A Standardized Palliative Care Referral Workflow and Educational In-Service at an Outpatient Congestive Heart Failure Clinic

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A Standardized Palliative Care Referral Workflow and Educational In-Service at an
Outpatient Congestive Heart Failure Clinic

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Defense Date: April 7, 2016
Dedication

For Dan, my husband, support system, and personal computer specialist, thank you for inspiring my work and dedication while sacrificing so many things. It seems like a thankless job, but you inspire me to be my best self and chase my dreams even though they never end and always change. To my parents, Sandy and Craig, who have set the bar high as two of the most loving and giving people I know. To my siblings, Sarah and Philip, family, friends, classmates, preceptors, and colleagues from near and far, thank you for the words of wisdom, support, prayers, love, and laughter. Lastly, for those patients and families whom I have been blessed to care for over the past decade, you have changed my life and made me a better person and nurse. I could not have done it without each and every one of you.
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Abstract

Cardiovascular disease is a significant health issue in the US as it is the leading cause of death and most cited reason of hospitalizations in Medicare enrollees (Centers for Disease Control, 2014; Unroe et al., 2011). The American Colleges of Cardiology and the American Heart Association Guidelines recommend palliative care for all patients with heart failure (Yancy et al., 2013). The purpose of the scholarly project was to address the gaps in current practice by creating a standardized palliative care referral process and education for clinicians in an outpatient Advanced Congestive Heart Failure (ACHF) Clinic. A referral tracking process was defined, a pre-test and post-test were used as measures for the education, a referral process was outlined, and the number of palliative care referrals increased from 0.6% to 1.4% during the project work.

Keywords: heart failure, palliative care, end of life, education, standardized, referral, and workflow
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Executive Summary

Integration of palliative care in ACHF disease management provides a holistic and comprehensive approach. In the US, palliative care is underutilized and end-of-life care is fragmented and uncoordinated (Institute of Medicine, 2014). Palliative care has been associated with: higher quality of life, effective communication and understanding of disease progression, and improved access to home healthcare and hospice (Adler, Goldfinger, Kalman, Park, & Meier, 2009; Yancy et al., 2013).

This scholarly project final report focuses on increasing palliative care for those with ACHF, the largest progressive chronic illness with the highest burden of symptoms (Centers for Disease Control, 2014; National Hospice and Palliative Care Organization, 2015). The project focused on increasing ACHF clinician knowledge, modifying attitudes toward death, and developing a standardized referral process (SRP). The project site was an Advanced ACHF Outpatient Clinic. The report includes background, evidence, conceptual framework, organizational assessment, project plan and outcomes, and implications to practice with dissemination of outcomes. Ultimately, relationship development and patient storytelling throughout the scholarly project work provided the catalysts for practice change. Thus, integration of evidence-based care in an ACHF Clinic was initiated.
Introduction and Background

Palliative care, end-of-life care, and hospice care provide holistic, person-centered care in the presence of advanced illness. Palliative care is provided in conjunction with traditional curative treatment and may be utilized for patients who will be cured of illness. End-of-life care is care for those who are dying who require knowledge and support during the dying process. Hospice care is a robust interdisciplinary approach for patients with a prognosis of six months or less, who are no longer seeking traditional or curative treatment (Ferrell, Coyle, & Paice, 2015). Evidence-based recommendations for Congestive Heart Failure (CHF) recommend integration of palliative care from the time of diagnosis (Yancy et al., 2013). Also, it has been found that palliative care in CHF increases access to hospice care. Both palliative and hospice care decrease the cost of care and healthcare utilization, increase quality of life, and increase length of life (Adler et al., 2009; Unroe et al., 2011).

Cardiovascular disease is the leading cause of death in the US (Centers for Disease Control, 2014). There are currently over 5.7 million people living with CHF; and it is expected to increase 25% by 2030 (Centers for Disease Control, 2014; Go et al., 2013; Heidenreich et al., 2011). Fifty percent of those with ACHF die within five years of diagnosis and for Medicare recipients a third will die within a year of diagnosis (Go et al., 2013; Unroe, et al., 2011). The annual cost of caring for those with CHF is over $30 billion (Adler et al., 2009; Heidenreich et al., 2011). This significantly impacts the US healthcare system. Addressing this problem aligns with the Triple Aim: improving the patient experience of care (including quality and satisfaction), improving population health, and reducing the per capita cost of healthcare (Institute of Health Improvement, 2015a).

Among the 5.7 million living with ACHF, it is estimated that approximately 5% (250,000) have end stage ACHF as defined by New York Heart Association Class IV (Costanzo,
End stage heart failure is associated with poor prognosis (Whellan et al., 2014). However, it has been shown that patients with end stage ACHF who receive hospice care have improved survival of 81 days, when compared with those who did not receive hospice and palliative care (Connor, Pyenson, Fitch, Spence, & Iwasaki, 2007; Wingate et al., 2011).

An Institute of Medicine (IOM) report (2014) states that most deaths are caused from a culmination of chronic illness requiring careful management. IOM calls for the harmonization of social, psychological, and spiritual support toward end of life. Also, IOM recommends end-of-life care that is person-centered, family-oriented, and evidence-based. A palliative care approach allows for the best chance of maintaining the highest possible quality of life for the longest amount of time (IOM, 2014).

The IOM report entitled Dying in America (2014) identified the following insufficiencies in palliative care: inadequate numbers of palliative care specialists; a lack of knowledge in palliative care among clinicians who care for individuals with advanced illness; and a healthcare delivery system that is fragmented with a lack of coordination. Specific to ACHF, the American College of Cardiology and the American Heart Association Heart Failure Guidelines recommend palliative care from the time of diagnosis, regardless of the severity of the disease (Yancy et al., 2013).

These evidence-based guidelines recommend palliative care for all ACHF patients. Thus, this project focused on beginning changes in the organizational culture of ACHF care in an ACHF Outpatient Clinic by developing a standardized palliative care referral process and educating staff. The scholarly project is the first step toward integration of palliative care within the culture of the ACHF Clinic. The project aimed to increase clinician palliative care knowledge and modify attitudes; develop, draft, and modify a standardized palliative care referral process; and ultimately,
increase access to palliative care for patients with ACHF. The project was developed based on the organizational assessment.

**Organizational Assessment**

To fully understand the palliative care needs of the Outpatient ACHF Clinic, an organizational assessment was conducted. The current culture of ACHF care within the organization is geared towards advanced therapies (i.e. Implanted Cardiac Defibrillators, intravenous inotropic medications, Left Ventricular Assistant Devices, or heart transplantation) without the involvement of palliative care. Due to this culture, CHF patients are re-hospitalized at a higher rate than the national average, transition to hospice care only in the final days of life, and die in the hospital. Key ACHF stakeholders identify palliative or hospice care as a “failure” in medical treatment and are resistant to change. However, financial implications of these outcomes include a 30-day re-hospitalization penalty for ACHF patients. Therefore, the timing of the scholarly work aligns with a larger scale organizational need, as a timelier transition from palliative care to hospice care will likely decrease re-hospitalization rates in ACHF.

