Comparison of home-based palliative care delivered by community health workers versus usual care: research protocol for a pilot randomized controlled trial

Study Protocol

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A. SIGNIFICANCE

A.1. Global Need for Evidence-Based Palliative Care Models. Annually over 40 million people worldwide could benefit from palliative care to control pain and other symptoms, but only about 10% receive these services.[1] Palliative care can improve the quality of life (QOL) of patients and their families facing life-threatening illness through pain and symptom management.[3] Medical conditions that frequently require palliative care include cancer, HIV/AIDS, and congestive heart failure.[3] In 2014, the World Health Organization (WHO) published the first Atlas of Palliative Care, documenting the global distribution of need and availability of palliative care. While palliative care primarily exists in North America, Europe and Australia, approximately 80% of patients who need these services live in limited resource countries.[1] Palliative care research has almost entirely been conducted in high resource countries.[1] Palliative care can reduce pain[4-5] and symptom burden,[2,6] increase QOL,[7-8] satisfaction with care,[9-11] and the likelihood of dying in one's own home.[2] At a health-system level, palliative care can reduce hospitalizations,[10-12] ER visits,[13] and healthcare costs.[2,14] Unfortunately, dissemination and implementation of palliative care to limited resource settings has been extremely limited.[15-16]

A.2. Availability of the WHO Palliative Care Toolkit as a Palliative Care Model. As part of their agenda to increase palliative care globally, the WHO released the "Palliative Care Toolkit: Improving Care from the Roots Up in Resource Limiting Settings" in 2014.[1] Originally developed by the Worldwide Hospice Palliative Care Association (WHPCA), the toolkit provides a training and implementation toolkit for empowering community members to deliver palliative care in resource poor settings. The premise of the toolkit is that basic, effective palliative care can be delivered within existing community and health infrastructure by people who do not have advanced specialized training. The toolkit provides educational materials and data collection tools for providing palliative care, which mirror the WHO definition of key palliative care components.[17] Toolkit materials include a symptom control guide and protocols for using palliative medications, forms for patient records, teaching aids and advocacy materials. In 2015, an evaluation of the toolkit was published, which reports on its utilization across 43 countries (46% in Africa, 29% in South Asia and 16% in South America), reflecting its global diffusion. Over 90% of respondents felt the toolkit improved their understanding of palliative care, enhanced their knowledge of implementing palliative care, and improved their confidence in case management. While the toolkit has not undergone extensive impact evaluation, it is based upon evidence-based palliative care principles.[17] In the Atlas of Palliative Care report, the WHO recommended research is urgently needed to implement and evaluate the toolkit in diverse settings. The synergy between the WHO global palliative care priorities and availability of the toolkit creates an optimal milieu to implement and evaluate a palliative care model for use in resource poor settings.

A.3. Community Health Workers (CHW) as a Novel Workforce to Deliver Palliative Care. Based on findings from a formative study we conducted in Kolkata, India in late 2015, CHWs were identified as a robust workforce that can help to expand the reach of limited palliative services to rural patients. CHWs have primarily been used in resource poor settings to deliver acute care such as maternal and child health, family planning, malaria control, treatment of diarrhea, immunization, health education and wound treatment.[18] This unique workforce evolved globally across low resource countries like India due to a lack of formally trained providers to care for rural patients.[15] Based on our formative interviews with cancer center stakeholders and patients, CHWs may be well-suited to facilitate delivery of palliative care for a number of reasons. First, CHWs are embedded in communities throughout India and are often the only healthcare providers available in rural areas.[16] Second, CHWs tend to be trusted community providers according to our stakeholder interviews. Third, most CHWs in India have completed a 2-year training program to prepare them to provide care for minor health problems. Despite these benefits of the CHW workforce, they are often underutilized as rural healthcare partners by the medical community due to the lack of formal medical training such as an MD or RN degree.[17,19] However, extreme need for palliative care has driven support to implement and evaluate novel models of care. As recommended in the WHO's Palliative Care Toolkit, palliative care in low resource countries must be well-integrated into existing healthcare systems, but also utilize community members to expand the reach of scarce healthcare providers.[2] Thus, we propose that a palliative care intervention built upon the WHO Palliative Care Toolkit and delivered by CHWs has enormous potential to efficiently leverage limited clinical resources in poor rural communities by tapping into CHW's knowledge of their communities and the healthcare system.

