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Original Research Article

Develop and test a palliative care screening tool for rural patients with serious chronic illnesses: a study protocol

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ABSTRACT

Background: Delayed admission to palliative and hospice services is prevalent and, especially in rural areas, contributing to poor quality of care, caregiver stress and burden, reducing patients' and their caregivers' quality of life and increasing healthcare costs. A reliable and sensitive screening tool would help clinicians identify patients in need of palliative care services. The purpose of the study is to develop and test a screening tool to be used by healthcare professionals in rural clinics and hospitals to identify patients with progressive, multiple chronic illnesses in need of primary palliative care services.
Methods: A longitudinal, sequential mixed-method methods design will be used to achieve the purpose of the study. A rural community hospital and its affiliated community clinics in the Midwestern United Sates are selected for the study. In Phase I, we will conduct a cohort study using existing electronic health records. The cross-sectional and correlational quantitative data analysis will be used to test the psychometric properties of the current and modified palliative care screening tools. In Phase II, we will prospectively collect functioning and physical activity level data from the patients admitted to the palliative care program over time (monthly for 6 months). Again, the primary focus is to conduct correlational quantitative analysis to evaluate the psychometric properties of the modified palliative screening tool
Conclusions: The implication of this project is to 1) reduce healthcare disparities, 2) improve quality of care for rural patients with chronic serious illness; 3) inform the development of a hybrid (both inpatient and outpatient) screening tool for identifying palliative care needs that can be integrated into primary palliative care programs; and 4) enhance our understanding of mechanisms and relevant variables related to palliative care in rural patients living with chronic serious illness, leading to future program research in this field.

Keywords: Palliative care, Hospice care, Chronic illness, Primary care, Rural health

INTRODUCTION

Advances in medical technology and effective disease prevention and treatment contribute to the growing aging population with serious chronic illness.[1] Despite vast healthcare expenditures, these patients receive poor quality of care, fragmented care, undertreated symptoms and distress, unmet care needs, lack of family support, high caregiver burden and poor education about self-management of their serious conditions.[2] The rural elderly population, in particular, receives care at healthcare facilities with limited resources.[2-4] As a result,

compared to their urban counterparts, rural elderly patients suffering from serious, chronic conditions, receive lower quality of care, less symptom relief and perceive lower quality of life.[5,6]

Palliative care is an interdisciplinary, specialized care that improves quality of life for patients with life-limiting illnesses through symptom relief, care coordination, patient/provider education, decision-making aids, and psychosocial support.[1-3] There are three levels of palliative care: primary, secondary, and tertiary.[7] Generalists deliver primary palliative care services, such as symptom management, care coordination, establishment of goals of care and patient/family support.[7,8] Secondary and tertiary levels of palliative care are done by palliative care specialists to manage more complex problems (e.g., refractory dyspnea).[7] Both secondary and tertiary levels of palliative care mainly take place in urban healthcare settings.[9] Considering low volume and a lack of required resources, the primary palliative care services provided by generalists (e.g., nurses and family practices) are most sustainable and feasible in rural communities.[10] Timely palliative care is critical to meet patients' and families' complex care needs and improve quality of care.[11]

To provide timely palliative care to rural patients, an appropriate, sensitive and reliable screening tool is needed. Clinicians need the screening tool to monitor patients' progress and predict the timing of the transition to hospice care. However, the existing palliative care screening tools have not been tested in rural populations living with serious chronic conditions. Their overall psychometric properties are unknown in the rural population. Furthermore, most of these screening tools are complex and include multiple components and domains.[12] Items in each domain are often subjective and lack clear definition.[13] Consequently, the screening process requires significant time and skill, which rural clinicians often do not have.[14]

The consensus report from the Center to Advance Palliative Care (CAPC) recommends a reliable screening tool that consists of indicators of functioning, disease severity, and healthcare utilization.[7] The Gold Standard Framework (GSF) prognostic indicators guideline and other studies on populations with chronic advanced illness also recommend functional limitation as an independent predictor of palliative care needs.[13-15] However, existing palliative care screening tools assess patient functioning by self-report, thus limiting the reliability and validity of these tools.[13] Moreover, the correlations between the existing screening tools and objective measures assessing functioning, disease severity and healthcare utilization have not been reported. To address these knowledge gaps, we propose 1) using objective measures to assess physical and cognitive functioning, as well as disease severity; and 2) examining the correlations between palliative care needs assessed by the screening tool and patients' functioning, disease severity and healthcare utilization over time.[16] In terms of physical functioning, studies show gait is the most sensitive parameter to detect physical functioning decline.[17] Additional studies reported balance measured by Tinetti performance-oriented mobility assessment (POMA) and walking duration assessed by the 6-minute walk test (6MWT) are sensitive parameters to monitor the level of functioning deterioration over time.[18] The Saint Louis University Mental Status (SLUMS) examination is the most commonly used cognitive functioning assessment tool in geriatric populations. It strongly predicts neuropsychological debilitation, hospitalization, nursing home placement and mortality in older adults.[19-21]

