PrPROGRAM PLAN PART I – CANDIDATE:
5.1.A. BACKGROUND AND EXPERIENCE

My passion for studying and reducing racial disparities in end-of-life (EOL) care is based on personal experience. As a child growing up in small town Arkansas, I appreciated the closeness of family. My mother served as a major influence in my life, and during my senior year of college she was diagnosed with breast cancer. During medical school, I made many trips to the emergency department with my mother for chemotherapy-related side effects that were construed by hospital staff as drug seeking visits. As her disease progressed, I often wondered why after repeated requests, she was not given adequate treatment for pain, and why nebulizer treatments were the only options offered for her shortness of breath. I also wondered why outside of our family and friends, her emotional and spiritual needs at the end of life were never considered, and why despite having a daughter in medical school, her prognosis was not disclosed to her or us until her last three weeks of life. My mother eventually died of breast cancer, and though we as a family did the best we could to comfort and support her at the end of life, the medical care she received was lacking. Because of these experiences, I have dedicated my clinical and research career to improving EOL care for African Americans (AA) and other underrepresented minorities and to working at institutions that serve these vulnerable populations.

I completed my internal medicine residency training at MetroHealth Medical Center, the safety-net hospital affiliated with Case Western Reserve University in Cleveland, Ohio. Following residency, I completed a clinical and health services research fellowship at Brown University. Through this fellowship, I received an MPH and completed courses in: statistics, epidemiology, survey design, and data analysis. There, I worked with my mentor Dr. Joan Teno, an internationally known palliative care researcher, and I examined access to hospice for AAs, racial disparities in perceptions of hospice quality, and factors that influence overall satisfaction with hospice services. This work resulted in three first authored publications in the *Journal of Palliative Medicine* and the *Journal of Pain and Symptom Management*. I subsequently received an NIA Research Supplement to Promote Diversity in Health-Related Research. This supplement allowed me to work with Dr. Teno on projects that examined the incidence of feeding tube insertion among nursing home residents with advanced dementia. This resulted in co-authorship on four additional papers. Overall, my work at Brown resulted in nine publications (including three first authored papers), and one first author editorial.

After three years at Brown, I was recruited to a geriatrics health services research faculty position at the University of Texas Southwestern Medical Center (UTSW). Moving to UTSW gave me the chance to join a strong and growing Division of Geriatrics that serves a large, urban population at Parkland Hospital--the sole safety net provider in Dallas County. It also began my relationship with my current mentor and General Internal Medicine Division Chief, Ethan Halm, MD, MPH, who is an experienced disparities and health services researcher who has successfully mentored junior faculty on 10 career awards. Since moving to UTSW, I completed a 2 year grant from the National Palliative Care Research Center (Mentor, Dr. Halm). With this award I used a national survey database and showed that family members of AA patients cared for in hospices with higher concentrations of AAs had more concerns about coordination of care and hospice quality compared to those with few AAs. This work was presented at the national AGS Annual Meeting, received a 2010 Merck New Investigator Award, and the manuscript was published in the *Journal of Palliative Medicine*. I also conducted a qualitative study with Dr. Simon Lee, a qualitative methods expert here at UTSW, interviewing palliative care providers about their perceptions on racial disparities in EOL care that was published in the *American Journal of Hospice and Palliative Medicine*.

I was selected to the highly competitive UTSW CTSA sponsored KL2 Clinical Research Scholar Program. This program has helped me broaden my research skills with masters-level courses in research design, multivariable regression, and health services research, and allowed me to participate in academic skills development workshops, and multidisciplinary works-in-progress meetings. I have begun collaborating with faculty here on projects that examine EOL care in the underrepresented. I've partnered with Dr. Elizabeth Paulk, Medical Director for Palliative Medicine here at UTSW, and analyzed data from the palliative care patient registry which recorded all inpatient and outpatient consults at Parkland over the past 11 years. The manuscript for this work was published in the *Journal of Health Care for the Poor and Underserved*. Dr. Paulk and I also mentored a former internal medicine chief resident (and current palliative care fellow) on a project that examines residents' perceptions of EOL care communication with seriously ill hospitalized patients, and this manuscript was published in the *American Journal of Hospice and Palliative Medicine*. In addition to

this collaboration, Dr. Paulk and I have also begun work with Dr. Herb Phalen, Associate Professor in the Department of Surgery at UTSW, on work that examines palliative care outcomes and decision-making for elderly trauma patients. This work has generated two *Journal of Palliative Medicine publications*. Dr Halm and I have completed creation of a pilot computer algorithm to identify hospitalized advanced cancer patients in need of EOL counseling. The manuscript describing this work was published in the *American Journal of Hospice and Palliative Medicine*. I recently mentored a palliative medicine fellow on a project examining end-of-life care utilization among HIV/AIDS patients in a safety net hospital system. The manuscript describing this study was recently accepted for publication in the *Journal of Pain and Symptom Management*.

I have become active in other research activities as well. I am now a part of the Population Science and Cancer Control Program at the Harold C. Simmons Cancer Center. This center is the region's only National Cancer Institute-designated cancer center, and the Population Science and the Cancer Control Program is led by my mentors, Drs. Halm and Skinner. I was fortunate to be selected to be a junior investigator member of the Palliative Care Research Cooperative Group (PCRC), and I was recently asked to be a member of the PCRC's Investigator Development Center advisory group. The PCRC, established in 2010 with foundational funding from the National Institute of Nursing Research, is led by Dr. Christine Ritchie and Dr. Jean Kutner (an off site mentor). Both investigators are leaders in the field of palliative care research.

5.1.B. CAREER GOALS

While my research efforts and scientific training to date have given me a strong foundation to build upon, most of my research has focused on secondary data analysis and *describing* disparities in end-of-life (EOL) care among patients and its determinants. I began to realize that the vast majority of studies that examine EOL care in African Americans deal with describing those disparities, and not *reducing* them. Consequently, my research goals and interests have led me to seek a new direction for my career. While I still hope to examine racial disparities in EOL care for cancer patients and their families, I hope to use these data to create culturally sensitive interventions to reduce these disparities. I want to design interventions that are multidisciplinary in scope, can be utilized in various settings and health care systems, and can be tailored for members of other underrepresented groups. In order to successfully progress from descriptive to action-oriented studies, I need additional advanced training and mentoring in: cancer control and disparities, theory-based behavioral intervention design, and the conduct of randomized controlled trials (RCTs). This grant application reflects the training, mentored research projects, and professional development activities designed to equip me with the additional knowledge, skills, experience, protected time, and track record needed to become an independently funded investigator focused on interventions to reduce racial disparities in EOL care.

This Cancer Control Career Development Award (CCCDA) application has been designed to help me realize my long-term goal of becoming a future leader in the fields of cancer control, palliative care and health disparities research in multiple ways. First, it will help me increase my exposure to the field of oncology and obtain the advanced training and mentored research experience I need in: supportive care for cancer patients, disparities and dissemination and implementation research, theory-based behavioral intervention design, and the conduct of randomized controlled trials of behavioral interventions. Second, it will provide me with the protected time and resources to conduct an integrated set of projects that will: 1) leverage the electronic medical record (EMR) to systematically identify patients with metastatic cancer in need of education about palliative and EOL care options and overcome provider barriers to underuse of these options for care ; 2) engage key stakeholders (oncologists and primary care providers) and obtain their feedback on my research; and 3) develop and pilot test a culturally targeted pilot intervention to overcome barriers and foster openness to EOL care discussions among African-Americans patients and families. Third, these projects will lay the groundwork and further enhance my research accomplishments so that I can successfully compete for an NIH R01 to conduct a fully powered RCT of a culturally tailored intervention to increase awareness and use of palliative care and hospice as options for minorities with advanced cancer.