B. INNOVATION

This study is innovative in many ways. First, CHWs will be used in a novel role to deliver community-based palliative care. This workforce has primarily been used in limited resource settings to facilitate acute care such as maternal and child health and immunization. Thus, our study expands the use of CHWs into a new focus area (palliative care), admittedly and purposefully blurring the lines between CHW and formally trained healthcare provider, as suggested in the WHO toolkit. Use of this workforce can efficiently leverage limited clinical resources by tapping into CHWs' knowledge of their communities, the healthcare system, and new palliative care skills to be developed through this intervention. Second, our pilot work indicated that existing technology infrastructure can support a novel tele-health approach, which will be employed to facilitate real time communication between CHWs, rural patients and the cancer center oncology team. We will use *Doxy.me*, a free, easy to use, HIPAA compliant platform that enables real time audio-visual communication**.** Third, conducting this research in partnership with the TMC provides a basis for future research collaborations. Fourth, if we can demonstrate effectiveness of this approach in rural India, it is likely such a strategy could benefit those in other resource-limited settings.

C. APPROACH

C.1. Interprofessional Team. Our team has the unique expertise and relationship with our global health partners to successfully conduct this study, including an existing pilot project with this group, training and experience in *dissemination and implementation science,* intervention and qualitative research, patient navigation, oncology and *palliative care,* global health, telehealth and biostatistics**.** Drs. Qanungo and Cartmell already have experience working on the formative study that led to the proposed project. Mr. Coyne is a renowned palliative care expert who will provide guidance for operationalizing our study protocols and consulting on logistical issues. Dr. Gaurav Kumar who will be the site lead PI is an experienced palliative care specialist at the TMC where the study will be conducted. *He brings to this study expertise in clinical* *palliative care and local context* to ensure project success. Dr. Mammen Chandy, the Director of TMC will also be involved in high level leadership regarding administrative decision making at TMC related to the project.

C.2. Preliminary Data. Our research team conducted a formative qualitative study in collaboration with the Saroj Gupta Cancer Center in Kolkata, India in November 2015 to assess feasibility of the proposed research and to identify stakeholder perceptions about how the Palliative Care Toolkit could be adapted to deliver home-based care for use in a cancer center setting. 22 interviews were conducted with clinical team members (n=9), potential CHWs (n=3) and patients/caregivers (n=10) at the local cancer center. Clinical team and CHW interview guide domains included how palliative care is currently delivered, barriers to delivering care, changes needed to the toolkit for use in delivering home-based care for rural cancer patients, and optimal design for a home-based palliative care program. The patient interview guide queried patient experiences with their illness and care, cultural perceptions about cancer and its treatment, family support, and physical, emotional and spiritual difficulties. Key findings are summarized in **Table 1.** We have also developed a structured intervention protocol, adapt toolkit forms, and develop a CHW training that is ready for use in the proposed study **(§Appendix).**

Table 1: Key Findings from Qualitative Interviews that Guide our Navigation Intervention
Patients Present with Late Stage Cancer: Patients typically wait until later stages to visit the cancer center, due to lack of health insurance and the perception that cancer is not treatable.
Potential Palliative Care Patients often Forego Cancer Center Care: Patients who are not candidates for curative treatment often forego palliative care due to financial burden and difficulty to travel to distant cancer center for palliative care. In most cases, family members travel to the cancer center each week on patient's behalf to obtain morphine.
Educational Message Targets: Education about cancer and palliative care were identified as a need to improve QOL. For example, education is needed to inform patients and caregivers that it is normal to use increasing doses of morphine, family members cannot "catch their cancer," and cancer is not caused by one's sins in the current or past life.
Extreme Need for Caregiver Support: Few families have sick leave benefits and must take unpaid leave to care for a relative. Most patients and caregivers verbalized emotional distress and the need for intensive emotional and practical support at home.
Lack of Formally Trained Providers in Rural Communities to Facilitate Palliative Care. There are virtually no MD or RN trained professionals available in rural areas to help facilitate home-based care.
CHWs Identified as Workforce to Deliver Palliative Care: We interviewed rural CHWs (non RN/MD) as potential palliative care CHWs. These practitioners represent a robust workforce working in communities for years, have basic medical training, tend to be trusted, and represent the only health infrastructure in most rural communities. Most CHWs have completed government certification to deliver basic medical care, have nominal billing system and are eager to expand their services
Morphine Policies and Access: Over 90% of the world's opium produced legally for medicinal use is grown in India and can be purchased at 1-10 cents per tablet,[21] hence the cancer center can provide free morphine to their home-based palliative care patients. However India has one of the most restrictive policies for accessing morphine in the world,[21] which is a barrier to morphine access, but which also minimizes risk of drug abuse. Consistent with the Indian government's strict morphine regulation, the cancer center maintains the morphine supply for all patients, and patients or "proxy" caregivers must visit the cancer center weekly to obtain and sign off on receipt of morphine, maintain documentation of pills administered and return remaining pills to the cancer center. We confirmed that the cancer center will permit CHWs to obtain morphine on patients' behalf via this protocol.
Palliative Care Toolkit Adaptations: Most changes are minor. These include adding context in the introduction of the toolkit to present the context for use of the toolkit in a cancer center setting for use by CHWs, making toolkit materials specific to cancer rather than to all palliative illnesses (e.g. HIV, TB); some toolkit forms are not needed or require modification to delete irrelevant fields (e.g. referral source since all patient referrals to CHWs will come from palliative team), and adding appointment forms for CHWs to help patients set up appointments with providers as needed.