In addition, the Palliative Performance Scale (PPS) is a gold standard measure to evaluate palliative care patients' functioning decline over time.[22] In terms of disease severity and healthcare utilization, the studies showed the LACE (length of stay, acuity, co-morbidities, emergency department visits) index, a common tool used to predict the risk of 30-day readmission, is a reliable measure.[23] In our previous randomized controlled trial which aimed to promote self-care in heart failure patients, many heart failure patients enrolled in the study were considered palliative care candidates by their rural care providers. We also found significant associations between physical functioning, disease severity and healthcare utilization in this study, which confirms our belief that a screening tool that is strongly associated with disease severity and functionality would predict patients care needs and healthcare utilizations. Therefore, the purpose of this study is to adapt an existing palliative care screening tool, thereby developing and testing the newly modified tool for reliability, validity and sensitivity to assessing patients for palliative care service in rural health care settings. The following aims will help achieve the purpose:

- Evaluate the psychometric properties of the various screening tools included in the Center to Advance Palliative Care (CAPC) criteria for identification of those in need of palliative care services.
- Revise the CAPC criteria based on both qualitative and quantitative data.
- Evaluate the psychometric properties of the modified CAPC screening tool (CAPC-R).
- Test the modified CAPC screening tool's sensitivity to the change of physical activity level, the change of functioning over time, as well as the utility of the modified tool.

The proposed study will impact nursing practice and research by enhancing our understanding of the linkage among the palliative care needs, functioning, disease severity and healthcare utilization, which contribute to the development of effective interventions to meet patients' palliative care needs. The newly developed palliative care screening tool will assist comprehensive assessments across multiple disciplines, promote holistic, interdisciplinary team approaches, and help standardize

the screening process for a palliative care continuum across settings, which leads to the improved on-going monitoring process and appropriate transition of patients to hospice care.

Conceptual framework

Based on Gelberg-Anderson's healthcare utility model and the international classification of function, disability and health (ICF) Model, we developed a conceptual framework to guide tool development as given in Figure 1.[24,25]

This framework represents a holistic approach to identifying the palliative care needs of patients with complex serious chronic diseases.[26] This framework posits that palliative care needs are a function of symptom severity, functioning, and contextual factors.