The organizational assessment identified the current state of palliative care in the Outpatient ACHF Clinic. Within the organization palliative care is a consultative service within the ACHF Clinic to assist in coordination of care. The relationship was established following designation as a transplant center. The organizational assessment identified the need for practice change. The findings included: (a) palliative care data tracking was not being conducted; (b) no known formal palliative care training for clinicians had ever occurred, although it had been scheduled and cancelled the prior year; (c) no standardized process for conducting a palliative care referral could be identified; and (d) palliative care follow-up was not being completed for hospitalized ACHF patients. The assessment indicated palliative care in the ACHF Clinic was likely insufficient and not meeting current patient needs.
Furthermore, data on the number of referrals from the ACHF Clinic to palliative care were not being collected until the scholar began this project. Palliative care referral rates were determined based on review of the electronic health records by the DNP scholar. A very low referral rate from the ACHF Clinic to palliative care was identified and substantiated. It was determined that approximately 0.6% of the patients were receiving palliative care.

The organizational assessment of palliative care knowledge within the ACHF Clinic identified no formal palliative care education for clinicians, registered nurses (RN), medical social workers (MSW), nurse practitioners (NP), or pharmacists had ever occurred. It was determined formal palliative care education was needed. Additionally, it had been requested prior to the scholarly work but was never completed due to changes in palliative care and ACHF staff.

In addition, during the organizational assessment, the DNP scholar could not identify a standardized process, or forms for conducting a palliative care referral in the ACHF clinic. The current state of the referral process included identification of a ACHF palliative care patient, order entry into the electronic health record, scheduling of the visit (typically within six weeks of referral), and may or may not include scheduling an appointment for advanced care planning. Furthermore, a gap was identified; that those vulnerable ACHF patients who had palliative care while hospitalized did not have palliative care continued in the ACHF outpatient clinic. The assessment also identified that the Gunderson Respecting Choices Advance Care Planning Conversation was being conducted in the ACHF Clinic by a trained NP facilitator but was independent from palliative care referrals. Based on the organizational assessment, the scholarly project targeted these identified palliative care needs.

The feasibility of conducting the scholarly work at the ACHF Clinic was examined by key stakeholders associated with the project site. This included the following: project advisor
and palliative care physician; Senior Director of Hospice and Palliative Care for the site; Hospice and Palliative Care Clinical Manager; and ACHF Program Manager. Also, the patients and families were stakeholders, as ultimately the processes would impact the outcomes of their care.

Based on issues identified in the organizational assessment and the willingness of managers and clinicians to improve palliative care referrals, it was highly likely that a standardized palliative care referral process, when fully implemented and supported by palliative care education, would increase palliative care referrals. Furthermore, the timing of this scholarly work aligned with other organizational quality initiatives to improve advanced care planning and transitions of care from inpatient to outpatient in ACHF care. Based on a quality and process improvement strategy, the initial referral process focused on identifying patients transitioning from inpatient to outpatient palliative care within the ACHF Clinic. The organizational assessment assisted the DNP scholar to define the problem statement for the scholarly project.

**Problem Statement**

The problem statement for this project is as follows: Will a standardized palliative care referral process and education in palliative care increase referrals to palliative care in the ACHF Clinic. The PICO (i.e., problem, intervention, comparison, and outcome) statement for this project is as follows. The problem (P) was lack of adequate palliative care for patients at the Outpatient ACHF Clinic. The intervention (I) was development of a standardized referral process and palliative care education for clinic staff. The comparisons (C) were the current state, the lack of SRP and palliative care education, compared to a SRP and palliative care education. The outcomes (O) were clinicians educated on palliative care; a defined palliative care referral process; and increased palliative care referrals. The problem statement and scholarly project were based on evidence-based recommendations and guidelines in ACHF care.
Evidence-Based Initiative

The two-fold, evidence-based interventions used in this project were the development of a standardized palliative care referral process and education for the clinicians in the ACHF Clinic. The interventions were conducted in collaboration with the interdisciplinary team from both the Palliative Care department and the Outpatient ACHF Clinic. The overall goal of these interventions was to initiate a culture change regarding palliative care, and over time, increase access to palliative care for patients with ACHF.

The Heart Failure Society of America suggests initially targeting and integrating palliative care for CHF patients who have been hospitalized in the past year; those with chronic poor quality of life (i.e. dependence of activities of daily living); and those on continuous inotropic therapy support. In addition, the Heart Failure Society of America (2010) recommends conversations about prognosis and quality of life throughout CHF disease management, as a part of palliative care. Although evidence clearly suggests integration of palliative care for those with CHF, a significant gap exists in clinical practice. Identifying the reason for the gap in practice is complex. Therefore, in order to make a sustainable practice and culture change, barriers were identified and addressed.

Evidence-Based Barriers to Palliative Care

Evidence shows that the majority of care for those diagnosed with ACHF focuses on disease management rather than quality of life goals and end-of-life care (Barclay, Momen, Case-Upton, Kuhn, & Smith, 2011). With regards to this project, barriers to the utilization of palliative care in the ACHF Clinic align with those found in the literature. The following were the identified barriers in the ACHF Clinic.

The main barrier that clinicians reported regarding palliative care referrals was that they were unsure about when a patient with ACHF might die. Clinicians cite prognostication, or how
long someone has to live, as a barrier to referral to palliative care, due to the lack of predictability of the disease trajectory (Barclay et al., 2011; Gott et al., 2007; Lingard et al., 2013). Given the perceived difficulty in accurately predicting when end of life might occur, clinicians are reluctant to integrate palliative care out of concern for destroying hope of patients with ACHF (Barclay et al., 2011; Gott et al., 2007; Lingard et al., 2013). In addition, clinicians identified ambiguity regarding standard versus palliative heart failure care and the lack of clear referral triggers as barriers to specialized palliative care (Gott et al., 2007; Kavalieratos et al., 2014; Lingard et al., 2013). Often, triggers for palliative care are suggested based on symptoms instead of prognosis especially in ACHF due to the difficulty in prognostication (Gadoud, Jenkins, & Hogg, 2013).

The concern about knowing with assurance when a patient might die aligns with the second barrier that clinicians in the ACHF Clinic reported. This barrier was that they believed only patients who were at end of life needed palliative care. Clinicians often perceive palliative care as only relevant for patients who are clearly dying (Murray, Boyd, & Sheikh, 2005; Lingard et al., 2013). Furthermore, most clinicians are unclear of the difference between palliative and hospice care (Kavaleratos et al., 2014). Evidence shows inadequate initiation of end-of-life conversations despite patient and family expectations (Barclay et al., 2011; Gadoud et al., 2013; Kavalieratos et al., 2014). Thus, referrals to palliative care are not generated despite the need.