C.3. Guiding Framework. As shown in Table 2, the RE-AIM framework guided our evaluation plan to measure the reach, effectiveness, adoption, implementation and maintenance of the home-based palliative care intervention (Pal-Care).[22]

C.4. Study Overview. This pragmatic clinical trial (PCT) will examine how the Palliative Care Toolkit, which provides comprehensive evidence-based materials for delivering palliative care, can be adapted for use by CHWs working with a cancer center to deliver home-based palliative care for rural patients. The study will compare an intervention group of patients who will receive home-based palliative services from

CHWs vs. a control group of patients who will receive cancer-center based palliative services. Diverse data sources will be used to evaluate the intervention within the REAIM Framework. These include patient care logs completed by CHWs, longitudinal surveys of intervention and control group patients, chart reviews of medical record and billing data and post-intervention interviews with the clinical team, CHWs and patients/caregivers.

C.4. Study Setting and Partners. This research is a collaboration between the Medical University of South Carolina (MUSC) and the Tata Medical Center (TMC), Kolkata, India. The study will be conducted at the TMC located in Kolkata, India. TMC is a premier regional cancer center in Eastern India, which has approval by the Indian government to conduct research, a well-established research infrastructure, including a variety of active studies, and its own institutional review board.

C.5. CHW Recruitment: The TMC team will recruit 6 CHWs from the *North and South* 24 Parganas Regions where the intervention will be piloted. During a palliative care presentation that Saroj Gupta cancer center hosted in 2014 to assess community interest in the proposed intervention (as part of the formative study), 47 community members attended. During this meeting, the cancer center learned that CHWs are likely to be a feasible and sustainable workforce for delivering home-based palliative care. CHWs are embedded in outlying areas around the cancer center and throughout India, they often represent the only providers in rural communities, and they tend to be trusted in their communities. CHWs have completed a two-year training course sponsored by the Indian government to prepare them to care for basic medical problems. [23] Since this initial meeting, the cancer center has continued to interact with the CHWs, who are enthusiastic to participate in this research project. For the project, CHWs will receive a monthly stipend of $125 and reimbursement for study-related travel costs.

C.6. Orientation Prior to the intervention, study PIs will travel to India to orient the cancer center team, including CHWs, oncologists, clinic nurses, administrators and the psychologist, social worker and research coordinator. Content will cover study purpose, design, protocol, along with roles and responsibilities of CHWs.

C.7. CHW Training: The CHW team will receive didactic and experiential training prior to the intervention, to be informed by our prior training of navigators and understanding the complexity of skills required to deliver palliative care. First, CHWs will participate in a 40-hour didactic *and experiential* training that covers content in the WHO Palliative Care Toolkit: palliative care principles, intervention protocol, assessment and management of pain and other symptoms, care for caregivers, communication skills, local resources for patient support, educational resources, strategies for team care and cultural and spiritual considerations in end-of-life care. *To reinforce didactic content, interactive case studies from the Palliative Care Toolkit will be used.* Second, CHWs will shadow clinical team members (oncologists, nurses, social worker, psychologist) on patient encounters for two weeks. Third, CHWs will participate in two days of *interactive case studies* to practice their new palliative skills. Case studies will focus on essential palliative care scenarios. A comprehensive pre-post training survey will assess attainment of palliative care knowledge domains and a skills checklist will assess mastery of palliative skills. The training will be led by our Co-I in India who is well-qualified and has extensive experience providing palliative care. Sessions will primarily be delivered by Dr. Kumar, with guest lectures by others from TMC (nurse, social worker, psychologist) and MUSC (Coyne, Cartmell, Qanungo) with discipline-specific expertise.

