Integrating the palliative care principles of shared decision making and advance care planning into heart failure management: a pilot project

Elizabeth Xiques Bolint

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[Signature] Nov. 21, 2018
Student Signature Date
DNP PROJECT APPROVAL FORM

Submitted by Elizabeth Xiques Bolint in partial fulfillment of the requirements for the degree of Doctor of Nursing Practice and accepted on behalf of the Faculty of the School of Graduate Studies by the DNP project committee.

We, the undersigned members of the Graduate Faculty of The University of Alabama in Huntsville, certify that we have advised and/or supervised the candidate on the work described in this DNP project. We further certify that we have reviewed the DNP project manuscript and approve it in partial fulfillment of the requirements for the degree of Doctor of Nursing Practice.

Nov 2, 2018 Rta Ferguson Committee Chair
(Date)

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ABSTRACT
The School of Graduate Studies
The University of Alabama in Huntsville

Degree: Doctor of Nursing Practice College: Nursing

Name of Candidate: Elizabeth Xiques Bolint
Title: Integrating the Palliative Care Principles of Shared Decision Making and Advance Care Planning into Heart Failure Management: A Pilot Project

Heart failure (HF) is a complex clinical syndrome associated with a high mortality rate, frequent hospitalizations, and significant symptom burden that often contributes to a poor quality of life. Palliative care (PC), historically associated with managing the end-of-life needs of cancer patients, offers opportunities to improve health-related quality of life for those with HF in conjunction with, or instead of, life-prolonging medical therapies. The aim of this project was to evaluate and address patient-specific needs for those with advanced HF. The Kansas City Cardiomyopathy Questionnaire (KCCQ) was administered to patients recently hospitalized for acutely decompensated heart failure who were referred to a hospital-affiliated heart failure clinic for ongoing disease management. Of 26 questionnaires administered, 10 patients met inclusion criteria and agreed to participate. These patients were randomly allocated in a 1:1 fashion to one of two groups, with either usual care or usual care plus PC intervention. All received guideline-directed HF treatment; the intervention group also participated in one-on-one semi-structured interviews with a nurse practitioner experienced in both HF management and PC. After three months, patients were re-evaluated with the KCCQ, and baseline and 3-month results were compared and analyzed using the Wilcoxon signed-ranked test. Although no statistically significant change was noted, clinically significant change was found through validated KCCQ score changes in both groups. This project emphasized the need for concurrent guideline-directed HF therapy and palliative interventions. Long-term, consistent care is essential for this patient population to achieve patient-centered care that is congruent with their needs and wishes.

Keywords: Heart failure, palliative care, shared decision-making, health-related quality of life, patient-centered care, advance care planning
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Integrating the Palliative Care Principles of Shared Decision Making and Advance Care Planning into Heart Failure Management: A Pilot Project

Identification of Problem

Heart failure (HF) is a chronic, progressive disease that presents a significant burden to patients, families, and health systems in the U.S. HF is a leading cause of hospitalization, with frequent readmissions (Feltner et al., 2014). Morbidity and mortality rates are high, contributing to nearly 10% of all deaths, and has a five-year mortality rate of about 50% (CDC Fact sheet, 2016). Incorporating palliative care services into standard treatment for advanced HF is largely presumed to improve health-related quality of life (QoL) and to provide patients and families the opportunity to discuss treatment options and wishes (Teuteberg & Teuteberg, 2016). Another proposed benefit of palliative care is the opportunity to manage common symptoms of dyspnea, fatigue, pain, depression, edema, and anxiety (Adler, Goldfinger, Kalman, Park, & Meier, 2009).

Although most HF management guidelines and consensus statements recommend the integration of specialist-directed palliative care into the management of HF, less than 10% of qualified patients receive these services (Xie, Gelfman, Horton, & Goldstein, 2017).

Palliative Care (PC) is defined by the World Health Organization (WHO) as an approach to care that focuses on improving the quality of life of patients facing serious, complex, or life-threatening illness (World Health Organization, 2018). In 2015, the WHO expanded the definition and goals of PC to include application early in the disease process, in conjunction with treatments aimed at prolonging life (World Health Organization, 2018). Redefining the terminology has expanded inclusion criteria to
patients with chronic illnesses, including those where prognosis and life expectancy were
difficult to predict, and is not limited to a particular care setting (Kydd, 2015). PC is
frequently thought to be interchangeable with hospice, or end of life care; however, PC is
focused on patient and familial support throughout the course of serious illnesses,
regardless of life-prolonging or curative treatment (Adler et al., 2009).

By providing palliative measures throughout the continuum of illness, care
became patient- and family-centered, thus addressed their physical, intellectual,
emotional, social, and spiritual needs (Mulvihill, 2015). Facilitating patient autonomy,
access to information, and informed choices encouraged collaboration and coordination
of high-quality care (Mulvihill, 2015). Palliative medicine strives to improve patients’
quality of life using a holistic, multidisciplinary approach to address physical,
psychological, and spiritual needs (Adler et al., 2009).

HF is a complex clinical syndrome resulting from other diseases or injuries such
as myocardial infarction, valvular disease, hypertension, or atrial fibrillation,
which damages the myocardium and affects the heart’s ability to pump
effectively (Treece et al., 2017). Heart failure is classified as either systolic, characterized
by low ejection fraction (EF) and reduced left ventricular contractility; or
diastolic, characterized by impaired relaxation of the heart muscle resulting in abnormal
left ventricular filling capacity, thus maintaining a preserved EF despite decreased
cardiac output (Treece et al., 2017). This failure of the myocardium to pump or to relax
adequately is representative of the end-stage sequelae of other diseases, typically
those involving the cardiac or pulmonary systems, though other causes cannot be
excluded (Treece et al., 2017). Advances in medical management have improved
mortality for patients with systolic heart failure, however these treatments have not proven beneficial for those with diastolic failure (Treece et al., 2017).

HF is progressive in nature and has a high mortality rate and is associated with a poor quality of life in spite of recent advances in treatment options (Mentz et al., 2014). For many patients the disease progression is disabling. Common symptoms of HF include dyspnea and angina, progressing from occurring primarily with exertion to occurring even at rest. Fatigue is a common complaint and negatively affects quality of life. Orthopnea and paroxysmal nocturnal dyspnea interfere with sleep and rest, and persistent edema may limit activity (Treece et al., 2017). The disease trajectory is typically marked with periods of relatively stable symptoms interrupted by acute decompensations. Functional decline may be abrupt or incremental, with about 50% of HF patients dying abruptly from sudden cardiac death, while the other half die after gradual debilitation and decline (Treece et al., 2017). Prognostication is difficult because the disease trajectory varies widely from patient to patient (Treece et al., 2017).

Advanced stages of HF carry significant symptom burden and patients commonly have multiple comorbidities. Although most HF guidelines and consensus statements recommend PC as a component of routine HF management, PC typically is not introduced until the patient enters the final stages of life and becomes eligible for hospice (Treece et al., 2017). Unlike hospice, PC services are available to patients at any stage of disease, even those pursuing curative or life-prolonging treatment. Care is focused on maintaining quality of life through shared decision-making, symptom management, establishing personal goals, advanced planning, and spiritual and psychosocial support.
**Significance to Health Care**

The prevalence and impact of HF places a significant burden on the health care system and is expected to increase further as the population of the U.S. ages. Within the U.S., 6.6 million adults are diagnosed with HF, and the American Heart Association expects this number to rise to almost 10 million by 2030, with 670,000 new cases diagnosed each year (American Heart Association [AHA], 2013). HF accounts for more than 1 million hospitalizations and 3.6 million medical clinic and emergency room visits each year (AHA, 2013). Direct medical costs for treatment are expected to increase from $21 billion in 2012 to $53 billion by 2030 (AHA, 2013).

**Goals and Objectives**

This project’s goal was to improve consistency of patient-centered care for those with advanced HF by incorporating PC principles of shared decision-making, medical management, and psychosocial support into routine outpatient care. These efforts support the goals of the heart failure clinic (HFC) to improve patient satisfaction and quality of life (QoL), to support caregivers, and to decrease costs as integral components in the management of patients with advanced HF. Clinical and medical management of patients treated in the HFC excels through consistent use of guideline-directed medication therapy, aggressive management of comorbidities, diagnostic evaluation for new or worsening disease, and referral to specialists; however, a gap still exists between guideline-recommended PC measures and clinical practice. Proposed means to bridge this gap included identifying and addressing QoL limitations using the Kansas City Cardiomyopathy Questionnaire (KCCQ), incorporating shared decision-making principles to involve patients’ goals into treatment plans, and investigating billing
methods to capture reimbursement for services as provided by Centers for Medicare and Medicaid Services (CMS).

**PICOT Question**

For patients with advanced heart failure, how does integrating the palliative care principles of shared decision making and advance directives into the standard treatment plan, compared to those who receive usual care, influence health outcomes in a three-month period.

**Review of Evidence**

**Search strategy**

The University of Alabama at Birmingham library database was searched to find evidence of the impact of PC on HF patients in an outpatient setting. The databases examined for adult human studies published between 2009 and 2018 include CINAHL, OVID, Cochrane Review, PubMed, Joanna Briggs Institute for EBP Database, and Google Scholar. Articles not available in full-text were requested through interlibrary loans. The search was limited to scientific, academic, peer-reviewed journals, and clinical trials.

Key search terms included: heart failure or congestive heart failure; palliative care; shared decision-making; communication; patient-centered care; advance directives; and health-related quality of life. Articles for review fell into three primary categories: health-related quality of life, communication and shared decision-making, and clinical guidelines and expert consensus statements.

Within the cardiology literature, there is a paucity of primary research and clinical trials pertaining to palliative care measures in HF treatment programs. However,
secondary data sources provided validation that this topic is being reviewed as pertinent to practice. In the past year several changes have been made to AHA and American College of Cardiology (ACC) Guidelines to implement palliative care into routine HF management. Palliative medicine journals provide more qualitative studies and offered methods to bridge the gap between traditional oncology-focused palliative interventions and those that are appropriate for heart failure patients.

**Health-Related Quality of Life**

Implementing PC principles into the routine treatment of HF remains in the early stages of discovery. There is a scarcity of quantitative clinical trials to guide evidence-based practices for integrating PC into HF management. Even within the existing research there is variance in implementation strategies, such as appropriate timing, site of care, who provides the PC intervention, and scales of measurement.

