2017

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Recommended Citation

Potts, Maryellen, "Improving the Reach and Effectiveness of Palliative Care in Low-Resource Countries" (2017). *MUSC Theses and Dissertations*. 341.
https://medica-musc.researchcommons.org/theses/341

Improving the Reach and Effectiveness of Palliative Care in Low-Resource Countries

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A dissertation submitted to the faculty of the Medical University of South Carolina in partial fulfillment of the requirements for the degree of Doctor of Philosophy in the College of Nursing.

November, 2017

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Acknowledgements

The support I have experienced during this dissertation adventure has been remarkable – friends, fitness class participants, and neighbors who stoutly listened as I practiced my elevator speech on palliative care in low resource countries and forgot about the simple activities of daily living such as groceries and laundry. My partner Michelle Sissine has earned triple gold stars in patience, understanding, and support. I appreciate my three sisters and my father, who all model academic and career achievement, and my mother, the best cheerleader of all.

At MUSC, I would not be as accomplished as I feel I am without my outstandingly collaborative dissertation committee, with chair Dr. Kathleen Cartmell, a superlative researcher and meticulous revisionist, Dr. Suparna Qanungo, whose connections and bright spirit made things come together, Dr. Lynne Nemeth, an incomparable scholar who welcomed me to the qualitative table, and Dr. Gautam Bhattacharjee, my external mentor in Kolkata, India, who taught me the importance of palliative care to cancer patients.

More thanks go to Dr. Lori Vick and Dr. Lori Muntz, colleagues at IWC who knew more about my capabilities than I did; my first points of contact at MUSC, Dr. Charlene Pope, Dr. Marilyn Laken, and Dr. Elaine Amella who all modeled the intersection of intellectual curiosity, hard work, and being at the top of their game; Dr. Michelle Nichols, whose patience with me in Integrative Review will never be forgotten; Dr. Teresa Kelechi for her enthusiastic conversations and Dr. Martina Mueller for her unflagging support with statistics; and members of my cohort who urged me onwards despite my not being a nurse, especially Karenmarie Davis, Kim Pickett, and Ann Marie

Johns. Thanks also go to Dr. Michael Johnson for his thoughtful responses to my work in Dr. Nemeth’s 742 Qualitative and Mixed Methods course, and to Dr. Matt Gregoski, who believed when I did not that I could do statistics, and that I would end up thinking like him. He might be right.

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CHAPTERS

Abstract

Purpose: The purpose of this compendium is to identify strategies to extend the reach and effectiveness of palliative care in low resource countries by 1) examining palliative care interventions, outcomes, and outcome measures, 2) evaluating a home-based palliative care program in rural India, and 3) exploring the concept of acceptability of rural medical practitioners in rural India.

Problem: Limited access to effective palliative care services remains an urgent global concern for the over 19 million people requiring palliative care, the majority of whom live in low resource countries. An accompanying lack of research into palliative care interventions in resource-poor areas to support the development of feasible, acceptable, and useful context-specific interventions also exists. This dissertation is a compendium of three manuscripts that represent studies designed to offer information about improving the reach and effectiveness of palliative care in low resource countries.

Design: The research designs used to carry out these studies included a systematic review of the literature that identified palliative care interventions and patient outcomes in low resource countries and the outcome measures used to evaluate the interventions (manuscript 1); the qualitative evaluation using a grounded theory approach of a pilot palliative care program in a rural area outside Kolkata, India, from the perspective of key stakeholder (manuscript 2) using a grounded theory approach, and dimensional concept analysis of the acceptance of rural medical practitioners (RMPs) as health care providers in rural India (manuscript 3).

Findings: Findings from the systematic review characterize the types of palliative care models available in low resource areas while highlighting the need for more rigorous research to help guide the development of effective palliative care programs. It also reports the need for validation of palliative care outcome measures that are designed for and validated in low resource settings. Findings from the qualitative evaluation of the palliative care program indicated the value of the program for stakeholders in terms of the delivery of palliative care to rural cancer patients. The palliative care program incorporating the training of RMPs as CHWs is a model worthy of consideration by other low resource areas of India. The results of the dimensional concept analysis revealed five dimensions and two sub-dimensions for acceptability: accessibility with two sub-dimensions of availability and proximity; affordable, familiar, satisfactory, and trusted. The findings suggest that using RMPs in health care interventions in rural India may be feasible because of their acceptability across stakeholders.

Conclusion:

The reach and effectiveness of palliative care in low resource countries may be expanded by additional rigorous research on palliative care interventions to support the development of context-specific programs. The evaluation of home-based palliative care programs from the perspective of key stakeholders will help identify strengths of the program and opportunities for improvement. The concept of acceptability may be used to design interventions that employ RMPs to deliver health care in rural areas of India.

Keywords: Palliative care, interventions, outcomes, systematic review, informal providers, rural medical practitioners, acceptability, concept analysis, India

Chapter 1: Introduction

Overview

This dissertation is a compendium of three manuscripts that represent studies designed to offer information about improving the reach and effectiveness of palliative care in low resource countries. A systematic review reports the results of studies on palliative care interventions, patient outcomes, and outcome measures in low resource countries. A qualitative evaluation using grounded theory reports the perceptions of key stakeholders in a piloted palliative care program using community health workers (CHWs) in rural India. A dimensional concept analysis reports the exploration of the concept of acceptability of unlicensed rural medical practitioners (RMPs) in rural India from the perspectives of patients, RMPs, and formal providers.

Background

Limited access to effective palliative care remains an urgent global concern for the over 19 million people requiring palliative care services, the majority of whom live in low resource countries (1). Patients with terminal diseases such as advanced cancer frequently suffer from pain and psychosocial distress that diminish their quality of life and burden their families. The World Health Organization (WHO) defines palliative care as "an approach that improves the quality of life of patients and their families facing the problem associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual" (2). However, only 14% of the 19 million patients needing palliative care at the end of life worldwide receive such services (1).

In 2011, 58% of the world's 234 countries had some level of hospice or palliative care services, but only 8.5% (20 countries) had achieved advanced integration of palliative care within their health systems (3). Barriers to palliative care in low resource countries remain great, including lack of national standards for quality care, lack of human and financial resources, lack of essential medicines for palliative care, and lack of research to supply high quality evidence needed to determine the best models of palliative care (4-8). Developing, testing, and evaluating the impact of palliative care interventions that are contextually appropriate for low resource countries is a humanitarian need.

Seventy-eight percent of the 40 million people needing palliative care live in low resource countries, and do not have access to palliative care (7). To be successful, palliative care programs in these settings must respond to local cultural contexts, be based in the community, and be integrated where possible into local health services, with clear access points among services (9). Palliative care programs in low resource settings need to be feasible, acceptable, and useful for all stakeholders, from patients to policy makers. Palliative care can be integrated into existing community and health systems and structures, and by using community health workers and volunteers, it can address many of the barriers to the delivery of palliative care services and meet the needs of stakeholders in low resource settings (10).

Understanding the cultural and social contexts of patients needing palliative care in low resource countries is foundational to developing appropriate and acceptable palliative care programs; however, research on palliative care in and from low resource countries has little representation within the palliative care literature (11). While the provision of palliative care is expanding in low resource countries, there is need for a greater base of evidence to continue documenting what palliative care models are most effective and under what circumstances (12,13).

Problem Statement

Understanding the various contextual factors that contribute to the feasibility, acceptability, and usefulness of palliative care interventions in low resource countries is imperative to the intervention's sustainability (9). To begin this process, identifying the models of palliative care programs in low resource countries that have reported patient outcomes is necessary. Another step in the process is to evaluate palliative care programs from the perspective of key stakeholders to reveal its strengths and places where improvement can occur. A third step is exploring the acceptability of the workforce that is integral to the success of palliative care programs in rural areas from the perspective of key stakeholders. Gathering data about the acceptability of people, processes, and implementation of the intervention is important to designing palliative care interventions that are sensitive to specific community contexts.

Gaps in Literature

The systematic review of palliative care intervention outcomes and outcome measures in low resource countries (manuscript 1) discusses the gap that exists in the reporting of intervention outcomes and the identification of reliable and validated instruments by which to measure the outcomes (14,12,13,15). In order to develop, implement, and improve palliative care interventions in low resource areas, research into outcomes is necessary. To date, much of the research evaluating the impact of palliative care on patients and health systems have been conducted in high resource countries such as the United States, Canada, and countries in the United Kingdom and Europe. In low resource countries, only a handful of palliative care interventions have been implemented and little research has been conducted to evaluate palliative care interventions within the context of a limited resource setting (12).

Research on palliative care in and from low resource countries has little representation within the palliative care literature itself (11). Because physicians and other clinicians are scare in rural India (16), it has been recommended that palliative care may be effectively delivered by community caregivers and volunteers supervised by trained personnel (17-19,7). Studies assessing the use of CHWs managing and delivering palliative care in rural India are few in number, and equally limited are qualitative studies that evaluate such palliative care interventions in terms of feasibility, acceptability, and usefulness from the perspective of key stakeholders. To identify the successes and challenges of implementing a home-based palliative care program delivered by CHWs in rural areas outside of Kolkata, India, manuscript 2 reports on an evaluation of feasibility, usefulness, and acceptability of a piloted palliative care program from the perspective of CHWs and the clinical team members who provided them with training and support.

Understanding successful intervention components and contextual factors may influence the appropriateness and adaptability of palliative care interventions from one setting to another setting, and determine whether it is suitable for dissemination and implementation in other similar low resource settings (20). Evidence from a dimensional concept analysis of the concept of acceptability of RMPs in rural India forms the discussion of manuscript 3. In rural India, health care providers who lack formal medical qualifications deliver up to 80% of all primary outpatient care (21,22). The utilization of these informal providers, who are also known as “rural medical practitioners” (RMPs), is driven by their widespread availability as well as the lack of trained medical providers in rural areas of India (21,23-25). Despite serving as the first point of care as well as entry into the health system in rural India, RMPs are rarely featured in scholarly studies (23,25-28). While a handful of studies assess the quality of care that RMPs provide (21,25,27, 29), fewer studies examine the feasibility of healthcare interventions that may employ RMPs. Potentially key to the success of such interventions is the RMP, a controversial figure in the eyes of the Indian state governments and the Indian Medical Association (IMA) due to their lack of formal medical training (25,29). Clarifying the acceptability of the RMP as an informal health care provider in rural India from the perspective of patients, formal providers, and RMPs may be useful in designing interventions in rural India that utilize this existing workforce.

Design and Methods

The design and method of the first manuscript in the compendium, a systematic review of palliative care intervention outcomes and outcome measures in low resource countries, follows the guidelines offered by the PRISMA Statement for transparent reporting of systematic reviews which involves specific and reproducible steps such as identifying pertinent records, choosing eligible studies, and extracting and synthesizing the data (30).

The design of the second manuscript is a qualitative descriptive study using a grounded theory approach that used individual semi-structured interviews to evaluate the palliative care program’s feasibility, acceptability, and usefulness from the perspective of key stakeholders. The transcripts from the interviews were analyzed according to the constant comparative method where existing data were repeatedly compared to new data and which involved continuous recoding (31). Open coding analytically breaks down data in which conceptually similar themes were be grouped into categories and subcategories (32).

The third manuscript used a dimensional concept analysis (DCA) approach described by Caron and Bowers (2000). Dimensional concept analysis is founded on the assumptions that reality is socially constructed, informed by multiple perspectives, and contextually situated (33). Dimensionalizing is a basic quality of the way we think; we understand or define a situation by separating its different relevant dimensions, and by putting the dimensions together, create a whole meaning of the situation. The perspective of the source of the dimensions as well as the context of the dimensions are integrated into the defining and understanding of the situation and thus become part of the analysis (33). In other words, DCA gives us a way of understanding a complex concept as it is situated within certain perspectives and contexts.

Theoretical Frameworks

The theoretical framework guiding the systematic review (manuscript 1) and the qualitative evaluation (manuscript 2) was Engel's (1980) Biopsychosocial Model (BPS). Since the impact of palliative care services on patients and families is multi-dimensional, including physical aspects of illness and health as well as psychosocial aspects, the BPS that sees illness, including pain, arising from the effects physical, social, and psychological factors have on each other (34) was useful to organize and analyze study findings. The second theory used in the two manuscripts was the Donabedian model, a systems model for evaluating the quality of care that includes three interconnected areas -- structure, process, and outcome (35). Structures are the human, material, and organizational resources, process describes the delivery and reception of the health services, and outcomes are the results or effect the services have on patients (35). In the systematic review, we embedded the BPS within the outcomes aspect of the Donabedian model to provide an interactive framework within which palliative care outcome measures and outcomes were organized and understood. In the qualitative evaluation, the BPS and the Donabedian model guided the development of the interview guide questions for stakeholders.

A third theoretical framework, the Social Ecological Model (SEM) (36), also informed the qualitative evaluation of the palliative care program in rural India (manuscript 2) since SEM addresses the social, institutional, and cultural contexts of people living in their environment (37). The SEM was used initially to inform the questions that were asked of each stakeholder group and subsequently to organize their input in terms of their role in the home-based palliative care model. By contextualizing the role of each stakeholder group, the SEM was useful in helping to capture the holistic nature of palliative care.

Two of the three theoretical frameworks were useful to the third manuscript, the dimensional concept analysis of acceptability of rural medical providers (RMPs) in rural India. The Donabedian Model was informative because the concept of acceptability of a person as a provider of healthcare falls into the realm of structure, human resources, and can influence the process and outcome of the intervention. The SEM was informative because acceptability is a subjective quality and thus may be perceived differently by actors at the various levels of the SEM. For example, an informal provider might be acceptable to patients and formal providers at the individual and interpersonal level, but not at the institutional and policy level of the model.

Brief Description of Three Manuscripts

The purpose of this compendium is to characterize strategies for optimizing the reach and effectiveness of palliative care in low resource countries. It aims to achieve this purpose through three manuscripts:

Manuscript 1 is a systematic review that examines palliative care interventions, outcomes, and outcome measures in low resource countries. It evaluated the outcomes and the outcome measures used to assess palliative care models studied in low resource areas.

Manuscript 2 is a qualitative evaluation of a palliative care intervention using a grounded theory approach based in a cancer center in Kolkata, India, that used CHWs to manage and deliver palliative care to rural patients in their homes. The evaluation used interview transcripts from key stakeholder interviews, including the CHWs and the clinical team members who trained and supported the CHWs.

Manuscript 3 is a dimensional concept analysis of the concept of acceptability of RMPs delivering health care to rural patients in India. The DCA utilized a literature search as well as interview transcripts from Manuscript 2 to develop five dimensions and two sub-dimensions of the concept of acceptability. The perspectives of patients, formal medical providers, and RMPs formed the basis of the analysis.

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Chapter 2: Manuscript 1

A Systematic Review of Palliative Care Intervention Outcomes and Outcome Measures in Low Resource Countries

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Figure 1: Conceptual model of palliative care with outcomes being evaluated

Figure 2: Overview of search strategy used to conduct the literature review

Word count: 6292, number of references: 64

Abstract

Context:

To meet the growing need for palliative care in low-resource countries, palliative care programs should be evidence-based and contextually appropriate. This study was conducted to synthesize the current evidence to guide future programmatic and research efforts.

Objectives:

This systematic review evaluated palliative care outcome measures, outcomes, and interventions in low resource countries.

Methods:

Following title searches, abstracts and full text articles were screened for inclusion. Data were extracted to report on intervention models, outcome measures used, and subsequent intervention outcomes.

Results:

Eighteen papers were reviewed, reporting on interventions conducted across nine low resource countries. These interventions evaluated home-based palliative care models, a community managed model, palliative care integrated with hospitals, hospices, or HIV clinics, and models focused on patient self-management. Three studies were randomized controlled trials (RTCs). Other studies used non-randomized trials, cohort studies, mixed methods, pre-post test evaluation, cost-accounting evaluation, and cross-sectional surveys. Thirteen studies measured physical outcomes, ten using multidimensional instruments. Nine studies measured psychological outcomes, eight using multidimensional instruments. Nine studies measured social outcomes, seven using multidimensional instruments. Nine studies measured outcomes across multiple domains. Across outcomes evaluated, results were reported in the direction of benefit associated with palliative care interventions.

Conclusion:

Many palliative care intervention models exist to serve patients in low resource countries. Yet, limited high quality evidence in palliative care research is available from low resource countries. Rigorous experimental studies and greater measurement of holistic, multidimensional aspects of palliative care are needed to advance the science of palliative care in low resource settings.

Keywords: Palliative care, systematic review, low-resource countries, palliative care measures, palliative care outcomes, palliative care interventions

Running Title: Palliative Care in Low Resource Countries

Introduction

The need for palliative care worldwide is reflected in the over 19 million adults who will require palliative care over the course of terminal and chronic illnesses and at the end of life, the majority of whom live in low and lower middle income countries (1). Developed as a way to improve the quality of life of patients with life-threatening or chronic conditions, palliative care is designed to prevent and treat suffering through identifying and evaluating pain and other physical, psychosocial, and spiritual issues (2).

Over 8 million people die of cancer every year and 50% of these cancers occur in low resource countries where palliative care services are scarce (3). People living with HIV/AIDS and other chronic diseases such as tuberculosis in low resource countries also require palliative care and prolonged support (4,5). Although acknowledged by the World Health Organization as an important part of health care and a basic human right, palliative care is still not widely available across the globe (2). In 2011, 58% of the world's 234 countries had some level of hospice/ palliative care services and only 8.5% (20 countries) had achieved advanced integration of palliative care within their health systems (6).

To date, the majority of studies evaluating the impact of palliative care on patients and health systems have been conducted in high resource countries such as the United States, Canada, and England. Evidence from these studies demonstrates that palliative care can improve the management of pain and other symptoms, reduce hospital stays, and enable patients to die at home (7). For cancer patients, integrating palliative care with curative treatments can lead to improved care, quality of life, and possibly longer survival (8). Recent studies also demonstrate that meeting national care standards reduces hospital admissions and deaths for patients and that combining hospice care with acute care for terminal cancer patients can improve quality of life (9,10). Studies in high resource areas also demonstrate that early palliative care for oncology patients can decrease the use of anticancer treatments in the last 30 days of life (11,12). Such studies are not routinely conducted in low resource countries (13).

Research in palliative care in low resource countries is lacking even as palliative care provision expands (14,15,16). Just over one percent of all palliative care literature published is contributed by low resource countries (3). High quality research is needed to provide an evidence base of effective interventions and their contextual implementation (14,15,17). To help fill this gap in evidence, the purpose of this paper is to offer readers a snapshot of the intervention models that have been evaluated in low resource countries, along with the instruments that have been used to carry out this work and associated intervention outcomes.

Theoretical Framework

The theoretical framework guiding this review is the Donabedian Model that offers an outline for evaluating health service systems and the quality of health care. It includes three interconnected domains -- structure, process, and outcome (18). Structures are the human, material, and organizational resources; process describes the delivery and reception of the health services; and outcomes are the results or effect the services have on patients (18). Thus, for the current study, the Donabedian Model provides a framework for organizing the literature in terms of both project implementation (processes and structures) and outcomes. The impact of palliative care services on patients and families is multi-dimensional, including physical aspects of illness and health as well as psychosocial aspects. The concept of palliative care reflects Engel's (1980) biopsychosocial model (BPS) that sees illness, including pain, arising from the interactions of physical, social, and psychological factors (19). The Donabedian Model, in conjunction with the BPS model, offers guided mapping of the domains and outcomes evaluated in low resource countries. Building on these conceptual models, Figure 1 provides an overview of the biological, psychological, social, and process/implementation domains and related outcomes and instruments that were evaluated within the context of this systematic review.

Methods

Design statement

A systematic literature review was conducted following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.

Search strategy

In consultation with a reference librarian, the CINAHL, PsycINFO, and PubMed databases were searched from October 6, 2016 through February 15, 2017. Hand searching of reference lists from retrieved journal articles, including systematic reviews, was also conducted to identify additional records that matched inclusion criteria.

Search terms

The search term string [(MH Palliative Care) OR “palliative care” OR (MH Hospice and Palliative Nursing) OR (MH Hospices) OR (MH Hospice Care) OR hospice OR (MH Hospice Patients) OR (MH Terminal Care) OR “end of life care”] was combined using the Boolean term AND with [(MH Outcome Assessment) OR (MH Treatment Outcomes) OR outcomes OR (MH Evaluation) OR evaluation OR (MH Program Evaluation) OR assessment OR findings OR results AND country string AND (intervention OR program OR service)]. The results were combined using the Boolean term AND with a list countries designated by the World Bank country and lending group classification as low income and lower middle income (i.e. low resource countries).

Inclusion/exclusion criteria

The literature search used the following inclusion criteria: inclusion of human subjects, published in English, describing a palliative care intervention, reporting quantitative intervention results, carried out in low resource countries. Studies were excluded if they were editorials, commentaries, or case studies only, and if they were not published in peer reviewed journals. Systematic reviews were hand searched for studies that met inclusion criteria.

Results

Figure 2 provides an overview of the search strategy used to carry out this literature review. A total of 2179 articles was identified by database searching with an additional two potential articles found by searching reference lists of identified articles and systematic reviews. After removing duplicates, 2021 articles were screened via title and abstract review with 1973 articles excluded because they did not meet our search criteria. For the remaining 48 articles, full-text articles were assessed for eligibility with 30 articles excluded because they were not carried out in a low resource country (n=22), they did not report palliative care outcomes (n=2), they were not a palliative care intervention (n=1), and because they were qualitative studies (n=5). Eighteen studies were retained for data extraction for this review. Table 1 provides an overview of these studies. Table 2 provides a description of outcome measures used and associated intervention outcomes, and Table 3 provides a description of process measures evaluated and associated process outcomes.

Settings and Samples:

In the 18 articles reviewed, nine countries were represented: India, Vietnam, and seven countries in Africa. One study was set in northern Vietnam (20). Six studies were set in India -- one in Mumbai (21), one in Chandigarh (22), two in Tamil Nadu (23,24), one in Kerala (25), and one in an unnamed area. The other 11 studies took place in Africa: three in South Africa (27,28,29), one in Zimbabwe (30), Tanzania (31), Nigeria (32), and Uganda (33), two in Kenya (34,35), and two in Malawi (36,37).

Settings for studies included patients' homes (21,24,25,27,33,34,37), regional hospitals and clinics (21-23,26,28,29,31,33,34,36,37), a hospital with daycare hospice center (32), HIV clinics (20,31,35,37), and hospices (27,30). Participants in the various studies included patients with advanced cancer, HIV/AIDs, or other end-stage chronic diseases. One study focused on the elderly and quality of life (24).

Interventions:

Palliative care interventions included two pilot studies geared towards self-management of pain and other symptoms. The first study examined use of a home-based pain assessment card for patients (34), and the other evaluated use of a color-coded symptom management kit and training for caregivers (23). Two studies examined home-based palliative care (21,25), and one study examined a community managed palliative care program for the elderly (24). Two studies reviewed expanding the reach and effectiveness of palliative care services through the training and supervision of community volunteers (27,30). Four studies reviewed interventions delivered by nurses: two educational programs set in HIV clinics (35,37), a children's palliative care program (33), and one testing a hospital-based palliative care intervention (29). Several studies examined palliative care programs set within existing structures. Five studies evaluated palliative care programs integrated with hospitals: a clinic in a radiology department (22), an outreach to rural patients (26), an analysis of hospital admissions and place of death (28), and two examining palliative drug therapy (32,36). Four studies evaluated delivery of palliative care services integrated within HIV clinics (20,31,35,37).

Study Designs:

Only three of 18 studies used a randomized controlled trial (RTC) design, with two randomized at the patient level (35,37) and one randomized at the cluster level (24). Two studies were non-randomized trials that compared outcomes among similar service units that did and did not receive a palliative care intervention (20,31). Six studies were cohort studies that used prospective (21,22,26,34) and retrospective (28,32) study designs. Three studies were mixed methods that included retrospective (33) and prospective (27,36) cohort analyses, respectively. One study was a pre-post test training evaluation survey (30), one study was a cost-accounting evaluation (29), and two studies used cross-sectional surveys (23,25).

Biological Measures:

Visual Analogue Scale (VAS). The VAS is a well-established validated tool for measurement of pain that has also undergone local validation using a modified verbal rating scale (MVRS) for use in sub-Saharan Africa (38). Strong statistically significant correlations were observed between the original VAS and MVRS by the same tester ($r=0.92$, $p<0.01$; $r = 0.89$, $p<0.01$respectively,) and between testers ($r=0.91$, $p<0.01$) (38). The VAS takes less than one minute to complete, and is easily understood in low literacy settings (38). Validity studies in the U.S. indicate high test-retest reliability with inter correlation coefficient (ICC) scores ranging from 0.71 to 0.99 (39).

Bisht, et al. (2010) reported a significant reduction in VAS pain scores for Indian patients after palliative drug therapy. Pain was reduced by 63% after 1 month for 93 patients (p<0.001) and by 71% after 2 months for 51 patients (p<0.001) (26). Palliative care services improved pain relief for Nigerian patients in the study by Elumelu, et al. (2013). Pain control was achieved for 57% of breast cancer patients from 3.02% at baseline, and for 69% of cervical cancer patients from 8.75% at baseline (32).

Two instruments in this review were developed from the VAS. In the study by Besley, et al. (2014), a color-coded, patient-held pain management card was created for patients in Kenya with translations into several local Kenyan languages. Besley, et al. (2014) found that 30% of usual care patients and 69% of intervention patients achieved pain relief (p-value comparing mean pain scores between groups = 0.0016).
Another scale developed from the VAS was the Indian Hundred Paisa Pain Scale (HPPS). The HPPS uses local currency (paisa) rated on a scale of 0 to 100 paisa to indicate pain intensity (40). Concurrent validity of the HPPS and VAS is strong (r = 0.855) (40).

Bansal, et al. (2003) found that among patients with uncontrolled pain referred to a radiology department’s palliative care clinic, 42% of patients experienced pain relief by the second visit. By the third visit, 50% of patients achieved a 50% -75% reduction in pain, and by the fifth visit, 56% of patients achieved a 75%-100% reduction in pain from baseline (22).

Brief Pain Inventory. The Brief Pain Inventory (BPI) includes items that report the sensory dimension of pain (severity) and the patient’s reaction to pain (interference with daily life) (41). The instrument includes front and back body diagrams, four pain severity items and seven pain interference items rated on a 0 to 10 scale (least to worst), in addition to a question about the percentage of pain relief achieved by analgesics (41). The instrument has been widely translated and validated for multiple populations with a variety of conditions from depressive disorders to cancer pain (41). The BPI has been used in sub-Saharan Africa (42). In the U.S., the BPI has a reliability of 0.87 (Cronbach's alpha) among cancer patients that is considered strong (43). The Brief Pain Inventory Pain Interference subscale (BPI-PI) has a reliability of 0.91 (Cronbach's alpha) among cancer patients in the U.S., which is also considered strong (43). The BPI short form takes five minutes to complete and is rated on a 0-10 scale with four pain severity items and seven pain interference items.

The BPI was used by Nkhoma, et al. (2015) to evaluate a patient pain education program in Malawi. Nkhoma, et al. (2015) reported that patients in the pain education group experienced a decrease in pain severity from 50.76 to 92.62 (higher scores represent better outcomes) (adjusted mean difference =21.25, p <0.001) and a decrease in pain interference from 49.1 to 93.67 (adjusted mean difference =24.5, p<0.001).