Being able to accomplish the above scientific and career development goals, and transitioning to an independently funded investigator with the help of this career development award, is my five year plan. My goal for the following 5 to 10 years is to establish a portfolio of externally funded grants focused on reducing, if not eliminating, racial differences in palliative and EOL care among cancer patients and develop a national reputation as a leader working at the intersection of academic geriatrics, oncology, palliative care and disparities research. While there have been some promising demonstration projects, there have been few rigorous studies of interventions to reduce disparities in EOL care. There are many real barriers to overcome,

and describing the problem and documenting the obstacles is not enough. My long-term goal is to lead a multidisciplinary research group that develops and evaluates different culturally sensitive patient, provider, and system-level interventions to improve EOL care for African Americans and members of other underrepresented groups. I also seek to become a role model for other women and minorities interested in academic and investigative careers in medicine in general, and cancer control, geriatrics, and hospice/palliative care specifically. Receiving support from the ACS would be a tremendous opportunity for me, and if I am fortunate enough to receive this CCCDA grant, it will assist me in achieving these goals.

5.1.C. CAREER DEVELOPMENT AND TRAINING PLAN

CAREER DEVELOPMENT/TRAINING ACTIVITIES DURING PROPOSED AWARD

Training Aim 1: Cancer Control and Cancer Disparities. Drs. Halm and Skinner will oversee my training in this area which will consist of attending national workshops and local seminars, participating in webinars and clinical experiences, and conducting mentored research that is specific to cancer control and cancer disparities. I realize that I will need training in dissemination and implementation research. Because of this, I plan to apply for the NCI-supported Mentored Training for Dissemination & Implementation Research in Cancer (MT-DIRC) program to be held at Washington University in June 2016. This innovative week-long education program places strong emphasis on mentoring, applying competencies and curriculum specifically focused on cancer disparities, and working with a diverse set of partners. Each cohort of fellows will attend the summer institute twice and then will be paired with a faculty mentor in the field of dissemination and implementation science for ongoing mentoring. To allow me to learn from other cancer disparities research leaders, I will attend the American Association of Cancer Research (AACR) Science of Cancer Health Disparities in Racial/Ethnic Minorities Conference and the national Cancer Survivorship Symposium, a collaborative effort between leaders in the disciplines of primary care and oncology that represents innovative approaches to education and patient care. I will attend the American Society of Clinical Oncology (ASCO) annual meeting to obtain additional exposure to experts in the field of cancer research. I will also participate in the monthly NCI-sponsored Research to Reality Cyber Seminar series that addresses issues related to cancer control research. I will continue my involvement with the Population Science and Cancer Control Program at Simmons Comprehensive Cancer Center here at UTSW, and I will attend the weekly lectures and seminars that are presented there. I will also continue my involvement with the Cancer Survivorship Research Group here at UTSW, attend their monthly research meetings, and present my work as it relates to cancer control.

Training Aim 2: Behavioral Theory, Intervention Design and Development. Dr.Skinner will provide mentorship in these areas. I will also attend the NIH-sponsored Advanced Training Institute on Health Behavior Theory, a 7-day intensive learning course that offers in-depth instruction on the use, development, and evaluation of health behavior theory.

Training Aim 3: Conduct of RCTs of Behavioral and Palliative Care Interventions. Drs. Skinner and Halm have experience in these realms and will mentor me on my research in this area. I will also attend the NIH Summer Institute on the Design and Conduct of RCTs Involving Behavioral Interventions, an intensive program that teaches skills in the planning, design, and execution of randomized trials in this area.

Mentors. Ethan Halm, MD, MPH (Primary Mentor) is Professor and Chief of the Divisions of General Internal Medicine and Outcomes and Health Services Research. He has 15 years of experience mentoring faculty in outcomes, health services, disparities, applied medical informatics, shared decision making, and comparative effectiveness research. He is a Medical Editor for the non-profit, Informed Medical Decisions Foundation and developer of one of its decision aids. He has mentored trainees on 10 career development awards. I will have biweekly mentorship meetings with Dr. Halm to integrate formal learning with my ongoing studies.

Celette Sugg Skinner, PhD (Secondary Mentor) is Professor and Chief of the Division of Behavioral and Communication Sciences. She is an expert in developing, implementing and evaluating theory-based, patient-targeted behavioral interventions. She is also the Key Function Director of the CTSA Community Engagement core and Associate Director for Population Science and Cancer Control for the NCI-designated Simmons Cancer Center. Dr. Skinner has mentored >20 individuals in these types of projects who are now independent investigators. I will meet with Dr. Skinner monthly to discuss the application of the courses and workshops to my projects.

Advisory Committee. With the 2 mentors above, 2 other senior faculty with complementary methodological and content expertise will form my Advisory Committee that will meet every 6 months to track and guide my progress on the plan above.

Craig Rubin, MD is Professor and Division Chief of Geriatric Medicine. He is PI of the Reynolds Foundation funded Southwestern Aging and Geriatrics Education program, which provides geriatric training for medical students, residents, fellows, and faculty. He will provide general academic geriatrics career advancement advice. Elizabeth Paulk, MD is Professor of Medicine and Director of the Palliative Care Program at UTSW and Parkland Hospital. She is a site PI on several NCI-funded studies of disparities in cancer treatment at the EOL that have uncovered how religious coping and spiritual care needs and beliefs among cancer patients influence underuse of advanced directives, palliative care and hospice services. Dr. Paulk will provide content expertise, and palliative care leadership support for the proposed focus groups, and pilot development and implementation.

Evaluation Plan and Deliverables. The Advisory Committee will meet every 6 months for the duration of the project. Prior to each committee meeting, I will submit a written progress report on my training goals (seminars and workshops), research activities, and academic accomplishments (manuscripts, meeting abstracts, and grant submissions). The Committee will provide specific and directive feedback on my training, research progress, and career development activities and future plans. Based on their recommendations, I will prepare a written action plan that will then be resubmitted to the committee for their approval. Progress on this action plan will be reviewed in the following Advisory Committee meeting. I plan on submitting at least 5 peer-reviewed manuscripts from the CCCDA related projects for publication with an overall goal of 2-3 papers published per year over the course of this award. In Year 2, I will write and submit a R01 application for a fully-powered RCT of the pilot intervention I will develop in this award.

Other Research Progress, Career Development, and Scientific Meetings. I will present my work locally at the research meetings including the monthly Division of Outcomes and Health Services Research Works in Progress meetings and the Cancer Survivorship Research Group meetings. My career development will be supplemented by continued participation in the weekly Department of Clinical Sciences Works in Progress meetings and quarterly Clinical Scholars/CTSA KL2 research retreats. Each year, I will submit abstracts to and attend 3 national conferences a year such as the: American Geriatrics Society (AGS), American Academy of Hospice and Palliative Medicine (AAHPM), and ASCO meetings (depending on the year) to gain feedback from national leaders in these fields, and keep apprised of advances in these methodological and content areas.

This CCCDA award will enable me to continue to devote 70% of my time to advanced scientific training and mentored research. With the remainder of my time, I will stay active in inpatient (6 weeks/year) and outpatient (two ½ days/week) clinical work as a practicing geriatrician and hospice and palliative medicine physician at UTSW and Parkland. I will also continue to participate in teaching medical students, residents, and fellows. This will include regular participation and presentations at weekly Geriatrics Grand Rounds, monthly Journal Club, and monthly Fellows' Conferences, and Palliative Care's monthly Journal Club and Evidence Based Palliative Care Medicine Conference.