In their groundbreaking randomized, controlled trial, Rogers and his team evaluated the impact of an interdisciplinary PC intervention on HF-related symptoms in patients with advanced HF (2017). In this large, single-site study, the authors used the Kansas City Cardiomyopathy Questionnaire (KCCQ) and the Functional Assessment of Chronic Illness Therapy-Palliative Care (FACIT-PAL) surveys to measure health-related quality of life (HRQoL) of patients who had been recently discharged from the hospital. The intervention was performed by PC specialists and consisted of assessment and management of physical symptoms, psychosocial and spiritual concerns, and advance care planning (Rogers et al., 2017). In this prospective, 2-arm, single center clinical trial, 150 patients with advanced HF were randomized to two groups and received usual care alone (UC) or UC plus palliative care intervention. Surveys were administered at baseline
and at designated intervals throughout the study. Results of both KCCQ and FACIT-PAL assessments showed clinically significant benefits of embedding a specialized palliative intervention in the routine treatment of patients with advanced HF, compared to those with UC alone, though no statistical significance was reported (Rogers et al, 2017). These findings were mirrored in a randomized controlled trial conducted by Brännström and Boman (2014), the aim of which was to evaluate the effects of an intervention using Palliative advanced home care and heart failure care (PREFER) on patient symptom burden and quality of life. In this open, non-blinded study design, 36 patients were randomized into two groups, an intervention group and a UC group. Usual care was provided by general practitioners and the nurse-led heart failure clinic. Patients in the intervention group received UC and palliative interventions, led by a specialized PC team. Quality of life was assessed at baseline and routinely throughout the study using three validated questionnaires: The Euro Qol-5D: health-related quality of life (EQ-5D), the Edmonton Symptom Assessment Scale (ESAS), and the Kansas City Cardiomyopathy Questionnaire (KCCQ). Results indicated that health related quality of life improved significantly in the intervention group at six months by all three questionnaires (Brännström & Boman, 2014).

In a 2011 qualitative study by Bekelman and colleagues, 33 adult outpatients with symptomatic HF and their families were separately interviewed to assess needs, concerns, and preferences pertaining to their HF treatment. The researchers’ primary goal was to identify unmet patient needs, salient concerns, and preferences to develop and guide a non-oncology, non-hospice palliative intervention in an outpatient HF setting. Using the KCCQ to gain patients’ perceived HF-specific QoL, these researchers found that
patients desired assistance in adjusting to the functional limitations of HF, help understanding the future course of the disease, relief of symptoms, and the involvement of family members in planning care. Many patients desired these elements early in the disease process rather than waiting until the disease progressed to advanced stages (Bekelman et al., 2011). Because PC is more widely used in the oncology setting, it is important to recognize the importance of customizing care to the needs of the patients with chronic diseases, particularly those difficult to prognosticate. Kavalieratos and others (2014) conducted a review of data of 1031 patients from the Palliative Care Research Review to evaluate the differences of care given to patients with cancer compared to those with HF. Their findings revealed that although physical and psychosocial needs of patients in these two groups are similar, patients with HF reported dyspnea more frequently than those with cancer. In spite of a similar symptom burden, there was a treatment gap in how symptoms were managed, with a lack of documented intervention for distress reported as moderate or severe (Kavalieratos et al., 2014).

Patients’ quality of life is impacted by the high symptom burden associated with HF. Two separate studies explored the effects of PC services on patients with HF. Evangelista and colleagues (2012) conducted a prospective comparative study to examine the impact and feasibility of outpatient palliative care consultation on the symptom burden, depression, and quality of life of patients with symptomatic heart failure. In this single site study, the researchers recruited 36 patients who were hospitalized for acute HF to participate in an outpatient PC consultation after discharge. During this consultation, multiple elements of the disease were addressed, including physical, psychosocial, and
spiritual aspects. The researchers then conducted phone interviews three months later to gather information about socioeconomic and clinical data. Several domains of HF were assessed, including: depression, using the Patient Health Questionnaire (PHQ); physical symptoms, using the Edmonton Symptom Assessment Scale (ESAS); and quality of life, using the Minnesota Living with Heart Failure Questionnaire (MLHFQ). The authors compared baseline data to results obtained after three months to a similar control group receiving UC only. Results indicated that both groups reported improvement in symptom burden, depression, and quality of life, though the intervention group had greater improvement than those receiving UC alone (Evangelista et al., 2012).

In a separate study, Evangelista and her colleagues (2014) conducted a descriptive-exploratory study to examine whether the type and frequency of palliative care services impacts patients’ symptom burden in advanced heart failure. In this study, referred patients were allowed to choose either a single palliative care consultation, or a consultation plus ongoing support. For those with ongoing support, referrals to a palliative care specialist, pharmacist, and social worker were arranged. Pharmacologic interventions were provided for symptom relief, and included opiates, anti-depressants, or both. After three months, the authors re-evaluated both groups. Their findings suggested that those who received additional palliative care services showed a clinically relevant improvement in symptom burden (Evangelista et al., 2014). Similar findings were reported by Schwarz and colleagues (2012) in a pilot study conducted to determine the effects of a PC intervention on symptom management, clarification of the goals of therapy, advance care planning, hospice referral, and end-of-life care for patients who were referred for heart transplant or ventricular assistive device (VAD). These findings
were supported in an article by Ghashghaei, Yousefzai, & Adler (2016) who recommended that PC consultation be provided for all HF patients, including those who are pursuing VAD, heart transplant, and other advanced therapies focused on prolonging life to ameliorate symptoms, facilitate care planning, provide emotional support to relieve suffering, and decrease unnecessary costs to patients. The authors also emphasized the need for physician education in PC, and to improve the underuse of PC services. This study found that patients reported moderate to significant improvement on HRQoL with the intervention. Interestingly, researchers in the above studies report finding no increase in the life expectancy of patients.

Systematic reviews by Siouta and others (2016) and Kavalieratos and colleagues (2017) found that while most clinicians supported early PC integration into the routine management of advanced HF, communication of complex decision-making and end-of-life topics are rarely initiated, resulting in patients who are less informed about their disease process and treatment options. They found that there are limited opportunities to discuss Advance Directives, emotional, or spiritual concerns. Siouta and associates (2016) noted a lack of a standardized and universal definition of PC, while Kavalieratos and colleagues (2017) pointed out that little emphasis is placed on QoL, complex decision-making, or providing PC concurrently with life-prolonging or advanced therapies.

These studies support the case for palliative care to be integrated into the standard management of HF. Treatment of HF should extend beyond medications that affect morbidity and mortality and include measures to ameliorate the distressing symptoms of
HF to improve patients’ QoL. More longitudinal and multi-center studies are needed to establish evidence and standards for PC intervention that best improve patients’ HRQoL.

Communication and Shared Decision Making

In March 2001, the Institute of Medicine (IOM) released the landmark publication *Crossing the Quality Chasm: A New Health System for the 21st Century*. In this report, the IOM proposed a new approach to the American health care system and how health care is delivered, in an effort to bridge the gap of what U.S. health care is, and what it could be. This report proposed six specific aims to improve health care, one of which is patient-centered care, when care is provided that is “respectful of and responsive to individual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions” (National Academies Institute of Medicine [IOM], 2001, p.3). Supporting this aim, the Patient Protection and Affordable Care Act (ACA) (2010) created a program to facilitate shared decision-making with the purpose of facilitating collaboration between patients, caregivers, and clinicians to create health care plans that incorporate patient wishes with sound and reasonable care options to formulate individualized medical plans (Office of the Legislative Counsel, 2010). The ACA also called for the development of decision aids, shared decision-making programs, and metrics to gauge the quality of decision-making (Office of the Legislative Counsel, 2010). Progression toward this transformation in the delivery of care requires a paradigm shift on the part of clinicians, patients, and caregivers alike.

Although communication is an essential component of both PC and HF management, clinicians tend to discuss only the medical management of the disease. Frequently the focus of patient-provider conversations is on ways to improve function
and prolong life. However, because HF is a life-limiting disease and there is no known cure, patients and their families should be informed of the elevated risk of sudden cardiac death or gradual demise (Goodlin, 2009). In fact, it is the legal and ethical responsibility of the health care provider to narrow the diagnostic and treatment options to those that are medically reasonable to consider (Allen et al., 2012). In fact, increasing patients’ awareness of the nature of HF is not only legally and ethically prudent, but may also serve to increase compliance with medications and dietary restrictions, and to provide the patient with an opportunity to plan for a worst-case scenario (Goodlin, 2009).

Two of the reviewed studies noted that a crucial component of communicating with HF patients and their families was advance care planning and designating a health care proxy (Adler et al., 2009; Gerlich et al., 2012). Addressing these issues early in the disease provided an opportunity for discussions about personal health care wishes and goals. A qualitative, longitudinal study conducted by Gerlich and associates (2012) found that by establishing patients’ goals of care early in the disease process, patients noted an increase in fulfillment of health-related and personal goals, and caregivers reported a reduction in stress and anxiety. These goals should be specific and identify their wishes in circumstances such as cardiopulmonary arrest or intubation, and patients should be assured that preferences can be changed at any time (Adler et al., 2009). The difficulties associated with this process include the time involved in conducting such discussions, a lack of clinician training in addressing these topics, and the inability of some patients to articulate decisions that are congruent with their stated goals (Allen et al., 2012).
As U.S. health care moves toward a more patient-centered approach, the concept of shared decision-making is gaining momentum. Collins & Storrow (2013) described shared decision-making as a collaborative interaction between patients, caregivers, and providers that lead toward care that is predicated on mutual agreement. The crux of patient-centered care is that the focus is moved away from the disease and focused on the patient and family systems (Collins & Storrow, 2013). The authors noted that this active engagement is an especially important component when health care decisions have significant consequences and persisting implications (Collins & Storrow, 2013).

Clinical Guidelines and Expert Consensus Statements

Current HF literature recommends integrating PC into the routine treatment of patients with advanced HF, and multiple agencies have outlined methods to do so. The Joint Commission requires that the HF team be prepared to address PC with patients, and to incorporate individualized advanced care planning into patient care in order to receive specialized credentialing (The Joint Commission, n.d.). In the ACC/AHA Clinical Guideline for the Management of Heart Failure, task force members developed comprehensive guidelines to manage HF, in which supportive and PC strategies are considered an appropriate component of treatment, whether as sole focus of care or in conjunction with life-prolonging measures (Yancy et al., 2013). An AHA policy statement asserts that attempts to prolong final stages of HF increase the burden of physical limitations and suffering onto patients, their families, and the medical system, and recommend that offering PC to these patients may lead to more conservative and less costly treatment, and reflect the patients’ personal goals (Heidenreich et al., 2013). In an
AHA Scientific Statement, the authors promoted the importance of shared decision-making to increase the probability of high-quality decisions which emerged from options that are medically reasonable and are in accordance with the values and goals of fully-informed patients (Allen et al., 2012). Teuteberg and Teuteberg (2016) noted that advanced care planning and making complex decisions increase in importance as HF progresses into advanced stages of the disease. This is especially true in conversations that include decisions about advanced therapies, such as inotrope therapy, circulatory support interventions, heart transplant, and left ventricular assistive device implantation (Teuteberg & Teuteberg, 2016).