Patient Pain Questionnaire-Knowledge. The Patient Pain Questionnaire (PPQ) is a 16-item scale that measures a patient's knowledge (9 items) and experience (7 items) in managing cancer pain. Items are formatted so that 0 is a positive outcome and 10 a negative outcome (44). As studied in the U.S., the PPQ has strong content validity (r= 0.95), good test-retest reliability (r= 0.65), and acceptable internal consistency (Cronbach's alpha =0.74) (44).

Family Pain Questionnaire-Knowledge. The Family Pain Questionnaire (FPQ) is a 13-item scale that measures caregivers' knowledge of pain management (9 items) and their experience and distress with a patient's pain (4 items) (45). Caregivers respond to the items on a VAS scale where 0 is least favorable response and 100 is most favorable response. The FPQ has an overall strong reliability of (Pearson's r=0.92, p=0.01) and good internal consistency of 0.81 (Cronbach's alpha = 0.81, p=0.01) (45).

Nkhoma, et al. (2015) used the 9-item pain subscale of both instruments to evaluate a patient and caregiver pain education program. Although not specifically validated for countries in Africa, informal testing of the scales by Nkhoma, et al. (2015) suggested the scales were usable by the study's population. Nkhoma, et al. (2015) reported that patients' knowledge of pain improved from 67.78 to 92.63 (adjusted mean difference = 20.39, p<0.001) (higher scores represent better outcomes) as it did for caregivers, improving from 65.29 to 91.36 (adjusted mean difference = 20.32, p<0.001).

Karnofsky Performance Status Scale. The Karnofsky Performance Status (KPS) scale describes ten levels of function and is scored from 100% (fully functional) to 0 % (deceased) (46). Commonly used and translated into many languages, the KPS has good reliability and moderate validity for cancer patients in the U.S. with inter-rater reliability of 0.89 (Pearson's correlation coefficient) and construct validity for all 18 variables correlating with the KPS for physicians at r> ± 0.4 (all p≤ 0.05) (47). It has been shown to predict survival among HIV-infected patients in rural Zimbabwe (48).

DiSorbo et al. (2010) reported that the percentage of Zimbabwean patients with a baseline KPS score of 80% or greater increased from 28% in year one to 50.5% in year two of a home-based palliative care outreach program using volunteer teams.

Psychological Measures:

The General Household Questionnaire -12. The General Household Questionnaire -12 (GHQ-12) is the brief version of the 60-item GHQ, and it measures psychological morbidity by asking whether the patient has recently experienced a particular symptom or behavior (49). Each item is rated on a four-point scale and recommended scoring ranges from 0 (best) to 12 (worst) (49). Taking about two minutes to complete, the GHQ-12 has been translated into many languages, has satisfactory reliability, and has been validated with different populations in different countries (50,51). For sub-Saharan Africa, the GHQ-12 has a sensitivity of 68% and specificity of 70% (35).

Lowther, et al. (2015) used the GHQ-12 to measure the psychological distress of Kenyan patients living with HIV infection and receiving palliative care. Statistically significant differences were not observed between the intervention and control groups, with 5- vs. 4-point reductions observed in these groups respectively (p-value for between group difference in change =0.95) (35).

Social Measures:

Island Hospice Supervision and Mentorship Checklist. The Zimbabwean Island Hospice Supervision and Mentorship Checklist was used by Di Sorbo, et al. (2010) to evaluate the training of home-based palliative care teams. The Checklist was transformed into the "Self-Assessment Checklist of Patient and Family-Centered Care" offered to hospice organizations registered with Global Partners in Care. No information on instrument items or the instrument's reliability, validity, or feasibility for the original checklist or the current version was identified through our literature search. DiSorbo, et al. (2010) reported that volunteer caregivers' scores improved from 0% to 66% between pre and post-test training evaluation.

Picot Caregiver Rewards Scale. The 16-item Picot Caregiver Rewards Scale (PCRS) measures positive appraisals of caregiving with a Likert format from 0 (not at all) to 4 (a great deal), with higher scores suggesting greater rewards (52). Validated in the U.S., the PCRS has good internal consistency of 0.88 (Cronbach's alpha) and strong test-retest reliability (r= 0.75) (52).

Nkhoma, et al. (2015) used the PCRS to evaluate a pain education program for patients and caregivers, and informal testing of the scale suggested that it was feasible for use by caregivers in Malawi. The study found that caregiver motivation in the intervention arm increased from 78.91 to 97.13 and the control group's motivation increased from 79.41 to 89.52 (higher score = better outcome) (adjusted mean difference =7.64, p <0.001) (37).

Multi-Dimensional Measures:

African Palliative Care Association (APCA) Palliative Care Outcomes Scale (POS). The APCA POS is a 10-item measure addressing multiple domains: physical and psychological symptoms, spiritual, practical and emotional concerns, and psychosocial needs of the patient and family. It was developed and validated in ten palliative care centers across eight sub-Saharan African countries (31). Questions 1-7 are directed at patients; questions 8-10 are directed at family informal caregivers. Items are rated on a Likert scale from 0 to 5. It combines two rating systems – one where high scores equal the best status and the other where low scores equal the best status. It is appropriate for a range of literacy skills (53). For sub-Saharan countries, the APCA POS has a moderate construct validity of 0.538 (Spearman's coefficient) when compared with the other African validated palliative care measure, the 26-item Missoula-Vitas Quality of Life Index (MVQoLI), and a low internal consistency of 0.60 (Cronbach's alpha) (53). It takes 5-7 minutes to complete (53). The APCA POS's moderate construct validity and internal consistency correlations with the MVQoLI is likely due to underlying differences between these two measures: the MVQoLI is longer than the APCA POS (26 items versus 10); it does not measure family caregivers' quality of life; and it also measures physical functioning (53).

The pain subscale of the APCA POS is a single question and it was used in three studies. Two studies used the subscale to evaluate patients' pain relief while enrolled in an HIV clinic: Harding et al. (2013) reported that the odds of patients' pain being reduced with drug therapy improved over 10 weeks ($p<0.001$) in Tanzanian clinics, and Lowther, et al. (2015) reported that Kenyan patient pain scores changed from 1 to 4.5 (0=worst outcome/5=best outcome) in the intervention arm, but that scores did not significantly improve compared with standard care (p=0.83) (35). The pain subscale was also used by Herce, et al. (2014) in a hospital study in Malawi that combined palliative care with curative care. Herce, et al. (2014) reported the mean APCA POS pain score decreased from 3.0 at baseline to 2.7 (0=best outcome/5=worst outcome) at follow up in those patients with documented baseline pain and pain assessment, but these results were not statistically significant (p = 0.5) (36).

The complete APCA POS was used to measure quality of life in six studies. Two of the six studies reported using the scale but did not report overall scale results (27,30).

Three of the six studies using the APCA POS examined palliative care programs integrated into HIV clinics: Harding, et al. (2013) reported improved patient mean POS scores from 18.95 at baseline to 2.15 (p<0.001) (lower score=better outcome) in Tanzanian patients. Lowther, et al. (2015) reported improved total APCA POS scores for patients moved from 19.0 at baseline to 31.0 at 4 months (*p*=0.001) (0=worst outcome/35=best outcome), and the mean difference of scores between the study group and the control group was statistically significant (p=0.04). Nkhoma, et al. (2015) reported improved quality of life for patients and caregivers in Malawi: scores improved from 44.78 to 90.58 in patients (adjusted mean difference = 28.76, p<0.001) and for caregivers, from 44.2 to 92.66 (adjusted mean difference = 34.16, p<0.001) (0=negative outcome/100=positive outcome).

A study by Hongoro and Dinat (2011) that evaluated wide ranging hospital-based palliative care services in South Africa, reported improvement in patients' quality of life: mean APCA POS scores for patients' pain, symptoms, worry, and family worry decreased by 51%, 56%, 53%, and 56% over baseline, respectively ($p < 0.005$).

City of Hope Quality of Life Survey. The City of Hope Quality of Life Survey (QOLS) is an earlier version of the Quality of Life – Cancer Survivors Instrument (QOL-CS) developed and tested by Ferrell, et al. (1995) in the U.S. The earlier QOLS was also developed and tested by Ferrell, et al. (1989) and is a multi-dimensional instrument consisting of 28 VAS questions scored 0 to 100 that measures quality of life for cancer patients. Based on psychometric testing in the U.S., the QOLS has robust internal consistency (Cronbach's alpha =0.88) and moderate test-retest reliability of $r > 0.60$ (54). Content validity was tested using a panel of experts in oncology and pain management, yielding a content validity index of 0.90 (54).

Bisht, et al. (2010), who used the City of Hope QOLS among patients with advanced cancer in rural India reported that that patients' quality of life scores improved 40% after one month of drug therapy in 93 patients ($p<0.01$) and 30% after two months in 51 patients ($p<0.01$) (26).

Edmonton Symptom Assessment Scale. The Edmonton Symptom Assessment Scale (ESAS), is considered the "gold standard" for symptom assessment as it addresses the patient's opinion of his/her symptoms (55,56). The ESAS assesses 9 common symptoms in cancer patients, from pain to wellbeing, and takes about 5 minutes to complete. Symptoms are rated on a scale of 0 to 10, with 0 meaning absence of symptom and 10 meaning worst aspect of symptom. For cancer patients receiving palliative care in the U.S., the overall Cronbach's alpha for the ESAS is 0.79 (57). The ESAS has been validated for cancer patients and translated into several languages and adopted for symptom screening in countries in North America, South America, Europe, Asia, and Africa (55).

Dhiliwal and Muckaden (2015) used the ESAS among patients in Mumbai, India, enrolled in home-based palliative care services coordinated by a hospital. The study reported that patients' pain score changed from 3.887 at the first home visit to 0.173 at the second visit, and patients' sense of wellbeing improved from 3.907 at the first home visit to 1.150 at the second visit ($p<0.005$) (21).

Medical Outcomes Study-HIV. The Medical Outcomes Study-HIV (MOS-HIV) measures HIV disease-related quality of life. It consists of 35 items assessing 10 dimensions of health in people living with HIV, ranging from mental health and quality of life to pain and social functioning, and it yields two summary scores: physical health score (PHS) and mental health score (MHS) (58). The MOS-HIV is feasible to use, as it only takes about 5 minutes to complete, and it has been translated into 19 languages. It is scored on a 0 to 100 scale with higher scores indicated better functioning. Based on psychometric evaluation in the U.S., internal consistency reliability for the PHS was 0.91 and for the MHS it was 0.94 (59). It has been validated for use with patients with HIV disease in the

U.S. with Cronbach's alpha coefficients mostly exceeding 0.70 (60). While most validation studies have been performed comparing the French, German, Italian, Dutch, and UK version of the scale (60), the MOS-HIV has also been validated in an African setting (31). Overall reliability when tested in rural Uganda was 0.79 (Cronbach's alpha) (33,61).

Two studies used the MOS-HIV to examine palliative care programs integrated within HIV clinics: Harding, et al. (2013) reported Tanzanian patients' mean PHS improved from 39.16 to 53.75 over 10 weeks ($p < 0.001$). The mean MHS in the intervention group improved from 47.65 to 59.98 ($p < 0.001$) (31). Lowther, et al. (2015) reported improvement in Kenyan patients' mean MHS from 44.8 to 57.9 ($p = 0.001$) and mean PHS from 45.0 to 55.7 ($p = 0.0016$). However, MHS and PHS scores between the study group and the control group were not statistically significant (MHS mean difference, $p=0.23$; PHS mean difference, $p=0.88$) (35).

World Health Organization Quality of Life Questionnaire, Brief Version. The WHOQOL-BREF is a 26-item instrument scored on a scale from 0-100 covering multiple domains of quality of life, including physical, psychological, social, and environment (62). The WHOQOL has been translated into many languages, including Tamil, the language of Tamil Nadu, India, and validated in many countries, such as Iran, Brazil, Norway, and Malawi. Psychometric properties for the WHOQOL-BREF were obtained by using cross-sectional data from persons across 23 countries from a variety of settings (63). For the total sample, internal consistency values for Cronbach's alpha were >0.7

and summary Pearson correlations (one-tailed test) ranged from 0.46 (physical versus social domain) to 0.67 (physical versus psychological domain) ($p<0.0001$) (63).

Set in villages in Tamil Nadu, India, the study by Dongre, et al. (2012) evaluated the quality of life of elderly persons served by a community-managed palliative care program. Researchers used a "validated 'Tamil' version" of the WHOQOL-BREF[24] (p. 220) with mean physical health scores being 10.47 (±1.80 SD) for project villages versus 10.17 (±1.82 SD) in control villages (higher scores=better outcome), although these results were not statistically significant ($p=0.13$) (24). Mean psychological health scores in project villages were 10.13 (±2.25 SD) versus 9.8 (±2.29 SD) versus control villages (higher scores=better outcome), which were also not statistically significant ($p=0.43$) (24).

Site-specific Measures. Defilippi and Cameron (2010) developed a 17-item survey designed to evaluate community caregiver competencies for patients enrolled in home-based palliative care. The results from the survey informed the development of a five-day palliative care training program after which the survey was conducted again. No specific information on the instrument was reported, but caregiver competencies were reported to improve by 28.5% post-test (27).

Implementation Measures:

Data on palliative care project implementation were derived from numerous sources, including retrospective chart reviews, hospital activity records, questionnaires, and satisfaction surveys. Table 3 describes the implementation outcomes reported in these studies.

Assessment and Treatment of Symptoms. In a study that examined the effect of a children's palliative care program in Uganda, the number of children prescribed morphine increased by 175% and the number prescribed chemotherapy increased by 118% (33).

Two studies reported results of palliative therapy integrated with an HIV clinic: Herce, et al. (2014) reported that in a Malawi clinic, 89% of cancer patients had baseline pain documented, 67% had morphine prescribed at first follow up and 33% had other analgesia prescribed at first follow up (36). Green, et al. (2010) reported an increase of 98% patients (338 of 345) assessed for symptoms in northern Vietnam with 93% patients (321 of 345) being assessed on return visits.

Patients' KPS scores were reported to be documented 100% of the time by palliative care staff embedded in a radiology clinic in the study by Bansal, et al. (2003). The study also reported that pain treatment for patients changed from visit 1 where 65% patients received codeine and acetaminophen to visit 5 where 26% patients received codeine and acetaminophen and 63% patients received morphine (22).

Assessment in the study by Dhiliwal and Muckaden (2015) in Mumbai, India, revealed that psychological counseling was needed by 17% of home-care patients and/or caregivers.

Place of Death. In a study by Dhiliwal and Muckaden (2015), over 57% of the patients registered with the Department of Palliative Care in Mumbai, India, for home-based care died at home or at their native place, with 23.81% dying in hospice, and 19.09% in hospital. In another study by DesRosiers, et al. (2014) in Cape Town, South Africa, that examined palliative care services offered in a weekly outpatient hospital clinic, a 40.1% increase in patients dying at home was observed.

Program preferences, satisfaction, and service delivery. Instruments used to evaluate preferences, satisfaction, and service delivery were surveys specifically designed by the study investigators. Five studies evaluated satisfaction with palliative care services. In the study by Amery, et al. (2009), 100% of children and caregivers rated the drugs provided for symptom control and chemotherapy to be a service strength. Sixty four percent of children, 67% of caregivers, and 60% of staff rated the provision of food packs as a service strength, and 80% of children, 58% of caregivers, and 50% of staff rated the provision of play and education as a strength (33). Additional questions were asked about the service but data were not presented numerically. The study by Chellappan, et al. (2011) evaluated caregiver satisfaction with a kit for symptom management and an accompanying training program. Twenty-nine of 30 caregivers used the kit: 93% were satisfied with color-coding for symptom management, 90% were satisfied with the training, and 93% were satisfied with symptom reduction in patients (23). A 48-item questionnaire used in the study by Santha (2011), evaluated palliative service delivery and program preferences. Ninety-six percent of patients surveyed were satisfied with medicines given, and 100% were satisfied with medical treatment. Reduction of pain was of greatest importance to patients and the maintenance or strengthening of their hope to be of next importance (25).

Dongre, et al. (2012) evaluated patients' satisfaction with the services provided by a community-based palliative care program for elderly residents in Tamil Nadu, India. Dongre, et al. (2012) reported that over one month's time, 91.3% of patients were satisfied with the available services, and that 28.5% received home visits, and 26.2% received extra support, such as help with purchasing drugs.

The study by Elumelu, et al. (2013) used a retrospective review of records to evaluate a Nigerian hospice and palliative care unit in a hospital for patients with uterine, cervical, or breast cancer. The study reported that 100% of patients were glad to have palliative care services and found them acceptable and that 46.6% of patients desired palliative care services at their homes in addition to those received at the hospital clinic (32).

Service Costs. Costs of palliative care services were examined in four studies. Amery, et al. (2009) reported that the average cost per child for palliative care services was £50.28 ($US 75.00). Hongoro and Dinat (2011) used a cost accounting procedure for a district hospital in South Africa and found costs for a home visit for patients was US $71.00, 50% less than the average cost of a patient spending a day in the hospital ($142.00). Cost savings was also reported in the study by DesRosiers, et al. (2014) in Cape Town, South Africa, reporting a total of 253 admission days cost $587.00 for intervention patients, representing 194 fewer days with a savings of $622.00 as compared to control patients. The study also reported that the mean number of days spent in hospital for intervention patients was 4.52 days versus 9.3 days for control patients (28). Chellappan, et al. (2011) reported similar cost savings for patients in Tamil Nadu, India. Prior to the intervention, all 30 patients visited hospitals for acute symptom management where 76% of patients paid between 100 to more than 200 Indian Rupees (INR) (US $2.25 - $4.50, 2006 rates) per hospital visit (23). After training the primary caregiver with the symptom management kit, only six patients (20%) made unscheduled visits to the hospital with 96.7% of the patients spending less than 100 INR (US $2.25, 2006 rates) (23). Eighty-three percent of caregivers were satisfied with reduced cost of medical care as a result of using the acute symptom management kit (23).

Discussion

A gap exists between the millions of people in low resource countries around the world estimated to need palliative care and the amount of research that has been conducted in these countries to evaluate which palliative care interventions are effective and under what circumstances. Low resource countries are generally those classified by the World Bank as low and lower middle-income countries[64]. Eighty-four countries are included in this designation, and only nine of these countries were represented in this review: India, Vietnam, and seven countries in Africa: Kenya, Malawi, Nigeria, South Africa, Tanzania, Uganda, and Zimbabwe.

This review revealed a substantial lack of rigorous RTCs conducted in low resource countries to evaluate palliative care interventions. Only three of the 18 studies included in this review used a RCT design that is considered the gold standard for establishing causal evidence (24,35,37), and just one of these reported statistically significant results for the primary outcome (37). While the findings from these 18 studies were promising, more data are needed, especially from rigorously controlled randomized trials, to guide development and implementation of optimal palliative care interventions in low resource countries.

Among the 18 studies in this review, thirteen studies measured physical outcomes (ten using a multidimensional instrument); nine studies measured social outcomes (seven using a multidimensional instrument); and nine studies measured psychological outcomes (eight using a multidimensional instrument). Five studies measured implementation outcomes.

Outside of the studies that used multidimensional instruments that included pain evaluation as part of the instrument, three studies used a VAS pain scale that is quick and simple for patients to use. One study used a hand-held card for patients to assess pain, and one study used two pain instruments that captured additional dimensions of pain, such as pain knowledge and management. In addition to using a multidimensional measure, one study used a psychological instrument to evaluate a patient's departure from mental and emotional well-being. Although using a multidimensional measure, two studies also used an instrument specifically for the social domain: one used a checklist for caregivers and another used a scale that examined the perceived rewards of caregiving. Of the nine studies that used multidimensional instruments, all used an instrument to evaluate QOL. Two QOL instruments focused disease related QOL. Six of the studies measuring QOL used the APCA POS that is validated for sub-Saharan Africa.

Using multidimensional instruments is recommended to capture the holistic nature of palliative care (13). In our review, we identified a gap in the use of multidimensional measures in general, and a lack of validation of some of these instruments in low resource countries. Nine of the 18 studies in this review used multidimensional measures. Six of these studies used the APCA POS, an instrument that provides the first multidimensional palliative outcomes scale that was developed as a comprehensive outcome measure and psychometrically tested for use in sub-Saharan Africa. Although the MVQoLI was the first palliative measure validated in Africa (Uganda), it was originally designed for clinical use and additional testing demonstrated it did not have the properties necessary for use with very ill patients in outcomes research (53). Of the remaining three studies that used multidimensional measures, only one used an instrument, the WHOQOL-BREF, validated for use in low resource countries.

Six of the 15 measures used by studies in this review had been validated within low resource countries: the WHOQOL-BREF, the GHQ-12, the HHPS, VAS, BPI, and the

APCA POS. Harding, et al. (2010) noted that the development of the APCA POS, used across six studies contained in this review, can help develop the missing evidence base for palliative care in Africa by providing an instrument for outcome measurement that was developed to fit the context of low resource settings. The standard use of some key instruments, such as the APCA POS, for measuring palliative outcomes across diverse low resource countries permits the comparison of findings across studies. However, many of the measures we identified had not yet been validated, translated, or commonly used in research across diverse global settings.

A wide array of palliative care intervention models that serve adult patients was identified through this review. Only one study evaluated a children's palliative care program (33), representing a critical gap in the evidence. Intervention models included home-based and community managed programs, those integrated with hospices, hospitals, or clinics, and those that gave patients and caregivers more control over patient symptoms. While all palliative care interventions reported findings in a positive direction across biological, psychological, and social outcomes, the findings did not consistently represent statistically or clinically significant program effects. The greatest gap identified through this review was not the lack of models for palliative care in low resource countries, but the lack of evidence from rigorously designed experimental studies and lack of contextually appropriate instruments for measuring palliative care outcomes in low resource countries.

Limitations

While the search strategy was developed with the assistance of a research librarian, it is always possible that relevant studies were missed. The studies in this systematic review were selected based upon their fit to the inclusion criteria by one researcher, which is a potential bias. A palliative care researcher was consulted if uncertainty about keeping or rejecting a study occurred.

Conclusion

Based on the results of our literature review, diverse palliative care intervention models were identified, but many gaps in the research base remain. There are a limited number of rigorously conducted experimental studies providing confirmatory evidence for the effect of many of the existing palliative care models. There are also a limited number of multidimensional outcome measures being used to capture the holistic nature of palliative care that include biological, psychological, and the social dimensions of care. The need exists for more research into assessing palliative care interventions from a multidimensional perspective. There is a need to expand the range of palliative care measures that have been validated within the context of low resource settings. Finally, there is a need for research to conducted in additional low resource countries and clinical populations, particularly in pediatric palliative care settings.

Acknowledgements: Thank you to Teri Lynn Herbert, MS, MLIS, Library Science and Informatics Department at the Medical University of South Carolina, for her assistance with this systematic review.

Figure 1: Conceptual model of palliative care with outcomes being evaluated

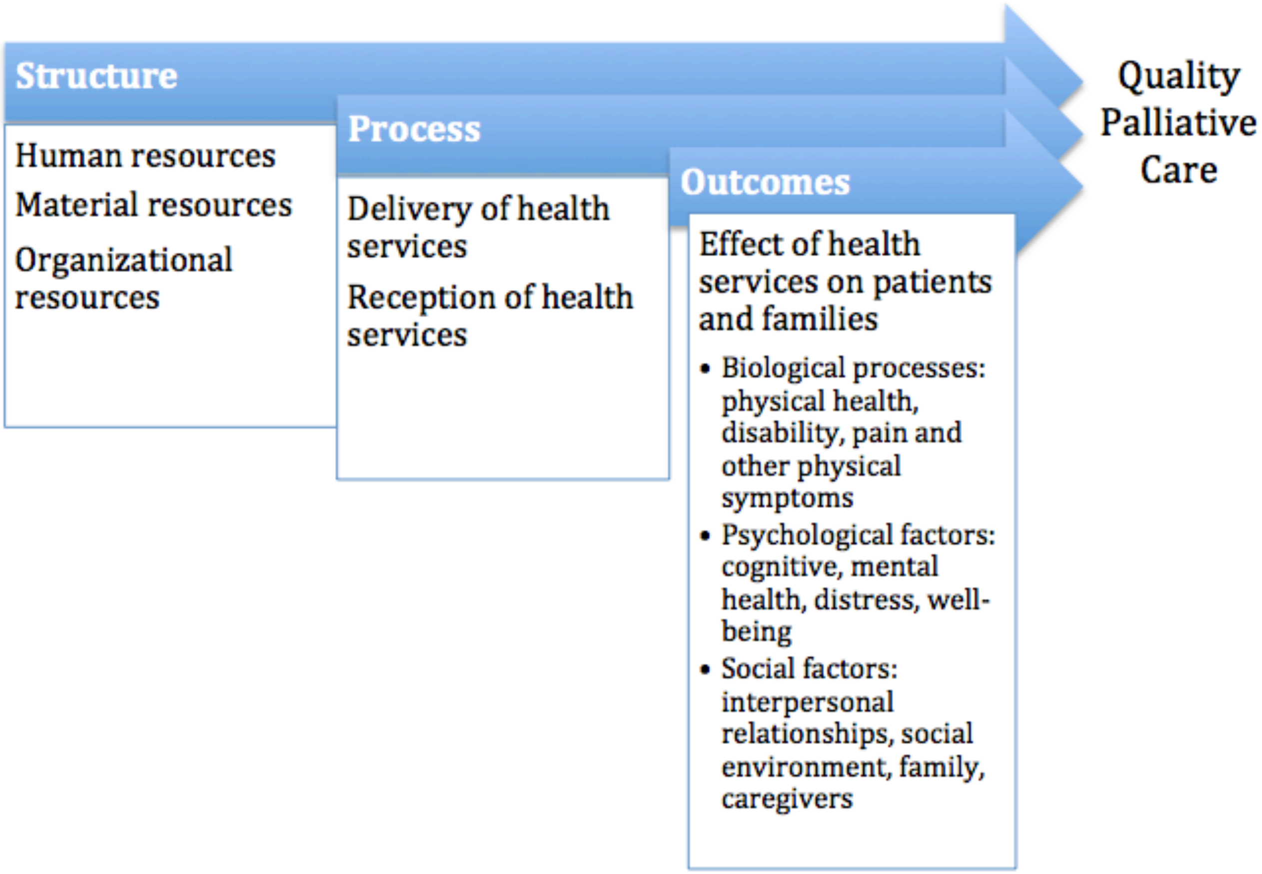

Figure 2. Overview of search strategy used to conduct the literature review

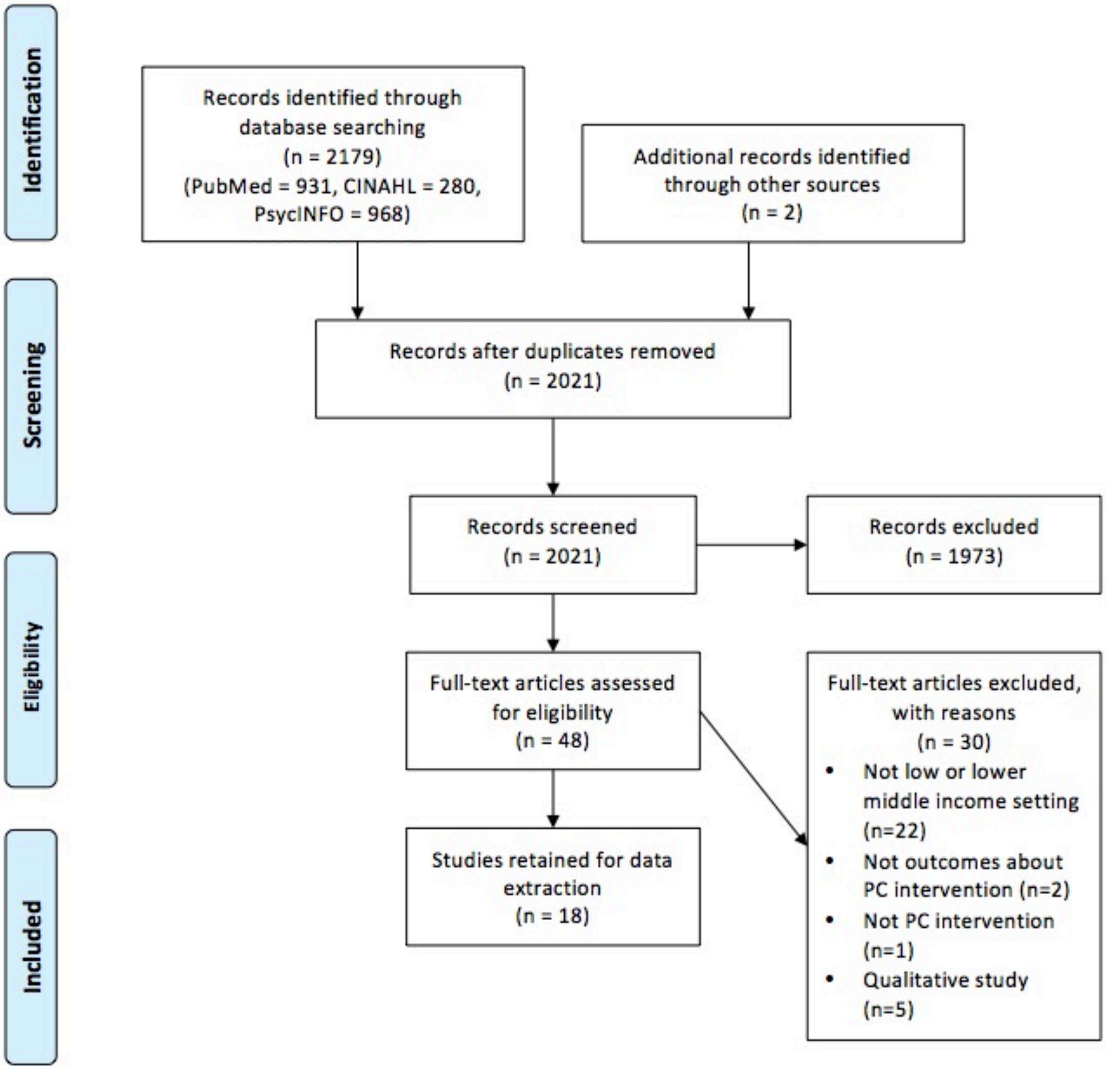

Table 1. Overview of studies assessing palliative care interventions with types of outcomes addressed