Career Development and Training Activities

	Career Development and Training		
	Aim 1: Cancer Control and Disparities	Aim 2: Behavioral Theory, Intervention Design	Aim 3: RCTs of Behavioral Interventions
Year 1			
Coursework & Workshops	MT-DIRC Institute & AACR Disparities Conference	NIH Institute on Behavioral RCTs	NA
Mentored Research	Halm	Skinner	Halm and Skinner
Year 2			
Coursework & Workshops	Cancer Survivorship Symposium	NIH Institute on Behavior Theory	NA
Mentored Research	Halm	Skinner	Halm and Skinner
Year 3			
Coursework & Workshops	NA	NA	
Mentored Research	Halm	Skinner	Halm and Skinner

5.1.D. CLINICAL AND TEACHING ACTIVITIES

Current Activities I am currently involved in several clinical and teaching activities that are related to cancer control. For instance, though I am a geriatrician, I am also a hospice and palliative medicine physician. I see patients in the Parkland Palliative Care Clinic, where I supervise medical students, residents and fellows. More than 80% of patients seen in the Parkland Clinic are cancer patients, and the palliative care providers work very closely with the medical oncologists there. I serve as one of the internal medicine ward attendings for the Eisenberg Service, a service that is staffed by Geriatric faculty who teach the principles of geriatrics, including pain management and end-of-life care. I am an Affiliated Ethics Program Faculty Member in the UTSW Program in Ethics in Science and Medicine and an Ethics Facilitator for the Academic Colleges Program here. Through these programs, I conduct didactic sessions with first and second year medical students as it relates to medical ethics. Topics include scholastic/research integrity, resource allocation, disclosure, and end-of-life care. I am the instructor for the geriatric and palliative care fellows' evidence-based medicine curriculum, and I teach them about basic research study design and methods. I have presented my research at Grand Rounds in the Division of Geriatric Medicine, Works in Progress meetings in the Division of Health Services and Outcomes Research, and Palliative Care Conference. I have also presented my research at the AGS and AAHPM annual meetings, and I have mentored trainees on research projects that relate to palliative care.
Additional Proposed Activities I plan to continue my involvement in teaching learners in the Palliative Care Clinic at Parkland Hospital, the Geriatric Care Clinic at UTSW, and during my assigned inpatient ward time. I have mentored internal medicine residents, geriatrics fellows, and palliative care fellows on palliative care projects that have led to publication, and I will continue to mentor learners who are interested in palliative care research. I will continue my work as an Ethics Facilitator for first and second year medical students, and continue to serve as instructor for the geriatric and palliative care fellows' course in evidence-based medicine. I will also present my research locally at the Cancer Survivorship Research Group monthly meeting and other research meetings and conferences listed above, and I will submit abstracts to and attend the ASCO annual Meeting. I will schedule monthly rotations with Dr. Desi Carozza, medical director of the University Hospital Palliative Care Clinic. This clinic is housed within the Simmons Comprehensive Cancer Center, and the majority of patient seen there have cancer as a primary diagnosis.

5.1.E. CANCER CONTROL PROJECT

SPECIFIC AIMS

Racial differences in health care are documented across the health care continuum,[1-7] and persist in aging[8-11] and end-of-life (EOL) care. African Americans (AA) and other underrepresented minorities often choose more aggressive therapies in the terminal stages of illness. Main reasons for these EOL disparities include: lack of knowledge of and misperceptions about palliative and hospice care, spiritual beliefs, and mistrust in the health care system.[12-27] Despite the presence of national hospice guidelines, interventions addressing these disparities have been limited and often not rigorously evaluated. Most interventions to promote EOL care were done in majority populations and focused predominantly on trying to change physician awareness of patient's pain, symptoms, and values or to change physician communication behavior. While these early studies made tremendous contributions to the study of EOL care and the needs of the terminally ill, the interventions associated with these studies did not reach their desired effectiveness.[28-33] We propose an innovative strategy that would focus specifically on previously identified physician and patient barriers to utilization of advance directives, palliative care, and hospice care among AA cancer patients. The goal of this patient-centered project is to increase the awareness of and willingness to discuss EOL care options among AAs with metastatic cancer. To overcome the dual challenges of physicians' difficulty with prognostication and reluctance to discuss EOL care, we will harness data in the electronic medical record (EMR) to automatically identify AA patients with metastatic breast, lung, and colorectal cancer who are eligible for counseling about palliative and EOL care options. To change AA patients' knowledge and attitudes toward palliative and EOL care options, and address issues of medical mistrust, we will design and pilot test a culturally sensitive, patient-targeted intervention that will combine multimedia materials and a culturally concordant lay health advisor (LHA) who will deliver tailored education and counseling. We have chosen a LHA delivery strategy because past studies have shown that they are best suited to address medical mistrust and perceived conflict between spiritual beliefs and health care decisions.[34-36] Our specific aims are the following:

Aim 1: Validate a computerized (e-EOL) algorithm using EMR data to identify patients in the outpatient setting with advanced breast, lung, and colorectal cancer who are appropriate for advance care planning, palliative and EOL care discussions (*to be referred to moving forward as EOL care options*).

Hypothesis 1: An IT-enabled electronic algorithm is currently being developed that will identify inpatients at Parkland Hospital who have advanced breast, lung, and colon cancer who would be most appropriate for counseling about EOL care treatment options. We plan to validate a similar algorithm for patients with metastatic (Stage III/IV) breast, lung, colon, prostate, or other advanced cancer in the outpatient setting so that it will have sufficient sensitivity, specificity, and positive predictive value.

Aim 2: Refine a culturally sensitive intervention to increase knowledge about, reduce barriers and promote intention to discuss EOL care options among AA advanced breast, lung, and colon cancer in the outpatient setting.

Hypothesis 2: A combination of DVD modules describing facts about EOL care and testimonials by AA patients, caregivers, physicians, and religious leaders, together with scripted counseling by a trained, culturally concordant lay health advisor will effectively improve knowledge and address barriers to receipt of EOL care (perceived conflict with spiritual beliefs and medical mistrust). These materials will be vetted by a group of outpatient primary care and oncology providers at Parkland Hospital.

Aim 3: Test the feasibility and acceptability of a theory-based, multifaceted pilot program that will identify AA patients with metastatic breast, lung, colon, and prostate cancer via the outpatient e-EOL algorithm and then test the preliminary efficacy of a culturally sensitive, patient-centered intervention to change knowledge and barriers about and intent to discuss EOL care options by conducting a small, pilot randomized controlled trial (RCT).

Hypothesis 3: An EMR-enabled, culturally sensitive, outpatient-based intervention targeting knowledge, beliefs, and behavioral intentions will be feasible and acceptable to AA patients and will result in increased willingness to discuss EOL care options versus a usual care control group. Patients with earlier stage cancers (I and II) may be chosen for the intervention based on co-morbidities, functional status, or other factors that we deem appropriate.

Aim 1 uses medical informatics and chart review methods to develop an EMR-enabled algorithm to identify patients with advanced cancer who are appropriate for EOL care option counseling in the outpatient setting. In Aim 2 we will continue our stakeholder engagement by conducting focus groups with oncologists and primary care providers to introduce our study and obtain feedback on, and further refine (if needed) the newly created DVD modules and LHA counseling scripts that communicate messages about EOL care options and overcome key barriers. Aim 3 combines the refined elements of Aims 1 and 2 into an integrated intervention and pilots it to assess feasibility, acceptability, and preliminary efficacy of the intervention in the form of a small, pilot RCT. This will provide the groundwork for a future R01 application for a fully powered RCT.

RESEARCH STRATEGY

B. Significance

African Americans (AA) and members of other underrepresented groups choose more aggressive therapies at the end of life (EOL), participate less often in advance care planning, and underutilize hospice services compared to whites.[12-27,37-47] This disparity is striking among AAs who make up 12.6% of the U.S. population,[48] but account for only 8.4% of hospice patients nationally.[49] Many patient, provider and system-level factors likely contribute to these disparities.