The call for normalizing PC as a part of HF management led the ACC to create a decision pathway for optimizing HF treatment in which seven key principles of PC are outlined, and specific actions are offered to help health care providers integrate these principles fully into practice. The principles outlined in the decision pathway are: 1) to reduce suffering through pain and symptom management; 2) meticulous management of HF therapies; 3) specialized palliative consult as needed for further amelioration of HF symptoms refractory to guideline-directed therapy; 4) assist with major treatment decisions over time and utilize patient decision aids to help frame options; 5) ongoing preparedness discussions and shared decision-making; 6) use of clinical milestones that affect disease trajectory to calibrate patient expectations, and 7) to assist quality survival periods between aggressive care and comfort only by revising medical regimen and frequently weighing benefits and burdens of specific treatments and medications (Yancy et al., 2013).
In spite of increasing calls to implement standards that include palliative measures in the treatment of heart failure, few patients receive these interventions until they are at the end of life. There is a discrepancy between expert recommendations and guidelines and the resources available to study and implement these measures. Without a solid base of evidence, utilization of these recommendations will be limited.

**Conceptual Framework**

The Quality Caring Model (QCM) (see Figure 1), designed by JoAnne Duffy to guide research and practice, asserts that the nature of nursing is centered on relationships, and the association of those relationships with quality health outcomes (Duffy & Hoskins, 2003). The QCM emphasizes the importance of relationships in the context of health care and focuses on the independent relationships of nurses with patients, as well as the collaborative relationships between nurses and other health care professionals to promote improved patient outcomes (Duffy & Hoskins, 2003). This model provides a structure for integrating these principles into patient relationships. The four primary concepts of this relationship-centered theory are: 1) humans in relationships; 2) relationship-centered professional encounters; 3) feeling “cared for”; and 4) self-advancing systems (Smith & Parker, 2015). In 2005, Dr. Duffy and her colleagues developed an in-home caring-based intervention for recently hospitalized older adults with HF (Duffy, Hoskins, & Dudney-Brown, 2005). Based on the QCM, a team of nurse researchers developed a nursing intervention to attain the goals of improving patient and system outcomes in a practical, low-cost design that could be completed by staff nurses as part of their daily work (Duffy et al., 2005). The premise was to develop caring, long-term relationships between nurses and these patients to facilitate individualized
understanding and help specific to each patient’s needs (Duffy et al., 2005). It is in establishing this rapport and trusting relationships that promote shared decision-making to assist patients to clarify personal goals and wishes.

**Humans in Relationships**

The QCM seeks to demonstrate the multiple dimensions of humans with unique characteristics that set them apart from others, and as a result, how these attributes affect patients and their family’s interactions with others in their given environment (Smith & Parker, 2015). Caring relationships promote positive outcomes such as preserving dignity, protection from harm, increased knowledge of self, improved health, and inner balance (Duffy & Hoskins, 2003). Caring relationships are believed to positively impact not only patients and their families, but health care providers as well (Duffy & Hoskins, 2003).

For patients with HF, a disease characterized by exacerbations that impact routine activity followed by periods of recovery, relationships with others often become stressed as the disease progresses. Therefore, in times of crisis, reliance on others increases and reflects the importance of interdependent relationships on many levels, personal and professional, making this theory an appropriate model for palliative care (Davidson, Cockburn, Daly, & Fisher, 2004).

**Relationship-Centered Professional Encounters**

*Caring* is typically considered the focus of a nurse’s work, and relationships with patients and their families is central to the concept of PC. Nurses are often the cohesive element in multidisciplinary health care teams, such as those demonstrated in palliative medicine. Collaborative relationships promote respect for the roles of other team
members and disciplines, shared responsibilities, and validation of others’ work (Duffy & Hoskins, 2003)

Relationships with patients and their families are a critical component of PC. Illness is a time of vulnerability. Nurses, therefore, have a responsibility to initiate, cultivate, and maintain intimate, interpersonal relationships. Relationships that are intentional and aimed at health and healing have the potential to impact patients’ overall health (Duffy & Hoskins, 2003). As a result, non-hospice PC services are currently emerging as a means to improve mortality, to decrease hospitalizations, and to improve patient outcomes (Duffy & Hoskins, 2004).

**Feeling Cared-For**

Palliative care exhibits a unique type of caring that comes from “specialized knowledge, attitudes, and behaviors that are specifically directed toward health and healing” (Smith & Parker, 2015, p. 394). Patients and families are encouraged to create change and advancement, which leads to positive emotions and behaviors such as beneficial risk taking, and to take part in the decision-making process which results in healthy new decisions or actions (Smith & Parker, 2015). Likewise, PC maintains patient dignity by honoring wishes, promoting acceptance of the disease process, providing means for management of distressing symptoms which ultimately improves patient-defined positive outcomes (Smith & Parker, 2015). This patient-family-practitioner interrelationship establishes trust and leads to discussions of difficult topics related to HF, such as prognosis, disease progression, and desired levels of care in advanced stages.
Self-Advancing Systems

Self-advancing systems are described as progressive phenomena that develop over time and reflect a positive dynamic process that impacts the well-being of a system or individual (Smith & Parker, 2015). Advancements are driven by caring relationships and emerge over time via these interpersonal connections, through a dynamic process that represents quality in the QCM (Smith & Parker, 2015). For older adults with advanced HF, performing self-care and activities of daily living is often compromised as a result of the disease process as well as other physical and socioeconomic confounding factors (Duffy et al., 2005). They often have unique needs that are not met with available resources, and the fragmentation of current health care leads to access barriers and follow-up care (Duffy et al., 2005). Self-advancing systems serve to provide a foundation for patient-centered care and mutual problem-solving.

Project Implementation

Ethical Considerations

Approval from the IRB committees of both the hospital (see Appendix A) and the University of Alabama (see Appendix B) were obtained prior to initiating this scholarly project. Informed consent was obtained from all participants in Group A. Interviews were conducted in an office separate from the open clinic, but in the same suite. No preferential treatment or compensation was given to those participating in the project. Written and electronic records containing any Protected Health Information (PHI) were maintained in a locked file.
Setting

The Heart Failure Clinic (HFC) is a hospital-affiliated, nurse practitioner (NP)-led outpatient clinic. The role of the clinic is to provide ongoing guideline-directed management and support for patients with acute and chronic HF, with the goals of improving patient outcomes, decreasing frequency of HF-related hospitalizations, and optimizing resource utilization. Patients’ scheduled appointments are made as indicated by health status, medication stability, and ongoing evaluation. Initial clinical information is collected by registered nurses (RNs), and evaluation and treatment are performed by NPs. Physician support is available. The HFC is managed by an NP who is actively involved in program development, functions as a liaison between the clinic and hospital administration, and represents the clinic within the community and hospital setting.

Treatment is focused on managing the disease process with the intent to slow progression and decrease frequency of acute decompensations. An average of 45-60 patients are seen daily by a staff of NPs, RNs, patient care technicians, and physicians. Medical treatment is guided by the AHA Get with the Guidelines (GWTG) for treatment of HF using current best-practice strategies (American Heart Association, 2017). Patient population includes adult patients, aged 19 years and older, although approximately 75% of patients are 65 years and older. The gender distribution is approximately 60% males, 40% females, and race distribution is 60% African American, 35% Caucasian, and 5% are of Hispanic, Asian, and Middle Eastern descent.
Sample and Participant Selection

Eligibility criteria for inclusion in the project was defined as follows: adults 19-years and older, with New York Heart Association (NYHA) Class III-IV symptoms (see Table 1) and/or with AHA Stage C-D disease (see Table 2) who score 60 or below on the Kansas City Cardiomyopathy Questionnaire (KCCQ) Overall Summary score (OS). Gender, age, and race information were collected for reference only after completion of the project. Clinical judgment, prognostic indicators, and clinical milestones (disease progression refractory to optimized therapy, increased symptom burden, and recurrent hospitalizations) were used to guide appropriateness for participation.

Newly enrolled patients during the 30-day recruitment period were administered the KCCQ (see Appendix C) at their first appointment by the primary RN. Those whose baseline KCCQ OS score was 60 or below were considered eligible for inclusion and were asked to participate in this project using a prepared script (see Appendix D). The patients who met inclusion criteria and agreed to participate (n=10) were randomly allocated in a 1:1 fashion into two groups, Group A (n=5) or Group B (n=5). Group A received usual care plus the palliative intervention (UC+PC) in the HFC, while Group B received UC alone. The UC component was managed by the HFC staff utilizing guideline directed therapies, medication titrations, and ongoing monitoring of end-organ function. The PC intervention was conducted by an NP dually trained in HF and PC.

There were 26 KCCQs administered in the one month of recruitment. Of those, 19 patients met the inclusion criteria using a convenience selection strategy and were approached to participate in the project. Of these 19, three patients declined to participate,
and six were lost to follow-up. Seven patients did not meet inclusion criteria, thus were excluded.

**Project Design**

After obtaining informed consent (see Appendix E), face-to-face meetings were scheduled with each patient in Group A. The intervention plan included individual semi-structured, goal-directed conversations about the patient’s wishes, options for care, and advance care planning. Interviews consisted of open-ended questions to determine patient readiness to participate in shared decision-making, address advance directives, and to help patients understand disease trajectory and prognosis (see Appendix F). Patient-reported quality of life measures were discussed using baseline KCCQ scores to address those symptoms with greatest impact on that patient's life, leading to individualized goal-setting and attainment strategies.

The KCCQ is a validated, reliable, widely used self-administered 23-item tool that quantifies six HF-specific domains and two summary scores, the Clinical Summary (CS) score and the Overall Summary (OS) score (Spertus, 2016). The selected cut-off score for inclusion was an OS score of 60. Scores are calculated and transformed into values that range from 0-100, with higher scores representing better health status and patient-perceived HRQoL (Rogers et al., 2017). Licensure to use the KCCQ was purchased through Outcomes Instruments, LLC (see Appendix G).