C.8. Study Protocol: *This PCT will be conducted at the TMC among cancer patients residing in the North and South 24 Parganas Region to evaluate the implementation and effect of the Pal-Care intervention. The intervention group will consist of n=45 patients who will receive home-based palliative care delivered by CHWs. The control group will consist of n=45 patients from the same area who will receive cancer-center based palliative care. Patients will be randomized to intervention or control group via simple randomization. Allocation concealment will be used so that patient allocation assignment will not be known until after consent. Block size will be varied to minimize the likelihood that next treatment assignment can be guessed. PIs and statisticians in the US will be blinded to which study arm patients are participating to avoid bias during analysis.*

C.8.2. Participant Recruitment and Informed Consent: All study recruitment and consent activities will be conducted onsite at the TMC. Using the NCI screening log, the research coordinator will systematically screen all TMC patients who require palliative care for study eligibility. Inclusion criteria: age 18+, any cancer type of which the PI feels have a cluster of symptoms that can be managed at home and not require hospitalization, late stage cancer, an ECOG status of 0-3, residence in 24 Parganas regions, physician documentation in paper medical record that patient is to receive palliative care, and patient willingness to participate in data collection. These broad eligibility criteria will be used, as the study will evaluate the intervention under real world conditions. For patients who meet eligibility criteria, the research coordinator will introduce the study and assess interest in participation. Interested patients will be referred to their palliative oncologist to answer questions about the study and complete informed consent. Next, the palliative care physician will randomly assign patients to intervention or control group. For each patient screened, the research coordinator will document if patient was offered, consented to and dropped out of study, and reasons for screen failure and drop out. This will enable assessment of feasibility of our recruitment plan, plus generalizability of study participants to the 24 Parganas Regions. Participants will receive $15 for study participation upon study enrollment and at each of three follow-up survey intervals towards their travel expenses.

Table 2: Evaluation Measures Organized within the REAIM Framework

Outcome	Measures	Collection/Time Points
Aim 1: Evaluation of Intervention Implementation		
CHW Training/ Orientation	Attendance rates for program orientation, trainings and meetings among CHWs and clinical team; Pre/post-test change in CHW's palliative care knowledge and perceptions; CHW's skills performance and perceptions of training content and format post-training	Minutes from home-based palliative program meetings TMC Co-Is will administer survey pre-post training & skills checklist post-training
CHW Role	Frequency of patient visits; assessment of patient problems (e.g. pain, transportation, depression); CHW actions (education, scheduling appt., obtaining morphine); problem resolution (pain control); frequency of debriefings with clinicians	Review of toolkit log data
Study Recruitment	Number, % and characteristics of eligible patients who are offered study participation, consent and complete/drop-out; reasons for screen fails and dropout	TMC research coordinator will complete recruitment and enrollment logs

Stakeholder Perceptions	Perceptions of Pal-Care intervention implementation/feasibility among clinical team members, CHWs and patients/caregivers, with comparisons by stakeholder type	Dr. Qanungo will conduct qualitative interviews
Fidelity to Study Protocol	Participant recruitment per inclusion criteria; data collection per protocol (% completion of patient surveys and each type of toolkit form), regular meetings with research team/sites with high attendance; timely reporting of adverse events	Patient record reviews, review of completed surveys and toolkit forms, meeting minutes
Aim 2: Evaluation of Intervention Effectiveness		
Patient Outcomes	Patient surveys will be conducted with intervention/control groups to assess: palliative needs via African Palliative Outcomes Scale;[24] QOL via WHO QOL Scale;[25-27] cancer symptoms via Edmondton Symptom Scale [28-29] and patient care experience via FAM-Care Scale.[30-31] Palliative care toolkit forms[3] filled out by CHWs measure outcomes for intervention group: use of pain, anti-emetics and laxative medications; performance status; survival days in palliative service; location of death.	TMC research coordinator will administer surveys by phone after baseline study visit and at 1 and 3 months Review of toolkit form data

C.8.3. Intervention Group: Intervention group participants will receive the Pal-Care intervention that we developed, which is based upon: 1) the Palliative Care Toolkit materials and 2) key adaptations we identified in our prior stakeholder interviews. The intervention will be delivered over a 6-month period. For patients in the intervention, the research coordinator will set up an appointment for the patient and their caregiver to meet with their CHW and clinical team, including the oncologist, social worker and nurse. At this meeting, a baseline health and needs assessment will be conducted and an individualized care plan will be created.

