

R21 Protocol and Analysis Plan

Protocol #: 18-1138

Project Title: Pilot Evaluation of Hospice Decision Support Tools

Principal Investigator: Dan Matlock, MD

Version Date: 01/08/19

I. Hypotheses and Specific Aims:

The goal of this project is to determine the feasibility and acceptability of a novel hospice patient decision aid (PtDA).

Aim 1: Determine the feasibility and acceptability of a hospice decision aid among a diverse population of older adults at multiple stages of illness and in two health care settings (an academic medical center and a county hospital system) using a mixed-methods approach.

Aim 2: Determine the preliminary efficacy of the hospice decision aid on decision quality, hospice knowledge, and values-concordance.

II. Background and Significance:

Although hospice has existed for more than 40 years, many people and even some physicians do not fully understand hospice care.¹ For example, many patients misunderstand the payment mechanism for hospice and incorrectly believe they are unable to afford hospice care, despite the fact that most payers cover hospice services. Some believe that enrolling in hospice requires institutionalization, despite evidence that 80% of hospice care occurs at home and those enrolled in hospice are more likely to die at home.¹⁻³ For some hospice conveys the message of “giving up”, even though evidence suggests that hospice enrollees and their loved ones report a sense of hope, relief, and improved quality of life.⁴⁻⁶ Finally, people report concerns that hospice hastens death, despite evidence that hospice is not associated with shorter survival and in some cases hospice enrollees live longer than those seeking curative treatments.^{5,7-10} To understand how to address these misconceptions, we performed a qualitative needs assessment with patients, caregivers and healthcare providers. We found, in addition to the aforementioned misunderstandings, that hospice is often not presented as an option until death is imminent and caregivers are consequently unaware of the potential support provided by hospice. Caregivers expressed regret for not knowing of and not enrolling in hospice earlier in the disease course of their loved ones. The patient decision aid (PtDA) being studied in this application is designed specifically to address these misperceptions of hospice care.

Hospice is underutilized. Despite the documented benefits of hospice, less than 2 million people utilize hospice services annually.² More than one third of all hospice users spend less than 7 days receiving care.² Approximately 40% of eligible Medicare beneficiaries die enrolled in hospice. In other words, almost two-thirds of eligible patients do not benefit from the documented advantages of hospice care. Racial and ethnic minority patients account for only 15% of all hospice users.^{2,11} When they are enrolled, they spend less time in hospice services than white patients, averaging fewer than seven days enrolled in hospice care.^{12,13} Further, the percentage of the oldest old utilizing hospice services has plateaued over the last several years with little more 50% enrolling in hospice.¹⁴ The reasons for underutilization are complex but include knowledge barriers and misunderstandings about hospice care by both physicians and patients,¹⁵⁻¹⁷ cultural beliefs about death,¹⁸⁻²⁰ lower health literacy in older adults and minorities,²¹⁻²³ physician gatekeeping and late referral,¹⁶ and disparities in access to quality healthcare.^{15,18,19,24}

The absence of quality shared decision making (SDM) and of quality patient-centered care is a disparity highlighted by the Institute of Medicine.²⁵ The goals of SDM include improved patient-provider communication, information sharing, and collaborative decision making.^{15,26,27} SDM is an important aspect of patient-centered care.²⁶ One strategy to support SDM is utilizing PtDAs which engage patients in the *process* of decision making by providing information on diagnosis and/or treatment options.^{28,29} PtDAs assume various forms including paper (e.g. leaflets, pamphlets, and booklets), electronic media (e.g. audio recordings, videos) and web-based interactive portals.³⁰ A Cochrane review of 115 randomized trials of PtDAs demonstrated a reduction of decisional conflict,

improved patient-provider communication, and increased patient involvement in medical decision making.³⁰ Video PtDAs are effective in older patients and patients with lower literacy and numeracy.³¹⁻³³ Critical to PtDAs is the presentation of balanced, evidence-based, accurate, neutral and unbiased information to patients.^{30,34}

III. Preliminary Studies/Progress Report:

We conducted and extensive qualitative needs assessment and environmental scan of available hospice decision aids. Though 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.