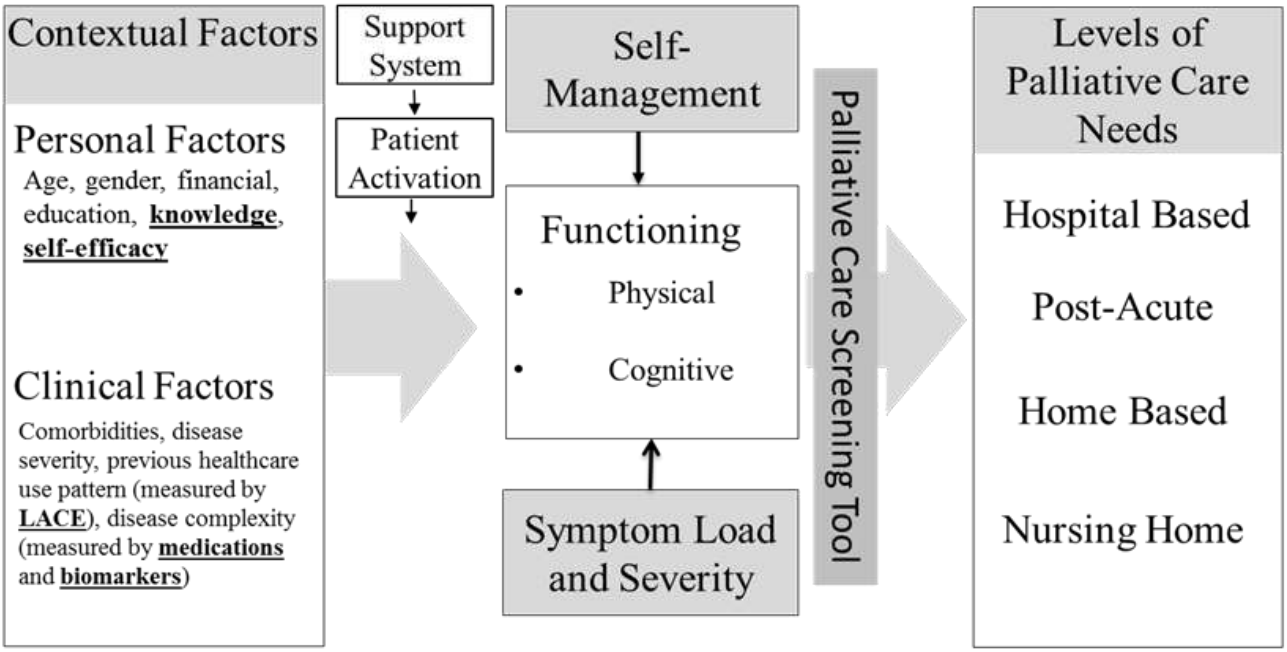

Figure 1: Factors influencing levels of palliative care needs.

METHODS

Research design

This is a pilot study using a longitudinal, sequential mixed method design.

Setting, subject and sample size

The proposed study will be conducted in a rural Midwestern critical access hospital (CAH) and its clinics, which provided inpatient care for approximately 600 patients with chronic serious conditions over the past twelve months. Patients are eligible for the study if they: 1) are 50 or older; 2) have more than one serious chronic conditions (e.g., heart failure, chronic obstructive pulmonary disease); 3) have the following measures in their records: SLUMS, Tinetti POMA, and 6MWT. Patients are not eligible for the study if they: 1) have acute neurological disease/disorders (e.g., multiple sclerosis, Lou Gehrig's disease, massive hemorrhagic stroke); or 2) have cancer as the primary diagnosis and undergo chemo and radiation therapies.

For quantitative data analysis during the tool development phase, the point of stabilization for correlations is typically around 250 participants for the type of instruments being used in this study. For qualitative data analysis, the literature recommends 10–18 experts to evaluate clinical tools.[27] For quantitative data analysis during the tool testing phase, we plan to use all the patients admitted to the palliative care program at the time of this study (N = 50).

Measures and instruments

Table 1 describes the study instruments and their psychometric characteristics.

Procedure

A two-phase procedure will be used to adapt and then test the palliative care screening tool to meet rural patients' and clinicians' needs. In Phase I, we will conduct medical record review using existing electronic medical records (EMRs). In Phase II, we will prospectively collect

functioning and levels of physical activity data from the patients admitted to the palliative care program.

Plan for data management/analysis

A longitudinal, sequential mixed method design will be used to address study aims. This approach provides a holistic view of developing and testing a rural-oriented palliative care screening tool. Before the analysis of the study aims, summary statistics (means, standard deviations, and proportions) will be calculated to describe the study sample. First, the correlational analysis between the CAPC criteria and the 6MWT, Tinetti POMA, SLUMS, and LACE will be conducted. Reliability will be reported with Cronbach's alpha for each instrument and subscale (AIM 1). Secondly, interviews with healthcare professionals will be conducted to help modify the existing tool (AIM 2). Third, a new set of correlational quantitative analyses between the modified screening tool and the aforementioned measures will be conducted to examine the psychometric properties of the modified tool (AIM 3). Last, the correlational analysis between CAPC-R and PPS scores, total activity counts will be conducted (AIM4). The concurrent qualitative data analysis will help inform the utility of the tool. All quantitative data will be analyzed in SPSS v23.[40]

Table 1: Variables, instruments, and their psychometric properties.