Additional barriers that were identified included: (a) clinicians in the ACHF Clinic were unaware of the palliative care program and referral potential; (b) limited provider knowledge and training regarding palliative care and end-of-life care; (c) attitudes and beliefs that palliative care is reserved for end of life; and (d) lack of palliative care training in formal and informal environments across the disciplines (Kavalieratos et al., 2014). Collectively, these barriers contributed to lack of palliative care referrals.
The state of the science suggests palliative care for those diagnosed with ACHF is lacking due to barriers in clinician knowledge (Adler et al., 2009; Barclay et al., 2011). Evidence strongly suggests the need for palliative care in all persons with ACHF, regardless of stage of the disease. Therefore, to create a culture change and embed evidence-based care into clinical practice, clinician education with exploration of attitudes toward death was undertaken along with the development of a standardized process to ensure timely access to palliative care for all patients diagnosed with ACHF in the clinic. This quality and process improvement project aligned with the organizational assessment.

**Standardization in Referral Process**

Standardization of healthcare processes improves patient outcomes and is considered best practice. The World Health Organization (WHO) Standardization in Patient Safety 5S Project was initiated in 2007 to reduce variability and increase standardization in care by focusing on standard operating protocols that use uniform technical specifications, criteria, methods, processes, designs, and practices as a format for improving workflow. Utilization of standardized practices in health care “reduces variability, and increases interoperability, safety, repeatability, thus, improving quality” (Leotsakos et al., 2014, p. 109).

Standardization of healthcare processes creates an environment for measurable, significant, and sustainable reductions in challenging clinical problems (Leotsakos et al., 2014). The WHO Standardization Project has lead to increased patient, staff, and organizational safety and quality (Leotsakos et al., 2014). Evidence from healthcare practice revealed lack of standardized care resulted in poor clinical outcomes; while removing variance reduced risks, inefficiencies, and decreased cost (Swensen et al., 2010).

One study found that in a multi-department organization, a required operationalized, standardized workflow as part of the infrastructure, improved the wait times of patients and
transition time between providers (Lee, Pressly, Okerman, & Boyd, 2015). So, patients had increased time with clinical staff and a decreased duration of visit. Additionally, the interprofessional team from multiple departments was successfully integrated into the standardized workflow; with statistically significant improvements in several patient outcomes (Lee et al., 2015). Finally, a systematic review focused on interventions related to outpatient primary care referrals to secondary care found that seeking strategies to ensure referrals were appropriate increased referral frequency. Effective strategies to increase referrals included dissemination of guidelines and use of structured referral processes, which standardized the workflow (Akbari et al., 2008).

Standardization of the palliative care referral process in the ACHF Clinic is a top priority and first step to increasing access to end-of-life care for those patients diagnosed with ACHF. Although evidence-based recommendations are to integrate palliative care for all ACHF patients, this project focused on those who had been recently hospitalized as the first step to change. To promote culture change, a conceptual and implementation model guided this project.

**Conceptual Model**

Lewin’s Change Management Model guided the implementation of the SRP and palliative care education in the ACHF Clinic. Lewin provides theoretical guidance utilizing a three-step approach. The three stages of the model include: unfreezing, changing, and re-freezing (Lewin, 1951).

The first stage, unfreezing, required an in-depth organizational assessment of the identified need by the organization and scholar. During the unfreezing, relationships were built between key stakeholders at the ACHF Clinic, the scholar, and palliative care mentor. These relationships were vital in initiating and motivating the change. Also, two key clinic staff members, both RNs, were identified and referred to as palliative care “champions” and were
highly motivated to change clinical practice. Unequivocally, certain stakeholders in the ACHF clinic identified palliative care as a standard of ACHF care by integrating it within the current model of care. The referral processes and education were both planned in conjunction with stakeholders to tailor clinic specific needs. The change began after buy-in, input, and feedback from the stakeholders were incorporated.

The second stage focused on changing what needed to be changed to increase access to palliative care for those with ACHF. During the initial change, a referral process was designed and formal education was undertaken. The education was provided to ACHF Clinic Staff to integrate understanding of palliative care and referral processes, the difference between palliative and hospice care, barriers to palliative care, and communication techniques for difficult conversations. Also, other unintended positive consequences developed to validate the Lewin’s Change Stage which included strengthening the interprofessional and interdisciplinary relationship and embedding the palliative care patient story. The initial change led to the final stage of re-freezing.

The third and final stage looks to make the initial change permanent. Sustainability of the practice change required a shift in the culture. The initial interventions focused on the most immediate needs: the development of a standardized referral process and clinic staff education and attitude clarification, which focused on known barriers to palliative care in the ACHF Clinic. Also, the unintended positive consequences along with streamlining of other palliative care processes led to change and ultimately re-freezing. To support integration of the practice change, the Plan Do Study Act (PDSA) implementation model also guided this project.

**Implementation Model**

The PDSA Cycle (see Appendix A) from the Associates in Process and Improvement and the Institute of Health Improvement (2015b) accelerates improvement in clinical practice
(Langley et al., 2009). PDSA is used by persons experiencing organizational change and helps to identify the following: What are we trying to accomplish? Why is the change needed? Does the change align with the organizations mission and vision? How will we know that change is an improvement? How will the change be sustained? A succinct process was followed to answer these questions.

First, the intended outcome to increase palliative care referrals among patients diagnosed with ACHF aligns with the evidenced-based practice recommendations. Second, the recommendation of a SRP and palliative care education were developed and deployed to support this improvement. Third, uptake and sustainability of the change and improvement will be known when palliative care referrals increase from the ACHF clinic. Fourth, the process aligns with the mission and vision of the organization. Lastly, the SRP and palliative care education will be sustainable in the ACHF Clinic through ongoing relationships and education and will be validated by increased palliative care referral numbers.

PDSA guided the development of the SRP and palliative care education. The following describes each phase. The plan phase (P) included setting the objective to increase palliative care referrals in ACHF patients by developing a SRP and palliative care educational in-service for clinic staff by April 2016. The doing phase (D) included two phases: (a) to develop the referral processes; and (b) to develop and conduct palliative care educational in-services for clinic staff.

The study phase (S) also occurred in two phases: (a) a review of the past and current state of referrals through the referral tracking; and (b) the synthesis of the pre-test and post-test responses from the educational in-services. It was presumed that immediate change would not be seen within the timeframe or context of the scholarly project. However, during the scholar immersion, the scholar reviewed referral patterns from the ACHF Clinic to palliative care from
September 2015 through March 2016. The act (A) phase will be the use of the SRP and continued informal and formal palliative care education for ongoing rapid cycle/continuous quality improvement. After demonstrating full integration of palliative care services in the ACHF Clinic, additional financial and quality measures will demonstrate the value of the scholarly work.

Purpose of Project

The purpose of this scholarly project was to increase palliative care utilization within the ACHF Outpatient Clinic. The objectives were: (a) to design a referral process; (b) educate clinicians and work toward attitude clarification towards death; (c) increase palliative care referrals; and (d) improve the quality of life for patients and families. Ultimately, the leadership team and this DNP scholar hope the approach increases access to palliative care in the ACHF Clinic. This quality improvement project was positioned to begin the change in the culture of care.