Detailed discussions to fully inform patients of treatment options included disease trajectory, prognostic indicators, and the benefits and burdens of available advanced therapy options. Medications, titrations, and rationale for each were discussed. If device implantation was being considered, such as automated implantable cardioverter
defibrillator (AICD), or implanted volume monitoring devices, the risks and benefits were explained. Advanced therapy options for treatment of end-stage heart failure include inotrope infusions, ultrafiltration, implantation of left ventricular assist device (LVAD), and heart transplant implications were discussed if appropriate. Careful word choice was imperative to appropriately inform patients without causing undue fear.

Patients were offered the Alabama Advance Directives documentation to review (see Appendix H). They were also be given the opportunity to discuss this form in detail if desired, however none accepted during the project.

Participants were queried about symptoms, which were then discussed with pharmacological and nonpharmacological treatment options. Spiritual and psychosocial concerns were addressed based on patient preference.

Analysis

A total of 26 KCCQs were completed during a one-month period. Of these, 19 met criteria to participate. The KCCQ OS score at baseline and 3-months were selected as the primary indicator of change in HRQoL between the two groups, UC or UC+PC intervention. Primary endpoints were measured by changes in baseline and 3-month OS scores on KCCQ. A 5-point change in the KCCQ OS score is the smallest increment that is considered clinically significant for individual patients (Pokharel et al., 2017).

Statistical analysis was performed using SPSS 25.0 software on the primary endpoint of measurement of QoL using the KCCQ OS score. The sample size was 10, (five per group), though only two post-intervention scores were obtained from Group A, thus not meeting criteria for an adequate sample size of at least three to measure
correlation coefficients. Average baseline KCCQ OS calculated scores for Group A (intervention group) were 45.25, and 31.18 for Group B (control group) (see Table 3). Mean change after three months was +3.7 points for Group A, with only two follow-up questionnaires completed, and +11.78 points for Group B, with all five participants completing a second questionnaire. Differences of KCCQ OS at baseline and after three months were compared on Group B, using the Wilcoxon Signed Rank Test, which determined that there was no significant statistical difference between baseline KCCQ scores and after three months (alpha = 0.05, significance level = 0.080) (see Table 4). However, validity testing of the KCCQ has determined that a 5-point change is considered clinically significant, in which case Group B shows a significant clinical difference for all five participants in the control group.

A third group, which was labeled Group C (n=9), were clinically eligible to participate, but declined to do so (n=3) or were lost to follow-up (n=6). The baseline OS scores for this group was 29.06 points. Those whose KCCQ scores did not qualify them for inclusion was labeled Group D (n=7), with an average OS score calculated at 72.69 points.

Baseline characteristics of age, gender, and race were collected after completion of project implementation and evaluated for reference purposes only and not included in statistical analysis. It should be noted, however, that compared to the population of the HFC and the larger community, a disproportionate percentage (90%) of Caucasian males were inadvertently included in the cohort. The other 10% was Caucasian female. Goals of care, advance directives, and personal preferences about direction of care were noted anecdotally.
Results and Discussion

Findings from this project reflect several aspects found in other studies conducted on this topic. Results of the KCCQ scores show that patients with HF carry a high symptom burden that impacts daily life. One of the appealing aspects of the KCCQ is that it measures five domains of HF-specific quality of life assessments, including the frequency, severity, and impact of symptoms; physical function; quality of life; social limitations; self-efficacy; and the stability of symptoms over previous 2-week recall period (Spertus, 2016). It is validated and widely used to evaluate disease-specific status in this population.

Within this project results varied from between about which symptoms, and to what degree, were most distressing, and the impact those symptoms had on QoL. Of the five original Group A members, only two completed 3-month follow-up questionnaires. The three who did not complete a second questionnaire still contributed valuable information to the project. Of these, two were hospitalized for acute decompensation of HF and were discharged home on hospice. The other one improved clinically enough to not require follow-up in the HFC within the 3-month period. Although this project did not result in statistically significant findings, there were clinically significant improvements noted in both groups. Interpretation of this may include the patient health status on the day that the questionnaire was administered, because of the potential for rapid changes in health status for HF patients. Other factors include the optimization of medications, improved life choices, and education that is a routine part of usual care leading to improved personal disease management.
Prognostication of HF is difficult, and the disease trajectory is unpredictable. Patients who have been recently diagnosed, or those who have been stable for a long period of time, may not be mentally prepared to have difficult conversations about goals of care and treatment options. For them, a grieving process may be necessary before considering the “what ifs”. For this reason, a longitudinal process is an important part of both HF management and PC considerations. Establishing trust and rapport between patient and clinician promotes a shared decision-making process. Clinicians are responsible for informing patients of valid and appropriate treatment options, and patients are responsible for articulating their wishes. This is difficult for many, so incorporating family and caregivers into discussions and care planning is valuable.

For this study there was an unintentional racial and gender disparity that did not reflect the population of the HFC or that of the larger community. In the study groups, 90% (n=9) were Caucasian men, and the other 10% (n=1) Caucasian female. Participants were aged 61-81 years. These data were gathered after the completion of the project and was an unintended consequence of that particular admission group during the enrollment period. Cultural considerations must also be taken into consideration about how people view and value life and death.

Health literacy and bi-directional communication is a relatively new concept in health care. Patients with HF tend to be older and still commonly rely on clinicians to make health decisions for them. They are often ill prepared to participate in discussions concerning health care decisions. Without proper understanding of the scope of options and the effects of different treatments, patients are at risk for poorly made decisions.
There are many variables that affect the course of HF over time. Some of these variables are controllable, while others are not. Health care providers should be educated about prognostic indicators that affect disease trajectory and be willing to initiate conversations with patients whose condition begins to decline. Recognizing clinical milestones such as increasing frequency of hospitalizations, worsening functional status, decreased tolerance to HF medications, and worsening end-organ function as opportunities to re-evaluate patient wishes and goals is an important element to clarifying the direction of care.

**Conclusions**

As the U.S. population continues to age, and chronic diseases such as HF become more prevalent, strategies should be implemented to improve patient outcomes, increase patient-centered care, promote open communication and shared decision-making, and optimize resource management. Comprehensive HF treatment should include PC principles throughout the course of care, regardless of whether treatment is focused on amelioration of symptoms or prolonging life with advanced therapies. Evidence-based HF management includes integrating PC into routine treatment, though more clinical trials are needed to determine best practices.
DNP Project Product

Professional Journal Selection

Heart & Lung: The Journal of Acute and Critical Care

Scope of Journal

This journal is the official publication of The American Association of Heart Failure Nurses, and presents original, peer-reviewed articles on techniques, advances, investigations, and observations related to the care of patients with acute and critical illness and patients with chronic cardiac or pulmonary disorders. The Journal’s heart failure articles focus on all aspects of the care of patients with this condition.

Aims of Journal

The aim of the Journal is to publish articles that represent a broad range of science and clinical practice in a variety of settings as it pertains to the target population. Authors are encouraged to submit manuscripts that reflect the global, interdisciplinary, multidisciplinary, and transdisciplinary nature of health care and health sciences.
Integrating the Palliative Care Principles of Shared Decision-Making and Advance Care Planning into Heart Failure Management
Abstract

Background: Heart failure (HF) is a complex syndrome with high mortality rate, frequent hospitalizations, and significant symptom burden. Palliative care (PC), historically associated with end-of-life care for cancer patients, offers opportunities to improve health-related quality of life in conjunction with life-prolonging medical therapies.

Objectives: To evaluate and address needs of patients with HF.

Methods: Within a hospital-affiliated heart failure clinic, two randomly assigned groups of recently hospitalized patients were administered The Kansas City Cardiomyopathy Questionnaire at baseline and after three months. Groups received either usual care or usual care plus PC intervention. Scores were compared after three months.

Results: Although no statistically significant change was found using the Wilcoxon Signed-Rank test, clinically significant change was found in both groups.

Conclusions: Emphasizes the need for concurrent guideline-directed HF therapy and palliative interventions. Long-term, consistent care is essential for patients to achieve care that is congruent with their needs and wishes.

Keywords: Heart failure, palliative care, shared decision-making, health-related quality of life, patient-centered care, advance directives
Integrating the Palliative Care Principles of Shared Decision-Making and Advance Care Planning into Heart Failure Management

Introduction

Identification of Problem

Heart failure (HF) is a chronic, progressive disease that carries significant burden to patients, families, and health systems in the U.S. HF is a leading cause of hospitalization, with frequent readmissions. Morbidity and mortality rates are high, contributing to nearly 10% of all deaths, and has a five year mortality rate of about 50%. Incorporating palliative care services into standard treatment for advanced HF is widely recommended to improve health-related quality of life (QoL) and to provide patients and families the opportunity to discuss treatment options and wishes. Another proposed benefit is the opportunity manage common symptoms of dyspnea, fatigue, pain, depression, edema, and anxiety. Although most HF management guidelines and consensus statements recommend the integration of specialist-directed palliative care into the management of HF, less than 10% of qualified patients receive these services.

Palliative Care (PC) is defined by the World Health Organization (WHO) as an approach to care that focuses on improving the quality of life of patients facing serious, complex, or life-threatening illness. In 2015, the WHO expanded the definition and goals of PC to include early application in the disease process in conjunction with treatments aimed at prolonging life. Redefining the terminology has expanded inclusion criteria to patients with chronic illnesses, including those where prognosis and life expectancy are difficult to predict, and is not limited to a particular care setting. PC, frequently thought to be interchangeable with hospice, or end of life care, rather focuses on patient and
familial support throughout the course of serious illnesses, regardless of life-prolonging or curative treatment. By providing palliative measures throughout the continuum of illness, care becomes patient- and family-centered, thus addressing their physical, intellectual, emotional, social, and spiritual needs. Facilitating patient autonomy, access to information, and informed choices encourages collaboration and coordination of high-quality care. Palliative medicine strives to improve patients’ quality of life using a holistic, multidisciplinary approach to address physical, psychological, and spiritual needs.

Heart Failure (HF) is a complex clinical syndrome resulting from other diseases or injuries such as myocardial infarction, valvular disease, hypertension, or atrial fibrillation which damages the myocardium and affects the heart’s ability to pump effectively. Heart failure is classified as either systolic, characterized by low ejection fraction (EF) and reduced left ventricular contractility; or diastolic, characterized by impaired relaxation of the heart muscle resulting in abnormal left ventricular filling capacity, thus maintaining a preserved EF in spite of decreased cardiac output. This failure of the myocardium to pump or to relax adequately is representative of the end-stage sequelae of other diseases, typically those involving the cardiac or pulmonary systems, though other causes should not be excluded. Advances in medical management have improved mortality for patients with systolic heart failure, however these treatments have not proven beneficial for those with diastolic failure.