Reference	Study design	Intervention	Sample	Setting	Types of outcomes assessed
Amery, JM, Rose, CJ, Holmes, J, Nguyen, J, Byarugaba, C. (2009)	Mixed methods, retrospective cohort study analysis	Nurse-led children's palliative care service for inpatients, outpatients, and through outreach offered by Hospice Africa Uganda (HAU)	All children using hospice services (n=11) Children's parents/legal caregivers (n=12) All hospice and hospital staff on oncology ward (n=10)	National children's oncology ward HAU site in Kampala and patients' homes	Implementation
Bansal, M, Patel, FD, Mohanti, BK, Sharma, SC. (2003)	Cohort study using prospective study design	Palliative care clinic set up in Department of Radiology	100 patients referred to palliative care clinic	PC clinic in Department of Radiology, Postgraduate Institute of the Medical Education and Research (PGIMER), Chandigarh, India	Implementation and biological BPS
Besley C, Kariuki H, Fallon M. (2014)	Cohort study using prospective study design	Patient-held, self-management pain assessment card	88 palliative care outpatient	AIJ Kijabe Hospital, Kenya and patients' homes	Biological BPS

Bisht, M, Bist, SS, Dhasmana, DC, Saini, S (2010)	Cohort study using prospective study design	Palliative care drug therapy for patients in pain from advanced cancer	100 patients with advanced cancer	Oncology clinics at tertiary care teaching hospital, India	Biological and multi-dimensional BPS
Chellappan, S, Ezhilarasu, P, Gnanadurai, A, George, R, Christopher, S. (2014)	Cross-sectional survey	Color-coded acute symptom management kit with palliative medications and structured training program on use	30 patients and their primary caregivers	Christian Medical College, a 2,012-bed teaching hospital with palliative care unit in Tamil Nadu, India	Implementation
Defilippi KM, Cameron S. (2010)	Mixed methods, prospective cohort study analysis	Supervision and training of caregivers to improve quality of care provided to patients at home	24 hospice patients with advanced HIV/AIDS disease 30 caregivers	St. Bernard's Hospice in East London, Eastern Cape of South Africa and patients' homes	Multi-dimensional BPS
DesRosiers, T, Cupido, C, Pitout, E, et al. (2014)	Cohort study using retrospective study design	Impact of palliative care service of a weekly outpatient group clinic and multidisciplinary clinical team on admissions and place of death	Intervention group: 56 deceased palliative care patients Control group: 48 deceased patients	Public district hospital in Cape Town, South Africa	Implementation
Dhiliwal SR, Muckaden M. (2015)	Cohort study using prospective study design	Home-based specialist palliative care services	690 adult palliative care patients with advanced stage cancer	Department of Palliative Medicine, Tata Memorial	Implementation and multi-dimensional BPS

			registered with Department of Palliative Care in 2012	Hospital, Mumbai, India and patients' homes 50-80 km distant	
DiSorbo PG, Chifamba DD, Mastrojohn Iii J, Sisimayi CN, Williams SH. (2010)	Non-randomized controlled trial with pre-post test training evaluation survey	Expansion of existing home-based palliative care teams through training new volunteers in rural areas	92 home-based caregivers and 115 palliative care patients from 3 sites	Island Hospice in Harare, Zimbabwe, Africa	Biological, social, and multi-dimensional BPS
Dongre, AR, Rajendran, KP, Kumar, S, Deshmukh, PR. (2012)	Randomized controlled trial, randomized at cluster level	Community-managed palliative care program for elderly	450 persons aged 60+ from study area 450 persons from adjacent control area	Patients' homes in 46 villages in project area of Tamil Nadu in southern India; 47 villages in adjacent control area	Implementation and multi-dimensional BPS
Elumelu, TN, Adenipekun, A, Soyannwo, OO, et al. (2013)	Cohort study using retrospective study design	Hospice and Palliative Care Unit in hospital offering outpatient daycare hospice and palliative care services, palliative/hospital consultations, and home-based care for patients	178 patients with uterine cervical cancer (n=80) and breast cancer (n=98) aged 17 to 96 years who accessed palliative care in daycare hospice center	Hospice and Palliative Care Unit of University College Hospital in Ibadan, Nigeria	Implementation and biological BPS
Green, K, Tuan, T, Vu Hoang, T, et al. (2010)	Non-randomized controlled trial	Palliative care services integrated into a HIV	822 adult people living with HIV enrolled in two out-patient ART	HIV clinics in Northern Vietnam	Implementation

		outpatient ART setting	clinics		
Harding, R, Simms, V, Alexander, C, et al. (2013)	Non-randomized controlled trial	Palliative care delivered from existing HIV outpatient setting with palliative care training for clinicians and PC drugs	60 HIV patients in control site and 68 HIV patients in intervention site	Two regional hospitals with HIV clinics in Tanzania, Africa	Multi-dimensional BPS
Herce, ME, Elmore, SN, Kalanga, N, et al. (2014)	Mixed methods, prospective cohort analyis	Neno Palliative Care Program (NPCP) designed to integrate pain and symptom relief and psychosocial support with curative treatment	63 adult patients with cancer (n=50) and HIV (n=61) enrolled in NPCP	Neno District Hospital in Neno District, Malawi	Implementation and biological BPS
Hongoro, C, Dinat, N. (2011)	Cost accounting evaluation	N'Doro Palliative Care project offering nurse-led, doctor supported specialist palliative services, outreach visits, in-hospital consultations, emerging drop-in clinic, and telephone advisory service	148 patients registered for home visits were sample for cost accounting 72 patients enrolled in program over 2 mos. period (HIV/AIDS n=53, cancer n=25) were sample for longitudinal study	Chris Hani Baragwanath Hospital, a large teaching hospital in Soweto, Johannesburg, South Africa	Implementation and multi-dimensional BPS
Lowther K, Selman L, Simms V, et al. (2015)	Randomized controlled trial, randomized at patient level	The Treatment Outcomes in Palliative Care trial (TOP-Care): A nurse-led palliative care intervention for HIV positive adults	120 adult patients with HIV infection, established on ART, and reporting moderate to severe pain symptoms	Private HIV clinic in Mombasa, Kenya, a low-income setting	Biological, psychological, and multidimensional BPS

Nkhoma K, Seymour J, Arthur A. (2015).	Randomized controlled trial, randomized at patient level	Nurse-led pain education intervention designed for patients and their family caregivers	182 adult patients living with HIV/AIDS and their caregivers	HIV and palliative care clinics of two public hospitals in Malawi, Africa, and patients' homes	Biological, social, and multi-dimensional BPS
Santha, S. (2011)	Cross-sectional survey	Level of satisfaction with Pain and Palliative Care units (PPC)	50 patients selected from database of PPC home care units 50% cancer patients	15 PPC units offering home care services in Ernakulam district, Kerala State, India, and patients' homes	Implementation

Table 2. Intervention patient outcomes organized within the context of Biopsychosocial measures

BPS biological domain	Outcome measure	Description	Reliability/ Validity	Feasibility	Study Results/Outcomes
Biological Domain	African Palliative Care Association Palliative Care Outcome Scale pain score subscale	The APCA POS pain subscale measures pain intensity on 0-10 scale, 0= no pain to 10 = worst pain	Reliability and validity for Africa: Construct validity Spearman's coefficient r = 0.538 Internal consistency Cronbach's alpha = 0.60	One question on pain intensity is quick to answer	**Harding, et al. 2013** Odds of reporting pain relief greater at intervention site (OR=0.60, 95% CI 0.50-0.72) than at control site (OR=0.85, 95% CI 0.80-0.90), *p*=0.001 **Herce, et al. 2014** Pain scored in this study 0 to 5; score ≥3 suggests moderate to severe pain and score =5 is worst pain Mean APCA POS pain score decreased from 3.0 at baseline to 2.7 at follow up in patients with baseline pain and complete pain assessment documentation, *p* = 0.5 **Lowther, et al. 2015** Pain scored in this study 0=worst to

					5= best Intervention group’s median pain score improved from 1.0 (0.0–2.0) at baseline to 4.5 (3.0–5.0) at 4 months Intervention had no significant effect on pain, p=0.95
Biological Domain	Brief Pain Inventory – Pain severity (BPI-PS) -- Pain interference (BPI-PI)	•The BPI assesses pain severity and pain’s impact on functioning in cancer patients. Means of 4 items can measure pain severity (PS) and means of 7 items can measure pain interference (PI)	BPI-PS reliability Cronbach’s alpha =0.87 among cancer patients BPI-PS construct validity moderately strong (r>0.50) overall with SF-36 for patients with non-cancer pain BPI-PI reliability Cronbach’s alpha =0.91 among cancer patients	BPI short form takes 5 minutes to complete	**Nkhoma, et al. 2015** Higher scores mean more positive outcome BPI-PS: Improved mean pain severity score from 50.76 (SD± 24.86) at baseline to 92.62 (SD± 8.23) at follow up (adjusted mean difference $P < 0.001$) BPI-PI: Improved mean pain interference from 49.91 (SD± 27.97) at baseline to 93.67 (SD± 9.33) at follow up (adjusted mean difference $P < 0.001$)
	Family Pain Questionnaire –	FPQ-K 9 items measure family	FPQ overall reliability Pearson’s	Using only knowledge subscale	**Nkhoma, et al. 2015**

Biological Domain	Knowledge subscale (FPQ-K)	caregivers' knowledge of managing patient's pain; 3 items measure perception of patient's pain	correlation coefficient r=0.92 (p=0.01) FPQ internal consistency Cronbach's alpha =0.81	on FPQ reduces burden on patients and caregivers	Higher scores mean more positive outcome Improved family pain knowledge from 65.29 (SD± 16.93) at baseline to 91.36 (SD± 7.8) at follow up (adjusted mean difference *P* < 0.001)
Biological Domain	Hundred Paisa Pain Scale (HPPS)	Musculoskeletal pain relief assessed using the Indian Rupee scale of 25 paisa or less (no to moderate pain) (0-25%), 50 paisa or less (25-50%), 75 paisa or less (50-75%), and equal to 1 rupee (severe to worst pain) (75-100%)	Concurrent validity of HPPS and VAS (r=0.855) and HPPS and NRS (r=0.918) Test-retest reliability of HPPS ICC =0.85 (95% CI 0.76-0.91) Correlation coefficient with VAS and NRS (r=0.85-0.91)	Patients familiar with counting money regardless of literacy; available in public domain	**Bansal, et al. 2003** From baseline, 42% patients at visit 2 and 50% patients at visit 3 reported 50% -75% pain relief; 56% patients at visit 5 reported 75%-100% pain relief
Biological Domain	Karnofsky Performance Status Scale (KPS)	KPS classifies 10 areas of functional impairment from 0 (dead) to 100 (normal, no evidence of disease	Interrater reliability Pearson Correlation r=0.89 Construct validity – all 18 variables correlated at 0.05 level	11-item scale useful for patient assessment	**DiSorbo, et al. 2010** Increase in percentage patients with KPS score ≥80 at year one = 28%, year two = 50.5%

Biological Domain	Patient-held pain assessment card	Color-coded "trigger zones" cue patient when he/she needs drugs for pain NRS for physician purposes 0 = no pain, 10 = worst pain	Not reported	Color-coded zones of action instead of number scale for patients with less education Created for Kenyan patient population and translated into multiple "mother-tongues"	**Besley, et al. 2014** Satisfactory pain relief increased from 29.78% pre-intervention to 68.29% during intervention; difference in means (*P*= 0.0016)
Biological Domain	Visual Analog Scale (VAS) for pain	VAS measures pain intensity on continuous scale 0 = no pain, 4-6 moderate pain and 10 = worst imaginable pain	Test-retest reliability VAS (ICC=0.71-0.99) Convergent validity correlated with NRS and (MPQ) = 0.30-0.95 Concurrent validity with NPRS = 0.71-0.78	The VAS takes less than one minute to complete	**Bisht, et al. 2010** Reduction in mean pain scores from 7.06 (SD± 2.1) at baseline to 2.47 (SD± 2.1) after 1 month (*P*<0.001), and to 2.02 (SD± 1.9) after 2 months (*P*<0.001) **Elumelu, et al. 2013** Increase in pain relief from 3.02% (breast cancer patients reporting VAS 0-3) to 57.3% after morphine Increase in pain relief from 8.75% (cervical cancer patients reporting VAS 0-3) to 69% after morphine

Biological Domain	Patient Pain Questionnaire - Knowledge subscale (PPQ-K)	PPQ-K 9 items measure patient's knowledge and experience of cancer pain—adapted from FPQ	PPQ content validity =0.95, test-retest reliability r=0.65, internal consistency Cronbach's alpha = 0.74	Using only knowledge subscale on PPQ reduces burden on patients and caregivers	**Nkhoma, et al. 2015** Higher scores mean more positive outcome Improved pain knowledge from 67.78 (SD± 16.61) at baseline to 92.63 (SD± 8.16) at follow up (adjusted mean difference *P* < 0.001)

Psychological domain	Outcome measure	Instrument details	Reliability/ Validity	Feasibility	Results/Outcomes
Psychological Domain	General Household Questionnaire-12 (GHQ-12)	GHQ-12 is shorter version of the 60 item GHQ and measures psychiatric morbidity 0=best to 12=worst	Validated for sub-Saharan Africa with sensitivity of 68% and specificity of 70% compared with gold standard CIDI	•Shortened version puts less burden on patients • GHQ-12 translated into Kenyan Kiswahili	**Lowther, et al. 2015** Intervention group's median GHQ-12 score improved from 6.0 (IQR 3.0-9.0) at baseline to 1.0 (0,0-3.0) at 4 months Intervention had significant effect on psychiatric morbidity, *p*=0.04

Social domain	Outcome measure	Instrument details	Reliability/ Validity	Feasibility	Results/ Outcomes

Social Domain	Island Hospice Supervision and Mentorship Checklist	• Island Hospice Supervision and Mentorship Checklist assesses caregiver palliative care knowledge and skills Score ≥ 50% indicates successful palliative care knowledge/skills	Not reported	Not reported	**DiSorbo, et al. 2010** Scores improved from baseline 0% to follow up 66% (average score ≥ 50%)
Social Domain	Picot Caregiver Rewards Scale (PCRS) for caregiver motivation	The PCRS 16 items measure rewards of caregiving	Internal consistency Cronbach's alpha =0.88; inter-item correlations from r=0.05 to r=0.61 Test-retest reliability coefficient r=0.75 Tested by study researchers for acceptability in Malawi	16 items manageable for caregivers to complete	**Nkhoma, et al. 2015** Improved motivation from 78.91 (SD± 11.29) at baseline to 97.13 (SD± 5.87) at follow up (adjusted mean difference $P < 0.001$)

Multiple Domains	Outcome measure	Outcome measure description	Reliability/ Validity	Feasibility	Results/ Outcomes
	African Palliative Care Association (APCA) African Palliative Care Outcome Scale (POS)	The APCA POS measures outcomes of the care given to patients and families on a scale of 0 (none or not at all) to 5 (worst or yes, a lot) Responses use combination of high score = best status and low score = best status Questions 1-7 are directed at patients; questions 8-10 are directed at family informal caregivers	Reliability and validity for Africa: Construct validity Spearman's coefficient r = 0.538 Internal consistency Cronbach's alpha = 0.60	10 questions take a short time to administer.	**Defilippi and Cameron, 2010** Only summarized results are depicted though summary illustrates improvement in average scores **DiSorbo, et al. 2010** The APCA POS was administered to patients during one visit as a baseline. No scores reported. **Harding, et al. 2013** Scored so low score = more positive outcome Improvement in intervention mean APCA POS scores from 12.96 (SD± 5.06) to 2.15 (SD± 2.92) (*P*<0.001) **Hongoro and DInat, 2011** Mean scores for pain, symptoms, worry, family worry decreased by 51%, 56%, 53%, and 56%, respectively (*P* < 0.005)

					Lowther, et al. 2015 Scored so low score = more negative outcome, 35 best outcome Intervention group's POS score improved from 19.0 (IQR 15.0-22.5) at baseline to 31.0 (25.0-34.0) at 4 months *p*=0.002 **Nkhoma, et al. 2015** Scored so low score = more negative outcome APCA POS patient subscale: Improved quality of life from 44.78 (SD± 22.79) at baseline to 90.58 (SD± 9.0) at follow up (adjusted mean difference *P* < 0.001) APCA POS carer subscale: Improved quality of life from 44.2 (SD± 18.95) at baseline to 92.66 (SD± 8.84) at follow up (adjusted mean difference *P* < 0.001)
	Caregiver Competencies Survey: Intervention specific	17 questions covered all caregiver duties from basic patient	Not reported; locally created for hospice in South	Comprehensive and simple to administer	**Defilippi and Cameron, 2010** Improvement in competencies averaged 28.5% over 2 years

	instrument	care to emotional care, assessments, family issues, bereavement, and future planning.	Africa		
	City of Hope Quality of Life (QOL) Survey	28 VAS items score from 0 to 100: psychological and physical well-being, general symptom control, specific symptom control, and social support	Overall rest-retest reliability *r*=0.89 Internal consistency Cronbach's alpha =0.93 Overall validity of QOL-CS with FACT-G r=0.78	High illiteracy rates did not permit self-report; researcher served as proxy	**Bisht, et al. 2010** Improvment in mean quality of life scores from 950.39 (SD± 238.27) at baseline to 1336.67 (SD± 291) after 1 month (*P*<0.01), and to 1405.49 (SD± 368.32) after 2 months (*P*<0.01)
	Edmonton symptom assessment scale (ESAS)	The ESAS scale is a 9-item and one "other problem" patient-rated symptom visual analog scale (scoring 0-10)	Validated for cancer patients Overall Cronbach's alpha =0.79 Test-retest Spearman correlation coefficient for summary distress measure r=0.86 at 2 days	ESAS takes about 5 minutes to complete.	**Dhiliwal and Muckaden, 2015** Patients receiving specialized home care had significant relief of all symptom items on the scale (P < 0.005)
	Medical Outcomes Study-HIV (MOS-HIV)	35 items measure give two summary scores measuring	Tested in rural Uganda, overall internal	35 items to complete may place undue	**Harding, et al. 2013** MOS-HIV physical score intervention improved from 39.16

		physical health and mental health Scoring numerical scale 0=worst to 100=best)	consistency reliability Cronbach's alpha ≥0.79. Physical health score r= 0.79; psychological health score r= 0.85	burden on respondents	(SD± 12.58) to 53.75 (SD± 12.93) (P<0.001) MOS-HIV mental health score intervention improved from 47.65 (SD± 10.71) to 59.98 (SD± 5.25) (P<0.001) **Lowther, et al. 2015** Intervention group's MOS-HIV physical health score improved from 45.0 (IQR 30.2-53.7) at baseline to 55.7 (46.8-58.4) at 4 months p=0.06 Intervention group's MOS-HIV mental health score improved from 44.8 (IQR 35.9-55.1) at baseline to 57.9 (52.4-63.0) at 4 months p=0.01
	World Health Organization-Quality of Life—Brief version (WHOQOL-BREF)	WHOQOL-BREF consists of 26 items that measure physical health, psychological health, social relationships,	WHOQOL-BREF domain scores correlate to approx. 0.9 with WHOQOL-100 domain scores	WHOQOL-BREF is a shorter version of the original instrument Original instrument designed to be	**Dongre, et al. 2012** Mean score for perceived physical quality of life in project area higher (10.47 SD± 1.80) than mean score (10.17 SD± 1.82) in control area (P = 0.013 Mean score for psychological

		environment		cross-culturally and contextually appropriate	support (10.13 SD± 2.25) in project area higher than mean score (9.8 SD± 2.29) in control area (*P* = 0.043)

CIDI: Composite International Diagnostic Interview
FACT-G: Functional Assessment of Cancer Therapy – General
MPQ: McGill Pain Questionnaire
NPRS: Numeric Pain Rating Scale
NRS: Numeric Rating Scale
SF-36: 36-Item Short Form Health Survey

Table 3. Intervention implementation outcomes organized within the context of a systems approach

Reference	Implementation outcome measure	Implementation outcomes
Amery, et al. (2009)	• Measures derived from a retrospective, comparative survey: • Morphine prescriptions dispensed • Chemotherapy prescriptions dispensed • Service costs • Satisfaction survey	• Results included 175% increase in number of children prescribed morphine and 118% increase in number of children prescribed chemotherapy • Total service cost per year = £27,657.55 and average cost per child = £50.28 ($US 75.00) • 100% of children and caregivers rated the drugs provided a service strength; 64% of children, 67% of caregivers, and 60% of staff rated food packs as a service strength, and 80% of children, 58% of caregivers, and 50% of staff rated play/education a service strength
Bansal, et al. (2003)	• Measures included: • Karnofsky Performance Status Scale (KPS) • Pain management using WHO 3-step pain ladder	• Results included 100% documentation of KPS scores by PC clinic staff • Pain treatment changed from visit 1 where 65% patients received Level 2 codeine and acetaminophen to visit 5: where 26% patients received Level 2 meds and 63% patients received Level 3 morphine
Chellappan, et al. (2011)	• Measures derived from color-coded questionnaire and opinion survey with 10 Likert-like scale questions: • Frequency of emergency hospital visits • Money spent during acute symptom episodes • Feasibility and acceptability of training program • Use of acute symptom management kit	• Results included 80% reduction in emergency hospital visits, and 100% reduction in money spent per episode of acute symptoms greater than INR 200 • Satisfaction with training and kit: 93% caregivers satisfied with color coding for symptoms management, 90% caregivers satisfied with training, 83% caregivers satisfied with reduced cost of medical care, 93% caregivers satisfied with symptom reduction • 96.7% caregivers used kit
DesRosiers, et al. (2014)	• Measures derived from routine hospital activity records: • Hospital admissions • Place of death	• Results included 26.5% reduction in hospital admissions of at least one day (Fisher's exact test, $P < 0.001$) • Increase of 40.1% of patients dying at home • Mean reduction in costs of admission bed days per patient of

	- Formal costs over fixed time period until death	R4977
Dhiliwal and Muckaden, (2015)	- Measures derived from prospective study assessing home-based palliative care: - Psychosocial support - Home-based death	- Results included 87 out of 506 patients and/or caregivers required counseling at home - 57.08% patients died at home/ at their native place, 23.81% died in hospice, and 19.09% died in hospital
Dongre, et al. (2012)	- Measures derived from 30 day records of village-level palliative care service provision: - Number of home visits - Support from palliative care program - Levels of satisfaction with services	- 104 of 365 patients (28.5%) had home visits - 96 of 365 patients (26.2%) received support from the palliative care program (e.g. 34 [9.3 %] to buy drugs, 16 [4.4%] for home care) - 53 of 58 patients (91.3%) were satisfied with the available services
Elumelu, et al. (2013)	- Measures derived from retrospective review: - Level of satisfaction and acceptability of palliative care	- 100% of patients were glad to have palliative care services and found it acceptable - 46.6% of patients desired palliative care services at their homes
Green, et al. (2010)	- Measures derived from assessment palliative care integrated with HIV/cancer services: - Identification and treatment of pain and other symptoms - Prevalence of depression and anxiety among patients	- Results included increase of 98% in patients having symptoms recorded and being assessed for palliative care with 93% patients assessed on return visits - 47% patients received at least one mental health session
Herce, et al. (2014)	- Measures derived from chart review: - Pain management - Retention-in-care	- Results included documenting 56 patients (89%) for baseline pain with 13 pain free (23%) and 43 reporting pain (77%) - For patients reporting pain, 10 (23%) began analgesia and 15 (35%) added a drug or changed its regimen - Morphine prescribed for 14 out of 21 patients (67%) at first follow up (POS = 3.1, SE 0.3) and other analgesia prescribed for 7 of 21 patients (33%) at first follow up (POS= 2.6, SE 0.5) - 56% of patients (35 of 63 total) had at least one follow up encounter
Hongoro and Dinat,	- Measures derived from cost accounting procedure: - Average costs per home visit and per in -	- Results included US$71.22 for a home visit and US$79.86 for in-hospital - Cost of US$665.28 (recurrent) per patient registered for home

(2011)	hospital visit • Average costs per registered patient for home and in-hospital visits	visits and US$143.25 (recurrent) per patient registered for in-hospital visit • Cost of US$943.54 (global-recurrent + capital) per patient registered for home visits and US$196.69 (global-recurrent + capital) per patient registered for in-hospital visits
Santha, (2011)	• Measures derived from structured, locally created 48-item questionnaire with five point scale and included among others: • Ranking of type of relief after receiving treatment • Satisfaction with present medicines • Satisfaction with present medical treatment • Ranking areas where palliative services could be improved	• Results included patients ranking type of relief after treatment: Pain ranked #1, hope maintained/strengthened #2, feeling more comfort #3, I feel relaxed #4 • 28 of patients highly satisfied, 20 satisfied, 2 no opinion (X^2=1.489 with 2 df with medicines • 32 of patients highly satisfied, 18 satisfied (X^2=0.142 with 1 df) with medical treatment • Patients ranked services of doctors as #1 in areas to be improved, service of nurses #2, medicines #3, services of volunteers #4

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Chapter 3: Manuscript 2

A Qualitative Evaluation of a Palliative Care Program Using Unlicensed Rural Medical Practitioners as Community Health Workers in India

Abstract

In India, the need for rural palliative care services is increasing with the rising number of people diagnosed with late stage cancers. Rural areas have a shortage of trained medical personnel to deliver palliative care. To address both of these needs, a home-based palliative care program using RMPs as community health workers to deliver care was developed to extend the reach of the local cancer center's palliative care services outside of Kolkata, India. The aim of this qualitative study was to evaluate the feasibility, usefulness, and acceptability of this palliative care program from the perspectives of stakeholders: community health workers (CHWs) and the cancer center's clinical team members who provided the CHWs with training, supervision, and support. A grounded theory approach with an emerging design was used to analyze the data. Ten interviews, three with CHWs and seven with clinical team members, were conducted and digitally recorded using semi-structured interview guides, at the site of the local cancer center. Results indicated the value of the program for stakeholders in terms of the delivery of palliative care to rural cancer patients. Three major themes concerning the feasibility, usefulness, and acceptability of the home-based palliative care program emerged through data analysis of the interviews: a) CHW desire and need for more training, b) need for clear protocols and expectations for stakeholders, and c) questions about program sustainability. The study provided evidence that the training of RMPs as CHWs to

facilitate the delivery of palliative care is a model worthy of consideration in low resource areas around the world.