Project Plan

The quality improvement project plan was developed in September 2015 during the scholarly immersion. First, the scholar initiated a referral tracking system. The tracking system consisted of a common working file in a secured excel spreadsheet to determine the number of palliative care referrals. Data tracking elements were based on palliative care physician mentor input and included the following patient demographics: age; diagnosis; first, next, and total palliative care visits; the number of emergency department visits and hospitalizations in the prior 12-months; the reason for the consult (i.e. symptom management, goals of care, or advanced care planning); and transitions of care if the patient moved to home-based services (i.e. palliative care to hospice care). Establishing a referral tracking system was instrumental to establish a baseline within the current care model and in measuring outcomes.
The palliative education was developed based on evidence and conducted in collaboration with the palliative care physician, the program manager, and the DNP scholar. It was scheduled based on clinic staff availability. A palliative care resource manual was planned for clinic staff in both paper and electronic form. Also, the education materials were added as a resource for new employee orientation at the ACHF Clinic and to existing patient education materials of the palliative care department. It was assumed the referral process and education would have benefits to current and future ACHF patients, the clinic, and the organization. It is also assumed education will need to be ongoing and will be explored in future work.

**Setting and Resources**

The resources needed to complete the project include a thorough assessment and understanding of the current palliative care referral process at the ACHF Clinic. The referral process at another outpatient palliative care clinic within this organization was reviewed through telephone interviews and was used to establish the new referral process. Key stakeholders provided support and the allotted resources of preparation, space, and paid clinic staff time to participate in this important work to improve patient care.

**Design for the Evidence-Based Initiative**

The co-designed, standardized referral process required work from the interdisciplinary team and occurred from September 2015 to March 2016. The process was drafted (see Appendix B) to capture the most vulnerable hospitalized patients with ACHF with follow-up from inpatient to outpatient palliative care. It aligns closely with a process already in place for the home to office ACHF post-hospitalization visits. The SRP was created with input from the Palliative Care Providers and ACHF Clinic Staff. The design of the referral process considered current resources such as the number of palliative care providers available for consultation at the ACHF Clinic and the limited amount of clinic space, with an impending relocation to a new building.
Incorporation of these factors into the new SRP required a stepwise implementation approach over time.

The education sessions included three, 20-minute PowerPoint modules. Each module had specific objectives (see Appendix C, Figure 1) and was offered twice to accommodate clinical staffing needs. The ACHF Clinic Program Manager required attendance to each module from all of her staff, which included one RN program manager, six RNs, three NPs, one MSW, and one pharmacist. Outcomes for the modules were measured by a pre-test and post-test comparison of clinician attitudes and knowledge about palliative care (see Appendix C, Figure 2 and 3).

The first educational in-service objectives included: (a) define the background and purpose of palliative care, including operationalizing the difference between palliative care, hospice, and end-of-life care; (b) provide evidence-based support for palliative care, exemplary scripting for discussing palliative care to patients and families, and storytelling about a long-term mutual patient from both the ACHF Clinic and Palliative Care who had utilized palliative and home-based services over the course of the project; and (c) describe common symptoms and treatment in palliative care including pain medications with applicable cardiology side effects.

The second session focused on home-based resources for those with advanced illness and palliative care and included the following objectives: (a) identify current state of home-based resources utilized in the palliative care clinic (i.e. home-based primary care and hospice); and (b) review criteria and eligibility for home-based primary care, palliative care, and hospice care with ongoing storytelling of the same case scenario in the first session.

The third educational in-service focused on the Medicare Care Choices Model and included the following objectives: (a) define the background and purpose of the Medicare initiative; (b) define the eligibility and criteria for enrollment; and (c) identify collaborative
skills, continue storytelling, and determine patient outcomes associated with the case scenario from the past sessions; and (d) describe the referral process.

**Participants**

The participants in the evidence-based scholarly project included clinical staff from the ACHF Clinic and Palliative Care Services. The quality improvement project was led by the scholar, the Palliative Care Physician in the ACHF Clinic, and the ACHF Program Manager. Also, the ACHF Clinic Staff were involved in operationalizing the standardized referral process. The attendance numbers by discipline and by session (see Appendix C, Table 1) included: (a) two RNs; (b) three RNs, one MSW, and one NP; (c) four RNs, one MSW, one NP, and one pharmacist; (d) one RN; (e) no attendance; and (f) three RNs. The number of participants varied during each offering of the educational in-service from 0-7 attendees. Total participation included 12 clinicians.

**Measurement: Sources of Data and Tools**

The evaluation and measurement for the scholarly project included the review of palliative care referrals from September 2015 to March 2016. Due to limitations of the project, the referral process was drafted and not implemented into clinical practice. Future integration of the standard referral process will lead to a significant amount of data in regards to access and quantity of palliative care referrals from the ACHF Clinic.

The evaluation of the education sessions were based on the pre-test measurement, given prior to the initial in-service during session one or two (see Appendix C, Figure 2), and the post-test measurement, given immediately following the third or final in-service during session five or six. Permission for use of the tool requested via the University of Pennsylvania School of Nursing and Genesis Palliative Care Center (2004) website was received from the author and representative, Dr. Neville Strumpf, by email (see Appendix D).
Implementation and Timeline

The steps for implementation of the project began in September 2015. Implementation was initiated after conducting the organizational assessment in Fall 2015. Drafting of the referral process took place over the course of six months and ended in March 2016. The educational inservices were scheduled in February 2016 and offered in March 2016. The dates included: (a) module one on March 2nd and March 4th; (b) module two on March 16th and March 21st; and (c) module three on March 23rd and 24th. Over the course of the project, the timeline was adjusted based on staff availability.

Budget

The budget for the scholarly project included limited expense for the stakeholder and organization. Estimated costs associated include the following: time to attend the training, loss of clinic staff productivity; time of the trainer and mentor to develop, deploy, and evaluate the project; time to track the palliative care referrals; and cost of supplies for education material and resource manual. Costs of ACHF Clinic staff time, measured in approximated hourly wage and based on organizational average, would equal $500, (Spectrum Health, 2013). The loss of productivity would be difficult to evaluate as a majority of the attendees were RNs who perform non-billable services.

Ethics and Human Subjects Protection

The Institutional Review Boards (IRB) at Grand Valley State University and the organization reviewed and approved the project related to the protection of human subjects. The initial review was conducted by the Grand Valley State University Human Research Review Committee and was determined to be non-research (see Appendix E, Figure 1). The application was then submitted to the organization’s IRB, which approved the project as non-human research
(see Appendix E, Figure 2). The ethical considerations are limited as this scholarly quality improvement project included no direct patient or family (human subject) contact.

Project Outcomes

Project outcomes of the scholarly work include an established tracking system for referrals; a drafted SRP for palliative care referrals (see Appendix B); initiation of ongoing education for ACHF Clinic Staff; a Palliative Care Resource Manual (see Appendix F); and identification of additional non-project palliative care work, which will be reflected upon later in this project report. The tracking system helped to understand referral patterns and process. After identification of this need to track referrals, a work order was placed with the electronic health record support team to create a sustainable system of identifying and tracking palliative care patients in the ACHF Clinic. This process was established by the end of the scholarly project. Project outcomes for the standardized referral process development included interdisciplinary and inter-specialty (i.e. palliative care and cardiology) collaboration.