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.³⁵

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.³⁵

IV. Research Methods

A. Outcome Measure(s):

Overview: The goal of the project is to determine the feasibility, acceptability and preliminary efficacy of a novel hospice decision aid. We will achieve this goal through a series of quantitative surveys and through qualitative methods.

Aim 1. Feasibility and Acceptability Outcomes:

Acceptability of the decision aid will be measured using the Ottawa Acceptability Scale (OAS). The OAS scale consists of 8 questions on a 5-point Likert scale with additional yes/no questions.³⁶ Feasibility will be assessed asking patients when they viewed the decision aid, if the used the paper version, the video version or both. We will also ask for input on the overall design and usefulness of the decision aid in facilitating their decisions.

Aim 2. Preliminary Efficacy:

Efficacy will be measured qualitatively and quantitatively through surveys. We are trying to determine if the decision aid improves hospice knowledge, decreases decisional conflict and improves self-efficacy.

- **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.

- **Knowledge of Hospice Test:** The Knowledge of Hospice Test is a 23-item scale with true/false questions.^{1,38} 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.³¹

Hospice Beliefs and Attitude Scale (HBAS): The HBAS is an 8-item scale developed to measure beliefs and attitudes towards hospice care.³⁹ It has a Cronbach's $\alpha = .74$ for the scale, indicating a good degree of internal reliability.

B. Description of Population to be Enrolled:

Patients: Patients will be older adults age ≥ 65 with at least one life-limiting illness or syndrome as defined by the clinicians.

Exclusions: We will exclude patients who cannot speak English. In future work, we plan to make a Spanish version if this version is deemed acceptable. We will exclude patients with cognitive impairment as determined by ability to provide informed consent. We will also exclude patients on isolation precautions due to resistant bacteria or impaired immune function.

C. Study Design and Research Methods

Settings: For this pilot, we will recruit from Denver Health Medical Center and UCHealth. At each site, we will recruit patients from both the inpatient and outpatient palliative care services and the outpatient geriatric and primary care clinics. In order to get perspectives on feasibility of the PtDA in populations at different places in their illness trajectory. We plan to recruit 120 patients (**Figure 1**).

Hundreds of patients each year who meet our eligibility criteria are served in each setting, so we will have no difficulty recruiting 20-25 patients from each site/setting.

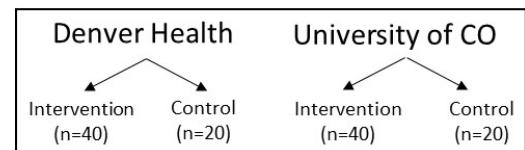


Figure 1. Recruitment

Recruitment: Patients will be identified differently in each setting:

- **In the outpatient setting,** 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. Reasons for non-approach will be recorded. If eligible and appropriate, a research team member will approach the patient and introduce the study following their clinical encounter.
- **In the inpatient settings,** the study team will speak with the palliative care teams twice a week to identify eligible patients who are currently being followed by the consult service. Then, a member of the study team will contact the attending physician of record for the patient to determine if he or she has concerns with the patient being approached regarding enrollment in the study. If eligible and appropriate, a research team member will approach the patient and introduce the study.

Research Methods: This will be a patient-level trial randomized in a 2:1 intervention: control (see figure 1 above).

- **Control - No PtDA:** Patients assigned to the control group will receive usual care. On the palliative care service, this typically includes a team with a physician, an advanced practice nurse, and occasionally other team member including a chaplain or a social worker. This consultation typically includes a discussion of advanced directives, symptoms, and prognosis. In the primary care settings, this is more variable and is a function of the primary care physician's practice and the patient's clinical situation.

- **Intervention - PtDA:** In addition to usual care, patients assigned to the intervention group will also be asked to view the hospice-PtDA. In the inpatient setting, the PtDA can be utilized anytime in the course of their hospitalization (all hospital rooms have a DVD player for the video). This could be before, during, or after the palliative care team consultation. In the outpatient setting, the patient will receive the PtDA after a clinic visit and will be allowed to take it home. In both settings, we have chosen a model with the PtDA delivery facilitated by research staff. The staff will NOT sit with patients while they watch the PtDA, as to allow patients to declare their desired use without study staff influence.