Introduction

In India, cancer is one of the leading causes of death among adults (WHO, 2017a). More than one million new cancer cases occur annually in India, where over 80% of cancer patients are diagnosed with stages 3 and 4 cancers (Khosla, et al., 2012; Singh and Harding, 2015). Since these patients are most commonly diagnosed when the cancer is advanced, often the only realistic patient care plan is managing pain and other symptoms (NPCS, 2012). Although India has a National Cancer Control Program that emphasizes the prevention and treatment of cancer as well as the provision of palliative care for cancer patients (NCCP, 2005), fewer than 3% of cancer patients in India have access to adequate pain relief due to such factors as restrictive laws regulating morphine (Clemens, 2007; Kar, et al., 2015), patients' lack of financial resources to pay for drugs (Azeez, 2015), and lack of transportation to receive services (Clemens, et al., 2007; Kumar, 2013). India is classified by the Worldwide Palliative Care Alliance as having "generalized palliative care provision" (Lynch, et al, 2013) with 19 out of 29 (65.5%) Indian states without evidence of any palliative care provision (Singh and Harding, 2015). About 250 palliative care centers operate in India, but at least 180 of them are located in Kerala State, where there has been a concerted effort to build robust palliative care services (Rajagopal, et al., 2012). Most palliative care and hospice care services are offered in large cities and regional cancer centers (Khosla, et al., 2012; Kumar, 2013). For rural cancer patients, accessing palliative care services can be challenging for many reasons, such as lack of economic resources, and lack of insurance and transportation to healthcare facilities at the patient level (Azeez, 2015; Khosla, et al., 2012; Kumar, 2015; Love, 2015). At the health systems level, access to palliative care is limited by lack of healthcare facilities and the coordination of health care services; at the societal level, access is limited due to an underdeveloped workforce (Azeez, 2015; Khosla, et al., 2012; Kumar, 2015; Love, 2015).

Physicians and other clinicians are scare in rural India; for every 10,000 people living in rural areas, there is only one licensed, qualified physician (Rao, et al., 2013). In such low resource areas, it has been recommended that palliative care may be effectively delivered by community caregivers and volunteers who are supervised by trained personnel (Kar, et al., 2015; Naimoli, et al., 2014; Schneider, et al., 2016; WHO, 2017b). Community health workers (CHWs) may be defined as "a health worker who receives standardized training outside the formal nursing or medical curricula to deliver a range of basic health, promotional, educational, and outreach services, and who has a defined role within the community system and larger health system" (Naimoli, et al., 2014). CHWs can help to improve health behaviors and extend health services when supported by robust training, a strong clinical team, and when integrated into the health care system (Earth Institute, 2011; Perry, et al., 2014). CHWs may educate community members about health risks, promote healthy lifestyles, and connect community members with formal providers at health care facilities (Pallas, et al, 2013; Perry, et al., 2014).

In India, there are a number of different CHW models that are utilized to facilitate the delivery of healthcare. These include Accredited Social Health Activists (ASHA), lay volunteers, and informal providers. ASHA are CHWs that link rural villagers to health care centers. They form a large workforce of women that came into existence as part of India's National Rural Health Mission (NRHM) in 2005 (Abhay and Sanjay, 2014). This purpose of this workforce was to extend the reach of insufficiently staffed government health centers trying to serve a large rural population (Abhay and Sanjay, 2014; Perry, et al. 2014). The ASHA workers were trained by the government to promote access to healthcare at the household level by providing villages with basic information about nutrition, sanitation, and hygiene in order to empower women to make better health choices (Abhay and Sanjay, 2014). Lay volunteers form another CHW workforce that is trained to deliver palliative care in Kerala State. Here, the volunteers are recruited from the local area and are trained and supported by palliative care professionals to identify patients in need of palliative care; they form the backbone of Kerala's community-owned palliative care, the Neighborhood Network in Palliative Care (NNPC) (Kumar and Palmed, 2007). Part of their role is to help patients access appropriate interventions (Kumar and Palmed, 2007). Informal providers also deliver health care services in rural India. These rural doctors or rural medical practitioners (RMPs) are unlicensed and do not have formal medical training, but do offer basic health care services for rural patients (Mondal, 2015). Common in rural villages, these informal practitioners treat patients for minor health problems and are attractive because of their proximity to patients and their reliable availability (Kanjilal, et al. 2007). Thus, India has a robust history of utilizing CHWs to support delivery of healthcare, a workforce that may be feasible in facilitating the delivery of palliative care in rural India.

To identify the successes and challenges of implementing a home-based palliative care program delivered by CHWs in rural areas outside of Kolkata, India, this qualitative study reported on an evaluation of feasibility, usefulness, and acceptability of a piloted palliative care program from the perspective of CHWs and the clinical team members who provided them with training and support.

Methods

Parent Study: Home-based Palliative Care Program

A small-scale feasibility study was carried out to evaluate a home-based palliative care program that used RMPs as CHWs to deliver palliative care services for rural cancer patients in Kolkata, West Bengal, India. In India, some RMPs may have a bachelor's degree in Ayurvedic or homeopathic medicine (BAMS or BHMS), a Diploma in Pharmacy (D Pharm), a certificate in paramedics, or some other type of informal, short-course training, but they are not formally trained or licensed medical physicians (Kumar, et al., 2007). Some RMPs train under qualified medical physicians, some under unqualified practitioners, and others may have inherited the business from a family member (Kumar, et al., 2007). The piloted palliative care program was a collaborative project between the Saroj Gupta Cancer Center and Research Institute (SGCCRI) and the Medical University of South Carolina (MUSC). The study was designed to extend the reach of the SGCCRI's current home-based palliative care that provides basic inpatient, outpatient, and limited home care within a 25 km (15.5 miles) of the SGCCRI by using RMPs as CHWs.

The feasibility study used a single group non-randomized pragmatic trial design. Six RMPs already in practice in their communities were recruited to work as CHWs for the palliative care program. One of the recruits did not participate in the study since he did not attend the training. Five of the RMPs signed on as CHWs; however, only three of the five RMPs had patients in their village for whom they could help facilitate the delivery of palliative care services. Of the three RMPs who participated in the study, two had degrees in homeopathic medicine, and one had a certificate in paramedics. Ten patients were recruited for the study. The CHWs were trained by an interdisciplinary clinical team from SGCCRI and MUSC using materials from the Worldwide Palliative Care Alliance (WPCA) Palliative Care Toolkit (2008). After training, CHWs were assigned to support the clinical team in assessing and managing the diverse palliative care needs of the rural cancer patients living in their communities, supervised by the clinical team at SGCCRI. For three months, CHWs visited patients on a weekly basis and, using the materials in the Palliative Care Toolkit to monitor the patient's condition and provide basic palliative care such as medications and wound care. The CHWs also monitored pain and symptom control, and helped patients contact their oncologist and other supportive resources when necessary. Teaching family members to deliver care was also part of the CHWs' role. The CHWs documented patient needs and services provided. Table 1 describes the Palliative Care Toolkit forms used in patient management.

Study design

This qualitative descriptive study was conducted to learn the perspectives of key stakeholders related to the successes and challenges of utilizing CHWs to deliver home-based palliative care in a rural area surrounding Kolkata, India. The key stakeholders included the palliative care clinical team who trained, supported, and managed the work of the CHWs, and the CHWs facilitating the delivery of care. A grounded theory (GT) approach with an emerging design was used to analyze the data (Edmonds and Kennedy, 2013). The emerging design generates theory naturally from the data. We used the iterative constant comparative method to collect and analyze data from the key stakeholder interviews. This method guided changes to the interview guide in order to gain clarification on some topics and to ask new questions based on what we learned from earlier questions. Individual semi-structured interviews were conducted to evaluate the program's feasibility, acceptability, and usefulness, as well as stakeholders' experiences with the program. The semi-structured interview guides allowed stakeholders to actively participate in generating data and gave individual stakeholders the opportunity to present their experiences and the meaning that those experiences had for them, as well as giving them an opportunity to voice their feelings. Key stakeholders included members of the SGCCRI clinical team (oncologists, palliative care nurses, and the study coordinator) and the three CHWS.

Setting

Interviews took place at the SGCCRI cancer center in Kolkata (Calcutta), India,. The SGCCRI was established in 1973 as a non-profit organization. It is a Designated Center of Integrated Oncology and Palliative care recognized by the European Society for Medical Oncology (ESMO). The SGCCRI established its palliative care department in 2010 and it has grown over the years in response to vast patient need for palliative care. The home-based palliative care program that is the focus of the current study was piloted in 2017 with SGCCRI patients who resided within the South 24 Parganas Region of Kolkata, India.

Sampling strategy

Two groups of stakeholders were recruited: 1) the palliative care clinical team from SGCCRI that trained and supervised the CHWs, and 2) the CHWs who facilitated delivery of palliative care to rural cancer patients living 25 km outside of SGCCRI in the 24 South Parganas Region. Ten persons participated in interviews, including all clinical team members who participated in the palliative care program (n=7) and CHWs (n=3) who delivered palliative care during the program participated. Two additional CHWs who were recruited and trained as CHWs for the project were not included because they did not have any patients assigned to them during the project period.

Inclusion criteria included being an adult aged 21 or older and being a palliative care team member at SGCCRI (physician, nurse, psychologist/ behavioral counselor, study coordinator) or CHW involved in the home-based palliative care intervention.

Ethical approval

MUSC's Institutional Review Board approved this qualitative interview study. Written informed consent was obtained from all stakeholders prior to participating in any part of the study.

Data collection and management

A demographic survey was administered to each of the interview participants prior to their interview to collect information about type of stakeholder, professional role, age, sex, language, religion, and education, as appropriate. The survey was translated into the local language, Bengali, by a professional translator located in India.

Qualitative data were obtained through individual, semi-structured interviews that permitted research team members to probe the stakeholder's experiences about the program. For each stakeholder group, a tailored interview guide was used that included questions relevant across all stakeholder types as well as questions specific to each stakeholder group (i.e. clinical team members, CHWs) about the palliative care program. The multi-dimensional Biopsychosocial Model (Engel, 1980) and the Social Ecological Model (SEM) provided the frameworks for the questions in the guide to capture the holistic nature of palliative care, including biological and medical concerns, psychosocial and practical concerns, as well as the social, institutional, and cultural contexts the SEM addresses (McLeroy, et al., 1988). Using this multidimensional perspective, questions and probes addressed the palliative care program's feasibility, acceptability, and usefulness to stakeholders within the biopsychosocial framework. From the clinical team perspective, the guide assessed whether this model of palliative care delivery was feasible to operate, whether it was acceptable to CHWs, clinicians, and patients, and whether it was useful to patients and families in reducing patients' symptoms and psychosocial distress. From the CHW perspective, the guide assessed whether this model was feasible for them to participate in given their current workload in the community, whether it was acceptable to them and their patients, and whether the training, toolkit materials, and the support provided by the clinical team was useful to them in helping them care for palliative care patients. Table 3 illustrates the interview guides.

The interview guides were written in English. Interviews were conducted in a private location at SGCCRI with the stakeholder and the three research team members present. Stakeholder interviews were digitally recorded and a team member (KC) took copious notes during each interview. The interpreter was a research team member who is a native speaker of Bengali (SQ). The PI (MP) asked the interview questions in English. If the stakeholder did not speak English, the question was translated through the interpreter into Bengali. Stakeholders answered questions in English or Bengali, depending on their preference. When answers were given in Bengali, the interpreter translated the answers for the team members so that appropriate probes could be asked. The interpreter clarified uncertain words, phrases, and cultural terms during the interview as needed. The handwritten notes taken during the interview were recorded onto a template designed for the purpose that used neutral domain names matching each question (Hamilton, 2013). After the interviews, the audio recordings were compared to the handwritten notes and missing information was added; when any meanings of words or phrases were unclear or any discrepancies were found between data sources, team members discussed them until consensus was reached. Questions on the interview guides were modified as needed after each interview for clarity and appropriateness and to enable follow up and additional insight on topics identified during the previous interview. Data collection, transcription, and initial analysis took place over seven days.

Data analysis

Our grounded theory methodology was based upon an integrated deductive/inductive approach (Curry, 2015). The deductive aspect of data analysis acknowledged initial literature useful in contributing to the evaluation of palliative care models in this new context. The inductive aspect permitted the stakeholders' experiences to inform the resulting theory, thus creating new knowledge. Once interviews were transcribed, the transcripts were analyzed according to the constant comparative method where existing data was repeatedly compared to new data and which involved continuous recoding (Fram, 2013). An initial data dictionary was created from the domain template and was reviewed by a second team member. Transcripts were coded to identify emerging themes and subthemes that were compiled into a code structure that was also reviewed by a second researcher to identify additional themes and validate existing themes. The categories of the code structure became the basis of theoretical sampling and informed decisions on how to modify the interview guide based on initial data (Corbin and Strauss, 1990). Key quotations associated with codes were also identified. The PI also created a mind map (a branching diagram) as a graphic organizer of the themes (Burgess-Allen and Owen-Smith, 2010). The mind map demonstrated the relationships among developing themes and subthemes of the two interview data sources – the perspectives of the clinical team members and the perspectives of the CWHs. From the code structure and the mind map, the PI distilled the codes into three dominant themes with several subthemes under each main theme. Theoretical saturation was reached when thematic categories were accounted for, the differences between them explained, and the relationships between them tested and validated, which resulted in emerging theory (O'Reilly and Parker, 2012). By comparing the emerging theory with the context in which it appeared, the theory was stronger.

Results

Demographics

A total of 10 interviews were conducted. The characteristics of these stakeholders are described in Table 2. Clinical team members interviewed included four palliative care physicians, two palliative care nurses, and the study coordinator. Forty percent of stakeholders were aged 21-29 years old, 30% were aged 30-49, and 30% aged 50 or older. Seventy percent of the stakeholders were males. Ninety percent of stakeholders were Hindu and 10% Muslim. Forty percent of stakeholders held graduate degrees, 40% held bachelor degrees, and 20% earned diplomas or certificates.

Major themes and sub-themes

Overall, the CHWs in the palliative care program were able to deliver meaningful care to their patients and extend the reach of the cancer center's home-based palliative care program. They developed positive relationships with patients and found the experience rewarding personally, learned about diseases and symptoms from the training, and wanted the program to continue. Three major themes concerning the feasibility, usefulness, and acceptability of the home-based palliative care program emerged through interview data analysis: a) CHW desire and need for more training, b) need for clear protocols and expectations for stakeholders, and c) questions about program sustainability. Under each of these themes several sub-themes were identified. The themes, discussed below, highlight important factors to consider when developing a home-based palliative care program using RMPs as CHWs that is contextually appropriate for West Bengal, India. Table 4 outlines the three themes and accompanying sub-themes.

Training protocol: The palliative care training included 1) a 20-hour didactic classroom training delivered in five days collaboratively by SGCCRI and MUSC, and 2) experiential training where CHWS observed the clinical team delivering palliative care to patients at the hospital. The training palliative care training was based upon the Palliative Care Toolkit, a resource that offers evidence-based strategies to deliver home-based palliative care in low resource areas (WPCA, 2008). Training content was supplemented with additional educational materials from Pallium India, a charitable trust formed in 2003 that promotes the development of palliative care through education, policy, and research (Pallium India, 2017).

Didactic training for the CHWs began with a history of SGCCRI and its palliative care program, and an overview of the palliative care project and the research protocol, including such concepts as informed consent and data collection practices in research. The second day of training began with an introduction to the concept of palliative care, the basics of oncology and chemotherapy, and geriatric care. Day three focused on pain and other symptoms of cancer such as nausea and vomiting, breathlessness, and constipation and diarrhea. Day four discussed nutrition in cancer, pain assessment and the use of pain scales, antidepressants, palliative care emergencies and other topics such as spirituality, end of life care, and bereavement. Day five reinforced training on patient documentation and an overview of how to use the forms, the pain assessment tool, and other materials from the palliative care toolkit about managing patient symptoms. The didactic training also planned to use hands-on case studies of various care scenarios that involved common physical and psychosocial aspects of palliative care.

The experiential training first included CHWs going into the ward with the physicians where they examined charts of palliative care patients, then were introduced to patients by a nurse. The physician asked the CHWs to take brief interviews with the patients. The second part included the CHWs joining the oncologists in a separate room where the CHWs discussed the physical and emotional symptoms they identified and the CHWs learned about common cancers such as gastrointestinal, gynecological, lung, and cancers of the head and neck. The oncologists then gave a detailed explanation of the patient's history using medical illustrations and diagrams and explained how to modify the CHWs' ideas for symptom management to that of palliative care.

In addition to classroom and experiential learning, ongoing continuing education was to be provided to the CHWs in two ways. First, each CHW was to meet once a week with the SGCCRI palliative care oncologist to go over their patient caseload. Second, the CHWs together were to meet with the SGCCRI palliative care oncologist once a month for debriefing sessions that were designed to provide ongoing program improvement and support to the CHWs.

CHW desire and need for more training

Five main subthemes were identified where CHWs desired and needed more training on the following topics: 1) didactic and experiential training, 2) concept of palliative care, 3) delivery of psychosocial care, 4) using patient record-keeping forms, and 5) teaching patients and families regarding the nature and extent of palliative care services.

Theoretical and practical training:

CHWs were eager to learn from the oncologists and nurses and attended all trainings. CHWs wanted more training, both didactic and experiential. They desired more practical scenarios in which they might be expected to perform, and they wanted to be evaluated to build confidence in their skills. One CHW stated: "More practical training [case scenarios] would have been better, more theoretical [didactic training] and some of those emergency situation trainings would have been helpful." Another stated: "Five days training is just not enough for this program. We needed more of a clinical shadowing [experiential training] experience …" CHWs suggested conducting training on alternate weeks, or over one to six months, and for a shorter time period each day, explaining that, "extended training for whole 5-6 hours is too difficult for us" since the CHWs had patients in their own practices. However, CHWs stated that if the training extended over a longer period of time "for just 2-3 hours per afternoon, we can do it." Another CHW stated "it was a lot of content in a small amount of time. It's better if it was a two-week training. It was 12-6 pm---a shorter period of time for more days might be helpful in retaining the information." One CHW said evaluation on his skills would be helpful: "I want to know where I stood there, like an exam after the three months to see how I did running the navigation… Something to improve the process."

Physicians were happy with the CHWs' engagement with training materials and they also wanted more training for CHWs. One physician noted that the training was good but the CHWs should be given more classes in the clinical aspects of care: "at the end of the day, they [CHWs] must know how to identify and manage and treat symptoms and signs…." Doctors wanted the CHWs to meet with more pre-terminal palliative care patients because the patients CHWs saw during training were very ill: “Patients were so breathless, so sick, it was difficult for them to give an interview for five minutes.” Training over a month’s time, he suggested, would ensure the CHWs would see patients at different stages of their illness. Another physician noted that continuing education for CHWs at the cancer center was important “so they are out in the community doing the right thing” in their own practices and in the palliative care program. Another stated that going through the course in five days’ time was challenging: “The course was extremely elaborate… First, you cannot absorb that in a week’s time, it’s too much. It’s too difficult. Maybe in a year’s time...” Although extended training “would have been better,” stated a doctor, for CHWs to attend training “over 10-15 days doesn’t make sense because they are losing their own patients.” Based on input from both the CHWs and the cancer center clinicians, clear agreement was reached on the need for more initial didactic and practical training, for this content to be broken up into shorter periods per training to aid in knowledge retention, and for continuing education and support.

Concept of palliative care:

Two CHWs believed they were successful in working with patients if they were able to extend their life a little longer, which is inconsistent with the goal of palliative care. Making patients’ lives better was important, but CHWs seemed to equate quality of life with living longer. One CHW stated that the “target” of the palliative care program was “two or three months,” which he interpreted as meaning keeping the patient alive that long. He added: “My intention was to keep this patient happy and healthy if possible for two or three years using various processes.” Another CHW said that another hospital was interested in the care he was providing patients because “the emotional support I gave her [the patient] may have helped her live longer.” While comforting and supporting patients is part of palliative care, some physicians felt that the CHWs did not attend to family needs and focused on medical aspects: “They [CHWs] related to us about the patient in symptoms only…” Although training covered the difference between curative intent and palliative intent and “some psychological, emotional topics,” more emphasis on the concept of palliative care was necessary. CHWs needed to learn how to “customize that treatment to the patient’s needs. The practice should be uniform with palliative care physicians” at the cancer center. These findings suggest that RMPs, who are accustomed to providing curative treatment in their rural practices, may require greater initial training and continued education about the goals of palliative care.

Psychosocial care:

CHWs felt positively about their ability to comfort patients and offer support, but physicians believed that more emphasis on delivering psychosocial care was needed. One CHW stated that since his patients were in the terminal stages of their illness, “physical problems were out of the way and emotional support was what I was providing them.” Another CHW noted that the emotional issue his patients suffered from the most was the fear of death: “When those questions were asked, I used to comfort the patient and the family.” However, this perception was not supported by a doctor’s impression; during phone conversations with the CHWs, he noticed that “the family was never discussed. They should have brought up how well the family was coping….” Another clinical team member thought that the CHWs did not address psychological needs because the patient forms were not filled out to indicate assistance with emotional problems. However, a CHW stated: “The most striking part of the experience was the emotional aspects. I became so close to them [the patient and family] that they had one daughter who was getting married and they invited me to the wedding.” When the palliative care training was initially developed, there were plans to include case studies to allow the CHWs to practice delivery of emotional support, but this content was removed to reduce the length of the training. This finding suggests that the CHWs would substantially benefit from an additional training on the emotional aspects of delivering palliative care, particularly the use of case studies to practice these new areas of practice related to providing emotional support.

Keeping patient records:

In general, it was felt that there were too many forms for patient recording keeping, that some forms were redundant, and that they were sometimes too complex for CHWs to complete. Eleven forms were used in maintaining patient records. Table 1 describes the forms used in the program. The palliative care oncologist used the Patient Assessment and Care Plan form to describe the patient’s baseline condition, diagnosis, and palliative care plan. CHWs used ten forms altogether. Three forms helped CHWs manage their workflow with patients: the Patient Register, the Travel Log, and the Monthly Report. Four forms helped CHWs manage patient care: the Pain Assessment Tool that was used with the Patient Visit Record for Care Providers, the Referral to the Palliative Care Team, and an Appointment Reminder. Three other forms were patient-held forms: the CHW helped patients fill out the Drug Chart, the Morphine Dose Record, and the Record for

Home-Based Care. These latter three forms were intended to provide the patient with documentation of medications and their ongoing care plan.

Two separate trainings during the didactic teaching component were held to teach CHWs how to use the forms and the importance of maintaining good records. Most forms were successfully filled out by CHWs, with a few exceptions. For example, some confusion around who was responsible for filling out the forms was revealed during interviews. With respect to the patient-held forms, the Morphine Dose Record was to be regularly filled out by patients. The Drug Chart was to be filled out one time (or when medications changed) by the CHW so patients could follow their medication plan. The misunderstanding was that patients thought they had to record every dose of medication on Drug Chart that resulted in many pages of the form. A physician noted: "The daily medication chart was often not followed by patients. They [patients] said, 'I cannot read all that.' The CHWs used to go and help them out…I don't think they did it very correctly…" A CHW agreed the form was cumbersome when patients had many medications and he suggested that the form be made so as to get all the medications on one page. The Patient Visit Record for Care Providers asked for the location and date of the visit, the pain assessment of the patient, problems the patient was having, an action plan (assistance), and notes. Seventy codes for location, patient problems, and assistance, were to be used to fill in the chart, but these codes caused some difficulty and were not consistently used on this form. CHWs saw forms as asking for the same information multiple times. One CHW explained how the forms were repetitious: "You had a form how many times meeting with patient, then also had a travel form; how many times back and forth. Is this form needed? It feels redundant.” Overall, two forms were seen as not useful: the Patient-held Drug Chart because of the misunderstanding around its use, and the Patient-held Morphine Dose Record because it was too burdensome for the patient. Forms perceived as redundant by CHWs were the Patient-held Record for Home Care, the Patient Visit Record for Care Providers, and the Travel Log because the forms required similar information. Physicians and CHWs recommended a maximum of two or three forms for record keeping.

Training to teach family members:

Because CHWs felt they became “intimately involved with the families,” they desired more training on how to teach the family how to care for the patient. “We need to be trained more on how to train the patient’s family – how to clean the patient, how to keep the environment clean” stated one CHW. A clinician said that the concept of palliative care should be taught to patients and family members so that families don’t expect life-saving efforts, such as injections. In rural India, injections are popular and are perceived by patients as an effective treatment that offered quick relief from symptoms (Kumar, et al., 2007). A doctor stated: “We need to educate the family to know that the CHW’s injection is not going to save your family member, it is not palliative care. The less injections you [the CHWs] give, the better you manage. If you give an injection, your focus is on that…If you assure the family about what you need to do, tell them [the family] don’t be worried about the patient’s restlessness and anxiety because this is how the patient will die…” However, patients were not always informed they had a terminal disease and may not have realized they were in palliative care – a challenging gray area for the CHW. This finding suggests patients and family members needed more information about their medical condition, and that with the CHWs, needed more information about the process of dying, the concept of palliative care, and the scope of end of life care for the patients in the program.

Need for Clear Protocols and Expectations for Stakeholders

Two subthemes were identified regarding expectations: 1) patient and family expectations about emergencies, 2) patient and family expectations during and after the conclusion of the program.