Lastly, the integration of the inpatient and outpatient palliative care was the focus for the initial draft of the referral process. The inpatient and outpatient ACHF and Palliative Care are within the same practice group, therefore, including both is vital to increasing access to outpatient palliative care. Currently, the interdisciplinary team is focused on capturing and translating both advanced care planning and palliative follow-up from inpatient to outpatient. In fact, without this process many of the most vulnerable recently hospitalized ACHF patients would not receive either advanced care planning or palliative care services.

In the collaborative interdisciplinary team, the scholar focused on the process from an outpatient standpoint by integrating palliative care into an established clinical care process. Each cardiologist physician has a cardiovascular RN who is solely responsible for patient discharges and scheduling follow-up ACHF home to office appointments. Also, these RNs will now
schedule a palliative care follow-up before the patient is discharged from the hospital. Despite drafting a referral process and conducting educational in-services, the anticipated results of the project were not evident based on the defined outcomes.

Results

Results of the referral tracking substantiated the total number of referrals by month starting in September 2015. The number of monthly referrals ranged from 0-7 (see Appendix G, Figure 1). The results of referral tracking did not correlate with the education. Results of the educational in-services did not substantiate a change in knowledge or attitudes based on the pre-test and post-test comparison. However, the clinic staff identified barriers to palliative care and felt the education was helpful. In regards to the palliative care referrals, growth was seen over the course of the scholarly work from 12 in October 2015 (0.6%) to 27 (1.4%) in March 2016. In addition, referral tracking verified that about 25% of the palliative care patients transitioned to hospice care.

Pre-Test Results

The pre-test (see Appendix G, Table 2) was administered to a total of seven clinicians (n=7) from the ACHF Clinic. The disciplines included RNs, NPs, and MSWs. The pre-test included the same six questions as the post-test and were rated on a Likert Scale (1-5). A five indicated the clinician strongly agreed with the statement and one indicated the clinician strongly disagreed with the statement.

Question one stated, “End of life is a time of great suffering” and the response average was 2.86. Question two stated, “When a patient dies I feel that something went wrong” and the response average was 1.57. Question three stated, “I am not comfortable talking to families about palliative care” and the response average was 1.86. Question four stated, “Patients have the right to refuse a medical treatment, even if that treatment prolongs life” and the response
average was 4.14. Question five stated, “Palliative care is appropriate only in situations where there is evidence of declined or progression of disease” and the response average was 1.57. Question six stated, “Palliative care is a benefit to patients with ACHF” and the response average was 4.86. Synthesis of the responses indicated ACHF Clinicians felt patients have a right to refuse treatment even if it prolongs life; and palliative care is appropriate and beneficial for ACHF patients.

An additional measure included clinician-identified barriers to palliative care in ACHF, based on the most evidence-based options in the literature. The results (see Appendix G, Table 3) aggregate clinic staff selections. Each respondent selected between two and three options.

Post-Test Results

The post-test (see Appendix G, Table 4) was administered to a total of 3 clinicians (n=3) from the ACHF Clinic. The disciplines included only RNs. The post-test asked the same six questions as the pre-test. The response average for the post-test is as follows: question one - 2.67; question two - 1; question three - 1.67; question four - 5; question five - 1.67; question six - 5.

An additional measure included feedback as to whether the clinicians felt the palliative care education in-services were helpful. All of the post-test participants (n=3) indicated the education was helpful to their role in the ACHF Clinic. Finally, the same three clinicians participated in the pre-test and post-test. Low participation in the post-test was noted as a weakness of the educational portion of the project. Circumstances such as clinical practice needs, part-time staff, and vacations interfered with the education sessions.

Comparison of Pre-Test Versus Post-Test

A comparison of the pre-test and post-test results was done to further synthesize the outcomes of the palliative education (see Appendices G, Table 3 and 5). When compared to the pre-test results there were no statistical changes in aggregate knowledge or attitudes toward
death. Clinicians in both the pre-test and post-test consistently believed patients could refuse treatment and that palliative care was appropriate in ACHF care. The post-test capture rate was less than half of the pre-test due to uncontrollable circumstances within a busy clinical practice. Additional measures could have been taken to ensure accountability and attendance of the education for clinic staff. Twelve participants attended the education but not all of them attended the first session, which included the pre-test. No demographic data was collected from the clinicians.

**Unintended Consequences**

The unintended consequences of the scholarly work proved to be the most significant in initiating the culture change. Unfortunately, they are not currently measurable. The unintended consequences provided both positive and negative outcomes of the scholarly work.

**Positive Unintended Consequences**

First, the relationships built over the course of six months while working with palliative care in the ACHF Clinic established a strong foundation of trust and collaborative practice with clinic staff. Integrating and modeling care based on interdisciplinary and interspecialty collaborative practice had a positive impact on patient experience as evident by the case used for storytelling during the education in-services. The continued storytelling of a mutual patient over the course of six months provided insight and support for palliative care. Based on this continuous storytelling, key stakeholders within the ACHF Clinic were able to clearly delineate the added value of palliative care. For example, in this particular case, the patient needed spiritual support, visiting volunteer support, and reconciliation with an estranged relative, all of which were coordinated by palliative care. These were services not provided in traditional ACHF Care. This case ignited the desire for practice change to integrate palliative care into
ACHF Care. The identification of the ACHF Program Manager and clinic nurse as champions for change also emerged as they are very engaged to improve the quality of ACHF Care.

In addition to building strong relationships, key stakeholder buy-in was noted especially from the program manager. The program manager oversees and manages all ACHF clinical staff therefore she is able to influence new staff and current clinical practice. Due to her strong support, the culture is also evolving in regards to which clinician can consult palliative care. The current state of the organizational culture allows only physicians and NPs, but initial authorization has been obtained for RNs to consult palliative care. Fortunately, RNs are eager to assume making a referral to palliative care based on dialogue during the educational sessions. It is presumed in the near future; RNs will be able to consult palliative care in the ACHF Outpatient clinic.

Another additional consequence or change noted outside the measurable outcomes was a change in attitudes related to palliative care. Initially, it appeared the ACHF clinic would relocate during the scholarly work. However, the date and timeline changed and the move date had not been reset. Over the course of the scholarly project, the tone of the stakeholders changed from Fall 2015 stating they would not have enough room for palliative care at the new clinic location, to stating that it is not an option to go without palliative care for ACHF patients.