Some patients do not believe they are terminally ill, and are not informed about hospice as an option for EOL care.[45,46,50] Other patients have an inherent mistrust in or dissatisfaction with the health care system and its providers. Studies of AA cancer patients and bereaved family members of hospice patients reported higher levels of concerns about coordination of care, access to care, psychosocial care, and health information.[51,52] Further, some AA cancer patients have lower trust in physicians because they perceive them to be less supportive, less partnering, and less informative.[53] Low trust in medical providers has also been identified among family members and appears to contribute to high levels of caregiver burden among surrogate decision makers.[54] Bereaved family members of AA decedents who died within the hospital, nursing home, and home were more likely to have concerns about their care and were less likely to favorably rate the care their loved one received.[55] **Identifying and targeting these specific patient barriers of knowledge, conflict with spiritual beliefs, and mistrust may increase awareness of and intention to discuss EOL care options.**

Provider-level factors also contribute to disparities in EOL care. Physicians often have difficulty in accurately determining prognosis in disease states with varying trajectories, and have some discomfort in initiating EOL discussions.[56] Studies have shown that physicians' abilities to determine the prognosis of the

terminally ill are sometimes inaccurate and systematically optimistic.[57] Interestingly, cancer patients referred to hospice by physicians who are able to foresee their survival accurately are more likely to survive longer than patients referred by physicians who are not able to predict their survival accurately.[58] Disconnects in patient and provider goals and suboptimal shared decision-making and communication may also play a role. The SUPPORT study, describing care provided to seriously ill hospitalized patients, revealed that: physicians often misunderstood patients' resuscitation preferences, family members were dissatisfied with communication and decision-making, and patient race influenced the likelihood of medical intervention and preferences of the seriously ill.[28-33] Suboptimal cultural sensitivity in communications between providers and AA patients hinder shared decision-making and delivery of high quality, patient-centered care. Thus, new strategies for overcoming these persistent barriers and facilitating effective, culturally sensitive discussions about goals of care for seriously ill patients and their families are needed. A "culturally sensitive intervention" is defined as one that is respectful of and responsive to the cultural and linguistic needs of all individuals,[59] and though several prior studies describe racial disparities in EOL care, there have been few interventions addressing patients' barriers related to AA culture.

C. Innovation

Health information technology (HIT) is rapidly evolving, and adoption is increasing in efforts to improve access to, efficiency of and effectiveness of care.[60,61] More and more health care systems are using HIT to not only assist with basic patient care, but also to improve decision support, foster quality improvement, and improve code status documentation.[62,63] Given physicians' difficulties in identifying patients near the end of life, and the role poor prognostication plays in disparities in palliative care and hospice use, this proposal to harness data in the EMR to create a computerized e-EOL algorithm represents a next generation application of HIT to create intelligent decision support to assist physicians in identifying advanced cancer patients who would benefit from a discussion about EOL care options. This novel computerized algorithm will not only systematically identify all eligible patients; it will do so in real time, when the intelligence is actionable. While EMR-based screening algorithms have been effective in many areas, no study to our knowledge has applied these tools to identifying cancer patients at the end of life. The multi-component intervention we will develop and test has several innovative features including: creation of novel, culturally tailored messages and DVD modules on concerns about spirituality and medical mistrust to overcome key barriers to EOL use among AA patients, 2) use of a non-medical, culturally concordant lay health advisor (LHA) to bolster trust and facilitate shared decision-making about EOL options, 3) adaptation of an existing EOL education DVD designed for use in majority populations to AA patients, and 4) HIT implementation of the e-EOL screening algorithm to identify potentially eligible cancer patients in real-time. Collectively, this work will provide the foundation for an R01 application to conduct a fully powered randomized controlled trial (RCT) to evaluate the effectiveness of this patient-centered, multi-component intervention versus usual care.

D. APPROACH

D.1 PRELIMINARY STUDIES

Several pilot studies provide a solid foundation for the proposed research. To establish the feasibility of using EMR data to identify patients with advanced cancer, we have developed a preliminary electronic (e-EOL) algorithm adapting applied medical informatics approaches that Dr. Halm and others at UTSW have successfully used in prior studies.[64] To date, a prototype *inpatient* e-EOL algorithm has been piloted for patients with advanced lung and breast cancer based on the ICD-9 codes displayed in Table 1. A total of 369 breast and lung cancer patients were hospitalized at Parkland Hospital from 2009 – 2010. Of those, 14% were flagged by the algorithm as meeting national guideline criteria as most appropriate for an in-depth discussion about EOL care options. Of those identified, 39% had breast cancer and 58% had lung cancer. The e-EOL algorithm identified 53 (14%) patients that met assigned criteria (presence of metastatic disease and albumin < 2.5 g/dl), while physician chart abstractors felt that 64% of patients met criteria indicating a need for in-depth discussion about EOL care options. Over half (55%) of those identified by the e-EOL algorithm were African American (19% were white, and 25% Hispanic). When compared to physician chart review (the criterion gold standard), the sensitivity, specificity, and positive predictive value (PPV) of the pilot algorithm were as follows: 21% (95% CI: 16% to 26%), 96% (95% CI: 93% to 100%), and 91% (95% CI: 83% to 98%) respectively. Thus, this preliminary e-EOL algorithm had very good specificity and PPV and identified many AA inpatients with advanced breast and lung cancer. Additionally, construct validity in the form of survival analysis revealed that patients meeting e-EOL algorithm criteria ("test positive" cases) had worsened survival compared to those

who did not ("test negative" cases) The six month survival rate for test-positive cases versus test-negative cases was 46% (95% CI: 33%-58%) versus 78% (95% CI: 73%-82%) One-year survival for test-positive versus test-negative cases was 32% (95% CI: 20%-45%) versus 72% (95% CI: 67%-76%).[65] More work is being done to improve the sensitivity of the algorithm so we can detect more of the target population. Additionally, UTSW and all of its affiliated hospitals and clinics transitioned to ICD-10 on October 1, 2015, and the algorithm is being replicated with the appropriate ICD-10 codes. Data from the Parkland Tumor Registry corroborates the burden of Stage IV cancer among AAs at Parkland. From 2009-2011 there were 75 patients with stage IV breast cancer, 254 with Stage IV lung cancer, and 135 with Stage IV colorectal cancer. Most advanced cancer patients were AA (57% for breast, 61% for lung, and 55% colorectal cancers, and ranged in age from 30 to 80 years.

We analyzed 11 years of data from the Parkland Hospital palliative care consult service which offers some promising news. From November 1999 to December 2010, 5,267 Parkland patients were seen by the palliative care program, of which, 41% were AA, 31% white, and 24% Hispanic.[66] Once a patient was referred to the palliative care service, there were no racial disparities in referral to and acceptance of hospice services. We attribute this success to a strong multidisciplinary team approach which includes a chaplain, social worker, nurse practitioner, nurse, and four physicians experienced in working with minority patients and their families. This underscores that in our setting the 'quality chasm' in EOL care that needs to be overcome resides predominantly 'upstream', among patients with advanced cancer who have not yet had an informed discussion about their full treatment options including palliative care.