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 them 1 week later will be recorded (for outpatients, this will likely be at home by phone, for inpatients, this will likely be in the hospital.) Then the baseline surveys will be administered again by phone. 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 Hospice Knowledge Test, Decisional Conflict Scale, Decision Self-efficacy scale, SPMSQ, HADSA, PHQ-9 and demographics.
- **1 week Follow-up call (intervention only)-** Participants will be asked to complete the Hospice Knowledge Test, Decisional Conflict scale, Decision Self-efficacy scale and brief qualitative survey.
- **One Month Follow-up (control & intervention)-** At one month follow-up all participants will be asked to complete the Hospice Knowledge Test, Decisional Conflict scale and the Decision Self-efficacy scale.

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

The study team believes that 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. Audio-recordings of all qualitative will be kept on a secure server on the University network to which only the study to will have access. 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 the University's secure server will be used to store clinic audio files, interview audio files, transcripts and notes; 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. Data Analysis Plan:

Qualitative Data: The open-ended qualitative question will be analyzed using inductive and deductive content analysis.⁴⁰⁻⁴² 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. The quantitative acceptability and feasibility measures will be analyzed descriptively with means and interquartile ranges. Analysis of qualitative data will be a continuous process beginning with initial interviews and continuing throughout and beyond the data generation period. All interviews will be audio-recorded and professionally transcribed verbatim. A multidisciplinary team, led by Dr. Morris will begin the analysis process with repeated readings of the transcripts to achieve immersion. The team will then develop and apply a list of codes to the transcripts using an emergent rather than a priori approach, in order to emphasize interviewee perspectives and de-emphasize team member speculations.^{43,44} All coded data will be entered into Atlas.ti v 7.0 (GmbH, Berlin) for data management. Coded transcripts will be analyzed within and across sites and settings to develop the major themes or concepts that the participants reported. The trustworthiness of study results will be enhanced through triangulation of the data and an audit trail throughout the data collection and analysis process. Following the interpretation of the qualitative findings, we will compare and contrast the results with the findings from the quantitative surveys using methods consistent with the NIH guidelines on mixed methods research.⁴⁵

Quantitative Data: We will compare differences between intervention and control 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, self-efficacy and decisional conflict) and look for mediation and/or moderation effects of age, race, and gender; while controlling for potential confounders. There is no power calculation as this is a pilot trial designed to test feasibility and acceptability.

G. Summarize Knowledge to be Gained:

Through this R21 pilot project, we will answer several key questions regarding the utility of this hospice decision aid. Our innovative decision in which we intervene at three different time points (primary care, outpatient palliative care and inpatient palliative care) will provide valuable insights on when in the disease trajectory is appropriate to discuss hospice care with patients and loved ones. We will also gather data and when and how patients use these decision aids which will inform future research on implementation of decision aids and best formats (i.e. paper vs video) to present decision aids to patients. If this PtDA proves to be feasible and acceptable with positive preliminary efficacy, we will move forward with a multi-site pragmatic RO1.

H. References:

1. Cagle JG, Van Dussen DJ, Culler KL, et al. Knowledge about hospice: Exploring misconceptions, attitudes, and preferences for care. *American Journal of Hospice and Palliative Medicine®*. 2016;33(1):27-33.
2. NHPCO. National Hospice and Palliative Care Organization Facts and Figures 2015 Accessed 04/21/16. http://www.nhpco.org/sites/default/files/public/Statistics_Research/2015_Facts_Figures.pdf
3. Fischer S, Min SJ, Cervantes L, Kutner J. Where do you want to spend your last days of life? Low concordance between preferred and actual site of death among hospitalized adults. *Journal of Hospital Medicine*. 2013;8(4):178-183.
4. Bray Y, Goodyear-Smith F. Patient and family perceptions of hospice services: 'I knew they weren't like hospitals'. *Journal of primary health care*. 2013;5(3):206-213.
5. Candy B, Holman A, Leurent B, Davis S, Jones L. Hospice care delivered at home, in nursing homes and in dedicated hospice facilities: A systematic review of quantitative and qualitative evidence. Review. *Int J Nurs Stud*. Jan 2011;48(1):121-133. doi:10.1016/j.ijnurstu.2010.08.003
6. Rhodes RL, Mitchell SL, Miller SC, Connor SR, Teno JM. Bereaved family members' evaluation of hospice care: what factors influence overall satisfaction with services? *Journal of pain and symptom management*. 2008;35(4):365-371.
7. Bakitas M, Lyons KD, Hegel MT, et al. Effects of a palliative care intervention on clinical outcomes in patients with advanced cancer: the Project ENABLE II randomized controlled trial. *Jama*. Aug 19 2009;302(7):741-9. doi:10.1001/jama.2009.1198