Lastly, at the time of hire, all ACHF Clinic Staff will be required to read Atul Gawande’s book Being Mortal, which reflects on the journey in life, death, and advanced illness from his perspective as a surgeon and family caregiver. Gawande (2014) focuses on living life with advanced illness and choosing what is important for each individual and family system. The program manager is encouraging ACHF staff to understand the implications of healthcare decisions for aging persons with a chronic illness.
Other areas of improvement during the scholarly project included: (a) streamlined process for contacting the palliative care physician on non-clinic days; (b) process and procedure to include a potential pain contract for ACHF Clinic palliative care patients who were prescribed controlled substances; (c) examples of scripting with additional anticipated questions for staff to introduce palliative care to patients and families; and (d) scheduling of monthly recurring meetings between the ACHF Clinic and Palliative Care staff. All of the unintended consequences reflected on the work of the DNP scholarly project and the beginning shift in the culture of ACHF care.

**Negative Unintended Consequences**

A limitation of the project work was no physician participation in the palliative care education. This was attributed to clinical practice demands and organizational politics and culture. However, it was recognized to be a vital component of practice and culture change. Therefore, the palliative care physician as mentor to the DNP scholar arranged for an informal session with the Advanced Cardiologist to discuss the palliative care standard referral process and to receive feedback. During this meeting, support from the lead cardiologist suggested palliative care should be a standard of care for every patient.

**Implications for Practice**

Clinical practice at the ACHF Clinic has been impacted as a result of the scholarly project. In order to fully comprehend how, a reflection must be completed to determine the strengths, weaknesses, sustainability and future needs. First, the project strengths will be explored.

**Project Strengths**

Project strengths include the following. First, the scholar introduced the role and work of the DNP to key organizational stakeholders. Next, through project work, multiple positive
unintended consequences evolved. Also, a standardized process for referrals was drafted based on robust interdisciplinary collaboration, which aligned with other organizational work. Lastly, the project focused on the importance of the patient story in translating evidence into practice.

**Project Weaknesses**

Project weaknesses include the following. First, the educational in-services did not have full staff attendance despite being required. The ACHF physicians were not invited to the educational in-services. This could provide some significant barriers to clinical practice change. Furthermore, ACHF care is dispersed from multiple clinic sites, which offer different levels of care so the potential for poor follow-up of palliative care remains. Next, the ACHF clinic and palliative care teams and have undergone clinical staffing changes during the course of the scholarly work which created some inconsistencies in relationship building. Staffing changes included the hiring of three experienced RNs within the ACHF Clinic. Also, the electronic health records within the system are not interoperable between hospital, outpatient and home- care services. Lastly, the culture and politics of a large established organization are difficult to change, requiring time and ongoing support in order to transform and sustain change. Both the strengths and weaknesses are key to ensure the sustainability of the scholarly project.

**Project Sustainability**

Factors that promote sustainability of the project include the following. First, a palliative care nurse champion has been identified within the ACHF Clinic. The palliative nurse champion was instrumental in building the collaborative relationship in clinical practice. The champion nurse was instrumental in collaborating to initiate a cultural change. During the project work, she helped to identify ACHF Clinic specific needs along with scheduling, developing, deploying, and evaluating the education, development of the referral process, and continued work. Next, a Palliative Care Resource Manual has been created and provided to the ACHF Clinic for use
during conversations with patients and families. The manual (see Appendix F) includes all of the palliative care material and educational information utilized in the scholarly process plus additional community resources. Also, in collaboration with palliative physician project mentor, other processes have been identified and streamlined to ease the work and integration of palliative care within the ACHF Clinic. Lastly, the referral process has been designed and will be deployed in the next three months to ensure timely access to palliative care.

Throughout the system, the work of the scholar has gained attention of executives with assistance from the project mentor. This has provided motivation for the leaders in ACHF care to reflect on practice and evidence-base recommendations. The main factor in sustainability will be the continued relationship between the ACHF Clinic and Palliative Care services, which is planned with the palliative care physician. This will be sustained by updates from community-based services in the electronic health record as those clinicians are documenting in two system until they become interoperable. Despite a more taxing effort from the community-based services it continues the communication and reinforcement of the patient story. Future ACHF Clinic Palliative Care practice may include a full-time embedded palliative care provider to align the evidence with practice, the organizational mission and vision, and patient and family need.

Future Recommendations

Future work of this DNP and subsequent DNP students includes providing ongoing palliative care education to clinicians in more innovative formats to ensure participation. These innovative formats may include using the organization’s online learning platform, presenting at cardiology grand rounds, and presenting at the organization’s annual cardiology conferences. Recommendations based on this scholarly project would be to provide education in a one-hour in-service and to include patient stories to increase participation and impact on affective learning. This recommendation was based on feedback from both management and clinicians.
Future work to sustain the changes includes partnering with DNP students and the project mentor in identifying additional palliative care needs, processes, and quality improvement projects at the organizational level. Examples may include determining if a palliative care trigger or clinical decision support could be added to the electronic health record.

Next, further work could be done within the specialized population in cardiology which offers advanced therapies (i.e. intravenous inotropic medications, Implanted Cardiac Defibrillators, Left Ventricular Assist Device, or heart transplantation). Targeting the specialized population, would ensure regardless of the cardiology clinic site they would still receive palliative care. Within the organization often times the device patients receive care at multiple clinic sites and in the hospital. Although it is a Joint Commission requirement to involve palliative care prior to the LVAD or transplant, it should be a standard to involve palliative care to all advanced interventions as these patients have an end stage disease. This would ensure patients are receiving the type of care they want.

Finally, in order to validate the work of palliative care, more robust financial outcomes must be identified. Future measures of palliative care may include review of ACHF related emergency department visits and cost, re-hospitalization rates, and other financial implications of the transitions of care (i.e. home-based primary care, hospice care, or emerging models of community-based palliative care). In addition, palliative care should be measured based on patient and family satisfaction. This work is vital to this population but must align with healthcare reimbursement trends.

**Evidence and Healthcare Trends**

Palliative care is an emerging discipline in the current healthcare system as it assists in managing chronic and advanced illnesses as they progress. The specialty has been shown to decrease costs, improve quality of care and life, and increase length of life (Adler et al., 2009;
Payment models have supported mainly hospital based or consultative palliative care programs (Spivack, Bernheim, Forman, Drye, & Krumholz, 2014). Cardiology has been receptive to supportive care models due to re-hospitalization penalties associated with ACHF.

The Centers for Medicare and Medicaid have responded to the gap in current care with programs such as the Medicare Care Choices Model, which provides community-based palliative interdisciplinary services to those with life-limiting illness who elect to continue with traditional treatment. This program expands on the current palliative care structure. Lastly, healthcare reform changes in reimbursement from fee-for-service to quality based will have significant implications in the growing demand for palliative care.

**DNP Reflection**

The DNP journey is a transformative process, to begin collaborative efforts to improve healthcare (Moran, Burson, & Conrad, 2014). The DNP scholarly project incorporated all eight of the DNP Essentials. A specific focus was on essentials two and six. Additionally, the focus of the scholarly work not only aligns with the DNP Essentials Competencies, but also recommendations of the IOM, and the Triple Aim. The DNP scholar identified a significant gap in care and translated evidence to practice.