Patient expectations about emergencies

Patients' and families' expectations of the CHWs were high, and they were sometimes unable to discern between what constituted part of the CHW palliative services, and what constituted when an emergency visit was needed versus when the patient was experiencing a natural part of the dying process. Emergency measures in this case would be inappropriate. CHWs had the expectation that they should be able to help patients, and they were frustrated when they could not. CHWs were available to patients day and night, and were accessible by phone: "They would call me in the night and say [the patient] is dying. It was difficult for me to understand on the phone, so I would visit the patient in the night and then realize it wasn't that much of an emergency…" CHWs knew they were to visit the patient if an emergency occurred, and they knew that they were to refer their patient to the cancer center when the emergency was one they could not manage. Some emergencies, however, CHWs felt inadequately trained to manage. One CHW stated "…when we go to these patients' houses at the time of an emergency, they need a catheter, injection, or IV fluid and we do not have training for that…we have to contact the nearest doctor or nurse and sometimes they are not available. At that time it is shameful for us and we feel helpless and the patient's family also thinks, 'What help are you if you can't provide these services at times of emergency?'" These results suggest that RMPs are accustomed to providing round the clock care to their patients and that these CHWs did provide such care. However, the CHW was not required to be available 24 hours unless an emergency occurred since the home-based palliative care was not meant to be a 24-hour service. To align patient expectations of the program with the actual services of the program, training should include more education of CHWs on their scope of practice and more education for patients on what constitutes an emergency as well as what to expect with their illness.

Expectations during and after the program:

During the program, CHWs knew the patients needed them and this was rewarding for the CHWs. Regarding one patient, the CHW said, " Because she was in so much pain, she needed me, and the family saw that if the doctor [the CHW] comes, her pain will be less. They valued my help." Another patient relied on the CHW for medication: "He is poor and needs free medication, he has an expectation of me that I will get him these medications." These expectations of care continued after the program concluded. One CHW stated, "The thing that I value the most is the trust that each and every patient has developed in me. Even after the study they want me and hope for me to come back." Protocol stated that the care could be continued after the three month intervention period but that the families would have to pay for it and the CHW would have to be available.

One CHW related because he had a strong relationship with a particular patient and family, that after the study was over, the family still wanted him to treat the patient but they would have to pay for care; the CHW would not be able to come on a daily basis as before. The CHW stated: “That is the expectation that after the study, [I] would continue as usual.” The family agreed to the new conditions, but their expectations were still that he would be available in a moment’s notice. The patient developed complications, but the CHW was unavailable. The CHW stated: “The patient’s family wanted only me and when they couldn’t reach me, they were frustrated…” The findings illustrate the dedication of the CHWs for their patients in conflict with the their role after the conclusion of the study. Clearer guidelines need to be developed on how CHWs and families can maintain their relationship after the program closes. CHWs and patients need information on how to transition from a palliative care study into a relationship where the CHW can still care for the patient.

Sustainability of the Home-based Palliative Care Program

Three subthemes were identified regarding program sustainability: stakeholder perceptions of how to continue the program raised the issues of 1) the acceptability of CHWs, 2) an alternative workforce, and 3) financial support for program.

Acceptability of CHWs:

Qualifications and expertise:

The experience of CHWs in their own practices was seen as beneficial to the palliative care program. Despite the CHWs being unlicensed, they “already knew the basics of medical treatment,” according to a physician. “This is the best part, you are teaching people who may not be certified but they have the knowledge of how to manage medical complications at home, all of them were working under a certified doctor [GP].” The qualifications of two CHWs as homeopathic doctors and one with a diploma in paramedics were satisfactory; they “will actually be trained by us….We were not taking unprofessional people.”

Since the CHWs were part of their community, they were familiar with patients’ needs and connected to local doctors, which was beneficial to the program. CHWs believed they met the needs of their patients: “As long as I was in the house, I could see they used to feel relaxed and less stressed.” and an oncologist stated the CHWs in the program “can identify what is going on and send patients to the hospital… …They can help us.” Another said that in their own practices, the CHWs saw “all kinds of patients and they use modern medicines and prescribe them and they give injections and start a drip, but if things get too serious, they need to refer [the patient] to a nursing home or qualified provider….” The clinicians agreed that CHWs could handle many of the patients’ problems: “…through Skype, [the CHWs] show us the wound, the bedsores, talk about the patient problems, the general state of the patient, they have shown that…They [RMPs] could meet the outcome of the problem easily better than an ordinary CHW because they practice and report to us.” These findings confirm that RMPs, while unlicensed, were perceived as being able to provide their patients with common supportive care such as injections to meet their needs. However, the CHWs in the palliative care program did not perform such services and wanted to be properly trained in emergency skills such as performing an injection or inserting a catheter so as to better meet the needs of their palliative care patients; the findings suggest they were interested in enhancing their professional skills.

Legal issues:

As noted, some clinicians found the CHWs acceptable, but others did not because of potential legal problems. Two CHWs had a bachelor degree in homeopathic medicine, which is recognized by the government, and one had a diploma in paramedics. The CHWs were popularly called "doctor" and trusted by their patients, but while working in their own practices, they were not qualified, licensed medical doctors. One oncologist raised the concern about the tension between the Indian Medical Association (IMA) and the state government regarding RMPs. According to the IMA (2014), when untrained and unqualified RMPs practice allopathic (biomedicine), these people are "quacks" who should be prevented from practicing. An oncologist explained that at the time of the implementation of the palliative care study, "there has been a protest launched by [MD] physicians across the state against these kind of people, the CHWs… that we cannot allow these quacks to practice." However, when provided with proper training, it has been demonstrated that RMPs can serve in rural areas and thus decrease the gap in health care providers (Dutta, 2013; Mukherjee and Heinmuller, 2017). The tension between who is a bona fide medical doctor and who is a rural doctor is acknowledged by some clinicians who see the need for CHWs to deliver care when the clinical team cannot: "There will be some people who will not like this and some people who will like this, but the recipients [patients] will probably like this because they are getting benefits." These results highlight the need for more trained health providers in rural areas of India, and suggest that with training, CHWs are a feasible means to extend the reach of cancer centers and other healthcare organizations in delivering palliative care to patients.

Gender:

All of the CHWs in the program were male, and a clinical team member noted that “if a patient has a female condition, [she may] not be comfortable talking to a man.” Since the patients in the program live in villages outside the city, the issue of patients’ having daughters of marriageable age was also a concern: “In our society, if there is a marriageable girl in the family and an unknown male enters their home, socially it is a big issue. They [the family] are afraid about the situation because the neighbors don’t know that the person is a CHW. The neighbors don’t know if he was married.” The team member noted one female patient recruited for the program refused to participate because she had a marriageable girl in her home and did not want to have a male CHW visit. This finding suggests that the enrollment of patients in the program may be limited if the CHW workforce consists only of men.

Alternative workforce:

Because of the possible legal tension associated with using RMPs as CHWs, a doctor proposed an alternative workforce trained by the government: Accredited Social Health Activist workers (ASHA). These workers are “within the government framework…with proper training…they will be more in touch with palliative care, and that will be a mainstay of the society,” said a physician, and using government-sanctioned workers “would be a good project. It would be a long-lasting thing… they get a salary from the government." Using ASHA workers might not only create a sustainable workforce but might also mitigate concern about the tension between the Indian Medical Association (IMA) and the state government regarding unlicensed RMPs. Additionally, one doctor noted that ASHA workers are primarily women and "can empathize more easily with the patients, they look into the psychological issues much better…they are better to look into the social cultural aspects." These findings suggest that ASHA workers may represent another feasible CHW workforce that might be able to facilitate the delivery of palliative care services.

Financial support:

All the CHWs wanted the program to continue, as did most of the clinical team. The issue raised was about where the money to run the program would come from. Suggestions included fees charged by the cancer center to support the program. A CHW stated: "If the cancer center doesn't chip in, I don't think there is much that can be done. Some [patients] can pay and they might agree to have a nominal fee." The idea was to raise the fee for home-based palliative care services in order to cover the CHWs' fees. Another physician suggested incorporating the CHWs "into the cancer center as an associate employee. They can have some small payments from the cancer center or they can charge a small nominal fee." Yet another source of financing might be corporations. A doctor stated: "We need to convince corporate bodies to understand [that palliative care is social responsibility] and create some kind of collaboration because over the next five years, a company might sponsor this amount of home-based palliative care services, then we can actually continue this, sustain it." Another physician suggested that non-governmental organizations (NGOs) might be a resource for financial support. However, no one suggested the government as a potential funding source. These suggestions illustrate potential models of sustainability that might work in covering the cost of using CHWs to facilitate the delivery of palliative care.

Discussion

The results of our evaluation of the home-based palliative care program in Kolkata, India, indicated that the CHWs were able to deliver palliative care to patients, extending the reach of home-based care from the cancer center. We learned that CHWs want more training in several areas, that clear protocols and expectations need to be communicated regarding the palliative care program, and that the sustainability of the program will depend on finding a routine source of funding for home based palliative care programs.

Training

Successful programs using CHWs require ongoing training and education for the CHWs (Earth Institute, PIH, 2011; Perry, et al., 2014). Several models of training exist from rapid training to training that lasts over years and concludes in a certificate for the CHW (Earth Institute, 2011). The palliative care program we evaluated used a rapid training approach to bring CHWs into the program without a time lag between recruitment and deployment (Earth Institute, 2011). While the information covered in the training was comprehensive and included the types of medical concerns and psychosocial issues that palliative care patients and families often face, we found that the CHWs wanted more training from the cancer center team. They wanted more practical training in how to care for patients' physical needs and they wanted training in how to better teach the families how to care for the patient. They also wanted to build their skills and be better prepared for emergencies where an injection or a catheter might be necessary. We learned that a five-day rapid didactic training was insufficient. Initially case studies had been built into the training, but in order to accomplish the initial on-site classroom training within a week, the case studies were removed from the training curriculum. Case studies will be an important aspect of future CHW training to provide an opportunity to think about and practice new information and skills covered in the training. In order to include case studies and other required elements of the training, extended time frames over several weeks or months with shorter class periods, as well as continuing education, were recommended as potentially useful training strategies.

We also learned that the training should emphasize the proper use of forms more. While the CHWs indicated that they did provide psychosocial support to patients and families, clinical team members felt that psychosocial concerns were under-emphasized by the CHWs based on evidence from the CHW activity logs and phone calls with the clinical team. The CHWs did not refer to patients' psychosocial care during their phone calls with physicians, focusing only on the patient's medical care, and this was interpreted as not providing emotional care for patients. Additionally, we learned that it was not clear who should be filling out the forms; the morphine dose log was to be filled out by the patient but was too burdensome and the drug chart was to have been filled out once by the CHW to remind patients of drug timing and dosage. However, patients thought they were to record every dose of every medication they were taking and this was a misunderstanding. Solidifying the protocol for completely filling out the forms and reporting all aspects of care to the oncologists will help clear up miscommunications about patient care. Additionally, we learned a few of the forms seemed redundant to the CHWs, and they would prefer fewer forms for record keeping. The use of codes on the Patient Visit Record form, while useful from a research standpoint, was not useful from the CHWs perspective based on their own clinical practices.

Protocols and expectations

Patient and families need clearer guidelines regarding the nature of palliative care and the extent of CHW services. Emergency service was not part of the protocol, yet oncologists explained to the CHWs that they should respond to patients in an emergency. Moreover, CHWs were not always clear whether the situation was an emergency until they got to the patient's home. Families were not able to discern between symptoms that might be part of the dying process and an emergency. A difficulty here is that not all the patients were aware they had cancer. Family members may have known, but it could not be assumed the patient knew and it was not the CHW's place to tell the patient. Khosla, et al. (2012) states that practitioners are often unable to discuss death and dying with cancer patients transferring to palliative care. Patients and families have difficulty in switching from a curative treatment and are often reluctant to cease looking for a cure (Khosla, et al., 2012). Khosla, et al. (2012) recommends including discussion about palliative care and death earlier in cancer treatment to help overcome such difficulties. However, patients in our study were referred to palliative care late in the stages of their illness, and when CHWs meet them, were often already close to the end of life. Thus, this recommendation may be difficult to achieve in caring for many patients.

Another expectation of patients and families was about the availability of CHWs. CHWs told us that they were available to patients day and night, but this was not part of home-based palliative care the protocol. Patients and families expected CHWs to respond to emergencies as discussed, and they expected to receive services from the CHWs after the conclusion of the program. When such expectations were not met, families were sometimes frustrated. It is the responsibility of the PI on site and the CHWs to clarify expectations and the limits of the palliative care service for the patients and families. A difficulty here was that since the CHWs had their own practices, disappointing patients and not providing effective treatment could hurt their reputation and thus their business (Ager and Pepper, 2005).

Program sustainability

The sustainability of a CHW program takes concerted effort from all stakeholders. In the palliative care program we evaluated, the clinical team from the cancer center and the CHWs put great effort into managing and delivering care to patients in their homes. While evidence exists regarding the positive impact of CHWs as a care model in low resource countries (Perry, et al., 2014), little is known about effective strategies for the growth and maintenance of CHW programs (Pallas, et al., 2013). The most frequently cited factors that enabled the scale-up and sustainability of CHW programs in these areas included consistent management and supervision of the CHWs and of the program, CHWs from or by the community, and integrating the CHW and the program with the health care system or with existing health care providers (Pallas, et al., 2013; Perry, et al., 2014). In the palliative care program, CHWs were recruited from local communities and thus were familiar with their patients. Additionally, by linking these CHWs to the cancer center and training them by physicians, we found that most stakeholders wanted the program to continue. The most frequently cited barriers to scale-up and sustainability of CHW programs in the literature included lack of sufficient pay or incentive for CHWs, lack of community support or perceived value of CHWs, and the lack of respect for the CHW or a failure to integrate into the structure of the health system (Pallas, et al., 2013; Perry, et al., 2014). In our study, the second barrier of community support was not evident, but the first barrier of insufficient incentive for CHWs to continue working in the program was evident as was the third barrier of lack of respect or integration into the health care system. Our findings suggest that sustainability of the palliative care program will require careful problem solving with respect to financial support for program operations.

The CHWS and clinical team of the palliative care program offered suggestions for how financial sustainability could be built into the program – making it fee based, designating the CHWs as associate employees of the hospital, or working towards corporate sponsorship. However, raising palliative care service fees from the cancer center perspective did not appear to be a dependable solution. Providing financial incentive to the CHWs is also important for the program to go forward, especially considering that the CHWs had their own practices. Another aspect of sustainability was the acceptability of unlicensed rural medical practitioners as CHWs. Using a different workforce such as ASHA workers, who are formally employed CHWs working within the Indian government, may be a viable alternative to alleviate the licensure concern and may also alleviate the financial problem since the Indian government pays ASHA workers' salaries. The IMA's concern over the lack of training for unlicensed RMPs may become moot in that the West Bengal Government has supported efforts to train and evaluate unlicensed RMPs, and on the basis of the positive evaluation, has scaled up training for over 3,000 RMPs (Das, Oct. 24, 2016; Das, et al., 2016).

Limitations

The main limitation of this study was a sample size of ten; however, this small sample size represented the complete sampling frame of clinical team members and the CHWs who participated in the program. Another limitation was the absence of interviews with palliative care patients who participated in the program. We wished to hear from the patient stakeholder group because since they were rural patients, the mainstream medical community was not easily accessible to them. Learning about patients' experiences in the home-based palliative care program would offer additional insights into the development and eventual sustainability of the program. However, interviews with patients were not possible because the palliative care patients were very ill.

Conclusions

Unlicensed RMPs form an existing workforce providing basic health care for people in their communities (Kanjilal, et al., 2007; Kumar, et al., 2007; Mondal, 2015). Working as CHWs, they may provide a feasible and useful workforce for delivering palliative care to patients living in rural and remote regions. For such a program to be sustainable, it is important to consider extended and ongoing training in all aspects of palliative care for the CHWs, clarifying the expectations and the protocols regarding the scope of care, and giving attention to the acceptability of the workforce and the financial viability of the program. The palliative care program incorporating the training of RMPs as CHWs is a model worthy of consideration both in India and in other low resource global settings.

Acknowledgements

The authors are grateful to the SGCCRI, its palliative care team including the home-care team, and the community health workers for their support of the parent pilot project and in letting us use their site for conducting interviews for this qualitative evaluation. Thanks also go to the research coordinator, Mrs. Nibedita Dinda and the translator Mr. Somanth Dey who translated key documents for the study. The authors recognize the key roles of Mr. Anjan Gupta, Secretary of SGCCRI, Dr. Arnab Gupta, Director of the SGCCRI, and Dr. Rahul Roychowdhury, Head of Clinical Research, and acknowledge the MUSC Center for Global Health grant that supported the intervention on which this qualitative evaluation was based.

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Table 1: Palliative Care Toolkit Forms Used in Patient Management

Type of Form	Purpose	Completed by
Patient assessment and care plan	Described baseline patient needs at first hospital visit for palliative care. Recorded patient information, diagnosis, brief history of illness, patient knowledge about their illness, special concerns about patient/family, and plan of care including any emotional, social, or spiritual issues	Admitting oncologist
CHW Workflow		
Patient Register	Recorded patients in their case load: patient information, diagnosis, end of care date, and outcome	CHW
Travel log	Tracked travel for project, home visits and trips to cancer center and elsewhere	CHW
Palliative Care Monthly Report	Listed patients under care, end of care discharge outcome, patient and family contacts, types of trips to the cancer center; handed off to study coordinator monthly	CHW
Patient Care		
Pain Assessment Tool	A reference tool for assessing patient pain at each visit with finger rating scale, Wong-Baker faces scale, and visual analogue scale; used with Patient Visit Record	CHW
Patient Visit Record for Care Providers	At every home visit, recorded date, location, patient pain level, problem, action plan, notes, and resolution of problem. Multiple codes for location, type of problem, and assistance needed were to be used	CHW
Referral to Palliative Care Team	Completed on behalf of patient; recorded referral information, diagnosis for each patient referred to palliative care team at hospital	CHW
Appointment Reminder	Given to patients by CHW to remind them of upcoming appointments – reason for appointment, location, date and time, and with whom	CHW
Patient-Held		

Drug Chart	Maintained for individual patients and held at patient’s home; intended to remind patients of medication and dose, timing, and frequency	CHW
Morphine Dose Record	CHW taught patient/family to record each morphine dose taken at each point during day, every day morphine used	CHW Patient/Family
Record for home-based care	Recorded summary of patient problems and recommendations for care for each home visit	CHW

Table 2: Demographic Characteristics of Stakeholders

Characteristic	n (%)
Job type	
Clinicians	4 (40%)
Nurses	2 (20%)
Administrator	1 (10%)
Community health worker	3 (30%)
Age	
21-29 years old	4 (40%)
30-49	3 (30%)
50-60 +	3 (30%)
Sex	
Male	7 (70%)
Female	3 (30%)
Religion	
Hinduism	9 (90%)
Islam	1 (10%)
Education	
Graduate degree	4 (40%)
Bachelor degree	4 (40%)
Diploma or certificate	2 (20%)
Marital status	
Married	9 (90%)
Single	1 (10%)
Employment	
Employed with an institution	7 (70%)
Self-employed	3 (30%)
Household members, not including self	
One person	2 (20%)
Two to four persons	6 (60%)
Five to eight persons	2 (20%)

Table 3. Stakeholder Interview Guides

CLINICAL TEAM MEMBER INTERVIEW GUIDE	
Q# and Domain	**Cancer Center Clinician**
1 Job Prior	Please tell me about your role at the cancer center
2 Involvement	How did you become involved with the navigator program?
3 Overall Experience	Please tell me about your role in the navigator program. Trainer/ teacher? Other?
4 Patient Physical problems	What are the most common physical problems patients face? • From what you saw, how do you think the navigators worked with / helped patients with these problems?
5 Patient Emotional Problems	What are the most common emotional problems patients face? • From what you saw, how do you think the navigators worked with / helped patients with these problems?
6 Patient Practical Problems	What are the most common practical problems patients face? • From what you saw, how do you think the navigators worked with / helped patients with these problems?
7 N/A Medication Process	One role of a CHW is to obtain pain medication refills for patients. (Not used – ethics committee SGCRI, legal issues)
8 Challenges in Role	What challenges did you have while working with the navigators? (prompts: training, communication, motivation, confidence, paperwork, responsibilities, etc.)
9 Relationship with Patients	From what you saw, what was the navigators' relationships like with patients and their families?
10 Relationship with Team	What is your relationship like with the navigators?
11 Theoretical Classroom Training	Describe your experience with the theoretical training of the navigators. a. What was your role in training? b. What parts were most helpful? not as helpful? Why? c. How could the theoretical training be improved?
12 Clinical Practical Training	Describe your experience with the clinical training in the ward with the navigators. a. What parts were most helpful? not as helpful? b. How could the clinical training be improved?
13 Toolkit	How did you use the palliative care toolkit materials? (during training?) a. What parts of the toolkit were most useful? Not useful? why? b. How can we improve the toolkit?
14 Satisfaction	How did you like working with the navigators? What tasks were the navigators able to do well? What tasks were they not able to do?
15 improvement	What are your thoughts about the navigator program? a. Overall, what did you like best about the program? Least? b. How can the program be improved?
16 Sustainability	How do you think the program can continue?
17 Other	What else would you like to tell me?

COMMUNITY HEALTH WORKER INTERVIEW GUIDE	
Q# and Domain	**Community Health Worker**
1 Job Prior	What was your job like before being a navigator?
2 Involvement	How did you become a navigator?
3 **Overall Experience**	Please tell me about your experience working as a navigator a. What happens during a typical visit? b. How did you feel about your interactions with patients and families? c. What topics did you discuss with patients? d. How did patients and families follow your recommendations?
4 **Patient Physical problems**	What were the most common physical problems patients had? How did you help patients with this problem? (did you need to get help?, what kind of help?; how did you involve the family?)
5 **Patient Emotional Problems**	What were the most common emotional problems that patients had? a. How did you help patients with this problem? (did you need to get help?, what kind of help?, how did you involve the family?)
6 **Patient Practical Problems**	What were the most common practical problems that patients faced? (e.g. finances, travel, housing, bills) b. How did you help patients with this problem? (did you need to get help?, what kind of help?, how did you involve the family?)
7 N/A **Medication Process**	One role of a navigator is to obtain pain medication refills for patients. Can you tell me how this process worked?
8 **Challenges in Role**	What difficulties did you face as a navigator? a. Paperwork? Travel? b. Coordinating your work as a rural health doctor and as a navigator?
9 **Relationship with Patients**	Tell me about your relationships with patients and their families. a. What part of your job did you feel they valued the most?
10 **Relationship with Team**	Tell me about your relationship with the doctors, nurses and clinicians at the cancer center. a. What part of your job did you think they valued the most?
11 **Theoretical Classroom Training**	What did you think about the theoretical training you received at the cancer center? a. What parts were most helpful? Not helpful? Why? b. How could the theoretical training be improved?
12 **Clinical / Practical Training**	Tell me about the clinical/ practical training at the cancer center? a. What parts were most helpful? Not helpful? Why? b. How could the clinical training be improved?
13 **Toolkit**	How did you use the palliative care materials given to you during training? a. What parts of the toolkit were most useful? Not useful? Why? b. How can we improve the toolkit?
14 **Satisfaction**	What did you like best about being a navigator?

15 improvement	What are your thoughts about this program? How can we improve it?
16 Sustainability	How do you think this program can continue?
17 Other	What else would you like to tell me?

Table 4. Emergent Themes and Subthemes from Stakeholder Interviews

Themes and Subthemes		
Theme: CHW desire and need for more training *Subthemes:* 1. Theoretical and practical training 2. Concept of palliative care 3. Psychosocial care 4. Keeping patient records 5. Training to teach family caregivers about concept of palliative care, patient care	*Theme*: Need for clear protocols and expectations for stakeholders *Subthemes:* 1. Patient expectations regarding emergencies 2. Patient expectations during and after the program	*Theme*: Program sustainability *Subthemes:* 1. Acceptability of CHWs • Qualifications and expertise of CHWs • CHW gender • Legal issues 2. Alternative workforce ASHA workers 3. Financial support from • Patient fees • Cancer center – incorporating CHWs as associate employees • Corporations • NGOs

Chapter 4: Manuscript 3

Acceptability of Unlicensed Rural Medical Practitioners in Rural India: A Dimensional Concept Analysis

Abstract

Limited studies exist examining the unlicensed rural medical practitioner (RMP) as an informal provider of basic health care in rural India. Informal providers such as RMPs lack formal medical training and licensure, and while they are a controversial figure with the medical establishment, they are popular among villagers and deliver up to 80% of health care to rural populations. Because of their ubiquity and their service to villagers, it is important to consider what makes them acceptable to patients and to formal, qualified providers with whom they co-exist in order to design feasible and acceptable health care interventions. To clarify the concept of acceptability of RMPs, a dimensional concept analysis was conducted to examine how the concept of acceptability is socially constructed from the perspective of patients, formal providers, and RMPs. The results revealed five dimensions and two sub-dimensions for “acceptability”: a) accessible, with the sub-dimensions of availability and proximity, b) affordable, c) familiar, d) satisfactory, e) trustworthy. Given the vast need for additional healthcare providers in India, RMPs are a workforce that might be able to help expand the reach of extremely limited medical services. The feasibility of health care interventions that include RMPs should consider the acceptability of RMPs across stakeholders. This acceptability may be leveraged to design interventions that employ RMPs to deliver health care in rural areas of India.

Introduction:

In rural India, health care providers who lack formal medical qualifications deliver up to 80% of all primary outpatient care (Das, et al., 2016a; Dharmaraj and Duttagupta, 2013). These informal providers are known by several names, for example, rural doctors or rural medical practitioners (RMPs). Today, only doctors with medical degrees and who are eligible for registration may legally practice modern medicine, or allopathy (George and Iyer, 2014). In this paper, RMP will refer to rural medical practitioner.

The utilization of RMPs highlights their widespread availability as well as the lack of trained medical providers in rural areas of India (Kumar, et al., 2007; May, et al., 2014; Das, et al., 2016; Nahar, et al., 2017b). Evidence suggests that rural people tend to seek private practitioners, both private licensed doctors as well as unlicensed informal providers, over government health centers despite the proximity of government facilities or the lack of qualifications of informal providers (Das, et al., 2016a; Gautham, et al., 2011; May, et al., 2014; Rani and Bonu, 2003). RMPs routinely treat people seeking outpatient primary care for childhood illnesses, reproductive health, tuberculosis (TB), women's health, and common ailments such as fevers, diarrhea, and respiratory difficulties (Gautham, et al., 2011; Gautham, et al., 2014; George and Iyer, 2013; Kanijilal, et al., 2007; Phadke, et al., 2008). RMPs are not recognized by the formal health system, yet they often have well-established links with private doctors and government clinics (Gautham, et al., 2014; George and Iyer, 2013; Nahar, et al., 2017).

Often serving as the first point of care as well as an entry into the health system in rural India, RMPs are rarely featured in scholarly studies (Gautham, et al., 2011; Kumar, 2007; Mondal, 2015; Nahar, et al, 2017a; Nahar, et al., 2017 b). While a handful of studies assess the quality of care that RMPs provide (Das, et al., 2016; Gautham, et al., 2014; Mondal, 2015; Nahar, et al., 2017b), fewer studies examine the feasibility and acceptability of healthcare interventions that may employ RMPs, such as mHealth applications for diabetes and depression (Nahar, et al., 2017b) or women's gynecological issues (Rani and Bonu, 2003). Potentially key to the success of such interventions is the RMP, a controversial workforce in the eyes of the Indian government and the Indian Medical Association (IMA) because it is medically untrained (Gautham, et al., 2014; Nahar, et al., 2017b).