The CHW will make home visits to patients 1+ times weekly, depending on patient need. At each visit, the CHW will use resources from the Palliative Care Toolkit to: 1) monitor the condition of patient/caregiver, 2) provide basic palliative care (e.g. medication administration, wound care, catheter care), 3) teach caregivers to deliver care, 4) monitor pain and symptom control, and 5) assist patients to contact their oncologist or other resources when needed. To guide their work, CHWs will maintain care logs from the Palliative Care Toolkit. These include a patient caseload registry, a detailed log of patient needs and services provided, longitudinal assessment of patient pain/other symptom scores and administration of pain/other medication, referrals to cancer center and community resources and monthly service report. Based on findings from our formative work, CHWs will travel to TMC on patient behalf to obtain morphine, as this was identified as an overwhelming barrier to pain control for rural patients. They will also educate patients to dispel common myths about cancer and its treatment commonly described in our formative interviews. Examples of misperceptions to be addressed by CHWs include education that cancer is not contagious, it is not punishment for one’s sins in a past life, and it is acceptable to take increasing doses of morphine over the course of illness.

The CHW will meet weekly with the cancer center team to debrief on patients’ status, obtain guidance on caring for patients and obtain and sign for patients’ weekly morphine doses that they will then deliver to patients. To facilitate timely communication between CHW and clinical team, a simple, free HIPAA compliant telehealth platform (*Doxy.me)* will be used. This service works well in the TMC setting. We will provide tablets to CHWs to enable them to use Doxy.me as needed to link to the clinical team.

C.8.4. Control Group: The control group will receive “usual care” palliative services in which the patient or caregiver (by proxy) must visit the cancer center for care. TMC services include consultation with a multi-disciplinary team (oncologist, nurse, psychologist), a weekly 7-day medication supply (as morphine must be picked up each week), and basic training on medication usage, catheter and wound care and other topics as relevant, and psychological counseling. Patients are also provided a 24/7 hotline to call in case of emergency.

C.8.5. Post-Intervention Transition of Care: *After study participation, all patients (or family on their behalf) may continue to receive palliative care at the cancer center for as long as needed. As the cancer center will hire CHWs for the grant period, intervention group patients may continue receiving services from their CHW until the study ends (i.e. past the final 6-month assessment). Once the study ends and CHWs are no longer paid by the grant, intervention group patients may transition to cancer-center based care or continue receiving supportive services from their CHW for a small fee per visit. Fees traditionally charged by CHWs for home visits are very reasonable and we will work with them to establish a standard fee structure for palliative visits.*

C.9. Data Collection, Measures and Management: Table 2 displays study outcomes, strategies and time points for data collection, with mapping to RE-AIM Framework domains. The three primary data sources for this study include WHO Toolkit logs completed by CHWs, longitudinal surveys with intervention and control group patients/caregivers, and post-intervention stakeholder interviews. Supplemental data sources include meeting minutes, training evaluations, study recruitment logs, and chart reviews of cancer center medical record/billing data. Based on our pilot, cancer center stakeholders prefer using hard copy patient care logs and assessment tools. Thus, data will be collected via pen and paper, with data transfer into a password protected web-based data system, Research Electronic Data Capture (REDCap) **(§ Facilities and Other Resources).**

C.9.1. Patient Surveys. *Surveys will be conducted with study participants at study entry (baseline) and at 1, 3 and 6 months to assess patient outcomes. The TMC research coordinator, a native Bengali speaker, will administer the baseline survey after informed consent and will travel to patient homes to administer follow up surveys.* As patients have low literacy and are very sick, we selected brief instruments that use simple language and response options. Multi-dimensional palliative care outcomes will be assessed with the 10-item African Palliative Outcomes Scale that measures physical and psychological symptoms; spiritual, practical and emotional concerns; and psychosocial needs of patient/family on a 5-point likert scale.[24] QOL will be assessed with the 26-item WHO QOL Scale,[25-27] that assesses physical health, psychological health, social relationships and environment on a 5-point likert scale. Cancer symptoms will be assessed with the 9-item Edmondton Symptom Scale.[29-30] Experience with care will be assessed with the 16-item FamCare Patient Scale[30-31] measured on a 5-point likert scale. *These instruments have established validity and reliability and have been used in palliative populations and limited resource settings including India, but have not been translated into Bengali. Surveys will be translated using standard translation/back translation to ensure accurate translation.*

C.9.2. Palliative Care Toolkit Forms. Toolkit forms[3,33] include: 1) a record of patients in CHW's caseload; 2) a home visit record to track services, including main problems, care provided and visit notes; 3) a patient-held home care record to longitudinally document visits to patient, their condition and main problems, care provided and notes;

4) a patient-held drug chart to record name and purpose of each drug, dose and form of medication, and when each dose should be taken; 5) a patient held morphine record to document form, strength, and administration dates/times; 6) a referral form for services and resources; and 7) a monthly report to document number of patients under care, their diagnoses and contacts, new referrals, and end of care outcomes.