Project-specific enactment of the DNP Essentials included Essential two based on system and organizational leadership through leading the education, Essential six with strong interprofessional collaborative efforts with the project physician mentor, Dr. Simin Beg. Through collaborative efforts, both the scholar and mentor were able to improve clinical practice skills and knowledge. Through the continued work within the organization and collaboration, the value of the DNP in clinical practice has been demonstrated. In addition, the scholar and
mentor have future plans to disseminate work throughout the organization and academic journals and conferences.

**Dissemination of Outcomes**

The plan for disseminating outcomes includes the following: (a) submission to the Jonas Center for Nursing Leadership Engagement; (b) presenting a poster at the Grand Valley State University; (c) presenting a poster at the annual nursing research conference in which the project occurred; (d) deploying the final project written summary through scholar works online database for student projects; and (e) planning to submit a publication focused on a case story. Also, the findings will be shared with clinicians in Palliative Care and the ACHF Clinic, as well as leaders of the organization. Finally, the full impact of the project is difficult to measure at the current state and will likely require evaluation in the next year, which may yield further outcomes to disseminate.

**Conclusion**

The scholarly project has led to significant growth at the individual, organizational, and system level. The DNP student has been able to provide evidence and value for scholarly work in translating evidence to practice. The ability to be an expert clinician and translate evidence to clinical practice should not be underestimated. The scholarly work has begun the transformation to integrate palliative care into ACHF care. The DNP has been a catalyst for change in aligning practice to evidence while building community and system partnerships. The benefits of improved palliative care align with the Triple Aim to decrease costs by fewer hospitalizations and ER visits, improve quality of care, and improve quality of life, which are all vital to the transformation and sustainability of the healthcare system.
References


doi:10.3399/bjgp11X549018


doi:10.1177/0269216313494960

doi:10.1161/CIR.0b013e31828124ad
http://www.ihi.org/Topics/TripleAim/Pages/default.aspx
http://www.ihi.org/resources/Pages/HowtoImprove/default.aspx


Appendix A

Plan Do Study Act (PDSA) Cycle implementation model used for the scholarly project

Appendix B

SRP created by the scholar but based on prior work of the interdisciplinary team. The referral process focuses on the right side of the diagram to capture those with ACHF following up in the clinic.
Appendix C

Educational in-service preparation materials, participant evaluation, and discipline participation

Figure 1

Objectives for Palliative Care Education in the ACHF Clinic

Topic 1: Palliative Care

Objectives:

a) Define the background and purpose of palliative care
b) Evidence supporting palliative care and embedded case study from the ACHF Clinic
c) Common ACHF symptoms and treatments in palliative care including medication (norco, morphine, oxycodone, fentanyl, and methadone) with applicable cardiology side effects

Topic 2: Home Based Resources

Objectives:

a) Identify current state of home based resources for Hospice and Palliative Care & Dr. Beg
b) Individually review criteria/eligibility and what the resources available to ACHF patients/families
   1. Home Based Primary Care
   2. Palliative Care
   3. Hospice Care
   4. Care Choices (only briefly mention as will be the last presentation)
   5.

Topic 3: Care Choices

Objectives:

a) Background and purpose of the Medicare Initiative
b) Eligibility and criteria for enrollment
c) Case study current enrollee benefits of collaborative efforts on pt care
d) Referral process
e) Questions
Figure 2

*Pre-Test Survey grid to collect Responses*

<table>
<thead>
<tr>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Neutral</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>

- The end of life is a time of great suffering.
- When a patient dies I feel that something went wrong.
- I am *not* comfortable talking to families about palliative care.
- Patients have the right to refuse a medical treatment, even if that treatment prolongs life.
- Palliative Care is appropriate *only* in situations where there is evidence of decline or progression of disease.
- Palliative care is a benefit patients with ACHF

1. **Select all that apply**: What are the barriers to palliative care in Congestive Heart Failure?
   - a. Unpredictable disease progression or prognosis
   - b. Fear of diminishing patient and family hope
   - c. Uncertainty in the referral process to access palliative care
   - d. Discomfort in introducing palliative care
   - e. Belief it is reserved for end of life care only
   - f. Unsure what is the best care
   - g. Philosophy of Care
**Figure 3**

*Post-Test Survey grid to collect Responses*

<table>
<thead>
<tr>
<th></th>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Neutral</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>

The end of life is a time of great suffering.

When a patient dies I feel that something went wrong.

I am *not* comfortable talking to families about palliative care.

Patients have the right to refuse a medical treatment, even if that treatment prolongs life.

Palliative Care is appropriate *only* in situations where there is evidence of decline or progression of disease.

Palliative care is a benefit patients with Congestive Heart Failure (ACHF)

Do you feel the palliative education was helpful? ***Yes*** or ***No***

Any other topics or information about palliative care in ACHF you would like information on?
### Table 1

*Education session attendance by healthcare discipline*

<table>
<thead>
<tr>
<th>Session</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td>RN</td>
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<td>3</td>
<td>4</td>
<td>1</td>
<td>0</td>
<td>3</td>
<td>13</td>
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<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>NP</td>
<td>0</td>
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<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Pharmacy</td>
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<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>2</td>
<td>5</td>
<td>7</td>
<td>1</td>
<td>0</td>
<td>3</td>
<td>18</td>
</tr>
</tbody>
</table>
Appendix D

Permission to use the Attitudes Toward Death Survey from the University of Pennsylvania

University of Pennsylvania School of Nursing/Genesis Eldercare: Attitudes Toward Death Survey

Description:
A survey assessing knowledge, attitudes, skills and behaviors focused on death and dying for nursing home staff before and after an educational intervention.

Category:
Evaluation Tools - Education

Source:
University of Pennsylvania
School of Nursing
Hartford Center of Geriatrics
420 Guardian Drive
Philadelphia, PA 19104-6096
www.nursing.upenn.edu
or
www.nursing.upenn.edu/centers/hcgne/links.htm

Contact:
Neville Strumpf, PhD,RN
strumpf@nursing.upenn.edu

Keywords:
attitudes toward death, survey, nursing homes, attitude assessment, knowledge assessment, long-term care

To use this tool:
You may print and copy this tool for your own use from the website. Please credit source.

References:
Developed by the University of Pennsylvania School of Nursing and the Genesis Palliative Care Center for this project.

Email permission received from Dr. Strumpf on November 2016 for use in the DNP Scholarly Project.
Appendix E

Determination of research status from the HRRC and IRB for the university and organization

Figure 1.

_HRRC Grand Valley State University Letter of Determination of Non-Research Status_

GRAND VALLEY STATE UNIVERSITY
www.gvsu.edu

DATE: February 2, 2016

TO: Rachel Cardosa, DNP

FROM: Grand Valley State University Human Research Review Committee

STUDY TITLE: A Standardized Palliative Care Referral Workflow and Education at the Congestive Heart Failure Clinic

REFERENCE #: [857308-1]

SUBMISSION TYPE: New Project

ACTION: NOT RESEARCH

EFFECTIVE DATE: February 2, 2016

REVIEW TYPE: Administrative Review

Thank you for your submission of materials for your planned quality improvement study. It has been determined that this project:

DOES NOT meet the definition of covered human subjects research* according to current federal regulations. The project, therefore, DOES NOT require further review and approval by the HRRC.