HF is progressive in nature and has a high mortality rate with associated poor quality of life, in spite of recent advances in treatment options. For many patients the disease progression is disabling. Common symptoms of HF include dyspnea and angina,
progressing from occurring primarily with exertion to occurring even at rest. Fatigue is a common complaint and negatively affects quality of life. Orthopnea and paroxysmal nocturnal dyspnea interfere with sleep and rest, and persistent edema may limit activity. The disease trajectory is typically marked with periods of relatively stable symptoms interrupted by acute decompensations. Functional decline may be abrupt or incremental, with about 50% of HF patients dying abruptly from sudden cardiac death, while the other half die after gradual debilitation and decline. Prognostication is difficult because the disease trajectory varies widely from patient to patient.

Advanced stages of HF carry significant symptom burden and patients commonly have multiple comorbidities. Although most HF guidelines and consensus statements recommend PC as a component of routine HF management, PC typically is not introduced until the patient enters the final stages of life and becomes eligible for hospice. Unlike hospice, PC services are available to patients at any stage of disease, even those pursuing curative or life-prolonging treatment. Care is focused on maintaining quality of life through shared decision-making, symptom management, establishing personal goals, advance planning, and spiritual and psychosocial support.

**Significance to Health Care**

The prevalence and impact of HF places a significant burden on the health care system and is expected to increase further as the population of the U.S. ages. In the U.S., 6.6 million adults are diagnosed with HF, and the American Heart Association (AHA) expects this number to rise to almost 10 million by 2030, with 670,000 new cases diagnosed each year. HF accounts for more than 1 million hospitalizations and 3.6
million medical clinic and emergency room visits each year. Direct medical costs for treatment are expected to increase from $21 billion in 2012 to $53 billion by 2030.

Within the cardiology literature, there is a paucity of primary research and clinical trials pertaining to palliative care measures in HF treatment programs. However, secondary data sources provide validation that this topic is being reviewed as pertinent to practice. In the past year several changes have been made to AHA and American College of Cardiology (ACC) Guidelines to implement palliative principles into routine HF care. Palliative medicine journals provide more qualitative studies and offer methods to bridge the gap between traditional oncology-focused palliative interventions and those that are appropriate for HF patients.

In spite of the increased call to implement measures to include palliative care in the treatment of HF, few patients receive these interventions until they are at the end of life. There is a discrepancy between expert recommendations and guidelines, and the resources available to study and implement these measures. Without a solid base of evidence, utilization of these recommendations will be limited.

**Material and Methods**

The Heart Failure Clinic (HFC) is a hospital-affiliated, nurse practitioner-led outpatient clinic. The role of the clinic is to provide ongoing guideline-directed management and support for patients with acute and chronic HF, with the goals of improving patient outcomes, decreasing frequency of HF-related hospitalizations, and optimizing resource utilization. Patients’ scheduled appointments are made as indicated by health status, medication stability, and ongoing evaluation. Initial clinical information is collected by registered nurses (RNs), and evaluation and treatment are
performed by nurse practitioners (NP). Physician support is available. The HFC is managed by an NP who is actively involved in program development, functions as a liaison between the clinic and hospital administration, and represents the clinic within the community and hospital setting.

Treatment is focused on managing the disease process with the intent to slow progression and decrease frequency of acute decompensations. An average of 45-60 patients are seen daily by a staff of NPs, RNs, patient care technicians, and physicians. Medical treatment is guided by the AHA’s Get with the Guidelines (GWTG) for treatment of HF using current best-practice strategies. The patient population includes adults aged 19 years and older, although approximately 75% of patients are 65 years and older. The gender distribution is generally 60% males, 40% females, and race distribution is 65% African American, 35% Caucasian.

Sample and Participant Selection

Eligibility criteria for inclusion in this project was defined as: adults 19-years and older, with New York Heart Association (NYHA) Class III-IV symptoms (see Table 1) and/or have AHA Stage C-D disease (see Table 2) who score 60 or below on the Kansas City Cardiomyopathy Questionnaire (KCCQ) (see Appendix A) Overall Summary (OS) score. Gender, age, and race information were collected for reference only after completion of the project. Clinical judgment, prognostic indicators, and clinical milestones (disease progression refractory to optimized therapy, increased symptom burden, and recurrent hospitalizations) were used to guide appropriateness for participation.
Patients who were enrolled during the 30-day recruitment period were administered the KCCQ by a nurse at their first appointment. There were 26 KCCQs administered in the one month of recruitment. Of those, 19 patients met the inclusion criteria using a convenience selection strategy and were approached to participate in the project. Of these 19, three patients declined to participate, and six were lost to follow-up. Seven patients did not meet inclusion criteria, thus were excluded.

Those patients whose baseline KCCQ OS score was 60 or below were considered eligible for inclusion and were asked to participate in this project using a prepared script. The patients who agreed to participate (n=10) were randomly allocated in a 1:1 fashion into two groups, Group A (n=5) or Group B (n=5). Group A received usual care plus the palliative intervention (UC+PC) in the HFC, while Group B received UC alone. The UC component was managed by the HFC staff utilizing guideline directed therapies, medication titrations, and ongoing monitoring of end-organ function. The PC intervention was conducted by an NP dually trained in HF and PC.

**Project Design**

After obtaining informed consent, face-to-face meetings were scheduled with each patient in Group A. Interviews were semi-structured, consisting of open-ended questions to determine patient readiness to participate in shared decision-making, address advanced directives, and help patients to understand disease trajectory and prognosis. Patient-reported quality of life measures were discussed using baseline KCCQ scores to identify symptoms with the greatest impact on daily life, leading to individualized goal-setting and attainment strategies.
The KCCQ is a validated and reliable self-administered 23-item tool that quantifies six HF-specific domains and two summary scores, the Clinical Summary (CS) score and the OS score. The selected score to determine inclusion was an OS score of 60. Scores were calculated and transformed into values that range from 0-100, with higher scores representing better health status and patient-perceived HRQoL. Licensure to use the KCCQ was purchased through Outcomes Instruments, LLC.

Detailed discussions to inform patients about treatment options included disease trajectory, prognostic indicators, and the benefits and burdens of available advanced therapy options. Medications, titrations, and rationale for each were discussed. If device implantation was being considered, such as automated implantable cardioverter defibrillator (AICD), or implanted volume monitoring devices, the risks and benefits were explained. Advanced therapy options for end-stage heart failure include inotrope infusions, ultrafiltration, implantation of left ventricular assist device (LVAD), and heart transplant; the implications were discussed if appropriate. Careful word choice was imperative to appropriately inform patients without causing undue fear.

Patients were offered the state Advance Directives (AD) documentation to review. They were also given the opportunity to discuss AD in detail if desired, however none accepted during the project.

Participants were queried about symptoms, which were then discussed with pharmacological and nonpharmacological treatment options. Spiritual and psychosocial concerns were addressed based on patient preference.
Theoery/Calculation

A total of 26 KCCQs were completed during a one-month period. Of these, 19 met criteria to participate, seven scored above the cut-off of 60 calculated points. The KCCQ OS score at baseline and 3-months were selected as the primary indicator of change in HRQoL between the two groups, UC or UC+PC intervention. Primary endpoints were measured by changes in baseline and 3-month OS scores on KCCQ. A 5-point change in the KCCQ OS score is the smallest increment that is considered clinically significant for individual patients.10

Statistical analysis was performed using SPSS 25.0 software on the primary endpoint of measurement of QoL using the KCCQ OS score. The sample size was 10 (five per group), though only two post-intervention scores were obtained from Group A, thus not meeting criteria for an adequate sample size of at least three to measure correlation coefficients. Average baseline KCCQ OS calculated scores for Group A (intervention group) were 45.25, and 31.18 for Group B (control group) (see Table 3). Mean change after three months was +3.7 points for Group A, with only two follow-up questionnaires completed, and +11.78 points for Group B, with all five participants completing a second questionnaire. Differences of KCCQ OS at baseline and after three months were compared on Group B, using the Wilcoxon Signed Rank Test, which determined that the null hypothesis be retained, there was no significant statistical difference between baseline KCCQ scores and after three months (alpha = 0.05, significance level = 0.080) (see Table 4). However, validity testing of the KCCQ has determined that a 5-point change is considered clinically significant, in which case Group B shows a significant clinical difference for all five participants in the control group.
A third group, which was labeled Group C (n=9), were clinically eligible to participate, but declined to do so (n=3) or were lost to follow-up (n=6). The baseline OS scores for this group was 29.06 points. Those whose KCCQ scores did not qualify them for inclusion was labeled Group D (n=7), with an average OS score calculated at 72.69 points.

Baseline characteristics of age, gender, and race were collected after completion of project implementation and evaluated for reference purposes only and not included in statistical analysis. It should be noted, however, that compared to the population of the HFC and the larger community, a disproportionate percentage (90%,) of Caucasian males were inadvertently included in the cohort. The other 10% was Caucasian female. Goals of care, advance directives, and personal preferences about direction of care were noted anecdotally.

**Ethical Considerations**

Approval from the IRB committees of both the university and the hospital were obtained prior to initiating this scholarly project. Informed consent was obtained from all participants in Group A. Interviews were conducted in an office separate from the open clinic, but in the same suite. No preferential treatment or compensation was given to those participating in the project. Written and electronic records containing any Protected Health Information (PHI) were maintained in a locked file.

**Results and Discussion**

Findings from this project reflect several aspects found in other studies conducted on this topic. Results of the KCCQ scores show that patients with HF carry a high symptom burden that impacts daily life. One of the appealing aspects of the KCCQ is that
it measures five domains of HF-specific quality of life assessments, including the frequency, severity, and impact of symptoms on physical function, quality of life, social limitations, self-efficacy, and the stability of symptoms over previous 2-week recall period. It is validated and widely used to evaluate disease-specific status in this population.