Assessing the feasibility of a health care intervention includes considering its acceptability (Bowen, et al., 2009; Sekhon, et al., 2017). The quality of something or someone being acceptable is subjective, socially constructed, and contextually dependent. The purpose of this dimensional concept analysis (DCA) is to evaluate the acceptability of the RMP as an informal health care provider in rural India from the perspective of patients, formal providers, and RMPs. The DCA approach is useful in helping us understand how concepts are socially constructed, how they change depending upon perspective and context, and what are the assumptions we may have in approaching the concept (Caron and Bowers, 2000).

Background:

The health care system in rural India is pluralistic. The public sector includes medically degreed doctors (Bachelor of Medicine and Bachelor of Surgery [MBBS], a five and a half-year degree after 12 years of school comparable to U.S. MD) and other personnel who practice allopathic medicine (biomedicine) working in a variety of government-run health facilities. The private sector includes medically degreed doctors, unlicensed RMPs, practitioners of alternative systems of medicine such as Ayurveda or Homeopathy who may or may not hold degrees, as well as tribal and folk healers (Das, et al., 2016b; Kumar, et al., 2007; Gautham, et al., 2011; May, et al., 2014; Mondal, 2015; Mukherjee and Heinmuller, 2017). The term RMP includes three categories of health care providers: 1) those who practice without any formal training in any medical area, such as allopathy or homeopathy, 2) those who have a degree in medicine from unofficial organization, and 3) those who graduated with a non-allopathic degree such as homeopathy but who practice allopathic medicine (Mukherjee and Heinmuller, 2017). Practitioners in the private sector often use allopathic treatments for patients whether qualified or not (Gautham, et al., 2011; May, et al., 2014). Informal providers are known by many names, including rural medical practitioners (RMPs) (Sudhinaraset, et al., 2013), and for the purposes of this DCA, an RMP will be defined as a practitioner who holds a degree but it is not an allopathic medical degree, or a practitioner who does not hold any degree yet practices allopathic medicine.

Methods:

Dimensional concept analysis

The DCA approach used in this paper is that described by Caron and Bowers (2000). Dimensional concept analysis is founded on the assumptions that reality is socially constructed, informed by multiple perspectives, and contextually situated (Caron and Bowers, 2000). Dimensionalizing is a basic quality of the way we think; we understand or define a situation by separating its different relevant dimensions, and by putting the dimensions together, create a whole meaning of the situation. DCA is an explication of this process – the dimensions of the concept are carefully selected and organized so that the more relevant ones rise to greater significance and the less relevant become less significant. The perspective of the source of the dimensions as well as the context of the dimensions are integrated into the defining/understanding of the situation and thus become part of the analysis (Caron and Bowers, 2000). In other words, DCA gives us a way of understanding a complex concept as it is situated within certain perspectives and contexts.

Definitions of "acceptable"

The word "acceptable" was first recorded as coming into the English language in the late 14th Century and in origin was borrowed from the French, *acceptable*, meaning "agreeable" (OED, 2017). The word has its roots in Anglo-Norman and Middle French, *acceptable*, as well as in post-classical Latin *acceptabilis*, meaning probable, credible, in the late 2nd Century, and meaning pleasing, agreeable, welcome in Old Latin and in the Vulgate Latin (OED, 2017).

Exploring the denotative meanings of acceptable is an important part of understanding the concept since the word carries several meanings and degrees of meaning. Two common themes across the definitions were identified, one holding positive connotations and the other negative connotations. Eight dictionary, encyclopedic dictionary, and dictionary thesaurus sources were consulted, ranging in publication date from 1982 to 2017 and comprising both print and online sources. Four forms of the word were explored: accept, verb; acceptable, adjective; acceptability, noun; and acceptance, noun.

Data sources

Dimensional concept analysis requires selecting sources of information from diverse perspectives in order to illuminate the complexity of the concept as it is used in context (Caron and Bowers, 2000). Selecting sources is also a theoretical process in that the researcher chooses additional sources based on the ongoing concept analysis (Caron and Bowers, 2000). After creating a search string that covered many of the synonyms for "rural medical practitioner," we consulted with a research librarian to identify databases to search, specifically CINAHL Complete, Scopus, PsychINFO, PubMed, and ProQuest Health Management. Inclusion criteria were that the paper had to be written in English, set in India, had to discuss RMPs or synonym (i.e., met the definition of RMP as a non-allopathic degreed practitioner, or a non-degreed allopathic practitioner), and had to include the perspective of patients, formal providers, or RMPs in its analysis. Papers were excluded if they focused on traditional healers or evaluated the medical competency of RMPs without including the perspective of the RMP, patient, or formal providers in the assessment. The database search yielded 180 records that met inclusion criteria. After screening for title and abstract, 44 records were retained for full text screening. Eight records were retained for this analysis from the database searches.

Other searches included Internet searches on Google, specific website searches such as the World Health Organization and the Indian Medical Association, and cross-references identified from the articles and websites retrieved through these additional means, and referrals from research team members. The combined searches produced a total of 13 sources for this DCA: 2 blog posts by scholars, 1 research brief by a scholar, 1 systematic review, and 9 scholarly studies.

In addition to textual sources, transcripts from RMPs and other stakeholder interviews were used in this DCA. The transcripts were part of an evaluation study of a palliative care intervention in rural West Bengal, India. The palliative care program was a collaborative project between the Saroj Gupta Cancer Center and Research Institute (SGCCRI) and the Medical University of South Carolina (MUSC) supported by MUSC Center for Global Health designed to extend the reach of the SGCCRI's current home-based palliative care. RMPs who had been trained by the cancer center to work as CHWs managed and delivered the palliative care to patients in their homes. Data from two palliative care nurses, four medical physicians, and three RMPs were analyzed for this DCA.

Results

Definitions of acceptable

The most frequently cited meaning for "accept, verb" was to receive something gladly, willingly, to take or receive something with favor or approval. The second most cited meaning was to bear up, to endure or tolerate with patience or resignation and without protest. Colloquially, acceptable is often used in English in the negative sense, so as to express disapproval, i.e. a situation or person or behavior is "not acceptable" according to certain standards that are not necessarily stated or overt but may be tacitly and socially understood. Table 1 illustrates the definitions of the words “accept, verb,” “acceptable, adjective,” “acceptability, noun,” and “acceptance, noun.”

Dimensions of acceptability

Examining the retrieved sources (n=13) revealed five dimensions and two sub-dimensions for “acceptability”. Figure 1 illustrates the dimensions and sub-dimensions. The five dimensions included accessible (n=12), affordable (n=10), familiar (n=7), satisfactory (n=6), and trusted (n=8). Under the accessible dimension are two sub-dimensions, availability (n=8) and proximity (n=9). Accessibility may be summarized as the constant availability and the close proximity of RMPs. Affordability may be summarized as the flexible nature of financing for RMP services. Familiarity may be understood as social closeness. Satisfactory may be understood as the perceived effectiveness of care. Trusted may be seen as a function of the RMP’s status as a member of the community and the scrutiny that membership entails.

The findings of the literature search combined with the interview transcripts are organized according to the patient perspective, the formal provider perspective, and the RMP perspective. Table 2 summarizes the meaning of the dimensions of acceptability from these three perspectives.

Accessible

Patient perspective:

Across the different studies and other sources, the availability of RMPs at all hours of day and night was important to patients as well as the ability to contact them by mobile phone. The survey conducted by Mukherjee and Heinmuller (2017) in rural areas of West Bengal found that the main reason why rural patients prefer RMPs to government healthcare centers is the easy accessibility. In the study by Kanjilal, et al. (2007), 65% of West Bengali patients surveyed valued the constant availability of the RMP as most important. The nearby location of RMPs, being the nearest provider by foot (Gautham, et al., 2013), was also of value to patients, especially if transportation or weather was a concern (Ager and Pepper, 2005). Often, RMPs were the only health care option available to patients (Dalal, et al., 2015; Ager and Pepper, 2005). Kanjilal, et al. (2007) found that 74% of respondents chose proximity as the most important reason for choosing an RMP for healthcare. Dharmaraj and Duttagupta (2013) found that 65.4% of patients surveyed rated accessability of with RMPs as a value.

Formal provider perspective:

Dharmaraj and Duttagupta (2013) found that 90.9% of PHC doctors from Tamil Nadu, Kerala, and Andhra Pradesh believed that villagers consulted RMPs because they were available around the clock and 85.5% of PHC doctors believed it was because RMPs were accessible at any time. Mukherjee and Heinmuller (2017) report that 54.2% of auxiliary nurse midwives (ANM), a type of government health worker in rural West Bengal, believed that rural patients chose RMPs because of their easy accessibility and availability. Medical physicians in a palliative care program found them to be reachable by patients, and that the RMPs could reach patients easily, whether by bike or two-wheelers (MD2, MD3). The availability of RMPs by mobile phones was also seen as useful (MD3). A Public Health Center doctor noted that in the rural villages, no other option for health care was available (Dalal, et al., 2015). Other medical physicians agreed that there were "no doctors in the deepest corners of the state besides rural doctors" and since there were "no qualified providers in the area, [the RMPs] can offer services to villagers and villagers come to them" (MD 1, 2, 3). One physician noted that because RMPs are the only physicians there, they could bring rural patients into the health care system and to hospitals for diagnosis (MD1).

RMP perspective:

RMPs were always on call and accessible 24 hours a day, seven days a week (Ecks and Basu, 2014; George and Iyer, 2014). RMPs in a palliative care program stated that patients could and did call any time, whenever they needed the RMP: "My phone was open" (Nav 1, 2, 3). RMPs traveled far and wide to help patients (Ecks and Soumtia, 2014). Additionally, if patients could not come to his clinic, the RMP would travel to patients' homes.

Affordable

Patient perspective:

RMPs offered financial flexibility to patients: they were willing to provide treatment on credit (Gautham, 2013), or accept in-kind payments (Sudhinaraset, et al., 2013), and that patients could pay later or by installments (Kanjilal, et al., 2007; May, 2014; Mukherjee and Heinmuller, 2017). Kanjilal, et al. (2007) found that 61% of patients surveyed chose RMPs because they were cheap, and 90.5% of patients surveyed said RMPs charged the correct fee or a lesser fee (Mukherjee and Heinmuller, 2017). Choice of RMP over other doctors was also influenced by the cost of medicines (Ager and Pepper, 2005), the availability of medicines for purchase (Kanjilal, et al., 2007; Mukherjee and Heinmuller, 2017), and the cost of transportation to other providers (Sudhinaraset, et al., 2013). Dharmaraj and Duttagupta (2013) found that 68.5% of patients surveyed rated affordability of RMPs as a value.

Formal provider perspective:

Dharmaraj and Duttagupta (2013) found that 81.1% of PHC doctors believed that RMPs were consulted by patients because they were affordable. Formal providers acknowledged that patients who were indigent would be without any medical care due to financial issues if RMPs were not there to help out (Dalal, et al., 2015).

RMP perspective:

RMPs offered financial flexibility. For patients who could not pay immediately, they provided free treatment on credit or with delayed payments, and trusted that the patients would pay when they could (Ecks and Basu, 2014). Since RMPs are part of the community, they can better assess a patient's trustworthiness and offer creative financing as needed (Sudhinaraset, et al., 2013).

Familiar

Patient perspective:

Patients saw RMPs as familiar figures (Gautham, 2013; Dharmaraj and Duttagupta, 2013; Nahar, et al., 2017) and as familiar with their belief systems (May, et al., 2014).

Sudhinaraset, et al. (2013) found that across countries where patients consulted RMPs, the RMPs were perceived as socially accountable to patients due to their location within the community and their relationships with community members. Dharmaraj and Duttagupta (2013) found that 78.7% of patients surveyed rated familiarity with RMPs as the highest value, above affordability and accessibility.

Formal provider perspective:

While formal providers may disapprove of the presence of RMPs, they tolerate them (Dalal, et al., 2015), and 63.6% of PHC doctors surveyed believed that patients chose RMPs because they were familiar to them (Dharmaraj and Duttagupta, 2013).

RMP perspective:

Familiarity from the RMP perspective meant that they had a social bond with the members of the community and that they could understand what bothered the villagers (Ecks and Basu, 2014). This social closeness enabled the palliative care RMPs to offer emotional support, comfort, and hope to patients (Navs 1, 2, 3).

Satisfactory

Patient perspective:

In the study by Dharmaraj and Duttagupta (2013), 55.9% of patients surveyed ranked satisfying their needs as an important reason to seek RMPs as a health care provider. RMPs were viewed a satisfactory when they had medicines available (Kanjilal, et al., 2007; Sudhinaraset, et al., 2013), and because they offered fast, all-in-one service, i.e.

patients did not need to travel from a consultation to another provider for medications (May, et al., 2014; Sudhinaraset, et al., 2013). The study by Mukherjee and Heinmuller (2017) reported that 61% of patients surveyed chose RMPs because they provided all medicines and 69.2% were happy with the service. Eighty-six percent of patients surveyed said they would visit RMPs again for a similar problem (Mukherjee and Heinmuller, 2017). Patients believed treatment to be effective because the RMP used allopathic medicines and injections (May, et al., 2014).

Formal provider perspective:

The study by Mukherjee and Heinmuller (2017) found that 8.3% ANMs believed patients sought RMPs because they provide medicines. Nurses in a palliative care program perceived that satisfaction was derived from patients being happy with their care and being cared for at home (Nurse 1,2). Over 50% of PHC physicians surveyed believed patients sought care from RMPs because they satisfied the patient's needs (Dharmaraj and Duttagupta, 2013). Palliative care doctors stated that the RMPs "may not be certified but they have the knowledge of how to manage medical complications at home, they work under a certified doctor. They are not unprofessional" (MD2). Satisfaction was also rated by the lack of complaints from patients (MD2) as well as the impression that the RMPs left patients happy and satisfied with their service (MD 3).

RMP perspective:

The study by George and Iyer (2014) found that being perceived as a "good doctor" and offering satisfactory services was important to RMPs. Being a good doctor meant that the

RMP provided quick treatment when it was needed, used allopathic medicines, and gave injections (George and Iyer, 2014). The study by Mukherjee and Heinmuller (2017) found that 85.6% of RMPs in rural West Bengal practiced allopathic medicine, including intravenous injections (70%) and administering drips (64%). RMPs covered many aspects of care satisfactorily, but knew when their limit of knowledge was reached: they sent patients to formal providers for tests, treated patients in emergencies with first aid and then sent them to government facilities or other hospitals, and referred patients to doctors and government clinics when the scope of care was beyond them (George and Iyer, 2014; Mukherjee and Heinmuller, 2017).

Trusted

<u>Patient perspective</u>:

Trust between patients and RMPs was demonstrated several ways. Patients viewed their RMP as an integral member of the community (Dalal, et al., 2015; Gautham, 2013), someone who would do home visits (May, et al., 2014; Nahar, et al., 2017), who would be willing to accompany female patients to other doctors (Nahar, et al., 2017), and be seen as suitable for women’s health issues by family members as well as offering patients a sense of security with sensitive health issues (Sudhinaraset, et al., 2013). Being a member of the community meant that the RMPs record of performance and experience was available (Sudhinaraset, et al., 2013). Sudhinaraset, et al. (2013) also found that the RMPs offered a stable clinical environment as opposed to public clinics that often experience a high turn over of personnel. Ager and Pepper (2005) found that the reputation of the RMP was of primary consideration; if the RMP was known for delivering effective treatments, patients would overcome other barriers to see him, such as transportation, distance, and cost.

Formal provider perspective:

The study by Mukherjee and Heinmuller (2017) found that 33.3% auxiliary nurse midwives (ANMs) surveyed in rural West Bengal believed that patients trusted the RMPs.

RMP perspective:

RMPs perceived a sense of trust between them and the villagers, and were respected by some doctors and often had good relationships with them (Ecks and Basu, 2014). The study by Mukherjee and Heinmuller (2017) found that RMPs believed that referring patients to qualified doctors “in the right time” would engender trust from the community with the side benefit that patients would return to them and explain how they were treated. RMPs valued consulting with expert doctors and valued the training they received from these experienced medical physicians (George and Iyer, 2014). Mukherjhee and Heinmuller (2017) found that almost 95% of RMPs surveyed in West Bengal wanted training programs with qualified doctors. In some cases, RMPs were trusted to help out private doctors in private clinics when needed, and were able to learn by doing (George and Iyer, 2014). Similarly, RMPs in a palliative care program valued their time training with oncologists and desired more training (Nav 1,2,3). Their relationships with patients were based on trust: “Patients trusted me in an emergency; the trust is the pillar” (Nav 3).

Discussion

The results of this DCA help explain why the RMP is acceptable as an informal, private sector health care provider in rural areas of India despite his lack of formal medical training.

Data was found to support all five dimensions of acceptability. Across the five dimensions of acceptability, we found that the data meshed with the primary dictionary definition of "acceptable" as something or someone worthy of being accepted, welcome, and pleasing. The perspective of the patients reflected this definition about the RMP and his services in all five dimensions. The secondary definition of "acceptable" meaning tolerable, or adequate enough to meet a standard, was reflected in some perceptions of formal medical providers about the RMP, as in the proximity sub-dimension of accessibility and the dimension of familiarity, in that although the RMP was not medically qualified, he may be the only option for health care available in some rural villages.

We found no discrepancies in data across the five dimensions based on the three perspectives, patient, formal provider, and RMP; perceptions across the dimensions were parallel in nature. Only one perspective was found in the dimension of trust, where ANMs in West Bengal believed that the rural population trusted in the RMP for minor problems. RMPs revealed that they have good relationships with qualified doctors in government clinics and hospitals, appreciate learning from these professionals, help them out in clinics when needed, and refer patients to them when the scope of practice is beyond the RMP (Ecks and Basu, 2014; George and Iyer, 2014). However, the lack of more data supporting the dimension of trust from the perspective of formal providers is not surprising given that most state governments have not addressed the issues around RMPs at a policy level (Mukherjee and Heinmuller, 2017). Lack of data supporting the trust dimension is also influenced by the tension between the Indian Medical Association (IMA), the government, and RMPs, often called “quack doctors” in such discourse (Mondal, 2015; Mukherjee and Heinmuller, 2017).

The tension arises from the scarcity of medically qualified MBBS doctors in rural India; in 2005, 10 qualified doctors served in urban areas per 10,000 people, and only one qualified doctor served in rural areas per 10,000 people (Rao, et al., 2013). The dilemma continues: insufficient number of qualified MBBS (allopathic) physicians serve in rural areas, and this gap is filled by unqualified doctors. Mondal (2015) sums up the situation: Should government health departments allow RMPs to continue to practice in rural areas because they are popular, or should unqualified RMPs be stopped from practicing because they may do harm? In the study by Mukherjee and Heinmuller (2017), results indicate that 20.8% of ANMs surveyed in rural West Bengal sought the assistance of RMPs for certain government programs and that 80% of the ANMs believed that the role of the RMP can be strengthened by providing them with training. Training courses and training in new technologies have been demonstrated to be effective in improving the quality of RMP practice (Das, et al., 2016a; Gautham, et al., 2015; Takulia, et al., 1977). The results from our 10 interviews reveal that acceptability of the RMP as a health care provider outweighs the risk of potential harm from the patients’ perspective. From the RMPs’ perspective, risks to patients are reduced by referring them to hospitals, clinics, and qualified physicians. However, our analysis also suggested that formal providers may not trust the RMP, but found them acceptable in other dimensions such as accessibility.

The formal providers' ability to accept the RMP in one dimension and merely tolerate in another reflects the reality of the social construction of this concept, and the complexity of the context within which RMPs are situated.

Limitations:

The limitations of this study include a focus on RMP limited to publications in the Indian setting across several states and a qualitative study of palliative care in West Bengal, India. Indian states are socially and politically diverse, and while the Indian government has placed more emphasis on public education and health, for example, the implementation of such programming is uneven from state to state, in part due to this diversity (Kohli, 2012). Thus, the focus of this DCA is not intended to generalize all states but to deepen an understanding of the concept of acceptability in the Indian rural setting in the states that reported data.

Conclusion:

Recognizing that the RMP is a controversial figure in the rural health care landscape in India, this dimensional concept analysis clarifies the acceptability of the RMP as an informal health care provider. RMPs are a dominant part of the rural healthcare landscape in India, and their existence on the border of legal legitimacy and popular legitimacy makes them a workforce worth studying. Given the diversities of each Indian state, the feasibility of health care interventions that do not use RMPs must consider the acceptability of RMPs across stakeholders. Our analysis suggests that the acceptability of RMPs across its dimensions and across stakeholders, including patients, formal providers, and RMPs, may be leveraged to design interventions that employ RMPs to deliver health care in rural areas of India.

Table 1. Definitions of the words “accept, verb,” “acceptable, adjective,” “acceptability, noun,” and “acceptance, noun” using different sources.

Accept, verb	**Acceptable, adj.**	**Acceptability, noun**	**Acceptance, noun**
To receive something, willingly, gladly, to receive with favor [1-8]	Worthy of being accepted [1,5,8]; welcome, pleasing [2-4,6,7]	The quality of being acceptable [2,7]	Act of accepting or willingness to receive; favorable reception, approval [1-8]
To tolerate, receive with patience, endure without protest [1-4,6-8]	Adequate enough to meet a standard, satisfactory, [1,3,5,6,8]; tolerable, barely satisfactory or adequate,[1,3,4,6-8]	---	---

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Table 2. Dimensions and sub-dimensions of acceptability of RMPs from three perspectives: patient, formal provider, rural medical practitioner

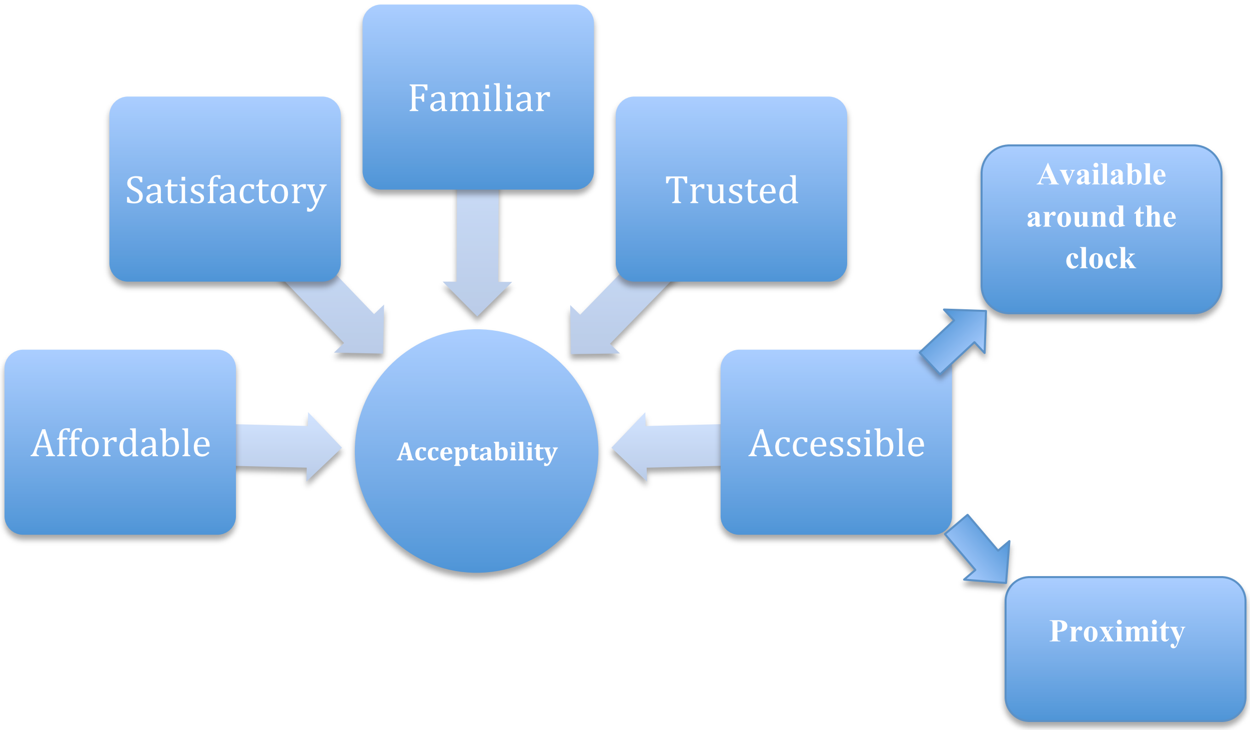
Dimension/ sub-dimensions	**Perspective**		
	Patient	Formal Provider	Rural Medical Practitioner
Accessible			
Available	•24 hour availability[3,6,8,9,11,12] •Available by mobile phone[6,10]	• 24 hour availability[3,13] •Reachable by patients by phone[E] •Close to homes[D,E]	•24 hour availability[4,8] •Always on call by phone[4,8,F-H]
Proximity	•Nearby[6,7,9-13] •Only option available[1,2]	•Only option available[2,C-E]	•Travel to patient homes[F,H] •Travel far and wide to reach patients[4]
Affordable	•Inexpensive[1-3,9,11,13] •Flexible financing[5,9,10,12,13] •Lack of transportation costs[12]	•Affordable to patients[3]	•No competition with formal providers in rural areas[4] •Flexible financing[8]
Familiar	•Familiar to patients[3,5,1]1 •Familiar with patients' belief systems[10] •RMPs socially accountable[12]	•Tolerates RMP presence[2] •Familiar to Public Health Center doctor[3] •Friendly, approachable, person next door[D] •Personal approach[E] •Speaks same language as patient[D]	•Social bond with patients[4] •Understands what bothers villagers[4] •Offers comfort, support, hope[F-H] •Close to families[G,H]
Satisfactory	•Satisfies needs[3,13] •Medicines in stock[9,12,13] •Quick service[10,12] •Effective allopathic treatment[10]	•Satisfies patients' needs[3,A,D,E] •Provides medicines[13] •Patients happy with care[A,B,D,E] •Not unprofessional[D]	•Door to door service rather than clinic based[8,F] •Quick treatment[8] •Allopathic treatment[8,13] •Refers patients to

			doctors[8,13]
Trusted	•Trusted, integral part of community[2,5,10,11] •Sense of security with women’s and sensitive health issues[11,12] •Track record and reputation available [1,12] •Stable presence’[12]	•Trusted by villagers[13]	•Trusted and respected by villagers[4,F-H] •Referring patients engendered trust[13] •Good relationship with, respected by some doctors[4,F] •Value training with doctors[4,8,13,F-H] •Helps out doctors[8]

1. Ager and Pepper (2005)
2. Dalal, et al. (2015)
3. Dharmaraj and Duttagupta (2013)
4. Ecks and Basu (2014)
5. Gautham (Dec. 3, 2013)
6. Gautham, et al. (2011)
7. Gautham, et al. (2015)
8. George and Iyer (2014)
9. Kanjilal, et al. (2007)
10. May, et al. (2014)
11. Nahar, et al. (2017)
12. Sudhinaraset, et al. (2013)
13. Mukherjee and Heinmuller (2017)

A. Nurse 1 = coded transcript 1
B. Nurse 2 = coded transcript 8
C. MD 1 = coded transcript 3
D. MD 2 = coded transcript 7
E. MD 3= coded transcript 10
F. RMP 1 = coded transcript 2 diploma in homeopathic medicine
G. RMP 2= coded transcript 4 diploma/certificate in paramedics
H. RMP 3= coded transcript 6 BHMS (Bachelor in Homeopathy Medicine and Surgery)

Figure 1. Acceptability of Rural Medical Practitioners in Rural India



Five dimensions and two sub-dimensions of acceptability of RMPs from three perspectives: patients, formal providers, and RMPs

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Chapter 5: Summary

Overview of Manuscripts

This dissertation is a compendium of three manuscripts that represent studies designed to offer information about improving the reach and effectiveness of palliative care in low resource countries. A systematic review reports the results of studies on palliative care interventions, patient outcomes, and outcome measures in low resource countries. A qualitative evaluation reports the perceptions of key stakeholders in a piloted palliative care program using community health workers (CHWs) in rural India. A dimensional concept analysis reports the exploration of the concept of acceptability of rural medical practitioners (RMPs) in rural India from the perspectives of patients, unlicensed RMPs, and formal healthcare providers.