C.9.3. Post-Intervention Interviews. *Dr. Qanungo, who is a well-trained interviewer and speaks Bengali, will interview stakeholders to evaluate the intervention.* She will conduct 20 in-person interviews (or until saturation is reached), *representing all Pal-Care clinical team members (n=6) and CHWs (n=6) and 8 patients/caregivers who participated in the intervention. Patients/ caregivers will be purposefully selected to represent experiences across different cancers, clinical problems and assigned CHWs. To fill in information gaps, additional stakeholders may be interviewed. Qualitative recommendations suggest thematic saturation is usually achieved with 15-30 participants.*[11] We will obtain informed written consent and provide $10 participant compensation. Clinical team and CHW interviews will query how CHW's conducted their work, training and support needed, and barriers, facilitators and optimal strategies for delivering care. Patient/caregiver interviews, to be conducted in patient homes, will query experiences with the CHW, education and support needed and if these needs were met, and service quality and efficiency *(**§Appendix**)*. Interviews will be digitally recorded, transcribed and analyzed in N-Vivo software.[34] The data collection protocol will take <1 hour.

C.11. Sample Size. For this pilot study, we will recruit 45 patients in the intervention and control groups (n= 90). As advocated by Leon, pilot studies "serve to check availability of eligible and willing subjects using the recruitment methods proposed, test feasibility of the treatment and measurement protocols, train researchers in study tasks, and set up data collection, checking, storage, and retrieval capabilities."[35] Leon also noted that pilots are deficient in estimating effect size with sufficient accuracy for future study design.[35] Thus, we will monitor the multiple process measures indicated in **Table 2** and obtain estimated variability of primary outcome measures. For a total sample of 90 participants, 95% CI estimates of *between groups* difference in change scores of palliative needs, pain, QOL and cancer symptom burden for the 2 groups can be estimated with precision ranging from ±1.0 to ±2.1 for standard deviations of difference scores ranging from 2.5-5.0 SD units.

C.12. Analysis Plan: Table 2 describes measures to be collected to evaluate study aims. Data will be analyzed in SAS.[36] *For aim 1, implementation mesures will be reported as means, standard deviations, medians, range, frequencies and proportions as appropriate. When appropriate, outcomes will be compared between intervention and control groups using t-tests and chi-square tests (or equivalent nonparametric tests) as appropriate. For primary analyses for aim 2 the intent-to-treat (ITT) sample will be used comprising all randomized patients. Descriptive statistics will be calculated for all variables. For continuous variables we will report means, standard deviation, medians and ranges. We will compare between group differences for continuous variables using either t-test for variables that are normally distributed or can be log-transformed or a Wilcoxon rank sum test for variables if normality cannot be approximated. For categorical variables, we will report frequencies, percentages and compare between group values with Chi Square or Fisher exact test. 95% CIs will be* *reported. In exploratory analysis to obtain variance estimates of effectiveness outcomes and the covariance structure of the longitudinal scores, generalized linear mixed models (GLMM) will be used to compare the two groups (intervention vs. control group) with intervention group as the primary independent variable and pain as the dependent variable. GLMM can account for clustering of measurements within CHW and within patients as well as accommodate missing data. Group (intervention vs. control group) will be a fixed effect; demographics (age, gender, distance from cancer center); and clinical (time since diagnosis, cancer type, baseline pain) variables will be adjusted for, along with a CHW variable accounting for cluster effects among patients by CHW. We will estimate the difference (via 95% CI) in average slopes between intervention and control groups and evaluate linearity of trajectories as input to inform a future trial. Further, dropout rate will be examined. If over 10% of data are missing, we will adjust data collection intervals in a future trial.*

Drs. Cartmell and Qanungo will independently analyze stakeholder interviews and iteratively work together using grounded theory (GT) to develop themes. A deductive/inductive approach will be used. Transcripts will be analyzed via constant comparison, comparing existing data with new data to refine codes. Open coding will be used to classify similar themes into categories and subcategories, which will become the basis of theoretical sampling to identify additional stakeholders for interview and modify the interview guide to fill in gaps. We will summarize stakeholder perceptions about usefulness, feasibility and acceptability of the intervention and materials and document barriers, facilitators and strategies for optimizing the intervention, study measures and data forms. Selective member checking in each stakeholder group will be conducted to enhance validity.