The results from this project showed a variation in which symptoms, and to what degree, were most distressing, and the impact those symptoms had on QoL. Of the five original Group A members, only two completed 3-month follow-up questionnaires. The three who did not complete a second questionnaire still contributed valuable information to the project. Of these, two were hospitalized for acute decompensation of HF and were discharged home on hospice. The other one improved clinically enough to not require follow-up in the Clinic within the 3-month period. Although this project did not result in statistically significant findings, there were clinically significant improvements noted in both groups. Interpretation of this may include the patient health status on the day that the questionnaire was administered, because of the potential for rapid changes in health status for HF patients. Other factors include the optimization of medications, improved life choices, and education that is a routine part of usual care leading to improved personal disease management.

Prognostication of HF is difficult, and the disease trajectory is unpredictable. Patients who have been recently diagnosed, or those who have been stable for a long period of time, may not be mentally prepared to have difficult conversations about goals of care and treatment options. For them, a grieving process may be necessary before considering the “what ifs”. For this reason, a longitudinal relationship is an important part
of both HF management and PC considerations. Establishing trust and rapport between patient and clinician promotes a shared decision-making process. Clinicians are responsible for informing patients of valid and appropriate treatment options, and patients are responsible for articulating their wishes. This is difficult for many, so incorporating family and caregivers into discussions and care planning is valuable.

For this project there was an unintentional racial and gender disparity that did not reflect the population of the HFC or that of the larger community. In the project groups, 90% (n=9) were Caucasian men, and the other 10% (n=1) Caucasian female. Participants were aged 61-81 years. These data were gathered after the completion of the project and was an unintended consequence of that particular admission group during the enrollment period. Cultural considerations must also be taken into consideration about how people view and value life and death.

Health literacy and bi-directional communication is a relatively new concept in health care. Patients with HF tend to be older and still commonly rely on clinicians to make health decisions for them. They are often ill prepared to participate in discussions concerning health care choices. Without proper understanding of the scope of options and the effects of different treatments, patients are at risk for poorly made decisions.

There are many variables that affect the course of HF over time. Some of these variables are controllable, while others are not. Health care providers should be educated about prognostic indicators that affect disease trajectory and be willing to initiate conversations with patients whose condition begins to decline. Recognizing clinical milestones such as increasing frequency of hospitalizations, worsening functional status, decreased tolerance to HF medications, and worsening end-organ function as
opportunities to re-evaluate patient wishes and goals is an important element to clarifying direction of care.

**Conclusion**

As the U.S. population continues to age, and chronic diseases such as HF becomes more prevalent, strategies should be implemented to improve patient outcomes, increase patient-centered care, promote open communication and shared decision-making, and optimize resource management. Comprehensive HF treatment should include PC principles throughout the course of care, regardless of whether treatment is focused on amelioration of symptoms or prolonging life with advanced therapies. Evidence-based HF management includes integrating PC into routine treatment, though more clinical trials are needed to determine best practices.

**Funding**

This project did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.
References


### Table 1. New York Heart Association heart failure symptoms classification

<table>
<thead>
<tr>
<th>Class</th>
<th>Patient Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I (Mild)</td>
<td>No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, rapid/irregular heartbeat (palpitation) or shortness of breath (dyspnea).</td>
</tr>
<tr>
<td>Class II (Mild)</td>
<td>Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity results in fatigue, rapid/irregular heartbeat (palpitation) or shortness of breath (dyspnea).</td>
</tr>
<tr>
<td>Class III (Moderate)</td>
<td>Marked limitation of physical activity. Comfortable at rest, but less than ordinary activity causes fatigue, rapid/irregular heartbeat (palpitation) or shortness of breath (dyspnea).</td>
</tr>
<tr>
<td>Class IV (Severe)</td>
<td>Unable to carry out any physical activity without discomfort. Symptoms of fatigue, rapid/irregular heartbeat (palpitation) or shortness of breath (dyspnea) are present at rest. If any physical activity is undertaken, discomfort increases.</td>
</tr>
</tbody>
</table>

### Table 2. American Heart Association heart failure stages

<table>
<thead>
<tr>
<th>Stage</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stage A</td>
<td>At high risk for heart failure but without structural changes or symptoms</td>
</tr>
<tr>
<td>Stage B</td>
<td>Structural heart disease but without signs or symptoms of heart failure</td>
</tr>
<tr>
<td>Stage C</td>
<td>Structural heart disease with prior or current symptoms of heart failure</td>
</tr>
<tr>
<td>Stage D</td>
<td>Refractory heart failure including specialized interventions</td>
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### Table 3. KCCQ group scores and averages

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Table 4. SPSS Calculation Tables

![Related-Samples Wilcoxon Signed Rank Test](image)

<table>
<thead>
<tr>
<th>Total N</th>
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<tr>
<td>Test Statistic</td>
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<tr>
<td>Standard Error</td>
<td>3.708</td>
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<td>Standardized Test Statistic</td>
<td>1.753</td>
</tr>
<tr>
<td>Asymptotic Sig. (2-sided test)</td>
<td>.080</td>
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</table>

**Hypothesis Test Summary**

<table>
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<th>Null Hypothesis</th>
<th>Test</th>
<th>Sig.</th>
<th>Decision</th>
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</thead>
<tbody>
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<td>The median of differences between Gp B KCCQOS baseline score and Gp B KCCQOS 3-month score equals 0.</td>
<td>Related-Samples Wilcoxon Signed Rank Test</td>
<td>.080</td>
<td>Retain the null hypothesis.</td>
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</table>

Asymptotic significances are displayed. The significance level is .05.

**Case Processing Summary**

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<th>Gp B KCCQOS baseline score</th>
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<th>Cases Excluded</th>
<th>Total</th>
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</thead>
<tbody>
<tr>
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<td>Percent</td>
<td>N</td>
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<tr>
<td>5</td>
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<table>
<thead>
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<th>Included</th>
<th>Cases Excluded</th>
<th>Total</th>
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<tbody>
<tr>
<td>N</td>
<td>Percent</td>
<td>N</td>
<td>Percent</td>
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</table>

<table>
<thead>
<tr>
<th>difference</th>
<th>Included</th>
<th>Cases Excluded</th>
<th>Total</th>
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<tbody>
<tr>
<td>N</td>
<td>Percent</td>
<td>N</td>
<td>Percent</td>
</tr>
<tr>
<td>5</td>
<td>100.0%</td>
<td>0</td>
<td>0.0%</td>
</tr>
</tbody>
</table>
Figure 1. QCM Model

Humans in relationships

Communities
Self
Patient goals & wishes
Personal experiences
Attitudes and beliefs
Support system

Intermediate outcomes
Acceptance
Symptoms managed
Wishes upheld
Improved outcomes as defined by patient

Relationship-centered professional encounters
Patient-Nurse,
Patient-Physician,
Patient-Family,
Patient-Self

Feel “cared for”
Confident in nurses’ knowledge in providing safety, comfort, anxiety relief, maintaining human dignity, positive experience of care

Self- Advancing Systems
Provide foundation for patient-centered care
Enhance collaborative practice
Facilitate staff-directed practice changes
Build relationships with community
Sustain professionalism
Balance “doing” with “being”
APPENDIX A
Huntsville Hospital IRB Exemption

April 24, 2018

Elizabeth Bolint, CRNP
Huntsville Hospital
101 Sivley Road, SW
Huntsville, AL 35801

RE: Request for Exemption from Institutional Review Committee Review -
"Integrating the Palliative Care Principles of Shared Decision Making and
Advance Care Planning into Routine Heart Failure Management"

Dear Ms. Bolint:

Thank you for forwarding the Institutional Review Committee Exemption from
Review Application to me for your proposed data collection study. Dr. John
Cox, Chair of IRC, and I have reviewed your information, and this study
qualifies and has been approved for Exemption from IRC review.

Please note: Any proposals or anticipated changes to the project must be
submitted to the IRC Coordinator and approved by the IRC Chair prior to
implementation. An Exemption from Review Update Form must be
submitted on an annual basis if the study remains open. When your project
closes, please advise me by letter or email.

Please contact Medical Records, for medical record access and HIPAA
compliance information, if necessary. If you have any questions or I can be of
further service, please feel free to call me at (256)265-6990.

Sincerely,

[Signature]
Allison E. Greene, Division Assistant/
Institutional Review Committee Coordinator

cc: John B. Cox, MD, Chair, IRC
    James Murphy, MD, Medical Director, CHF Clinic

/Enclosure
The UAH Institutional Review Board of Human Subjects Committee has reviewed your proposal, *Integrating the Palliative Care Measures of Shared Decision Making and Advance Directives into Routine Heart Failure Management*, and found it meets the necessary criteria for approval. Your proposal seems to be in compliance with this institution’s Federal Wide Assurance (FWA) 00019998 and the DHHS Regulations for the Protection of Human Subjects (45 CFR 46).

Please note that this approval is good for one year from the date on this letter. If data collection continues past this period, you are responsible for processing a renewal application a minimum of 60 days prior to the expiration date.
No changes are to be made to the approved protocol without prior review and approval from the UAH IRB. All changes (e.g. a change in procedure, number of subjects, personnel, study locations, new recruitment materials, study instruments, etc.) must be prospectively reviewed and approved by the IRB before they are implemented. You should report any unanticipated problems involving risks to the participants or others to the IRB Chair.

If you have any questions regarding the IRB’s decision, please contact me.

Sincerely,

Bruce Stallsmith
IRB Chair
Professor, Biological Sciences

Expedited:
☐ Clinical studies of drugs and medical devices only when condition (a) or (b) is met. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review. (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

☐ Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

☐ Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncamullated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.
☐ Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications).

☐ Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

☐ Collection of data from voice, video, digital, or image recordings made for research purposes.

☒ Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

**Exempt**

☐ Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. The research is not FDA regulated and does not involve prisoners as participants.

☐ Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interviews, or observation of public behavior in which information is obtained in a manner that human subjects cannot be identified directly or through identifiers linked to the subjects and any disclosure of the human subject’s responses outside the research would NOT place the subjects at risk of criminal or civil liability or be damaging to the subject’s financial standing, employability, or reputation. The research is not FDA regulated and does not involve prisoners as participants.

☐ Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement) survey procedures, interview procedures, or observation of public behavior if (a) the human subjects are elected or appointed public officials or candidates for public office, or (b) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. The research is not FDA regulated and does not involve prisoners as participants.

☐ Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner
that subjects cannot be identified, directly or through identifiers linked to the subjects. The research is not FDA regulated and does not involve prisoners as participants.

☐ Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs. The protocol will be conducted pursuant to specific federal statutory authority; has no statutory requirement for IRB review; does not involve significant physical invasions or intrusions upon the privacy interests of the participant; has authorization or concurrent by the funding agency and does not involve prisoners as participants.

☐ Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture. The research does not involve prisoners as participants.