If you have any questions, please contact the Research Protections Program at (616) 331-3197 or rpp@gvsu.edu. The office observes all university holidays, and does not process applications.
during exam week or between academic terms. Please include your study title and reference number in all correspondence with our office.

*Research is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 46.102 (d)).

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains: data through intervention or interaction with the individual, or identifiable private information (45 CFR 46.102 (f)).

Scholarly activities that are not covered under the Code of Federal Regulations should not be described or referred to as research in materials to participants, sponsors or in dissemination of findings.

Research Protections Program | 1 Campus Drive | 049 James H Zumberge Hall | Allendale, MI 49401 Phone 616.331.3197 | rpp@gvsu.edu | www.gvsu.edu/rpp
Spectrum Health Internal Review Board Letter of Non-Human Research Determination

February 15, 2016

Rachel Cardosa RN, MSN 750 Fuller Ave. NE MC 049 Grand Rapids, MI 49503

NON HUMAN RESEARCH DETERMINATION

SH IRB#: 2016-046 PROTOCOL TITLE: A Standardized Palliative Care Referral Workflow and Education at the

Spectrum Health Congestive Heart Failure Clinic

Dear Mrs. Cardosa,

On February 15, 2016, the above referenced project was reviewed. It was determined that the proposed activity does not meet the definition of research as defined by DHHS or FDA.

Therefore, approval by Spectrum Health IRB is not required. This determination applies only to the activities described in the IRB submission and does not apply if changes are made. If changes are made and there are questions about whether these activities are research involving human subjects, please submit a new request to the IRB for a determination.

A quality improvement project may seek publication. Intent to publish alone is insufficient criterion for determining whether a quality improvement activity involves human subject research. However, please be aware when presenting or publishing the collected data that it is presented as a quality improvement project and not as research.

Please be advised, this determination letter is limited to IRB review. It is your responsibility to ensure all necessary institutional permissions are obtained prior to beginning this project. This includes, but is not limited to, ensuring all contracts have been executed, any necessary Data Use Agreements and Material Transfer Agreements have been signed, documentation of support from the Department Chief has been obtained, and any other outstanding items are completed (i.e. CMS device coverage approval letters, material shipment arrangements, etc.).

Your project will remain on file with the Office of the IRB, but only for purposes of tracking research efforts within the Spectrum Health system. If you should have questions regarding the
status of your project, please contact the Office of the IRB at 616-486-2031 or email irb@spectrumhealth.org.

Sincerely,

Jeffrey Jones MD  Chair, Spectrum Health IRB

Human Research Protection Program

Office of the Institutional Review Board 100 Michigan NE, MC 038 Grand Rapids, MI 49503
616.486.2031  irb@spectrumhealth.org  www.spectrumhealth.org/HRPP

cc: Julie Bonewell

Page 1 of 1

HRP-524
Appendix F

Table of Contents for the Palliative Care Reference Manual

I. Palliative Presentations
   a. Palliative Care Overview
   b. Home Based Services (Home-Based Primary Care and Hospice)
   c. Care Choices
   d. Reference Sheet with Contact Information (Palliative Care, Hospice Care, Home-Based Primary Care, and Care Choices)
   e. Results from Pre/Post-tests of ACHF Clinic Staff

II. Outpatient ACHF Palliative Care
   a. Pain Contracts
   b. Process of Contacting Palliative Care Provider
   c. Scripting for ACHF Clinic Staff introducing Palliative Care
   d. Referral process

III. Health Home Based Primary Care
   a. Overview of Services and Staff
   b. Patient Pamphlet

IV. Care Choices
   a. Informational Sheet and Overview of Services and Staff
   b. Pamphlet Reference for Clinicians and Patients

V. Hospice Care
   a. Handheld Reference Card Trigger for Clinicians only
   b. Symptom Management Guide
Appendices G

Educational in-service attendance by discipline and pre-test and post-test results

Table 1

*Referral Tracking from September 2015 to March 2016*

<table>
<thead>
<tr>
<th>Month</th>
<th>Number of New Palliative Care Referrals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before August 2015</td>
<td>Not Collected</td>
</tr>
<tr>
<td>September 2015</td>
<td>0</td>
</tr>
<tr>
<td>October 2015</td>
<td>5</td>
</tr>
<tr>
<td>November 2015</td>
<td>4</td>
</tr>
<tr>
<td>December 2015</td>
<td>3</td>
</tr>
<tr>
<td>January 2016</td>
<td>7</td>
</tr>
<tr>
<td>February 2016</td>
<td>4</td>
</tr>
<tr>
<td>March 2016</td>
<td>4</td>
</tr>
</tbody>
</table>
### Table 2

*Pre-Test Survey (n=7) with Responses*

<table>
<thead>
<tr>
<th>Statement</th>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Neutral</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>The end of life is a time of great suffering.</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>When a patient dies I feel that something went wrong.</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>I am <strong>not</strong> comfortable talking to families about palliative care.</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Patients have the right to refuse a medical treatment, even if that treatment prolongs life.</td>
<td>5</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Palliative Care is appropriate <strong>only</strong> in situations where there is evidence of decline or progression of disease.</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Palliative care is a benefit patients with Congestive Heart Failure (ACHF)</td>
<td>6</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
Table 3

*Barriers Identified by ACHF Clinic Staff During the Pre-Test of the Educational In-Service*

<table>
<thead>
<tr>
<th>Barriers to Palliative Care in ACHF</th>
<th>Percentage of Participant Identified Barrier</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Unpredictable disease progression or prognosis</td>
<td>42.9%</td>
</tr>
<tr>
<td>2. Fear of diminishing patient and family hope</td>
<td>42.9%</td>
</tr>
<tr>
<td>3. Uncertainty in the referral process to access palliative care</td>
<td>28.6%</td>
</tr>
<tr>
<td>4. Discomfort in introducing palliative care</td>
<td>28.6%</td>
</tr>
<tr>
<td>5. Belief it is reserved for end-of-life care only</td>
<td>28.6%</td>
</tr>
<tr>
<td>6. Unsure what is the best care</td>
<td>42.9%</td>
</tr>
<tr>
<td>7. Philosophy of care</td>
<td>28.6%</td>
</tr>
</tbody>
</table>
Table 4

*Post-Test Survey (n=3) with Responses*

<table>
<thead>
<tr>
<th>Statement</th>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Neutral</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>The end of life is a time of great suffering.</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>When a patient dies I feel that something went wrong.</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>I am <em>not</em> comfortable talking to families about palliative care.</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Patients have the right to refuse a medical treatment, even if that</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>treatment prolongs life.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Palliative Care is appropriate <em>only</em> in situations where there is</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>evidence of decline or progression of disease.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Palliative care is a benefit patients with Congestive Heart Failure      | 3              | 0     | 0       | 0        | 0                 | (ACHF)