8. Cassel JB, Webb-Wright J, Holmes J, Lyckholm L, Smith TJ. Clinical and financial impact of a palliative care program at a small rural hospital. *J Palliat Med*. Nov 2010;13(11):1339-43. doi:10.1089/jpm.2010.0155
9. Cohen SR, Mount BM, Strobel MG, Bui F. The McGill Quality of Life Questionnaire: a measure of quality of life appropriate for people with advanced disease. A preliminary study of validity and acceptability. *Palliat Med*. Jul 1995;9(3):207-19.
10. Connor. US hospice benefits. *Journal of Pain and Symptom Management*. 2009;38(1):105-109.
11. US Census Bureau Quick Facts. <http://quickfacts.census.gov/qfd/states/00000.html>
12. Johnson KS, Kuchibhatla M, Payne R, Tulsky JA. Race and Residence: Intercounty Variation in Black-White Differences in Hospice Use. Article. *J Pain Symptom Manage*. Nov 2013;46(5):681-690. doi:10.1016/j.jpainsymman.2012.12.006
13. O'Connor AM, Stacey D, Entwistle V, et al. Decision aids for people facing health treatment or screening decisions [Systematic Review]. *Cochrane Database Syst Rev*. 2007;(4)Not in File.
14. Chapter 11: Hospice services: Assessing payment adequacy and updating payments 299-322 (2016).
15. Tiedje K, Shippee ND, Johnson AM, et al. 'They leave at least believing they had a part in the discussion': Understanding decision aid use and patient-clinician decision-making through qualitative research. *Patient Education and Counseling*. 10// 2013;93(1):86-94. doi:<http://dx.doi.org/10.1016/j.pec.2013.03.013>
16. Torres L, Lindstrom K, Hannah L, Webb FJ. Exploring Barriers Among Primary Care Providers in Referring Patients to Hospice. *Journal of Hospice & Palliative Nursing*. 2016;18(2):167-172.
17. Vig EK, Starks H, Taylor JS, Hopley EK, Fryer-Edwards K. Why don't patients enroll in hospice? Can we do anything about it? *Journal of general internal medicine*. 2010;25(10):1009-1019.
18. Quinones-Gonzalez S. BRIDGING THE COMMUNICATION GAP IN HOSPICE AND PALLIATIVE CARE FOR HISPANICS AND LATINOS. Article. *Omega-Journal of Death and Dying*. 2013;67(1-2):193-200. doi:10.2190/OM.67.1-2.w
19. Reese DJ, Ahern RE, Nair S, O'Faire JD, Warren C. Hospice access and use by African Americans: addressing cultural and institutional barriers through participatory action research. *Social work*. Nov 1999;44(6):549-59.
20. Rhodes RL, Teno JM, Welch LC. Access to hospice for African Americans: Are they informed about the option of hospice? Article. *Journal of Palliative Medicine*. Apr 2006;9(2):268-272. doi:10.1089/jpm.2006.9.268
21. Kabel A, Mazzier M, Russo J, Joy S. Health Literacy Challenges Among Older Adult Orthopaedic Rehabilitation Patients. *International Journal of Health Sciences and Research (IJHSR)*. 2015;5(7):301-308.
22. Kindig DA, Panzer AM, Nielsen-Bohlman L. *Health Literacy:: A Prescription to End Confusion*. National Academies Press; 2004.
23. Speros CI. More than words: Promoting health literacy in older adults. *OJIN: The Online Journal of Issues in Nursing*. 2009;14(3)
24. Ramey SJ, Chin SH. Disparity in Hospice Utilization by African American Patients With Cancer. Article. *American Journal of Hospice & Palliative Medicine*. Aug 2012;29(5):346-354. doi:10.1177/1049909111423804
25. Briere R. Institute of Medicine: Crossing the quality chasm. *Washington, DC*. 2001;
26. Charles C, Gafni A, Whelan T. Shared decision-making in the medical encounter: what does it mean?(or it takes at least two to tango). *Social science & medicine*. 1997;44(5):681-692.
27. Jones J, Nowels C, Kutner JS, Matlock DD. Shared decision making and the use of a patient decision aid in advanced serious illness: provider and patient perspectives. *Health Expectations*. 2014;
28. Elwyn G, Frosch D, Volandes AE, Edwards A, Montori VM. Investing in deliberation: a definition and classification of decision support interventions for people facing difficult health decisions. *Medical Decision Making*. 2010;30(6):701-711.