C13. Potential Problems/Alternative Strategies. Two primary study challenges are that: 1) it is being conducted in a low-resource country with primary oversight at MUSC, and 2) CHWs without prior palliative experience may find it challenging to deliver palliative care. To overcome these challenges, several plans are in place. Proactively, we partnered with a modern cancer center with an established palliative care program, experience conducting research and modern teleconferencing capabilities. Strategies to ensure fidelity include calls every two weeks with the TMC team, weekly meetings for CHWs to debrief with TMC team, and monitoring study data quality in RedCap. If issues are identified, we will schedule meetings with Dr. Gaurav Kumar to develop a remediation plan, which may include strategies such as extra training for the TMC research team on protocols, more palliative training for CHWs or modification to the CHW role.

C14. Translation and Dissemination. Affordable, contextually appropriate interventions are needed to bring palliative care to patients living in limited resource settings. Our intervention leverages an existing infrastructure of CHWs who care for patients in communities across India, often representing the only rural providers. *This study will provide a well-tested intervention protocol and adapted toolkit ready for use to deliver home-based palliative care for cancer patients. Study findings will inform future scale-up, implementation and evaluation of the intervention across multiple states in India in a larger R01 study. We will disseminate findings via national conferences and publications and also share our experience adapting the Palliative Care Toolkit with the WHO who has called for wide-scale utilization and evaluation of the toolkit in diverse* *global settings.*

References

1. World Health Organization and Worldwide Palliative Care Alliance. Global Atlas of Palliative Care at the End of Life. Geneva, Switzerland. 2014.
2. Gomes B, Calanzani N, Curiale V, McCrone PP, Higginson IJ, Brito M. Effectiveness and cost-effectiveness of home palliative care services for adults with advanced illness and their caregivers. Sao Paulo Med J. 2016;134(1):93-94. PMCID:PMC4473359
3. Worldwide Palliative Care Alliance. Palliative Care Toolkit: Improving Care from the Roots Up in Resource-Limited Settings. London, UK: Help the Hospices. 2013.
4. Grande GE, Todd CJ, Barclay SIG, Farquhar MC. Does hospital at home for palliative care facilitate home death? A randomised controlled trial. BMJ 1999;319(7223):1472–1475.
5. Greer DS, Mor V, Morris JN. An alternative in terminal care: results of the National Hospice Study. Journal of Chronic Diseases 1986;39(1):9–26.
6. McMillan SC, Small BJ. Symptom distress and quality of life in patients with cancer newly admitted to hospice home care. Oncology Nursing Forum 2002;29(10):1422–1428.
7. Bakitas M, Lyons KD, Hegel MT, Balan S, Brokaw FC, Seville J, et al. Effects of a palliative care intervention on clinical outcomes in patients with advanced cancer: the Project ENABLE II randomized controlled trial. JAMA 2009;302(7):741–9. PMCID:PMC3657724
8. Aiken LS, Butner J, Lockhart CA, Volk-Craft BE, Hamilton G, Williams FG. Outcome evaluation of a randomized trial of the Phoenix Care intervention: program of case management and coordinated care for the seriously chronically ill. Journal of Palliative Medicine 2006;9(1):111–126.
9. Jordhøy MS, Fayers P, Saltnes T, Ahlner-Elmqvist M, Jannert M, Kaasa S. A palliative-care intervention and death at home: a cluster randomised trial. Lancet 2000;356(9233):888–93.
10. Brumley R, Enguidanos S, Jamison P, et al. Increased satisfaction with care and lower costs: results of a randomized trial of in-home palliative care. J Am Geriatr Soc. 2007;55(7):993-1000.
11. Hughes SL, Cummings, J., Weaver, F., Manheim, L., Braun, B., and Conrad, K. A randomized trial of the cost effectiveness of VA hospital-based home care for the terminally ill. . Health Services Research. 2002;26(6):801-817.