Triangulating information across the three manuscripts yields information about palliative care interventions, intervention outcomes, and outcome measures used to evaluate palliative care. With respect to interventions, the systematic review (manuscript 1) described different models of palliative care interventions in low resource countries that have been evaluated quantitatively. We learned that in countries in sub-Saharan Africa, common models were those integrated with a hospital, a hospice, or a HIV clinic. In India, the common model studied was one integrated with a hospital. This type of palliative care model was qualitatively evaluated in manuscript 2, which studied a home-based palliative care program integrated with a local cancer center in rural areas outside the city of Kolkata, West Bengal. This palliative care program utilized a local workforce, rural medical practitioners (RMPs), that had been trained by the clinical team at the hospital to manage and deliver palliative care as community health workers (CHWs) to patients outside the reach of the hospital’s home-based palliative care team. The dimensional concept analysis (manuscript 3) examines the acceptability of such RMPs as health care providers in rural areas of India, and concludes that while the RMPs are unlicensed and medically untrained, with training, they may be a viable workforce for health care interventions with proper training. When planning palliative care interventions, it is useful to consider evidence from rigorously conducted trials about studied intervention models (manuscript 1), from qualitative evaluations studying the feasibility, usefulness, and sustainability of a specific intervention from the perspective of key stakeholders (manuscript 2), and information about the acceptability of the workforce delivering the intervention to patients (manuscript 3).

With respect to palliative care outcomes, the synthesis of the manuscripts illustrates the importance of studying and recording outcomes accurately. The systematic review (manuscript 1) illustrated that the vast majority of studies reported positive palliative care patient and implementation outcomes, although not all were statistically significant. The study by Lowther, et al. (2015) (1) reported that patients experienced pain relief as a result of the palliative care intervention that was integrated with a HIV clinic, but while the results were positive, they were not statistically significant. Other studies we reviewed did not report complete outcomes, offering only a preliminary picture of the effectiveness of the intervention. For example, the study by DiSorbo, et al. (2010) (2) reported baseline information about patients in the palliative care intervention but little follow up data. From a research perspective, documenting patient outcomes as completely as possible, even if not statistically significant, is important in helping refine the intervention where needed.

We learned in the qualitative evaluation of a home-based palliative care program (manuscript 2) that documentation is an important skill to teach to CHWs managing and delivering palliative care. For example, while the CHWs in the palliative care study generally filled out forms required for patient record keeping, the forms were not consistently filled out completely and accurately. Patient pain scores should have been recorded at every visit but this did not always happen, and specific codes were to be used to indicate patient problems and outcomes; this also did not occur. The CHWs in the program were unlicensed rural medical practitioners who each had their own private clinical practice, which suggests they were not well versed with the necessity of record keeping from a research perspective. Additionally, psychosocial data from patients was not recorded on the forms nor reported verbally to the clinical team members. The reported reasons for this from the CHW perspective was that they considered the oncologists of the clinical team as qualified doctors from whom they wished to learn medical information about their palliative care patients, how to diagnosis and treat them more effectively. The high level of respect that the RMPs/CHWs in the palliative care program have for qualified doctors was supported by the data from the dimensional concept analysis (manuscript 3). RMPs had good relationships with qualified doctors and desired to receive training from them. In sum, documenting palliative care outcomes offers a more complete picture of the effectiveness of the intervention (manuscript 1); it is important to train CHWs in this skill while emphasizing the reason for the documentation (manuscript 2); and because the RMPs so respect the medical physicians from whom they learn, it may be possible to train them to accurately document patient outcomes (manuscript 3).

With respect to outcome measures, the systematic review (manuscript 1) demonstrated the importance of validated, reliable instruments to research. The review also demonstrated that biological measures were the most common across the studies reviewed, and that six out of seven instruments measured pain; eight of the 18 studies measured pain with either a pain-specific instrument or a multidimensional measure. Multidimensional measures that capture the holistic nature of palliative care were used in half of the studies reviewed. Similarly, the importance of outcome measures was found in the qualitative evaluation of the palliative care program in rural West Bengal (manuscript 2). The study required the CHWs to measure patient’s pain with a VAS instrument, and although they were taught how to administer the VAS, the pain scores were not consistently recorded. The CHWs emphasized clinical treatment of their patients rather than the research. Additionally, the study incorporated psychosocial care of patients into the training of CHWs, and while CHWs did offer patients and families hope, comfort, and emotional support, this result was not reflected in the record keeping nor in the consultations the CHWs had with the oncologists. The dimensional concept analysis (manuscript 3) demonstrated that the RMPs looked to licensed physicians for medical information, rather than information on how to treat patients’ psychosocial needs. However, RMPs may be utilized in their communities to help teach patients about palliative care with proper training. In other words, outcome measures for palliative care should be multidimensional (manuscript 1); all aspects of palliative care should be carefully recorded during a palliative care program (manuscript 2); RMPs in a palliative care program need more training to understand the multidimensional nature of palliative care and to better use outcome measures (manuscript 2); and because RMPs as a workforce are part of their community and understand their patients values, they are in a prime position to help patients understand palliative care (manuscript 3).

Importance of Theory

Theory was foundational to two of the manuscripts in this compendium. In the systematic review (manuscript 1), the Biopsychosocial model (3) was the main structure on which the review was based. It organized the studies and the results of the review by type of outcome measured and the outcome measure used. The Donabedian model (1988) (4) of structure, process, and outcome for health systems was embedded with the biopsychosocial model as a framework for organizing the process, structure, and process pieces of the studies reviewed. In the qualitative evaluation study (manuscript 2), the biopsychosocial model helped inform the development of the interview guides to include specific questions in each domain. The Donabedian model was also used in the development of the interview guides to ask questions that covered each of the key structures and processes involved in the project, for example, in the CHW training, the use of palliative care forms, and the adherence to study protocols. Finally, the Social Ecological Model (SEM) (5) was used to guide the development of the stakeholder interview guides because it addresses the social, institutional, and cultural contexts of people living in their environment (6).

Limitations of Dissertation Research

In the systematic review (manuscript 1), the main limitation of the research was the literature search. Though the PI followed the PRISMA guidelines for conducting systematic reviews, the search may have been more thorough and yielded more studies if a team of researchers had done each step of the search to affirm inclusion or exclusion of studies. A limitation of the qualitative study (manuscript 2) was our inability to interview the patients and families in the palliative care program, an important stakeholder group. The cancer patients were too fragile to be interviewed. Another limitation in this study was the time that stakeholders had to give interviews. We scheduled interviews based on stakeholder availability, and in hindsight, should have allowed a longer time for the stakeholder to fully express his perceptions and feelings about the program. A third limitation was that this PI did not have an opportunity to travel to the villages where the CHWs delivered palliative care to patients to witness first hand the specific contexts in which the patients lived and the CHWs worked. Visiting the villages would have helped make the barriers to palliative care in rural areas, such as transportation, finances, and lack of local health care facilities, more concrete and understandable. A limitation of the dimensional concept analysis was that the literature search which is iterative in nature and guided by emerging data, was conducted by one person under time constraints. While good information was found in the search, this author feels the desire to continue the search and add to the rigor of the concept analysis.

Future Steps

The information in the manuscripts of this dissertation compendium provides a foundation for future research in palliative care in low resource countries. The systematic review illustrates opportunities to conduct rigorous studies assessing palliative care programs in low resource countries to contribute to the evidence needed to design more programs. Opportunities also exist to conduct validation studies for low resource countries on common palliative care instruments. The qualitative evaluation of a palliative care program offers opportunities to pursue similar research for other programs in low resource countries as well as in low resource settings in the United States as part of a feasibility study. Similarly, exploring the concept of specific workforces that deliver healthcare to rural Indian patients across the many states of India would be fruitful in designing interventions that were feasible, acceptable, and useful in India and beyond. An interesting study would be to conduct a comprehensive survey across the Indian states regarding the use of unlicensed informal providers and the attitudes towards them from the perspectives of rural patients, formal licensed providers, government health care workers, and local government representatives. Designing, conducting, and evaluating palliative care training programs for unlicensed rural medical practitioners would also be an opportunity to contribute to the research on this large, informal healthcare workforce in India, as well as in other countries.

Contribution to Health Sciences

The three manuscripts in this compendium contribute to the health sciences by considering ways to improve the reach and effectiveness of palliative care in low-resource countries. The systematic review provides other researchers with a snapshot of the current state of research on palliative care interventions, patient outcomes, and outcome measures used in low resource countries. The qualitative evaluation of a palliative care program in Kolkata, India, offered stakeholders the opportunity to share their perceptions and experiences of the program, and a chance to express their feelings. The findings of the qualitative analysis suggested that listening and analyzing stakeholder perceptions can inform the refinement of the intervention and increase its feasibility, acceptability, and usefulness in that context as well as in other similar contexts. This study, in addition to the dimensional concept analysis study, indicates that the unlicensed informal provider, or RMPs, may be a viable healthcare workforce in rural India if properly trained. The RMPs may extend the reach and effectiveness of palliative care and other health services and help fill the gap of insufficient health care providers in rural areas. Findings from dimensional concept analysis also illustrate that acceptability is a subjective quality and is socially constructed, and that it is possible that an intervention's sustainability, such as the palliative care program piloted at SGCCRI, may be influenced by stakeholders' understanding of the concept.

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Appendix A: MUSC IRB Approval Letter

Institutional Review Board for Human Research (IRB)
Office of Research Integrity (ORI)
Medical University of South Carolina

Harborview Office Tower
19 Hagood Ave., Suite 601, MSC857
Charleston, SC 29425-8570
Federal Wide Assurance # 1888

APPROVAL:
This is to certify that the research proposal **Pro00063758** entitled:
Stakeholder Perceptions of a Palliative Care Program for Cancer Patients in Rural India

submitted by: **Maryellen Potts**
Department: **Medical University of South Carolina**

for consideration has been reviewed by **IRB-I - Medical University of South Carolina** and approved with respect to the study of human subjects as adequately protecting the rights and welfare of the individuals involved, employing adequate methods of securing informed consent from these individuals and not involving undue risk in the light of potential benefits to be derived therefrom. No IRB member who has a conflicting interest was involved in the review or approval of this study, except to provide information as requested by the IRB.

Original Approval Date: **5/16/2017**
Approval Expiration: **5/15/2018**

Type: **Expedited**

Chair, **IRB-I - Medical University of South Carolina**
Susan Newman*

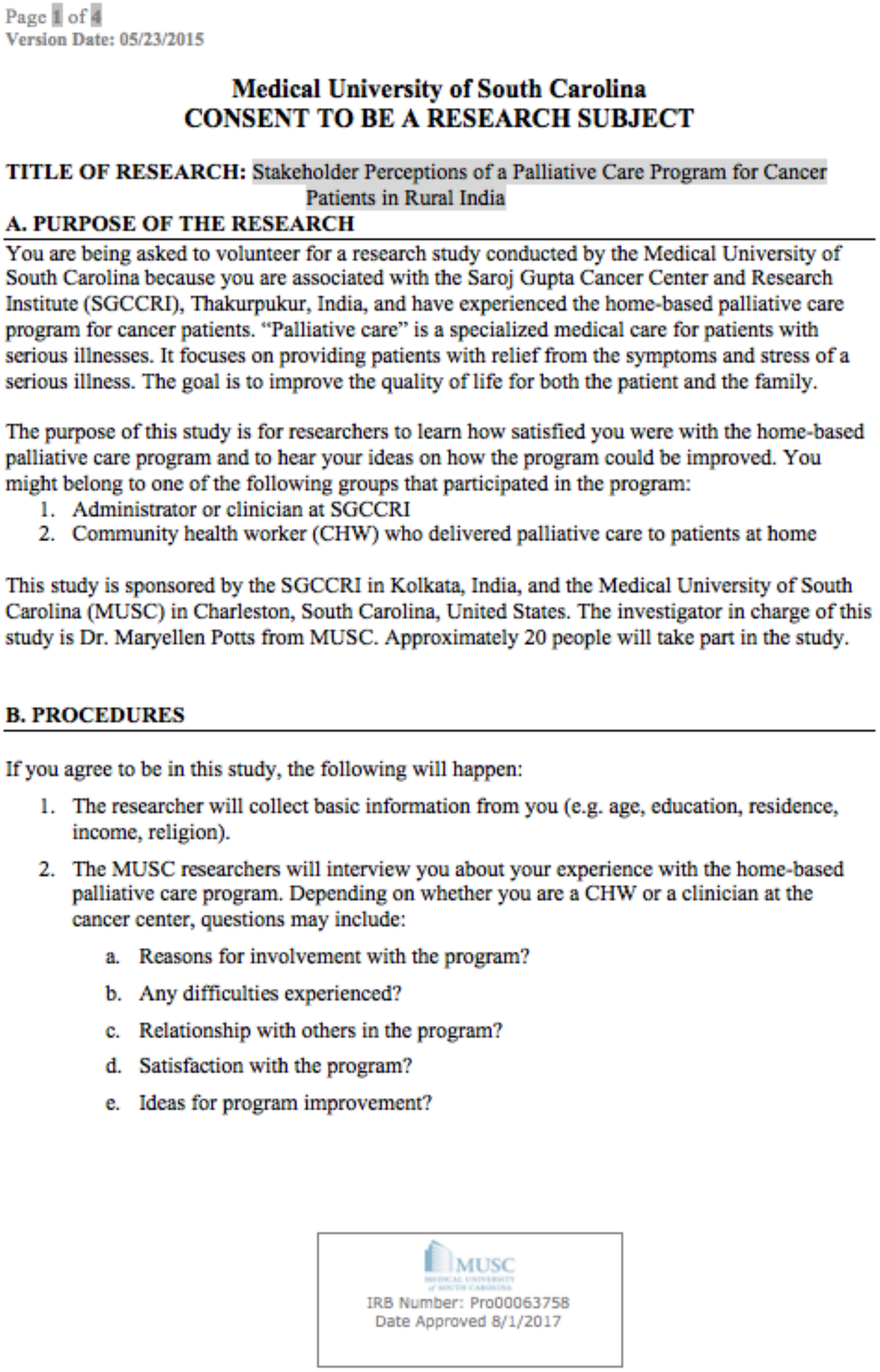
Statement of Principal Investigator:

As previously signed and certified, I understand that approval of this research involving human subjects is contingent upon my agreement:

1. To report to the Institutional Review Board for Human Research (IRB) any adverse events or research related injuries which might occur in relation to the human research. I have read and will comply with IRB reporting requirements for adverse events.
2. To submit in writing for prior IRB approval any alterations to the plan of human research.
3. To submit timely continuing review reports of this research as requested by the IRB.
4. To maintain copies of all pertinent information related to the research activities in this project, including copies of informed consent agreements obtained from all participants.
5. To notify the IRB immediately upon the termination of this project, and/or the departure of the principal investigator from this Institution and the project.

**Electronic Signature*: *This document has been electronically signed by the IRB Chairman through the HSSC eIRB Submission System authorizing IRB approval for this study as described in this letter.*

Appendix B: MUSC Stamped ICFs – English and Bengali



Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

TITLE OF RESEARCH: Stakeholder Perceptions of a Palliative Care Program for Cancer Patients in Rural India

A. PURPOSE OF THE RESEARCH

You are being asked to volunteer for a research study conducted by the Medical University of South Carolina because you are associated with the Saroj Gupta Cancer Center and Research Institute (SGCCRI), Thakurpukur, India, and have experienced the home-based palliative care program for cancer patients. "Palliative care" is a specialized medical care for patients with serious illnesses. It focuses on providing patients with relief from the symptoms and stress of a serious illness. The goal is to improve the quality of life for both the patient and the family.

The purpose of this study is for researchers to learn how satisfied you were with the home-based palliative care program and to hear your ideas on how the program could be improved. You might belong to one of the following groups that participated in the program:

1. Administrator or clinician at SGCCRI
2. Community health worker (CHW) who delivered palliative care to patients at home

This study is sponsored by the SGCCRI in Kolkata, India, and the Medical University of South Carolina (MUSC) in Charleston, South Carolina, United States. The investigator in charge of this study is Dr. Maryellen Potts from MUSC. Approximately 20 people will take part in the study.

B. PROCEDURES

If you agree to be in this study, the following will happen:

1. The researcher will collect basic information from you (e.g. age, education, residence, income, religion).
2. The MUSC researchers will interview you about your experience with the home-based palliative care program. Depending on whether you are a CHW or a clinician at the cancer center, questions may include:
    a. Reasons for involvement with the program?
    b. Any difficulties experienced?
    c. Relationship with others in the program?
    d. Satisfaction with the program?
    e. Ideas for program improvement?

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3. The interview will be held either at the cancer center at a place convenient to you. You will be interviewed in person by the researcher.
4. The interview will be audio recorded and hand-written notes will be taken to supplement the audio recording.
5. The researcher will explain how your identity and your information will be kept safe and confidential. Your answers will not include your name or any other information that could identify you during presentation of the study. Interviews, notes, audio recordings, and other documents will be destroyed after the study is completed and the results are published.

C. DURATION

Participation in the study will take about an hour to complete the interview and survey questions.

D. RISKS AND DISCOMFORTS

When someone participates in a research study, there is a risk for loss of confidentiality of your personal information. The researcher will use all possible means to keep your information confidential and not disclosed to anyone outside the research team.

During the interviews, you may find that some interview questions may be emotionally upsetting for you if you choose to answer the question. You may also experience mental fatigue and if you do, you may ask to take a break at any time or to interrupt the interview. You may choose not to answer any question and you can end the interview at any time without consequences.

To protect your information, audio recordings will be stored in an encrypted server and any written notes will be stored in a locked file cabinet. Study data will be entered on password-protected computer in a program that uses special coding to protect information. Your confidentiality will be protected and at no time will your name be used.

There is a risk of a loss of confidentiality of your personal information as a result of participation in this study.

E. BENEFITS

There are no direct benefits to participating in this study. A potential benefit of this research is that you will have the chance to tell us about your level of satisfaction with the home-based palliative care program. By telling us your ideas for improvement of the program, you will help us learn about how to deliver home-based palliative care in low and lower middle income countries. This information may benefit other cancer patients around the world with better home-based palliative care programs.

F. COSTS

There will be no additional costs to you as a result of participation in this study.

G. PAYMENT TO PARTICIPANTS

After completing the interview, you will receive compensation for your time and effort in participating in this study, according to the standard procedures of the Supta Garoj Cancer Center and Research Institute (SGCCR). Compensation will be approximately $10 US (600 INR).

Payments that you receive from MUSC for participating in a research study are considered taxable income per IRS regulations. Payment types may include, but are not limited to: checks, cash, gift certificates/cards, personal property, and other items of value. If the total amount of payment you receive from MUSC reaches or exceeds $600.00 in a calendar year, you will be issued a Form 1099.

H. ALTERNATIVES

Your alternative is to not participate in this study. Your decision to participate in this study, or not, will not affect any relationship you have with, or assistance or treatment you receive from SGCCRI.

I. EMPLOYEE PARTICIPATION

Your participation or discontinuance will not constitute an element of your job performance or evaluation, nor will it be a part of your personnel record at this Institution.

J. FUTURE CONTACT

The researcher in charge of this study might like to contact you in the future about other research opportunities. Please initial by your choice below:

____Yes, I agree to be contacted

____No, I do not agree to be contacted

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. The investigators associated with this study, the sponsor, and the MUSC Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

In the event that you are injured as a result of participation in this study, you should immediately go to the emergency room of the Medical University Hospital, or in case of an emergency go to the nearest hospital, and tell the physician on call that you are in a research study. They will call your study doctor who will make arrangements for your treatment. If the study sponsor does not pay for your treatment, the Medical University Hospital and the physicians who render treatment to you will bill your insurance company. If your insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to you. Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled.

The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, I may contact Dr. Gautam Bhattacharjee, the SGCCRI team member (Tel:+91 33 2467 8001) or the primary investigator, Dr. Maryellen Potts (Tel: 319-931-9027; email pottsm@musc.edu.

If I have any questions, problems, or concerns, desire further information or wish to offer input, I may contact Dr. Maryellen Potts directly, who will contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792-4148. This includes any questions about my rights as a research subject in this study.

I agree to participate in this study. I have been given a copy of this form for my own records. If you wish to participate, you should sign below.

____ ______________
Signature of Participant or Legal Guardian Date
(if applicable)

____ ______________
Signature of Person Obtaining Consent Date

মেডিক্যাল ইউনিভার্সিটি অফ সাউথ ক্যারোলিনাগবেষণায় অংশগ্রহণের সম্মতিপত্র

গবেষণার শিরোনাম: গ্রামীণ ভারতে ক্যান্সারের রোগীদের জন্য প্যালিয়েটিভ কেয়ার (উপশমকারী সেবা) প্রোগ্রামের সম্বন্ধে (স্টেকহোল্ডারের) ধারণা

A. গবেষণার উদ্দেশ্য

মেডিক্যাল ইউনিভার্সিটি অফ সাউথ ক্যারোলিনার সাথে একটি গবেষণার জন্য আপনাকে স্বেচ্ছাসেবী হতে আহ্বান করা হচ্ছে কারণ আপনি ভারতের ঠাকুরপুকুরের সরোজ গুপ্ত ক্যানসার সেন্টার অ্যান্ড রিসার্চ ইনস্টিটিউটের (এসজিসিসিআরআই), সাথে যুক্ত এবং ঘরে বসে ক্যান্সার রোগীদের জন্য প্রস্তুত প্যালিয়েটিভ কেয়ার (উপশমকারী সেবা) প্রোগ্রামের অভিজ্ঞতা আছে। "প্যালিয়েটিভ কেয়ার (উপশমকারী সেবা)" গুরুতর অসুস্থ রোগীদের জন্য একটি বিশেষ চিকিৎসা পরিষেবা। এটি প্রদানকারী রোগীদের উপসর্গ থেকে মুক্তির প্রসঙ্গে এবং একটি গুরুতর অসুস্থতার চাপের ওপর দৃষ্টি নিবদ্ধ করেছে। লক্ষ্যটি হল রোগীর এবং পরিবার উভয়ের জীবনের মান উন্নত করা।

এই গবেষণার উদ্দেশ্য হল গবেষকরা জানতে পারবেন যে আপনি হোম ভিত্তিক উপশমকারী কেয়ার প্রোগ্রামের সাথে কিভাবে সন্তুষ্ট ছিলেন এবং কিভাবে প্রোগ্রাম উন্নত করা যেতে পারে এই বিষয়ে আপনার ধারনা শোনার জন্য। আপনি কার্যক্রমে অংশগ্রহণকারী নিম্নলিখিত দলের একজন হতে পারেন:

1. এস.জি.সি.সি.আর.আই এ প্রশাসক বা ক্লিনিসিয়ান
2. কমিউনিটি হেলথ কর্মী (সি এইচ ডব্লিউ) যারা বাড়িতে রোগীদের লাঘবকর যত্ন প্রদান করে

এই গবেষণা এস.জি.সি.সি.আর.আই এর মধ্যে কলকাতা, ভারত, এবং চারলেস্টনের মধ্যে দক্ষিণ ক্যারোলিনা মেডিকেল বিশ্ববিদ্যালয়(এম.ইউ.এস.সি), দক্ষিণ ক্যারোলিনা মার্কিন যুক্তরাষ্ট্র দ্বারা স্পন্সর হয়। এই গবেষণার ভারপ্রাপ্ত তদন্তকারী হলেন এম।ইউ.এস.সি থেকে ডঃ মারিলেন পটস । প্রায় 20 জন শিক্ষার্থী এই গবেষণায় অংশগ্রহণ করবে।

B. কার্যপ্রণালী

আপনি এই গবেষণায় অংশগ্রহণে সম্মত হলে নিম্নলিখিত প্রক্রিয়াসমূহ সংঘটিত করা হবে:

1. গবেষকরা আপনার কাছ থেকে মৌলিক তথ্য সংগ্রহ করবে (যেমন বয়স, শিক্ষা, বাসস্থান, আয়, ধর্ম)।

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2. এম.ইউ.এস.সি গবেষকগণ ঘরে বসে প্যালিয়েটিভ কেয়ার (উপশমকারী সেবা) প্রোগ্রামের অভিজ্ঞতার মূল্যায়ন করতে আপনার একটি ইন্টারভিউ নেবেন। আপনি ক্যান্সার কেন্দ্রে সি.এইচ.ডব্লিউ বা ক্লিনিশিয়ান কিনা তা্র উপর নির্ভর করে প্রশ্নগুলি পরিবেষ্টিত হতে পারে
    a. প্রোগ্রামের সাথে জড়িত হওয়ার কারণ?
    b. কোন অসুবিধার সম্মুখী্নের অভিজ্ঞতা?
    c. প্রোগ্রামে অন্যদের সঙ্গে সম্পর্ক?
    d. আপনি কি প্রোগ্রামে সন্তুষ্ট?
    e. প্রোগ্রাম উন্নতির জন্য ধারণা?