Variables	Instruments	Psychometric properties
Contextual Factors: measured at Phase I: Step 1; Phase II: baseline		
Demographics and Clinical Variables	Demographic and clinical variables tool	Not available
Disease Severity	LACE index scores range from 1-19 and predict disease acuity, complexity, readmission or death.[23]	Discrimination (Cochran's C statistic 0.684) and accurate (Hosmer–Lemeshow goodness-of-fit statistic 14.1, p = 0.59)
Functioning: measured at Phase I: Step 1 and 3; Phase II monthly x 6		
Cognitive Functioning	Saint Louis University Mental Status examination (SLUMS) is an 11-item, 30-point cognitive screening.[28]	Concurrent validity with Mini-Mental State Examination (MMSE) ($\gamma = 0.75$; $p < 0.001$).
Physical Functioning	Tinetti Performance Oriented Mobility Assessment (Tinetti POMA) evaluates gait and balance abilities by an ordinal scale of 0 (most impairment) to 2 (independence).	Correlation with Functional Independence Measure (FIM) and gait speed scores at hospital admission (r = 0.55 and 0.70) and discharge (r= 0.55 and 0.82, test-retest reliability (ICC = 0.84), great discriminant, convergent, and predictive validities and responsiveness to changes in performing activities of daily living.[29,30]
	Six Minute Walk Test (6MWT) used in Phase I: examines physical functioning capacity by assessing walking distance over a total of six minutes on a hard, flat surface.[31]	Test-retest reliability as ICC = 0.88 - 0.91 overtime in heart failure patients.[32] Criterion validity was demonstrated in heart failure patients (r=0.56 to r=0.88).[33,34]
	Fitbit Charge HR™ measures physical functioning and provides real-time feedback, assessing heart rate and counting steps.[35]	The inter-device reliability: ICC = 0.97-1.00) for all walking speeds. The within-participant correlation of Fitbit-estimated energy expenditure was 0.88 for wrist device.[36] Fitbit significantly correlated with caloric expenditure in older adults.[37]
Overall Functioning and Prognosis	The Palliative Performance Scale (PPS) measures disease progression among palliative patients by five observer-rated parameters. Patient is graded from PPS 0% (dead) to PPS 100% (healthy).[38]	PPS is reliable with ICC values for consistency and absolute agreement of 0.96.[22]
Palliative Care Needs: measured at Phase I, Step 1		
Palliative Care Screening Tool	Center to Advance Palliative Care (CAPC) screening identifies patients' palliative care needs. The patient receiving a score of 4 or more will be provided palliative care services.[39]	The inter-rater reliability of CAPC screening tool was higher (k = 0.99-0.81) in cancer patients than in chronically ill patients (k = 0.80-0.61). The psychometric testing of this tool has not been conducted in rural populations.

Table 2: Detailed procedure of the study.

Phases	Procedure details
Phase I	• Obtain IRB approval → data extraction from EMR to obtain the variables listed in Table 1→ develop dataset → test the psychometric properties of existing tool by examining the correlation between the CAPC criteria and the 6MWT, Tinetti POMA, SLUMS, LACE, and other contextual factors (e.g., personal and clinical variables) • Identify and recruit interviewees → get informed consent → interview a minimum of 15 interviewees from three types of healthcare professionals (i.e., primary care, acute care, special care) → transcribe the interview transcripts →conduct qualitative data analysis → modify CAPC criteria • Test the psychometric properties of adapted screening tool by examining the correlation between the CAPC-R and aforementioned measures and variables in #1. • Compare the differences in psychometric properties between the CAPC criteria and CAPC-R
Phase II	• Get informed consent → data extraction from activity tracking devices and EMR to obtain total activity counts, heart rate by the minute, and PPS scores, → develop dataset → test the psychometric properties of adapted tool by examining the correlation between the CAPC-R and PPS scores, total activity counts in relation to heart rate. • Identify and recruit interviewees → get informed consent → interview a minimum of 15 interviewees (e.g., palliative care patients, family members, nurses, other providers) → transcribe the interview transcripts conduct qualitative data analysis → further modify the tool to improve the utility

DISCUSSION

Less than 10% of patients received palliative or hospice services in the last year of their lives.[41] Timely palliative care relieves patients' suffering, caregiver stress, and improves end of life quality.[42] A disproportionate number of older patients with multiple serious chronic conditions live in rural communities.[12] A reliable palliative care screening tool is critical for rural general practitioners to identify patients' needs for palliative care. The proposed study will help developing and testing a reliable and valid tool. Consequently, this tool may enable healthcare professionals to identify patients with palliative care needs earlier, develop strategies to meet their needs, and appropriately transition them to hospice care. This contribution to nursing practice will reduce healthcare disparities in end of life care. By increasing the understanding of specific palliative care needs in rural populations, this research will also lay the groundwork for future research in developing a hybrid (both inpatient and outpatient) and integrated primary palliative care program aimed at providing high-quality care at an affordable cost.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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