12. Ahlner-Elmqvist M, Jordhoy, M.S., Bjordal K., Jannet, M., and Kaasa S., Characteristics and quality of Life of patients who choose home care at the end of life. Palliative Medicine. 2008;36(3):217-227.
13. Brumley RD, Enguidanos S, Cherin DA. Effectiveness of a home-based palliative care program for end-of-life. J Palliat Med. 2003;6(5):715-724.
14. Greer DS, Mor V. An overview of National Hospice Study findings. Journal of Chronic Diseases 1986;39(1):5–7.
15. Bhatia K. Community health worker programs in India: a rights-based review. Perspect Public Health. 2014;134(5):276-282. PMID:25169614
16. Unicef. What works for Children in South Asia: Community Health Workers. Kathmandu, Nepal2004.
17. WHO. World Health Organization Definition of Palliative Care. 2016; http://www.who.int/cancer/palliative/definition/en/ Accessed June 3, 2016.
18. Lehmann U, Friedman, I and Sanders, D., Review of the Utilisation and Effectiveness of Community-based Health Workers in Africa. South Africa: University of the Western Cape. 2004.
19. Prasad BMMVR. Community Health Workers: A Review of Concepts, Practices and Policy Concerns. Madras, India: International Consortium for Research and Equitable Health Systems. August, 2007.
20. The Hospice Team. http://hospicenet.org/html/team.html. Accessed June 12, 2016
21. Shariff UEK. An Epidemic of Pain in India. The New Yorker. December 5, 2013.
22. Gaglio B, Shoup JA, Glasgow RE. The RE-AIM framework: a systematic review of use over time. Am J Public Health. 2013;103(6):e38-46. PMCID:PMC3698732
23. 2-year diploma courses for para-medical training in West Bengal https://en.wikipedia.org/wiki/College_of_Medicine_%26_Sagore_Dutta_Hospital. Accessed on June 12, 2016.
24. Harding R, Selman L, Agupio G, et al. Validation of a core outcome measure for palliative care in Africa: the APCA African Palliative Outcome Scale. Health Qual Life Outcomes. 2010;8:10. PMCID:PMC2825183
25. Skevington SM, Lotfy M, O'Connell KA, Group W. The World Health Organization's WHOQOL-BREF quality of life assessment: psychometric properties and results of the international field trial. A report from the WHOQOL group. Quality of life research: an international journal of quality of life aspects of treatment, care and rehabilitation. 2004;13(2):299-310.
26. Development of the World Health Organization WHOQOL-BREF quality of life assessment. The WHOQOL Group. Psychol Med. 1998;28(3):551-558.

27. Berlim MT, Pavanello DP, Caldieraro MA, Fleck MP. Reliability and validity of the WHOQOL BREF in a sample of Brazilian outpatients with major depression. Quality of life research: an international journal of quality of life aspects of treatment, care and rehabilitation. 2005;14(2):561-564.
28. Bruera E, Kuehn N, Miller MJ, Selmser P, Macmillan K. The Edmonton Symptom Assessment System (ESAS): a simple method for the assessment of palliative care patients. J Palliat Care. 1991;7(2):6-9.
29. Chang VT, Hwang SS, Feuerman M. Validation of the Edmonton Symptom Assessment Scale. Cancer. 2000; 88(9):2164-2171.
30. Lo C, Burman D, Rodin G, Zimmermann C. Measuring patient satisfaction in oncology palliative care: psychometric properties of the FAMCARE-patient scale. Quality of life research: an international journal of quality of life aspects of treatment, care and rehabilitation. 2009;18(6):747-752.
31. Lo C, Burman D, Hales S, Swami N, Rodin G, Zimmermann C. The FAMCARE-Patient scale: measuring satisfaction with care of outpatients with advanced cancer. Eur J Cancer. 2009;45(18):3182-3188. PMID:19786345
32. Baidya A. Mobile Phone Subscribers in India Q2 2015. http://dazeinfo.com/2015/09/04/number-mobile-phone-subscribers-india-q2-2015-growth-airtel-vodafone-bsnl-broadband-trai/. Accessed May 27, 2016.
33. Lavy V. Palliative Care Toolkit: Trainer's Manual. London, England: Worldwide Palliative Care Alliance and Help the Hospices; 2015.
34. QSR International. N-vivo 10. 2016.
35. Leon AC, Davis LL, Kraemer HC. The role and interpretation of pilot studies in clinical research. J Psychiatr Res. 2011;45(5):626-629. PMCID:PMC3081994
36. SAS Institute I. SAS Version 9.4. Cary, NC.