HBAS), and decision self-efficacy scale (all measurements described above). Additionally, all participants will be asked to briefly describe in writing “what is hospice” in their own words. Prior research shows this brief writing exercise exposes many of the misconceptions of hospice care and provides insights into overcoming knowledge barriers.³⁷ A trained research assistant will be available to answer questions and provide clarification if necessary. Additionally, the participants’ preferred method of contact or phone number will be recorded for the follow-up visit (Aim2). After completion of baseline surveys, participants will be randomized for Aim 2 of the study.
- **Follow-up Visits (Aim 2) -** Participants randomized to the intervention group will be asked to review the PtDAs within 1 week of the baseline visit. Each participant will be contacted one week after the Phase 1 visit to complete follow-up assessments by phone. All participants, regardless of study arm, will be called 1-month after the baseline visit to complete the follow-up surveys by phone. The control and intervention groups will complete the primary outcomes surveys (Hospice Knowledge, decision self-efficacy & HBAS). The proposed intervention and follow-up are consistent with other shared decision making and PtDA studies.²⁶

Data collection: For patients who agree to participate, the study coordinator will collect baseline demographic and quantitative data (surveys described above in Section A). The research coordinator will then open the envelope to determine the patient’s allocation. Control patients will be asked to complete the baseline measures at time of enrollment and again at 1-month follow-up. Intervention patients will be given the decision aid and asked to review it within the next week. Then the best way to contact participants for follow-up calls will be recorded. Finally, each participant (control and intervention) will be contacted at one month for the final data point collection. \$25 gift cards will be given for baseline and one-month follow-up surveys.

- **Baseline visit (control & Intervention)-** All participants will be asked to complete the brief writing exercise, REALM test, Hospice Knowledge Test, Hospice Attitudes and Beliefs Scale, Decision Self-efficacy scale, and demographics.
- **One Week Follow-up call (intervention only)-**Participants will be asked to complete the Hospice Knowledge Test, Hospice Beliefs and Attitudes Scale, Decision Self-efficacy scale, the decision aid acceptability scale and brief decision aid feasibility questionnaire.
- **One Month Follow-up (control & intervention)-**At one month follow-up all participants will be asked to complete the Hospice Knowledge Test, Hospice Beliefs and Attitudes Scale, and the Decision Self-efficacy scale.

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

This project poses minimal risk to all subjects involved. The intervention involves review of decisional support materials and a series of quantitative and qualitative questions. Data collection from participants includes questions and medical record review to screen for eligibility and only limited demographic data will be obtained. There is always a risk that

participants may feel uncomfortable discussing hospice or end-of-life decisions. Participants will be informed of their right to refuse to answer any question they do not wish to answer, and may terminate participation in the study at any point (and that should they decline to participate, answer a question or withdraw this will not affect their medical care).

Data collection and storage has been planned to appropriately protect participant confidentiality. All patients will be given a unique identification number, and study data and identifiable information will always be kept separate. REDCap, the COMIRB-preferred system, will be used to store all survey and enrollment data, and access to both REDCap and the secure server will be limited to study personnel only. All paper documents will be stored in a secure and locked file cabinet in a secure and locked office building – again, all study data paperwork will be stored separate from paperwork with identifiable information (i.e. signed consent forms) and be accessible to study personnel only.

E. Potential Scientific Problems:

Will participants with low health literacy/numeracy be able to understand decision aid (DA)?

A key challenge in DA research is assuring that the resultant products are accessible to all populations. Because most DAs require a minimum level of education, they risk widening disparities by being unavailable to poorer populations. The DA has been developed in accordance with recommendations for clear communication. The current protocol is limited to English speaking and reading participants. In this first stage of intervention assessment we are limited to an English version of the DA since there is currently no staff with credentials to conduct health language translation in Spanish, Amharic, Congolese, Mandarin, Arabic, etc. Upon successful evaluation of this protocol, discussions for DA translation will be conducted.

F. Data Analysis Plan:

Qualitative Analysis- The open-ended qualitative question will be analyzed using inductive and deductive content analysis.³⁹⁻⁴¹ The deductive approach will identify participant knowledge of key domains of hospice. The inductive approach will identify any key misconceptions or fallacies expressed by participants in the study. All qualitative analysis will be done with Atlas.ti. 8.0 (GmbH, Berlin).

Quantitative Analysis-We will compare differences between intervention and control pre/post intervention using t-tests for continuous outcomes and chi-square tests for dichotomous outcomes. We will perform a multivariate analysis of our outcome variables (i.e. hospice knowledge, hospice beliefs and attitudes scale) and look for mediation and/or moderation effects of level medical mistrust, level of perceived discrimination (schedule of racist events) age, race, and gender; while controlling for potential confounders.^{42,43} The total sample size required for phases 1 and 2 is 150participants. The study is powered to achieve an alpha of 0.05 and a medium effect size of 0.5 as determined by a power analysis completed in STATA⁴⁴ and confirmed by G*Power. G*Power is a specialized program designed for use in social, behavioral and medical research studies.^{45,46}

G. Summarize Knowledge to be Gained:

Hospice services are vastly underused in all populations but especially in minority communities. The proposed research aims to specifically target older African Americans who are especially vulnerable to hospice underuse. The decisional support materials used in the proposed research will provide valuable insights into issues and barriers that prevent African Americans from enrolling in hospice while simultaneously evaluating whether or not hospice decisional support materials are a salient means to improve hospice knowledge and attitudes and beliefs towards hospice in older African Americans. This study is designed to obtain pilot data to support a planned multi-site RO1 addressing hospice

underutilization in minorities communities and if patient decision aids are effective in improving knowledge.

H. References:

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