3. সাক্ষাত্কারটি ক্যান্সার কেন্দ্রে আপনার পক্ষে সুবিধাজনক স্থানে অনুষ্ঠিত হবে। আপনার সাক্ষাত্কারটি ব্যাক্তিগতভাবে গবেষক দ্বারা করা হবে।
4. সাক্ষাত্কারটির অডিও রেকর্ড করা হবে এবং হস্তাক্ষর নোট অডিও রেকর্ডিং এর সম্পূরক দ্বারা গ্রহণ করা হবে।
5. গবেষক আপনার পরিচয় এবং আপনার তথ্য নিরাপদ এবং গোপনীয় কিভাবে রাখা হবে তা ব্যাখ্যা করবে। আপনার নাম বা অন্য কোনও তথ্য অন্তর্ভুক্ত করা হবে না যা গবেষণা উপস্থাপনার সময় আপনাকে সনাক্ত করতে পারে। গবেষণা সম্পন্ন হলে এবং ফলাফল প্রকাশের পরে সাক্ষাতকার, নোট, অডিও এবং অন্যান্য লিখিত তথ্যগুলি নষ্ট করে ফেলা হবে।

C. সময়সীমা

গবেষণায় অংশগ্রহন ও প্রশ্নাবলী নিরীক্ষণ করতে প্রায় ১ ঘন্টা সময় প্রয়োজন।

D. ঝুঁকি এবং অস্বস্তি

যখন কেউ গবেষণা অধ্যয়নে অংশগ্রহণ করবে তখন আপনার ব্যক্তিগত তথ্যের গোপনীয়তাহানির ঝুঁকি আছে। আপনার তথ্য গোপনীয় রাখতে এবং গবেষণা দলের বাইরে কেউ না জানে তার জন্য গবেষকরা সব সম্ভাব্য উপায় ব্যবহার করবে।

সাক্ষাত্কারের সময়,কিছু সাক্ষাত্কারের প্রশ্ন আপনার জন্য আবেগগতভাবে বিপর্যস্ত হতে পারে যদি আপনি সেই প্রশ্নের উত্তরগুলি দিতে পছন্দ করেন। আপনি মানসিক ক্লান্তি অনুভব করতে পারেন এবং যদি আপনি মানসিক ক্লান্তি অনুভব করেন তবে আপনি যেকোনো সময় একটি বিরতি নিতে বা সাক্ষাত্কারে সাময়িক বিরতি চাইতে পারেন। আপনি যেকোনও প্রশ্নের উত্তর না দিতে পারেন এবং ফলাফল ছাড়াই আপনি যেকোনো সময় ইন্টারভিউ শেষ করতে পারেন।

আপনার তথ্য রক্ষা করতে, অডিও রেকর্ডিং একটি এনক্রিপ্ট সার্ভারে সংরক্ষণ করা হবে এবং যেকোন লিখিত নোট একটি লক ফাইলের ক্যাবিনেটের মধ্যে সংরক্ষণ করা হবে। তথ্য সংরক্ষণের জন্য বিশেষ কোডিং ব্যবহার করে একটি প্রোগ্রামে পাসওয়ার্ড-সুরক্ষিত কম্পিউটারে স্টাডি ডেটা প্রবিষ্ট করা হবে। আপনার গোপনীয়তা রক্ষা করা হবে এবং কোন সময়ে আপনার নাম ব্যবহার করা হবে না।

এই গবেষণায় অংশগ্রহণের ফলে আপনার ব্যক্তিগত তথ্যের গোপনীয়তাহানির ঝুঁকি রয়েছে।

E. সুবিধাসমূহ

এই গবেষণায় অংশ নিলে কোন সরাসরি সুবিধা থাকবে না। এই গবেষণার একটি সম্ভাব্য সুবিধা হল যে আপনার হোম ভিত্তিক প্যালিয়াটিভ কেয়ার প্রোগ্রামের সাথে আপনার সন্তুষ্টি স্তর সম্পর্কে আমাদের বলার সুযোগ থাকবে। প্রোগ্রামের উন্নতির জন্য আপনার ধারণাগুলি আমাদের বলার দ্বারা, আপনি আমাদেরকে কম এবং নিম্ন মধ্যম আয়ের মধ্যে দেশে কিভাবে হোম ভিত্তিক প্যালিয়াটিভ কেয়ার পরিচর্যা বিতরণ করা যায় তা শিখতে সাহায্য করবেন। এই তথ্যটি সারা বিশ্বের অন্যান্য ক্যান্সারের রোগীদের আরও ভাল হোম ভিত্তিক প্যালিয়াটিভ কেয়ারের প্রোগ্রামগুলির সাথে উপকারী হতে পারে।

F. ব্যয়

এই গবেষণায় অংশগ্রহণ করার জন্য আপনার কোন অতিরিক্ত খরচ হবে না।

G. অংশীদারিত্বের জন্য অর্থ প্রদান

সরোজ গুপ্ত ক্যান্সার সেন্টার ও রিসার্চ ইনস্টিটিউট (এস.জি.সি.সি.আর) এর প্রমিত পদ্ধতি অনুসারে সাক্ষাৎকারটি শেষ করার পর, এই গবেষণায় অংশ নেওয়ার জন্য আপনার সময় এবং প্রচেষ্টার জন্য ক্ষতিপূরণ পাবেন। ক্ষতিপূরণ হবে প্রায় 10 মার্কিন ডলার (600 টাকা)।

এই গবেষণায় অংশগ্রহণের জন্য আপনার এম. *ইউ.এস.সি থেকে প্রাপ্ত পেমেন্টগুলি প্রতি আই আর.এস প্রবিধানে করযোগ্য আয় হিসাবে বিবেচিত হয়। পেমেন্টের প্রকারগুলি এতে অন্তর্ভুক্ত থাকতে পারে কিন্তু সীমাবদ্ধ নয়: চেক, নগদ, উপহার শংসাপত্র/ কার্ড, ব্যক্তিগত সম্পত্তি এবং মূল্যের অন্* ***যান্য আইটেম। যদি আপনার এম.*** *ইউ.এস.সি থেকে প্রাপ্ত অর্থের মোট পরিমাণ একটি ক্যালেন্ডার বছরে $600.00 তে পৌঁছায় বা অতিক্রম করে থাকে তবে আপনাকে একটি ফর্ম 1099 জারি করা হবে।*

H. বিকল্প

বিকল্পরূপে এই গবেষণায় অংশগ্রহণ না করতেও পারেন। এই গবেষণায় অংশ নেওয়ার বা না নেওয়ার সিদ্ধান্ত, আপনার সাথে যে সম্পর্ক রয়েছে সেগুলিতে অথবা আপনার এস.জি.সি.সি.আর.আই থেকে সহায়তা বা চিকিত্সা গ্রহণের ওপর প্রভাবিত হবে না।

I. কর্মচারীর অংশগ্রহন

আপনার অংশগ্রহণ বা বিচ্ছিন্নতার ওপর আপনার কাজ কর্মক্ষমতা বা মূল্যায়নের উপাদান গঠন করা হবে না, অথবা এই প্রতিষ্ঠান এ আপনার কর্মিবৃন্দের রেকর্ডের একটি অংশ হবে না।

J. ভবিষ্যত যোগাযোগ

এই গবেষণার ভারপ্রাপ্ত গবেষক অন্যান্য গবেষণায় অংশগ্রহণের সুযোগ সম্পর্কে ভবিষ্যতে আপনার সাথে যোগাযোগ করতে পারেন। অনুগ্রহ করে নীচের পছন্দের বিকল্পের একটিতে স্বাক্ষর করুন:

____হ্যাঁ, আমার সাথে যোগাযোগ করবেন

____না, আমার সাথে যোগাযোগ করবেন না

এই গবেষণার ফলাফল এই গবেষণায় বর্ণিত উদ্দেশ্যে ব্যবহার করা হবে। এই তথ্য প্রকাশ করা হতে পারে, কিন্তু আপনাকে চিহ্নিত করা হবে না। এই গবেষণায় প্রাপ্ত তথ্য যা

আপনাক চিহ্নিত করে, তা স্টেট তথা ফেডারেল আইনের অধীনে যথাসম্ভব গোপন রাখা হবে। এই গবেষণার সাথে জড়িত তদন্তকারী, স্পনসর, এমইউএসসি ইনস্টিটিউশনাল রিভিউ বোর্ড ফর হিউম্যান রিসার্চ এবং সরোজ গুপ্ত ক্যান্সার সেন্টার অ্যান্ড রিসার্চ ইনস্টিটিউটের গবেষকদের কাছে গচ্ছিত থাকবে। দক্ষিণ ক্যারোলিনার সব রেকর্ড আইন একটি আদালত দ্বারা শাসন সাপেক্ষ হয়

এই গবেষণায় অংশগ্রহণের ফলে আপনি আহত হলে , আপনাকে অবিলম্বে ইউনিভার্সিটি হাসপাতালের ইমারজেন্সী কক্ষে যেতে হবে বা নিকটতম হাসপাতালে যেতে হবে এবং ডাক্তারকে বলতে হবে যে আপনি একটি গবেষণায় সাবজেক্ট হিসেবে অংশগ্রহণ করেছেন। তারা আপনার স্টাডি ডাক্তারকে ডাকবে যারা আপনার চিকিত্সার ব্যবস্থা করবে। যদি অধ্যয়নের পৃষ্ঠপোষক আপনার চিকিৎসার জন্য অর্থ প্রদান না করেন, তাহলে মেডিকেল ইউনিভার্সিটি হাসপাতাল এবং চিকিৎসক যারা আপনাকে চিকিৎসা প্রদান করবে তাদের বীমা কোম্পানী বিল প্রদান করবে। যদি আপনার বীমা কোম্পানী কভারেজ অস্বীকার করে বা বীমা উপলব্ধ না হয়, তাহলে আপনাকে আপনার দেওয়া সমস্ত পরিষেবাগুলির জন্য অর্থ প্রদানের জন্য দায়ী থাকবে।
এই গবেষণায় আপনার অংশগ্রহণ স্বেচ্ছাধীন। যেকোন সময় আপনি এই গবেষণায় অংশগ্রহণে অস্বীকার করতে পারেন বা এই গবেষণায় অংশগ্রহণ করা বন্ধ করতে পারেন। আপনি এইরকম কোনো সিদ্ধান্ত নিলে এই গবেষণায় ভারপ্রাপ্ত তদন্তকারীকে অবিলম্বে জানাবেন। আপনার সিদ্ধান্তটি আপনার বর্তমান বা ভবিষ্যতের চিকিৎসা পরিষেবায় বা আপনার প্রাপ্য সুযোগসুবিধাকে কোনোভাবে প্রভাবিত করবে না।

তদন্তকারী এবং / অথবা স্পনসরগণ এই গবেষণায় আপনার অংশগ্রহণকে যেকোনও সময় বন্ধ করে দিতে পারেন যদি তারা মনে করেন যে এটি আপনার স্বার্থের জন্য সবচেয়ে ভালো। যদি আপনি তদন্তকারীদের নির্দেশাবলী অনুসরণ না করেন সেক্ষেত্রেও তারা এই পদক্ষেপ নিতে পারেন।

স্বেচ্ছাসেবক বিবৃতি

আমাকে এই গবেষণার সম্পর্কে প্রশ্ন জিজ্ঞাসা করার সুযোগ দেওয়া হয়েছে। এই প্রশ্নগুলির উত্তর আমাকে সন্তুষ্ট করেছে। এই গবেষণায় বা অধ্যয়ন সম্পর্কিত আঘাত সম্পর্কে আমার কোনও প্রশ্ন থাকলে, আমি এসজিসিসিআরআই দলের সদস্য ডঃ **গৌতম** ভট্টাচার্যের সাথে (টেলিফোন: +৯১ ৩৩ ২৪৬৭ ৮০০১) বা প্রাথমিক তদন্তকারী ডঃ মেরিলেন পোটসের সাথে (টেলিফোন: 319-931-9027; ইমেইল pottsm@musc.edu তে যোগাযোগ করতে পারি।
যদি আমার কোনও প্রশ্ন, সমস্যা বা জিজ্ঞাস্য, বিশদে জানবার থাকে বা ইনপুট দিতে ইচ্ছুক হলে, আমি ডঃ মেরিলেন পোটসের সঙ্গে সরাসরি যোগাযোগ করতে পারি, যিনি এসসি ইনস্টিটিউশনাল রিভিউ বোর্ড ফর হিউম্যান রিসার্চ আইআরবি বা অফিস অব রিসার্চ ইন্টিগ্রিটি ডিরেক্টরকে ফোনে (৮৪৩) ৭৯২-৪১৪৮ যোগাযোগ করবেন। কোন গবেষণার সাবজেক্ট হিসেবে আমার অধিকার সম্পর্কে আমার এই প্রশ্নগুলি অন্তর্ভুক্ত।

আমি এই গবেষণায় অংশ নিতে সম্মত। আমার নিজের রেকর্ডের জন্য আমায় এই ফর্মের একটি প্রতিলিপি দেওয়া হয়েছে।
আপনি অংশগ্রহণ করতে ইচ্ছুক হলে, নীচে স্বাক্ষর করুন।

____
তারিখ সহ অংশগ্রহণকারীর বা আইনী অভিভাবকের স্বাক্ষর
(প্রযোজ্য হ'লে)

____
সম্মতির তারিখ গ্রহণকারী ব্যক্তির স্বাক্ষর

Appendix C: SGCCRI Letter of Support

SAROJ GUPTA CANCER CENTRE & RESEARCH INSTITUTE
formerly known as
CANCER CENTRE WELFARE HOME AND RESEARCH INSTITUTE
Mahatma Gandhi Road, Thakurpukur, Kolkata - 700 063, India
Ph : 91-33-2453-2781 / 82 / 83, 91-33-2467-8001/8003, Fax : 91-33-2467-8002, 91-33-2453-6711
E-mail : cancercentre6@gmail.com / cancerwelfare@yahoo.co.in, Website : www.cancercentrecalcutta.org

Dated: January 31st, 2017

Dear Maryellen,

It is my great pleasure to write this letter of support to invite you to visit our institution, the Saroj Gupta Cancer Center and Research Institute (SGCCRI), in Thakurpukur, Kolkata, India. We have an excellent team of clinicians here and our team has established successful collaborations with Dr. Suparna Qanungo and Dr. Kathleen Cartmell, your mentors. I am the external mentor on your dissertation committee and now look forward to serving as your primary mentor at the SGCCRI for the proposed project. In my role here at the cancer center, I am radiation oncologist and the Head of the Department of Radiotherapy as well as Palliative Care. I understand that you will spend up to two weeks here at our Cancer Center and in the surrounding area. I would like to invite you to stay at our Cancer Center's guest house which will allow you to integrate better into the cancer center environment. I understand that you are here to work on your dissertation project -- to interview the participants in the home-based palliative care program in which we have partnered with MUSC under the guidance of your mentors, Dr. Cartmell and Dr. Qanungo. I presume some amount of translations and transcriptions will be required - the cost of which you will have to bear if you wish to use local services from here.

I believe that your work with the people here at the cancer center and in the community who were involved in the home-based palliative care program will empower you with the knowledge and understanding for working in under-privileged and rural areas, and in low-resource settings. This work will also help inform the palliative care program so that it may be implemented in other areas of India and beyond. The real life research experience that you will gain from working here will prepare you to become a more culturally aware nurse scientist.I am confident that you will return to the USA with a whole new perspective towards global health.

I wish you all the best for a successful grant application and look forward to your visit.

Sincerely,

Dr. Gautam Bhattacharjee, M.D.
Head of the Department, Radiotherapy and Palliative Care,
SGCC&RI, Thakurpukur, Kolkata, INDIA

Appendix D: Research Documents

Potts, M. Demographic Survey Pro00063758 English/Bengali

Q1: Stakeholder: Are you one of the following?
- Clinician
- Administrator
- Rural health care provider /community health worker
- Caregiver
- Patient

Q2. Age: Which category is your age?
- 17 or younger
- 18-20
- 21-29
- 30-39
- 40-49
- 50-59
- 60 or older

Q:3 Sex: Are you male or female?
- Male
- Female

Q.4 Religion: Please specify your religion.
- Hinduism
- Islam
- Sikhism
- Christianity
- Buddhism
- Other

Q5. Education: What is the highest level of school you have completed or the highest degree you have received?
- Less than high school degree
- High school degree or equivalent (e.g. GED)
- Some college but no degree
- Associate degree/Diploma/Certification
- Bachelor degree
- Graduate degree
- If you have obtained a degree/diploma/certification, please specify ________________________________

Q6. Marital Status: Which of the following categories best describes your marital status?

- Single, never married
- Married or live-in-relationship
- Widowed
- Divorced
- Separated

Q7. Employment Status: Which of the following categories best describes your employment status?

- Employed with an organization
- Self-employed
- Not employed, looking for work
- Not employed, NOT looking for work
- Retired
- Unable to work

Q8. Household Income: What is your total monthly household income combined from all members of your household?

- Less than INR 2,000
- INR 2,100 to INR 5,000
- INR 5,100 to INR 15,999
- INR 16,000 to INR 30,999
- INR 31,000 to INR 49,999
- INR 50,000 to INR 99,999
- INR 100,00 (1 lacs) or more

Q9: Household Size: How many members do you have in your household apart from yourself?

- 1
- 2 to 4
- 4 to 8
- >8

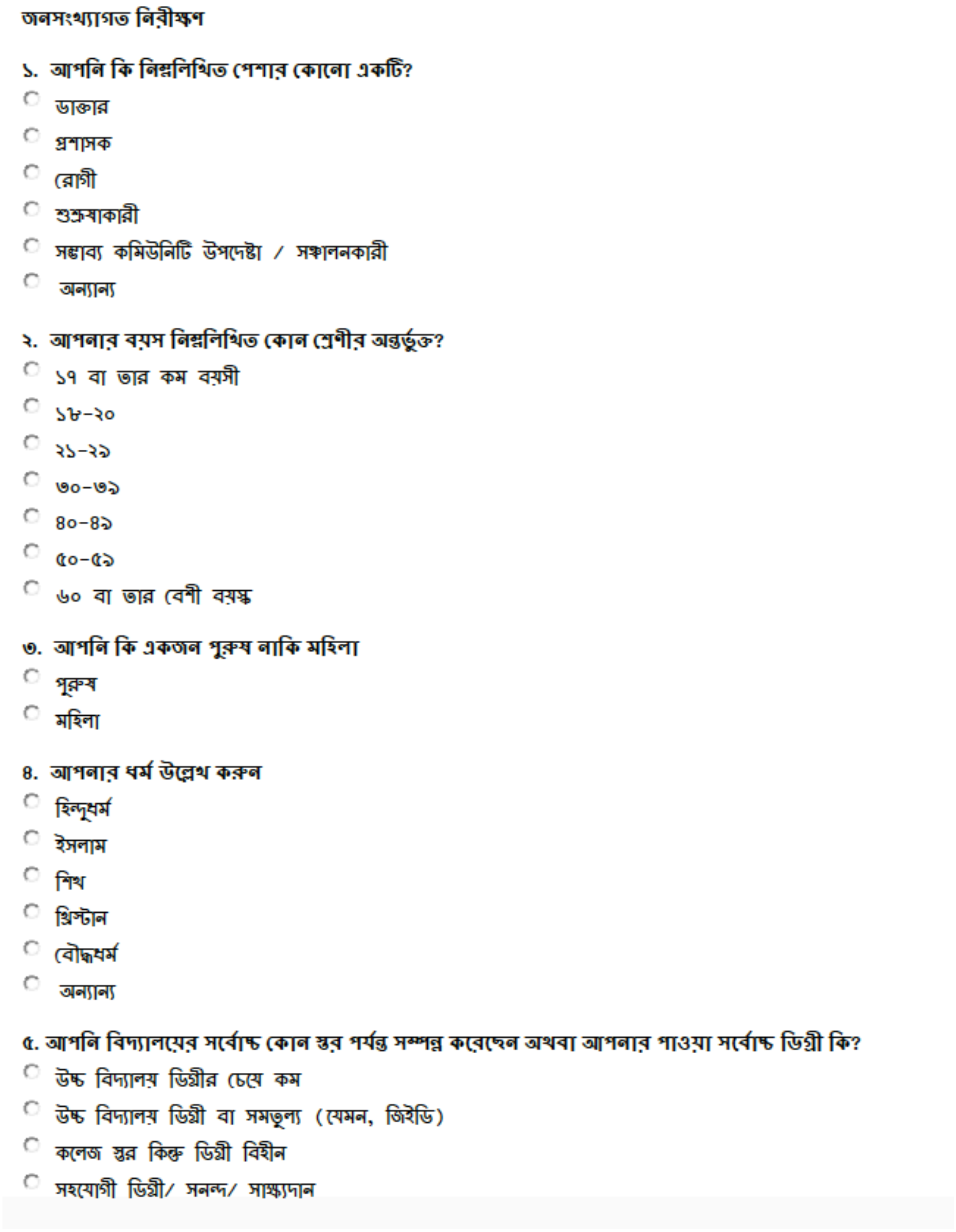
Q10: Patient Status: If you are a patient, what has been the duration of the your illness?

- < 4 months
- 4-12 months
- >12 months

Q11: Residence: What best describes where you live?

- Rural village
- Suburban town
- Urban city
- Please state your district of residence

  ____



জনসংখ্যাগত নিরীক্ষণ

১. আপনি কি নিম্নলিখিত পেশার কোনো একটি?

○ ডাক্তার

○ প্রশাসক

○ রোগী

○ শুশ্রূষাকারী

○ সম্ভাব্য কমিউনিটি উপদেষ্টা / সঞ্চালনকারী

○ অন্যান্য

২. আপনার বয়স নিম্নলিখিত কোন শ্রেণীর অন্তর্ভুক্ত?

○ ১৭ বা তার কম বয়সী

○ ১৮-২০

○ ২১-২৯

○ ৩০-৩৯

○ ৪০-৪৯

○ ৫০-৫৯

○ ৬০ বা তার বেশী বয়স্ক

৩. আপনি কি একজন পুরুষ নাকি মহিলা

○ পুরুষ

○ মহিলা

৪. আপনার ধর্ম উল্লেখ করুন

○ হিন্দুধর্ম

○ ইসলাম

○ শিখ

○ খ্রিস্টান

○ বৌদ্ধধর্ম

○ অন্যান্য

৫. আপনি বিদ্যালয়ের সর্বোচ্চ কোন স্তর পর্যন্ত সম্পন্ন করেছেন অথবা আপনার পাওয়া সর্বোচ্চ ডিগ্রী কি?

○ উচ্চ বিদ্যালয় ডিগ্রীর চেয়ে কম

○ উচ্চ বিদ্যালয় ডিগ্রী বা সমতুল্য (যেমন, জিইডি)

○ কলেজ স্তর কিন্তু ডিগ্রী বিহীন

○ সহযোগী ডিগ্রী/ সনন্দ/ সাক্ষ্যদান

○ স্নাতক ডিগ্রী

○ স্নাতকোত্তর ডিগ্রী

যদি আপনি একটি ডিগ্রী/ সনদ/ সাক্ষ্যদান লাভ করে থাকেন, অনুগ্রহ করে উল্লেখ করুন .-------------

৬. নিম্নলিখিত শ্রেণীগুলির কোনটি আপনার বৈবাহিক অবস্থা বর্ণনা করে

○ একক, বিবাহিত না

○ বিবাহিত অথবা সম্পর্ক বাস

○ পতিহীনা

○ তালাকপ্রাপ্ত

○ বিভক্ত

৭. নিম্নলিখিত শ্রেণীগুলির কোনটি আপনার কর্ম সংস্থানের অবস্থা বর্ণনা করে?

○ একটি প্রতিষ্ঠানে নিযুক্ত

○ স্বনির্ভর

○ বেকার, কাজ খুঁজছেন

○ বেকার, কাজ খুঁজছেন না

○ অবসর প্রাপ্ত

○ প্রতিবন্ধী, কাজ করতে অক্ষম

৮. আপনার পরিবারের সকল সদস্যদের আয় মিলিয়ে আপনার মাসিক মোট পারিবারিক আয় কত?

○ ২,০০০ টাকার চেয়ে কম

○ ২,১০০ টাকা থেকে ৫,০০০ টাকা

○ ৫,১০০ টাকা থেকে ১৫,৯৯৯ টাকা

○ ১৬,০০০ টাকা থেকে ৩০,৯৯৯ টাকা

○ ৩১,০০০ টাকা থেকে ৪৯,৯৯৯ টাকা

○ ৫০,০০০ টাকা থেকে ৯৯,৯৯৯ টাকা

○ ১,০০,০০০ (১ লক্ষ) বা তার অধিক

৯. আপনি ব্যতীত আপনার পরিবারে কজন সদস্য আছেন?

○ ১ জন

○ ২ জন থেকে ৪ জন

○ ৪ জন থেকে ৮ জন

○ ৮ জনের অধিক

১০. আপনি যদি একটি রোগী হন, কি সময়কাল হয়েছে আপনার অসুস্থতার?

○ <৪ মাস

○ ৪-১২ মাস

○ >১২ মাস

১১. নিম্নলিখিত কোনটি আপনার বসবাসকে বর্ণনা করে?

○ গ্রাম

○ শহরাঞ্চল

○ শহর

আপনার বসবাসের জেলার নাম উল্লেখ করুন---

Table of Interview Guide Questions for Palliative Care Stakeholders
Pro00063758 Potts, M.

Q#	Community Health Worker	Cancer Center Clinician
1	What was your day like before deciding to become involved in the cancer center's palliative care program?	Please tell me about your clinical role at the cancer center
2	How did you become involved with the cancer center's home-based palliative care program?	How did you become involved with the cancer center's home based palliative care program?
3	Please tell me about your experience working as a palliative care community health worker. e. What happens during a typical visit? f. How did you feel about your interactions with patients and their family members? g. What topics did you discuss with patients and their family members? h. How did patients and family members follow your recommendations?	Please tell me about your experience working as a member of the cancer center's home-based palliative care program.
4	What were the most common physical problems that patients faced? [List: …Ask question below for each problem] a. How did you help patients with this problem? (did you need to get help?, what kind of help?; how did you involve the family?)	In your experience, what are the most common physical problems patients face?
5	What were the most common emotional problems that patients faced? [List: …Ask question below for each problem] c. How did you help patients with this problem? (did you need to get help?, what kind of help?, how did you involve the family?)	In your experience, what are the most common emotional problems patients face?
6	What were the most common practical problems that patients faced? (e.g. finances, travel, housing, bills) [LIST: …Ask question below for each	In your experience, what are the most common practical problems patients face?

	problem]: d. How did you help patients with this problem? (did you need to get help?, what kind of help?, how did you involve the family?)	
7	One role of a palliative care community health worker is to obtain pain medication refills for patients. Can you tell me how this process worked? a. What problems did you encounter picking up these medications? Do you have ideas about how to improve this process?	One role of a CHW is to obtain pain medication refills for patients. Can you tell me how this process worked? a. What problems did you observe with this process? b. How could this process be improved?
8	What difficulties did you face as a community health worker? c. What about the paperwork? d. What about the travel to see patients and to visit the cancer center? e. What about trying to coordinate your responsibilities as a rural health doctor and as a community health worker? Other challenges?	What challenges did you face while working with the CHWs? (prompts: paperwork, coordination of responsibilities, etc.)
9	Tell me about your relationships with patients and their families. f. What part of your role did you feel they valued the most? Tell me about your relationship with the doctors, nurses and social workers at the cancer center. g. What part of your role did you think they valued the most?	From your experience, what is your relationship like with patients and their families? From your experience in the palliative care program, what is your relationship like with the community health workers?
10	How can we improve the program?	What were your thoughts about the home-based care program? a. Overall, what did you like best about the program? b. Overall, what did you like least about the program? c. How can the program be improve
11	What else would you like to tell me?	What else would you like to tell me?

12	What did you think about the training you received at the cancer center to be a palliative care community health worker? c. What parts of the classroom training were most helpful? d. What parts of the classroom training were not as helpful? e. How could the classroom training be improved?	How were your experiences with the training of the community health workers (CHWs). a. What was your role in training the CHWs? b. What parts of the classroom training do you think were most helpful? c. What parts of the classroom training do you think were not as helpful? d. How could the classroom training be improved?
13	Can you tell me about your experience shadowing clinical team members from the cancer center? c. What parts of the shadowing experience were most helpful? d. What parts of the shadowing experience were not as helpful? e. How could the shadowing experience be improved?	Please tell me about your experience being shadowed by the CHWs? c. What parts of the shadowing experience do you think were most helpful? d. What parts of the shadowing experience do you think were not as helpful? e. How could the shadowing experience be improved?
14	How did you use the palliative care toolkit materials to care for your patients? c. Which resources in the toolkit were most useful? And why? d. Which resources in the toolkit were not as useful? And why? e. How can we improve the toolkit?	What were your experiences with the palliative care toolkit materials? c. Which resources in the toolkit were most useful? And why? d. Which resources in the toolkit were not as useful? And why? e. How can we improve the toolkit?
15	Tell me about your relationship with the doctors, nurses and social workers at the cancer center. c. What part of your role did you think they valued the most?	Please tell me about your experience working with the CHWs. d. What topics did you commonly discuss with the CHWs?
16	What did you like best about being a palliative care community health worker	How satisfied were you with the role of the CHWS? e. What tasks were the CHWs able to do well?