To examine barriers to completion of advance directives, utilization of palliative care, and hospice enrollment among African Americans, we conducted qualitative interviews with African American providers and recipients of hospice or palliative medicine and African American members of the clergy. Semi-structured, videotaped interviews were conducted with 8 African Americans who have had personal and/or professional experience with EOL care. Interviewees included an African American hospice medical director, an African American palliative care nurse practitioner, three African American ministers (one of whom also had experience as a hospital chaplain), one African American hospice patient, and two African American caregivers of patients who had received or were currently receiving hospice care. Several themes regarding barriers to EOL care were confirmed in conducting these interviews, including perceived conflict with spirituality, mistrust in the medical system, and overall lack of knowledge about EOL care options or misunderstanding of the various options.[67] Segments of these videotaped interviews that addressed these specific and previously identified barriers to EOL care among African Americans were selected and combined with culturally sensitive imagery, voice over narration, and text to create a DVD tentatively titled *Planning for the Care You Want*. Palliative care and geriatric medicine faculty and staff who care for patients at Parkland Hospital have vetted the DVD. Additionally, we conducted two focus groups with 16 community-dwelling African Americans who are patients and/or caregivers of patients who receive their care at Parkland Hospital, Clements University Hospital, and their affiliated clinics. These focus group participants were also community religious leaders and members of the UTSW PCOR Community Advisory Panel; they provided feedback on the newly created DVD to determine if the DVD segments conveyed messaging about EOL care options as intended. All groups provided feedback on messaging, duration, and imagery of the DVD that has been used in the editing process.[68]

Taken together, this preliminary work demonstrates the: 1) large numbers of AA patients with advanced cancer at Parkland with substantial unmet needs for counseling about EOL care options, 2) preliminary feasibility of our e-EOL strategy to systematically identify such patients, 3) adequate "downstream" capacity and skill of our existing palliative care service to care for such patients in a culturally-sensitive way once a palliative care consult is formally made, and 3) acceptability of a culturally sensitive DVD that addresses specific barriers to AA EOL care among AA patients, AA caregivers, palliative care providers, and geriatric medicine providers,

D.2. Research Design and Methods

D.2.1. Overview of Research Approach

We propose a three-phase project to improve awareness of use of advance directives, palliative care and hospice services among patients with metastatic cancer by creating and evaluating a multifaceted culturally sensitive intervention that targets specific previously identified barriers to EOL care for AAs, including: knowledge, attitudes, and awareness of options for care, conflict between patients' spiritual beliefs,

and the general hospice and palliative medicine philosophy of care, and medical mistrust. Aim 1 will refine and validate the e-EOL computerized algorithm to identify persons with stage III and IV breast, lung, colorectal, and prostate cancer who are appropriate candidates for discussions about advance care planning, palliative care, and hospice in the outpatient setting. The work in Aim 1 seeks to overcome the upstream barrier that physicians often have difficulty with prognostication and are reluctant to discuss prognosis and EOL care options with patients. Aim 2 will involve continued stakeholder engagement and the conduct of focus groups with oncologists and primary care providers at Parkland Hospital and it affiliated clinics to determine how to make the intervention feasible and acceptable to patients, caregivers, and providers. We also will obtain feedback on our newly developed video and written educational materials that communicate key messages about EOL care options and overcome common barriers. In Aim 3, we will test the preliminary feasibility, acceptability, and efficacy of the intervention that uses the e-EOL algorithm to identify AA patients with advanced cancer who are eligible for care discussions and then deploy a culturally concordant behavior change intervention that combines a Lay Health Advisor (LHA) and video and written materials. Of note, patients with earlier stage cancers (I and II) may be chosen for the intervention based on co-morbidities, functional status, or other factors that we deem appropriate. Use of an LHA will help overcome the providers' reluctance or lack of time to discuss EOL care issues and mitigate medical mistrust. The three linked studies provide the necessary sequence of research projects and multidisciplinary learning experiences needed to accomplish the PI's scientific and training goals. It will also lay the groundwork for a fully powered RCT to test the efficacy of a multifaceted EOL care counseling intervention vs. usual care.

D.2.2. Conceptual Framework: Figure 1 shows the conceptual model that underpins our design and methods. It is informed by the existing empiric literature, health behavior and implementation science theories, and our prior related work. Our goal is to change patients' stage of intent to discuss EOL care options (primary outcome). We grouped the key factors influencing this outcome by the PRECEDE-PROCEED model.[69]

Figure 1. Conceptual Framework of Intervention Components and Key Factors Influencing Primary Study Outcome

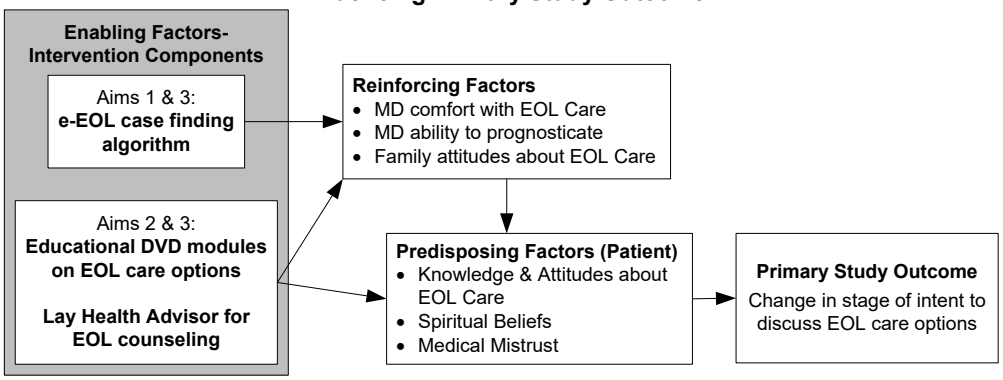

Table 1. *Revised* e-EOL Algorithm

Pilot Inpatient Algorithm	**ICD-10 Codes**	**Additional Variables**
Breast Cancer	C50.011-C50.929; D05.80-D05.92	
Lung Cancer	C34.10–C34.92; D02.20-D02.22	Albumin < 2.5 gm/dl
Metastases	C77.0 – C79.9	
Outpatient Algorithm	**ICD-10 Codes**	**Documentation of**
Breast Cancer	C50.011-C50.929; D05.80-D05.92	ED/Hospital Visits
Lung Cancer	C34.10 – C34.92; D02.20-D02.22	Medications for cancer-related Sx
Colon Cancer	C18.2-C18.9; C19	Radiation Tx Chemotherapy
Metastases	C77.0 – C79.9	

Predisposing factors are patient-level knowledge and attitudes about EOL care, spiritual beliefs, and medical mistrust that are modifiable and are antecedents to our primary study outcome. Reinforcing factors are providers' comfort with EOL care and ability to prognosticate, and patient and caregivers' attitudes toward EOL care. These factors: 1) influence the predisposing factors and 2) provide incentive/opportunity for the primary study outcome. Enabling factors are the intervention resources (e-EOL algorithm, educational DVD modules, and LHA) to facilitate health behavior change. Our intervention addresses the negative attitudes listed under predisposing factors. The DVD segments will role model optimal shared decision-making to help patients build skills so to engage in shared decision-making when communicating about their own EOL care options. The primary behavior change outcome is the intent to discuss EOL care options based on the

"Stages of Change" Transtheoretical Model.[70] The intervention seeks to promote "stage migration" towards a higher level of willingness to discuss EOL care options (See D.5.3. for definitions).

D.2.3.Study Setting Parkland Health and Hospital System (Parkland) is a population-based, integrated delivery system that includes: a 900 bed hospital, 12 community-based primary care centers (COPCs), and subspecialty clinics (including onsite palliative care and oncology clinics), which all use the comprehensive, Epic EMR.[71] Parkland is the sole safety net provider in Dallas County, so it is responsible for the care of over one million uninsured individuals and provides $532 million of uncompensated care annually. It is also the largest teaching site for UTSW medical students, residents, and fellows. Parkland is an ideal setting for disparities research given the large, diverse racial and ethnic populations it serves. Overall, 41% of Parkland patients are AA, 32% Hispanics, 20% White, and 7% other race/ethnicities. All inpatient and outpatient provider notes, diagnoses, orders, medications, laboratory, imaging, and pathology results, referrals, sociodemographics, insurance, and health care utilization information is recorded in the EMR.

D.3. Details of Research Design and Methods for Aim 1: Refine an e-EOL algorithm to identify patients with metastatic cancer in the outpatient setting. Aim 1 will expand and validate the e-EOL algorithm to identify patients with Stage III and IV cancer who are appropriate candidates for discussions about EOL care options in the *outpatient* setting. The e-EOL algorithm will assist physicians with determining prognosis more accurately and will provide a mechanism for systematically identifying candidates for a subsequent EOL care counseling intervention outlined in Aim 3.