29. Elwyn G, Laitner S, Coulter A, Walker E, Watson P, Thomson R. Implementing shared decision making in the NHS. *BMJ*. 2010-10-14 23:09:55 2010;341doi:10.1136/bmj.c5146

30. Stacey D, Legare F, Col NF, et al. Decision aids for people facing health treatment or screening decisions. Review. *Cochrane Database of Systematic Reviews*. 2014;(1):335. Cd001431. doi:10.1002/14651858.CD001431.pub4

31. Jibaja-Weiss ML, Volk RJ, Granchi TS, et al. Entertainment education for breast cancer surgery decisions: A randomized trial among patients with low health literacy. Article. *Patient Education and Counseling*. Jul 2011;84(1):41-48. doi:10.1016/j.pec.2010.06.009

32. Kreuter MW, Holmes K, Alcaraz K, et al. Comparing narrative and informational videos to increase mammography in low-income African American women. Article. *Patient Education and Counseling*. Dec 2010;81:S6-S14. doi:10.1016/j.pec.2010.09.008

33. Volk RJ, Jibaja-Weiss ML, Hawley ST, et al. Entertainment education for prostate cancer screening: A randomized trial among primary care patients with low health literacy. Article. *Patient Education and Counseling*. Dec 2008;73(3):482-489. doi:10.1016/j.pec.2008.07.033

34. O'Connor A, Llewellyn-Thomas H, Stacey D. IPDAS Collaboration background document. *Collaboration IPDAS, editor*. 2005:54.

35. Finnigan-Fox G, Matlock DD, Tate CE, Knoepke CE, Allen LA. Hospice, She Yelped: Examining the Quantity and Quality of Decision Support Available to Patient and Families Considering Hospice. *J Pain Symptom Manage*. 2017;54(6):916-921. e1.

36. Barry MJ, Fowler FJ, Jr., Mulley AG, Jr., Henderson JV, Jr., Wennberg JE. Patient reactions to a program designed to facilitate patient participation in treatment decisions for benign prostatic hyperplasia. *Med Care*. Aug 1995;33(8):771-82.

37. Matsuyama RK, Balliet W, Ingram K, Lyckholm LJ, Wilson-Genderson M, Smith TJ. Will patients want hospice or palliative care if they do not know what it is? *Journal of Hospice & Palliative Nursing*. 2011;13(1):41-46.

38. Webb NM, Tucker D. Young adults' opinions about hospice and home death. *Journal of palliative medicine*. 2009;12(4):337-342.

39. Johnson, Kuchibhatla M, Tulsky JA. Racial differences in self-reported exposure to information about hospice care. *J Palliat Med*. Oct 2009;12(10):921-7. doi:10.1089/jpm.2009.0066

40. Patton M. Qualitative Research & Evaluation Methods. 3rd ed2002. Thousand Oaks, CA: Sage Publications; 2002.

41. Thomas. A general inductive approach for analyzing qualitative evaluation data. *American journal of evaluation*. 2006;27(2):237-246.

42. Fereday J, Muir-Cochrane E. Demonstrating rigor using thematic analysis: A hybrid approach of inductive and deductive coding and theme development. *International journal of qualitative methods*. 2008;5(1):80-92.

43. Patton MQ. *Qualitative Evaluation and Research Methods*. Sage Publications; 1990.

44. Crabtree BF, Miller WL. *Doing Qualitative Research*. 2nd ed. Sage Publications, Inc.; 1999:424.

45. Creswell JW, Clark VLP. Designing and conducting mixed methods research. 2007;