Surveys, interviews, or observation of public behavior involving children cannot be exempt.
APPENDIX C

Kansas City Cardiomyopathy Questionnaire

The following questions refer to your **heart failure** and how it may affect your life. Please read and complete the following questions. There are no right or wrong answers. Please mark the answer that best applies to you. **Heart failure** affects different people in different ways. Some feel shortness of breath while others feel fatigue. Please indicate how much you are limited by **heart failure** (shortness of breath or fatigue) in your ability to do the following activities over the past 2 weeks.

<table>
<thead>
<tr>
<th>Activity</th>
<th>Extremely Limited</th>
<th>Quite a bit Limited</th>
<th>Moderately Limited</th>
<th>Slightly Limited</th>
<th>Not at all Limited</th>
<th>Limited for other reasons or did not do the activity</th>
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</thead>
<tbody>
<tr>
<td>Dressing yourself</td>
<td></td>
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<tr>
<td>Showering/Bathing</td>
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</tr>
<tr>
<td>Walking 1 block on level ground</td>
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<tr>
<td>Doing yardwork, housework or carrying groceries</td>
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</tr>
<tr>
<td>Climbing a flight of stairs without stopping</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Hurrying or jogging (as if to catch a bus)</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. *Compared with 2 weeks ago,* have your symptoms of **heart failure** (shortness of breath, fatigue, or ankle swelling) changed?

My symptoms of **heart failure** have become...
3. Over the past 2 weeks, how many times did you have swelling in your feet, ankles or legs when you woke up in the morning?

- Every morning
- 3 or more times a week, but not every day
- 1-2 times a week
- Less than once a week
- Never over the past 2 weeks

4. Over the past 2 weeks, how much has swelling in your feet, ankles or legs bothered you?

It has been...

- Extremely bothersome
- Quite a bit bothersome
- Moderately bothersome
- Slightly bothersome
- Not at all bothersome
- I've had no swelling

5. Over the past 2 weeks, on average, how many times has fatigue limited your ability to do what you want?

- All of the time
- Several times per day
- At least once a day
- 3 or more times per week but not every day
- 1-2 times per week
- Less than once a week
- Never over the past 2 weeks

6. Over the past 2 weeks, how much has your fatigue bothered you?

It has been...

- Extremely bothersome
- Quite a bit bothersome
- Moderately bothersome
- Slightly bothersome
- Not at all bothersome
- I've had no fatigue

7. Over the past 2 weeks, on average, how many times has shortness of breath limited your ability to do what you wanted?

- All of the time
- Several times per day
- At least once a day
- 3 or more times per week but not every day
- 1-2 times per week
- Less than once a week
- Never over the past 2 weeks

8. Over the past 2 weeks, how much has your shortness of breath bothered you?

It has been...

- Extremely bothersome
- Quite a bit bothersome
- Moderately bothersome
- Slightly bothersome
- Not at all bothersome
- I've had no shortness of breath

9. Over the past 2 weeks, on average, how many times have you been forced to sleep sitting up in a chair or with at least 3 pillows to prop you up because of shortness of breath?
10. **Heart failure** symptoms can worsen for a number of reasons. How sure are you that you know what to do, or whom to call, if your **heart failure** gets worse?

<table>
<thead>
<tr>
<th>Not at all sure</th>
<th>Not very sure</th>
<th>Somewhat sure</th>
<th>Mostly sure</th>
<th>Completely sure</th>
</tr>
</thead>
</table>

11. How well do you understand what things you are able to do to keep your **heart failure** symptoms from getting worse? (for example, weighing yourself, eating a low salt diet etc.)

<table>
<thead>
<tr>
<th>Do not understand at all</th>
<th>Do not understand very well</th>
<th>Somewhat understand</th>
<th>Mostly understand</th>
<th>Completely understand</th>
</tr>
</thead>
</table>

12. Over the *past 2 weeks*, how much has your **heart failure** limited your enjoyment of life?

<table>
<thead>
<tr>
<th>It has extremely limited my enjoyment of life</th>
<th>It has limited my enjoyment of life <em>Quite a bit</em></th>
<th>It has <em>moderately</em> limited my enjoyment of life</th>
<th>It has slightly limited my enjoyment of life</th>
<th>It has <em>not limited</em> my enjoyment of life at all</th>
</tr>
</thead>
</table>

13. If you had to spend the rest of your life with your **heart failure** the way it is *right now*, how would you feel about this?

<table>
<thead>
<tr>
<th>Not at all satisfied</th>
<th>Mostly dissatisfied</th>
<th>Somewhat satisfied</th>
<th>Mostly satisfied</th>
<th>Completely satisfied</th>
</tr>
</thead>
</table>

14. Over the *past 2 weeks*, how often have you felt discouraged or down in the dumps because of your **heart failure**?

<table>
<thead>
<tr>
<th>I felt that way <em>all of the time</em></th>
<th>I felt that way <em>most of the time</em></th>
<th>I occasionally felt that way</th>
<th>I rarely felt that way</th>
<th>I never felt that way</th>
</tr>
</thead>
</table>

15. How much does your **heart failure** affect your lifestyle? Please indicate how your **heart failure** may have limited your participation in the following activities over the *past 2 weeks*.

<table>
<thead>
<tr>
<th>Activity</th>
<th>Severely limited</th>
<th>Limited <em>Quite a bit</em></th>
<th>Moderately limited</th>
<th>Slightly limited</th>
<th>Did not limit at all</th>
<th>Does not apply or did not do for other reasons</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Hobbies, recreational activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Working or doing household chores</td>
</tr>
<tr>
<td>Visiting family or friends out of your home</td>
</tr>
<tr>
<td>Intimate relationships with loved ones</td>
</tr>
</tbody>
</table>
Appendix D

Participant Recruitment Script

Mr./Mrs. ____________, my name is Betsy Bolint. I am a nurse practitioner in the Heart Failure Clinic. We are trying to improve our care for our patients and want to ensure that you have a voice in your care. We feel that shared decision-making of including you and your family/caregiver in planning your care of heart failure and including your choices in those plans. We want you to understand what all of your options are, as well as the risks and benefits of each, so that you can help us know you consider to be important.

I would like to discuss with you about what heart failure is and why you feel how you do, the medications and procedures that we use to treat heart failure, and what you may be able to expect over time. Some other things I would like to talk about are more about you and your wishes, such as personal goals, what you consider to be a “high quality” life, what brings you joy, and what worries you most about having heart failure. I want to assure you that there are no “right” or “wrong” answers or choices, so please be completely honest in your responses.

Some parts of what I would like to talk about may be difficult or unpleasant, so if you feel uncomfortable at any point please feel free to let me know. I want you to understand that the treatment you receive in the heart failure clinic will not be affected in any way by what you tell me in this room or elsewhere. If you choose not to participate, you will continue to receive the same level of care in the clinic, and there will be no repercussions whatsoever. If you tell me at any point in time that you do not want to participate, I will shred all of your personal information.

At this point do you think you are interested in participating in this project?
Appendix E

Informed Consent Form

You are invited to participate in a research study about improving your health-related quality of life. This study is designed to help us to better understand what you would like us to know about guiding your care in regard to heart failure.

The primary investigator is Elizabeth (Betsy) Bolint from the University of Alabama in Huntsville and the Huntsville Hospital Heart Failure Clinic.

PROCEDURE TO BE FOLLOWED IN THE STUDY: Participation in this study is completely voluntary. Once written consent is given; you will be asked to participate in at least 1 individual discussion and complete a questionnaire. Topics that may be discussed include: your heart failure and some things you may experience as a result of disease progression, treatment options and choices you may be expected to make about your treatment, establishing personal goals and wishes, discussion of advance directives, and prognostication of disease. The questionnaire has 23 questions and asks how heart failure affects your quality of life in regard to symptoms such as shortness of breath, fatigue, and activity tolerance. This session is expected to last approximately 30 minutes. A second 30-minute session for further information and care coordination may be requested by the participant.

DISCOMFORTS AND RISKS FROM PARTICIPATING IN THIS STUDY: There are no expected health risks associated with your participation. You may become sad or emotionally upset during this study. If you continue to feel sad or upset, you can ask to speak with a Social Worker or Chaplain.

EXPECTED BENEFITS: Results from this study can improve your understanding and involvement in your care and will help the Heart Failure Clinic staff better understand how you would like to participate in decisions about your care.

INCENTIVES AND COMPENSATION FOR PARTICIPATION: There are no financial compensations or incentives for participation.

CONFIDENTIALITY OF RESULTS: Participant numbers will be used to record your data, and these numbers will be made available only to those researchers directly involved with this study, thereby ensuring strict confidentiality. This consent form will be destroyed after 3 years. The data from your session will only be released to those individuals who are directly involved in the research and only using your participant number.

FREEDOM TO WITHDRAW: You are free to withdraw from the study at any time. You will not be penalized because of withdrawal in any form. If you choose not to participate, you will continue to receive the same level of care in the clinic. Investigators reserve the right to remove any participant from the session without regard to the participant’s consent.
CONTACT INFORMATION: If you have any questions, please ask them now. If you have questions later on, you may contact the Principal Investigator Betsy Bolint in the Huntsville Hospital Heart Failure Clinic or at exb0002@uah.edu, or the Faculty Supervisor Dr. Rita Ferguson in UAH at through the University Graduate office at 256-824-6669 or email at: rf0001@uah.edu. If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the Office of the IRB (IRB) at 256.824.6101 or email the IRB chair Dr. Bruce Stallsmith at irb.@uah.edu.

If you agree to participate in our research, please sign and date below.

This study was approved by the Institutional Review Board at UAH and will expire in one year from May 31, 2018.

__________________________          ____________________
Name (Please Print)                             Signature                        Date

__________________________
Name of Legally Authorized Representative (Please Print)            Signature Date
Appendix F
Interview Topic Guide

Question wording and follow up will be tailored to patient circumstances and phrased sensitively and appropriately according to context.

- **Introduction.**
  - To researcher and study.
  - Nomination of lay and professional caregivers for study.
  - Issues of future consent and capacity.
    - Completion of advance statement of preferences.
  - Completion of consent to interview.
- **Background and current circumstances.**
  - Current health: what’s been happening?
  - Main issues related to illness and treatment
  - Who is providing care and support?
    - Informal.
    - Professional.
  - Current problems/concerns/coping?
- **Knowledge and understanding of illness and prognosis.**
  - Preferences for information: verbal, written, full, partial.
  - Adequacy and sources of information.
- **Making decisions and involvement in care.**
  - Preferences regarding involvement/responsibility for decisions about treatment.
    - Specific/general options and issues.
    - Caregivers involvement/influence in decisions (who).
    - Issues/concerns?
• Thinking about the future.
  • How does Patient see the future, at this point in time?
  • Discussed with others (who: family, friends, HCPs)?
  • Recorded preferences for future care? (As appropriate).
  • Advance directives
  • Healthcare power of attorney
  • Issues/concerns?