National guidelines that aid health care providers in determining a patient's eligibility for hospice and EOL option discussions are available,[72] and several national organizations recommend guidelines for the institution of palliative care.[73-75] The *inpatient* e-EOL algorithm operationalizes the application of hospice guidelines and clinical experience by 'flagging' those individuals with advanced cancer meeting guideline criteria for hospice eligibility; however, the *outpatient* e-EOL algorithm will target patients who are earlier in the cancer disease trajectory and would benefit from early palliative care consultation. The preliminary *inpatient* e-EOL algorithm was based on simple ICD-9 codes from the index admission (cancer, metastasis) and albumin measurements; however, UTSW, Parkland and all of their affiliated clinics adopted ICD-10 on October 1, 2015, and the algorithm is now being tested using these updated codes. The *outpatient* algorithm will harness a broadened range of factors contained in discreet fields from the EMR including: patient characteristics (age, race), initial determination of metastatic cancer diagnosis (stage III or IV disease), medications to treat pain and other cancer-related symptoms (opioids/NSAIDs/steroids, anti-emetics, appetite stimulants, antidepressants), processes of care (chemotherapy, radiation therapy), as well as number of ED visits, hospitalizations and ICU stays related to the primary cancer diagnosis. *Albumin < 2.5 mg/dl will not be used in this algorithm as it is a marker of poor prognosis, and we hope to detect patients with metastatic disease earlier in their disease trajectory.* We will explore the impact of different types of Boolean logic combining these factors. We will also broaden our net to include ICD-10 codes in diagnosis, problem lists, and encounter fields of all prior inpatient and outpatient encounters in the past 12 months. Our goal is to increase have sensitivity of the inpatient algorithm of 40-50% and specificity of >90%.

Our approach to validating the e-EOL algorithm in the outpatient setting is based on prior work by Dr. Halm and other UTSW investigators which has extracted a complicated combination of EMR data elements to identify patients hospitalized with heart failure,[76] AIDS,[64] and cirrhosis in the first 2 days of admission. For example, the heart failure algorithm used data on admitting diagnoses and co-morbidities (from index and prior inpatient and outpatient encounters), labs, vital signs, and notes (chief complaint symptoms and imaging results.[76]

Most research in this area relies on administrative data and diagnoses to identify cases ***after the fact***. For the e-EOL algorithm to be actionable, it needs to flag a patient *early in their advanced disease stage* so that counseling about EOL care options (and a potential palliative care consultation) can occur. A recently completed study by researchers here proves our ability to automatically identify cases in real time using an EMR-based algorithm, and successfully deployed an intervention that reduced the risk of readmission.[77]
As we did in our pilot project, three board certified internal medicine physicians and experts in hospice, palliative medicine and/or geriatrics will independently perform implicit and explicit chart reviews of each "test positive" and "test negative" case to make the criterion standard judgment about whether the patient meets criteria for hospice eligibility based on the national guidelines and clinical experience. All reviewers will undergo training on the process and criteria to be judged, and practice reviews on selected advanced cancer "positive"

and "negative" cases to help them develop a shared understanding. Once the training is completed, two reviewers will independently review the EMR for each case and render a final judgment about whether the patient: 1) has Stage III/IV breast, lung, colon, prostate or other advanced cancer, and 2) meets guideline criteria for being eligible for an EOL care options discussion. Initial agreement and Kappa scores will be computed, and areas of disagreement will be resolved by discussion. The third reviewer will be used if consensus cannot be reached. Sensitivity, specificity, and positive/negative predictive values for the algorithm will be calculated. The e-EOL algorithm results define ''test positivity'' and physician chart review as the criterion standard (denominator). The e-EOL algorithm will be iteratively refined to improve its test operating characteristics. For the purposes of this project, assuring adequate specificity (80-90%) will be more important than optimal sensitivity (40-50%).

D.4. Details of Research Design and Methods for Aim 2: Refine components of a culturally sensitive intervention to improve knowledge of and intent to consider EOL care options.

Use of decision aids, educational videos, and LHAs has been shown to be effective in improving medical knowledge and shared decision making and reducing racial disparities for several clinical conditions.[78-83] Though there have been few applications of these promising approaches to palliative and EOL care, recent use of decision aids in improving knowledge about the goals of care for persons with advanced dementia, have shown promise.[82] Aim 2 will iteratively refine the intervention messages delivered through a combination of novel DVD segments that we have developed, print materials, and guided discussions by a culturally concordant LHA. Through qualitative methods, including cognitive interviews, the team will test the language, framing, and communication strategies for conveying intervention messages and obtain feedback from primary care and oncology providers at Parkland Hospital to verify the appropriateness of these messages as intended by investigators. Participants for cognitive interviews will be recruited from the Community Research Registry database from the Health Topics Survey (STU# 112010-061, PI: Celette Sugg Skinner, PhD) maintained by the Department of Clinical Sciences and be issued a $15 gift card for participation.

D.4.1. Continued Stakeholder Engagement and Eligibility Criteria for Oncology and Primary Care Provider Focus Group Participants: The PI and research assistant will work to identify primary care physicians and oncologists who are eligible to participate in our focus groups. Eligible participants will: 1) identify as oncologists who specialize in treatment of breast, lung, prostate, and colorectal cancer, or 2) identify as primary care providers (Internal Medicine or Family Medicine), and 3) be employed at Parkland Hospital or one of its 12 COPCs. We aim to conduct two focus groups with 6-10 participants per group. Both focus groups will be audiotaped and transcribed, and will last 60 to 90 minutes. The PI has developed the focus group moderator guide that was used to obtain feedback on these novel DVD segments during focus groups conducted with geriatric and hospice and palliative medicine providers, and she has successfully completed a similar project the results of which were published in the *American Journal of Hospice and Palliative Medicine*.[84] The goal will be to engage these important stakeholders and obtain their feedback with regard to the language, framing, and strategies they use in their discussions with AA patients and caregivers both to convey key health messages about EOL care options, as well as to overcome common stated or unstated reasons for resistance (including perceived conflict with religious beliefs and medical mistrust). In addition, we will get their reactions to the newly developed DVD and print educational materials about EOL options. All sessions will be audiotaped and transcribed.

D.4.4. Analysis of Provider Focus Group Data: Two members of the study team will analyze the content of the focus groups using standard qualitative methods approaches.[85] They will perform in-depth, line-by-line coding of all the patient and provider transcripts using qualitative analysis software. A codebook of themes will be developed through an iterative process of coding, discussion, and recoding. Coding decisions will be compared, new themes identified, and areas of disagreement resolved through further discussion with the research team. Challenges and discrepancies will be discussed and resolved by the investigative team.

D.4.5. Formative Approach to Building and Testing Intervention Components: Based on our analysis of the previously conducted AA patient, caregiver, minister and hospice and palliative medicine provider interviews, we have created a matrix identifying the theory-based concepts to be addressed (e.g. spirituality), the key communication messages (e.g. palliative care is not against God's will), and the strategy for communicating it (e.g., video, counseling) [See Table 2]. We have developed a novel DVD that includes the key communication strategies described below.

Table 2. Theoretical Constructs, Targeted and Associated Communication Messages, and

Theoretical Construct	Communication Message	Intervention Strategy
Lack of Knowledge About EOL Care Alternatives	1) Palliative and curative care can be complementary. 2) Hospice and palliative care can help with pain, symptoms	1)Information session led by an AA LHA that includes: 2) DVD segments explaining EOL care options, including advance care planning, palliative care, and hospice care.
Conflict with Spiritual Beliefs	1) Advance care planning is not "giving up" or "losing faith." 2) Choosing palliative care /hospice is not going against God's plan.	1) Information session led by an AA LHA that includes: 2) DVD segments that address this conflict. (i.e., a testimonial from an AA clergy person with personal and/or professional experience in hospice/palliative medicine)
Mistrust in the Health Care System/Providers	1) Many AA patients have had positive experiences with hospice and palliative medicine and its providers.	1) Information session led by an AA LHA that includes: 2) DVD segments that address this construct (i.e., testimonials from current AA palliative care /hospice patients **and/or** testimonial from an AA physician with personal /professional experience with EOL care)

D.4.6. Development and Testing of DVD Segments: DVD segments have been created to: 1) address the perceived conflict between spiritual and religious beliefs and the hospice and palliative medicine philosophy of care, and 2) address AA patients' mistrust in the health care system. These new DVD segments combine text, voice-over-text narration, along with video testimonials of AA patients, physicians and religious leaders. To address the spirituality issues, AA clergy with experience with hospice and palliative medicine discuss their experiences with EOL care and how spirituality and EOL care philosophies can coexist without conflict. To address medical mistrust, we have included short video testimonials from an AA hospice patient and two AA caregivers of hospice patients who discussed their positive experiences with hospice care. Additionally, an AA hospice and palliative medicine physician and an African American palliative care nurse practitioner discuss their personal and professional experiences with EOL care. The videos were filmed without the use of prompts or stage directions to convey candid realism. The UTSW Medical Television group has done all filming and editing based on previously published filming and was guided by content input from Dr. Skinner,[86] Dr. Halm, and other content experts.

We have tested these DVD segments among community-dwelling African Americans who receive their care or serve as caregivers for patients who receive their care at UTSW, Parkland, and their affiliated outpatient clinics. We have obtained feedback from these participants to assess: 1) understandability of the materials; 2) how effectively the gist messages were communicated; 3) acceptability and cultural-sensitivity of the messages and materials. Given sensitivities about the perceived conflict between spirituality and choosing palliative care, we recruited focus group participants who were active members of their churches (including ministers). We have also presented the videos to the broader group of social scientists in Dr. Skinner's Division of Behavioral and Communication Sciences. Based on feedback from our primary care/oncology provider focus group, the segments will be iteratively refined, and re-evaluated as appropriate. This formative approach to intervention component development, testing, and refinement has been used successfully by Drs. Skinner and others for a variety of behavior change trials.[86-94]

D.4.8. Culturally Concordant LHA/Coaching Model: There is evidence for the value of combining 'health coaching' with a video or written health information and behavior change materials.[78-83] A LHA is a 'health coach,' who will be a trained counselor who will introduce a topic to a patient and talk with them after viewing or reading standardized health information. This helps provide supplemental information tailored to the patient's individual clinical and personal situation, enables the patient to ask clarification questions, and provides moral, spiritual and motivational support for behavior change for patients and caregivers. The intervention we plan for Aim 3 will combine the DVD segments along with a face-to-face counseling session with a culturally concordant LHA with training in EOL care discussions. We will recruit an AA LHA from the community (preferably a prominent AA church or faith-based organization in Dallas) who, along with the PI, will undergo training in providing culturally sensitive EOL care counseling via the Respecting Choices® First Steps® ACP program.[95] This rigorous, evidence-based program provides training for healthcare and community leaders in facilitation and effective communication about advance care planning.[96,97] The LHA will be actively involved in script and intervention protocol development. The LHA will also attend sessions in the

Palliative Care Clinic, and will observe the palliative care providers as they conduct their clinic sessions. The LHA will do a progressive series of in-service work with the Parkland palliative care team and the PI to give them a chance to observe other experts engage patients in EOL care discussions, practice co-leading these discussions, and finally counseling individuals themselves. The PI will observe the LHA on several interactions and give them feedback until competency in this area is assured.

D.5. Details of Research Design and Methods for Aim 3: Assess the feasibility and acceptability of a multifaceted EOL care behavior change pilot intervention. The pilot intervention will combine the refined elements from Aims 1 and 2, to conduct a small pilot RCT comparing the intervention group to a usual care control group. All of these aims taken together lay the groundwork for a future, fully powered RCT.

D.5.1. Study Subject Identification and Enrollment: We will use the refined e-EOL algorithm in real-time to identify AA patients with Stage III or IV breast, lung, colorectal, prostate, or other advanced cancer for EOL care counseling. The e-EOL algorithm will run once every day to flag potentially eligible candidates using an IT protocol used successfully in previous intervention research at Parkland.[76,77] The eligibility criteria are the same as those outlined in D.4.1. (AAs, ≥ 21 years, with advanced breast, lung or colon cancer, are English proficient, competent, cognitively intact by Mini-cog test, and no prior palliative care consult or receiving palliative care). Patients with earlier stage cancers (I and II) may be chosen for the intervention based on co-morbidities, functional status, or other factors that we deem appropriate. The research assistant will contact the patients' physicians to confirm eligibility and get permission to introduce the study to the patient. Once eligibility is confirmed, the research assistant will introduce the study to the patient, obtain informed consent, and administer the pre-intervention survey and needs assessment (described below). Each patient will be asked to identify a primary caregiver that will be able to participate in the intervention. Caregivers must be: 1) identified by the selected patient, 2) ≥ 21 years of age, 3) English proficient, and 4) competent to participate. The research assistant will then notify the EOL LHA of any study participants. The EOL LHA will contact each patient's primary caregiver by phone to confirm their participation in the study, and arrange a time to meet with both the patient and caregiver to conduct the intervention. We will recruit up to 60 patients and their caregivers, if a caregiver is available to participate, to allow us to pilot the intervention and sort out logistics of administering the intervention in a clinical setting prior to randomization. Overall, at least 48 patient-caregiver pairs will be randomized in the study representing an approximately even distribution across different cancer diagnoses. Twenty-four patient-caregiver pairs will be randomized to the intervention arm of the study, and twenty-four will be randomized to the usual care control group.

D.5.2.a Description of the Pilot Intervention: The EOL LHA will meet with eligible patients and their caregivers to tell them their doctor approved of them receiving more information about their treatment options. The LHA will then assist the eligible patients and caregivers in watching the EOL care DVD segments (the video modules described in Aim 2 targeted to their pre-intervention survey needs assessment). After the patients and caregivers watch the DVD, the LHA will answer questions and provide additional information. They will then use counseling scripts created by the PI and research team to probe in more depth the patient's goals of care, and understanding of their clinical condition, prognosis, and treatment options. They will tailor the discussion to the patient's values, preferences, concerns, and clinical circumstances. Those who express interest in hearing more about EOL care options will be encouraged to discuss this with their doctor. The counselor will offer to update their physician on their discussion and help communicate the patient's desire for a palliative care consult or advance directive (if that is something they wanted). After patients have viewed the intervention video, the LHA will follow up with patients the next business day to answer any questions that may have come up and inquire about the patient's thoughts regarding executing any advance care planning documents. As appropriate, the LHA will follow up again within one week to address questions or concerns and guide patients about how to complete documents and facilitate referrals, as needed. Specific questions about prognosis will be referred to the treating physician. Formal palliative care referrals will be ordered and performed in the usual fashion with the exception that the patient may ask the LHA to update the palliative care team on their prior discussions, concerns, and preferences. All intervention sessions will be audiotaped to ensure intervention fidelity. Patients randomized to receive the intervention will receive a $20 gift card for their time and effort.

D.5.2.b. Usual Care: Participants randomized to usual care will proceed with clinical care as already routinely implemented by their physicians. At the time of recruitment, they will be asked to identify their primary caregiver who will also be contacted. Patient-caregiver pairs who are randomized to usual care will also be

asked if they would be willing to be contacted at 1, 3 and 6-month intervals to complete the post-study assessment. Participants in this group (as well as the intervention group) will be given a $10 gift card after completing each of four surveys for their time involved with the study. All participants will be mailed a reminder letter that study staff will be contacting them to participate in follow-up surveys a couple of weeks prior to the 1-, 3-, and 6-month surveys. The reminder letter sent prior to the 1-month survey will include an informational brochure that briefly and simply summarizes advance care planning options.

D.5.3.Study Measurements and Data Collection Strategy: Table 3 outlines the primary and secondary patient outcomes and other measurements we will do at baseline, 1, 3, and 6 months of follow-up.

Primary Outcomes: Feasibility and acceptability are the main process outcomes. Feasibility is success in accurately identifying eligible patients via the e-EOL algorithm (number flagged, specificity, positive predictive value), and numbers and rates of patients completing the pilot intervention and follow-up interviews. Acceptability will be measured with Likert scale items rating "understandability, informativeness, balance, right amount of information, helpfulness, and "recommending this to others" used in published trials of decision aids.[86,98] We will also ask open-ended questions on things they did or did not like about the intervention. The primary decision making outcome is change in intent to discuss EOL care options based on the Transtheoretical Stages of Change Model,[70] an approach used in many other realms.[99-102] We will categorize patients into the following stages: 1) Pre-contemplation: is unaware of EOL care options/has not thought about discussing this with a provider; 2) Contemplation: is aware of EOL care options/thinking about discussing options; 3) Preparation: intends to discuss EOL care issues with the doctor/has a plan for talking about it; 4) Action: has a discussion with the provider about EOL care. The completion stage is not applicable in this medical situation because the goal of the intervention is for the patient to have an informed discussion about benefits and harms of all treatment options including EOL care. The intent is NOT to get all patients to choose palliative care or hospice, or complete and an advance directive, but for them to understand how palliative care may benefit them now or in the future, and how it can be combined with curative care. *The goal is for the patient to make "the right decision for them" based on knowing all of the facts and options.*

Secondary Outcomes we expect to be changed will also be measured. 1) Knowledge of prognosis and EOL care options: will be measured by a questionnaire from prior NCI-funded palliative care studies;[103,104] 2) Decisional conflict will be assessed by the Decisional Conflict Scale, a validated 16 item scale measuring uncertainty about the best course of action and factors contributing to uncertainty. Scores <25 (on this 100-point scale) are associated with implementing decisions, and scores >38 with decisional delay;[105] 3) Quality of life (QOL): will be assessed with the McGill QOL Questionnaire, a well-validated 20-item scale developed to measure QOL at the EOL;[106,107] 4) Healthcare utilization will include: outpatient visits (incl. palliative care), ED visits, hospitalizations, total hospital days, and use of hospice services (type and time to hospice initiation); 5) We will also record the date and place (hospital, hospice, home) of deaths within a 6 month follow-up period.

Other Patient and Treatment Variables will be measured to inform exploratory subgroup and effects mediation analyses such as: 1) Sociodemographics: age, race/ethnicity, gender, education, marital status, religious preference, insurance, income, social support; 2) Clinical and treatment data: cancer type and stage, ECOG performance status,[108] reason for admission, advance directive status, inpatient and outpatient provider details (specialty, presence of a primary care provider, usual source of care), and discharge plan and location;[103,104] 3) Health literacy as measured by the Cancer Health Literacy Test * 4) Spirituality: will be measured by the Brief RCOPE measurement tool, a 14-item measure of religious coping with major life stressors that is commonly used to measure of religious coping for research purposes.[103,104,109]

Table 3. Study Variables, Data Sources and Time Frame of Measurements

Variable	Reference	Source	Index Visit	Time Frame		
				1 month	3 months	6 months
Sociodemographics, clinical, treatment data	NA	Chart review	X			
Knowledge of prognosis, EOL care options	Balboni[103,104]	Interview	X	X	X	
Feasibility and acceptability of the intervention	Matlock[90], Barry[98]	Interview	X	X	X	
Spirituality	Balboni[103,104] Pargament[109]	Interview	X			

Health Literacy	NA	Interview	X			
Intent to consider EOL care options	NA	Interview	X	X	X	X
Decisional conflict, quality of life	O'Connor[105] Cohen[106,107]	Interview	X	X	X	
Healthcare and EOL utilization	NA	Interview, chart	X	X	X	X

D.5.4.Statistical Analysis Plan: We will use descriptive statistics to characterize study participants and proportion of intervention elements and follow-up assessments completed. The specificity and positive predictive value of the e-EOL algorithm operating in real world practice will be assessed using methods described for Aim 1 with physician chart review as the criterion standard. Acceptability and feasibility process data will be tallied. The main decision making outcome will be *change in the stage of intent to discuss EOL care options* from baseline through all follow-up intervals. Movement to an adjacent stage is a 1 point change. We will assess several aspects of stage change based on the proportion of patients at each time interval showing: 1) *any* stage pro/regression, and 2) *full progression to* the action stage of discussion EOL care options. Mean and range of progression at each interval will also be reported. The proportions above and means for *persistent* change will also be defined as the difference between baseline and 6 months (or 3 months if no 6 month contact or patient deceased). We will similarly examine pre- and post-intervention changes over time in knowledge, attitudes, and beliefs about EOL care and prognosis, decisional conflict, and QOL using non-parametric tests among the intervention group versus controls. Pre-specified subgroup analyses will stratify change in outcomes by: condition, mistrust, and spirituality. To achieve sensitivity of around 50% (with 10% confidence intervals, e.g. CI: 40% to 60%) in the outpatient algorithm, we will need to review 150 charts of patients diagnosed with metastatic (Stage III or IV) breast, lung and colorectal cancer (75 "test positive" and 75 "test negative" cases). The controlled pilot study in Aim 3 is designed to establish: feasibility, acceptability, detect preliminary efficacy signals (changes in behavioral intent, knowledge, attitudes, beliefs, decisional conflict), and generate point/variance estimates to be used to in power calculations for a future fully-powered RCT. We propose a small pilot RCT that will include 24 patient-caregiver pairs in each arm (intervention versus a usual care control group). This will yield greater than 80% power to detect a large intervention effect defined as an absolute difference in desired primary outcome of 40% (across a range of different point estimates), and between 60-70% power to detect a more modest absolute difference of 30% between the two groups (across a range of point estimates).[110-114] To ensure the ability to recruit the additional patient-caregiver pairs for the study, we will extend the enrollment period from 15 months to 18 months. Parkland Hospital providers care for more than 900 breast, lung and colon cancer patients per year, and roughly 40% are African American; consequently we believe that we will able to successfully enroll this number of participants within our 18 month timeframe.

D.5.5.Future Steps: These results will provide the foundation for a R01 application to conduct a fully-powered study that will randomize AA patients with advanced cancer to the multi-component EOL counseling intervention vs. usual care. If a preliminary efficacy signal is absent, or feasibility problematic, will we first pursue a R21 grant to further refine and pilot the intervention. Other next steps would include adapting and testing a bilingual version of the intervention for Hispanics with advanced cancer, as well as testing the DVD and counseling intervention in the community setting. The e-EOL algorithm will also facilitate systematic identification of patients eligible for EOL care counseling for future audits of the quality and appropriateness of care for patients with advanced illness.

Table 4. Work Plan and Timeline

TASK	Year 1				Year 2				Year 3			
Adapt the e-EOL Algorithm for the Outpatient Setting	■	■	■									
Present Findings and Write Manuscript on e-EOL algorithm development	■	■	■									
Preparation, Recruitment, and Conduct of Primary Care/Oncology Provider Focus Groups	■	■	■									
Analyze, Present Findings and Write Manuscripts on Qualitative Data	■	■	■									
Lay Health Counselor Recruitment and Training	■	■	■									
Final Preparation and Pre-Testing of Intervention		■	■	■								
Recruit and Enroll Patients in Intervention Pilot			■	■	■	■	■	■				

Conduct Intervention Pilot											
Complete Post-Intervention Follow-up Interviews (1, 3, 6 month)											
Analyze, Present and Write Manuscript on Pilot Intervention Results											
Write and Submit NIH R01 of Fully-Powered RCT											

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