• Communication.
  • Review and reflection: how does patient feel about ease and quality of communication:
    • with informal caregiver(s)
    • with Health Professionals
    • issues/concerns?

• Conclusion
  • Anything else, not discussed?
  • Confirm personal details (if not known/as appropriate).
    • Age; former employment; illness history and duration; network of informal and professional support, family circumstances.

• Debriefing.
  • How does Patient feel after the interview?
    • Explore concerns, offer contacts for support, bring discussion to a neutral plane.
    • Arrangement for follow up.
    • Thanks!
Appendix G

KCCQ License Agreement

OUTCOMES Instruments, LLC

LICENSE AGREEMENT

THIS LICENSE AGREEMENT is made as of this 06 April 2018, by and between Outcomes Instruments, LLC, a for-profit organization in Missouri, whose address is 18 W. 52nd Street, Kansas City, Missouri, 64112, United States ("Licensor") and University of Alabama- Huntsville, a not-for-profit organization in Alabama, whose address is 15100 Wade Point Rd Se, Huntsville, Alabama, 35803, United States ("Licensee").

RECITALS

A. Licensor has rights in certain research methodologies, technical developments, know-how, discoveries, works of authorship, questionnaires, registries, study protocols, processes, datasets and other useful art, whether or not protected by patents, copyrights, trademarks, trade secrets or other laws protecting intellectual property rights, as more particularly described on Schedule A attached hereto and incorporated herein by this reference (the “Licensed Properties”).

B. Licensee is engaged in that certain study more particularly described on Schedule B attached hereto and incorporated herein by this reference (the “Subject Study”).

C. Licensor desires to grant Licensee the right to use the Licensed Properties solely in connection with the Subject Study, and Licensee desires to use the Licensed Properties in connection therewith, subject to all of the terms and conditions hereof.

NOW, THEREFORE, in consideration of the premises and the mutual promises and undertakings contained herein, the parties hereto agree as follows:

1. Subject to the terms and conditions hereof, Licensor grants to Licensee a non-exclusive, non-transferable, non-assignable limited license to use the Licensed Properties solely in connection with the conduct of the Subject Study.

2. As between Licensor and Licensee, Licensee acknowledges that Licensor retains all ownership rights in and to the Licensed Properties, and any improvements, modifications and derivatives thereof (whether prepared by Licensor or Licensee or otherwise), and that except for the rights granted hereunder, Licensee has no right, title or interest in and to the Licensed Properties. Licensee agrees to reproduce the appropriate copyright legends and/or trademark symbols on all written or displayed versions of the Licensed Properties and/or the results attributed to the use thereof. Licensee further acknowledges and understands that Licensor reserves the right to (i) grant others the license to use the Licensed Properties and (ii) use the Licensed Properties in its own research and investigations, without the need to account to Licensee in connection with such activities.
3. In consideration for the license granted hereunder, Licensee shall pay Licensor the license fees set forth on Schedule C attached hereto and incorporated herein by this reference, at the times, and in the manner, set forth on such Schedule.

4. Licensor represents and warrants to Licensee that Licensor has the full power and authority to execute and deliver this Agreement and to perform its obligations hereunder without need to obtain the consent of any third party.

5. Licensor shall have the right to inspect and observe from time to time through such agents or representatives as Licensor may designate, on Licensee’s site, the activities conducted by or for Licensee with respect to the Licensed Properties to determine whether Licensor is using the Licensed Properties in a proper fashion as provided hereunder. To the extent Licensor is granted access to a patient’s “protected health information” (“PHI”), as such term is defined in the Health Insurance Portability and Accountability Act of 1996 and the regulations promulgated thereunder, the parties agree to negotiate and execute a Business Associates Agreement containing customary covenants regarding the confidentiality and limited use of such PHI.

6. Licensee shall keep and maintain comprehensive and accurate records pertaining to its use of the Licensed Properties, and the status and progress of the Subject Study. Such reports shall be available for examination by Licensor and its agents or representatives at any time upon reasonable advance notice.

7. Licensee agrees that it shall use the Licensed Properties only as permitted hereunder and further agrees to refrain from modifying, altering or amending the Licensed Properties or taking any action which could adversely affect the validity, goodwill and reputation thereof. Upon the termination or expiration of this Agreement, Licensee shall immediately discontinue all use of the Licensed Properties.

8. As between Licensor and Licensee, only the Licensor shall have the right to commence or prosecute any claims or litigation to protect or enforce its rights in and to the Licensed Properties. Licensee agrees that it will immediately provide notice to Licensor upon learning of any litigation, whether actual or threatened, against Licensee in connection with Licensee’s use of the Licensed Properties. Licensee further agrees that it will cooperate fully with Licensor by providing any information requested by Licensor in any litigation arising in connection with Licensee’s use of the Licensed Properties.

9. LICENSEE ACKNOWLEDGES THAT THE LICENSED PROPERTIES ARE LICENSED “AS IS’, WITH ALL FAULTS. LICENSOR HAS MADE NO REPRESENTATION OR WARRANTY THAT THE LICENSED PROPERTIES ARE SUITABLE FOR LICENSEE’S USE IN CONNECTION WITH ITS SUBJECT STUDY. LICENSEE SHALL RELY ON ITS OWN JUDGMENT IN EVALUATING ITS USE OF THE LICENSED PROPERTIES AND ANY OUTCOMES ATTRIBUTABLE THERETO, WITHOUT RELYING ON ANY MATERIAL OR INFORMATION PROVIDED BY LICENSOR. LICENSOR DISCLAIMS ANY REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY REPRESENTATIONS OR WARRANTIES AS TO THE LICENSED PROPERTIES’ MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT SHALL LICENSOR BE LIABLE FOR SPECIAL, CONSEQUENTIAL, EXEMPLARY OR PUNITIVE DAMAGES. LICENSOR’S LIABILITY HEREUNDER SHALL BE LIMITED TO LICENSEE’S DIRECT DAMAGES RESULTING FROM LICENSOR’S BREACH OF ANY OF ITS OBLIGATIONS HEREUNDER WHICH CONTINUES UNREMEDIED FOR THIRTY DAYS AFTER WRIT TEN NOTICE BUT SHALL IN NO EVENT EXCEED THE AMOUNT OF THE FEES ACTUALLY PAID BY LICENSEE TO LICENSOR HEREUNDER.

10. Licensee hereby agrees to hold Licensor harmless of and from and indemnifies it against any and all losses, liabilities, claims, damages and expenses (including attorneys’ fees and expenses) which Licensor may incur or be obligated to pay, or for which it may become liable or be compelled to pay in any action, claim or proceeding for or by reason of any acts, whether of omission or commission, that may be claimed to be or are actually committed or suffered by Licensee arising out of Licensee’s use of the Licensed Properties. The provisions

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of this paragraph and Licensee’s obligations hereunder shall survive the expiration or termination of this Agreement.

11. Subject to Section 9 hereof, Licensor hereby agrees to hold Licensee harmless of and from and indemnifies it against any and all losses, liabilities, claims, damages and expenses (including attorneys’ fees and expenses) which Licensee may incur or be obligated to pay, or for which it may become liable or compelled to pay in any action, claim or proceeding for or by reason of any breach of any representation, warranty or agreement on the part of Licensor under this Agreement.

12. During the term of this Agreement, the parties may have access to trade secrets, proprietary information, or other sensitive materials belonging to the other which are not generally known to the public (“Confidential Information”). During the term of this Agreement and for a period of five (5) years after termination or expiration hereof, the receiving party (“Recipient”) agrees to maintain in trust and confidence all Confidential Information of the other party (the “Disclosing Party”). The Recipient agrees to safeguard the Confidential Information using the same standard of care it uses to protect its own Confidential Information. The Recipient will not disclose any Confidential Information to any third party, or make any use thereof other than as expressly permitted hereby, without the prior written consent of the Disclosing Party. As used herein, Confidential Information does not include any information which the Recipient can demonstrate (i) was known to the Recipient or to the general public at the time of disclosure; (ii) was independently developed by the Recipient without the use of any of the Confidential Information; or (iii) was disclosed by a third party without violating any restriction or duty to the Disclosing Party.

13. Notwithstanding the general restrictions set forth in Section 12 above, the parties agree that publication of the results of research activities serves their mutual interests in improving the quality of healthcare. Accordingly, Licensee shall be free to publish the results of its research and development activities carried out with respect to the Licensed Properties and the Subject Study. Licensee agrees to refer to Licensor and the Licensed Properties in the bibliography section of the publication.

14. Subject to the provisions of Section 15 hereof, this Agreement shall remain in effect from 04/04/2018 to 01/04/2019. Subsequent renewal of this Agreement shall be optionally available through application through the website.

15. Licensor shall have the right to immediately terminate this Agreement by giving written notice to Licensee in the event Licensee: (i) fails to perform any of its duties and obligations set forth herein, and the continuation thereof for thirty (30) days after notice; (ii) files a petition in bankruptcy or is adjudicated a bankrupt or insolvent, or makes an assignment for the benefit of creditors; (iii) makes any use of the Licensed Properties not otherwise expressly permitted herein or (iv) the Subject Study is cancelled, abandoned, withdrawn or suspended. In such event, Licensee shall immediately cease and terminate its use of any of the rights granted hereby and shall, upon the request of Licensor, return to Licensor all records, copies, documents, media and files making use of the Licensed Properties, or furnish evidence, satisfactory to Licensor, of the destruction thereof.

16. The parties further acknowledge that the breach, whether threatened or actual, of any of the terms hereof by Licensee shall result in immediate, irreparable injury to Licensor and its goodwill and that accordingly, Licensor shall be entitled to apply for a preliminary and/or permanent injunction to restrain the threatened or actual violation of the terms hereof by the Licensee or to compel specific performance of the terms and conditions of this License Agreement. Nothing set forth herein shall be construed as prohibiting the Licensor from pursuing any other remedies available for such breach or threatened breach, including the recovery of damages and costs incurred, together with attorneys’ fees.

17. 

a. This Agreement together with the exhibits hereto constitutes the entire understanding between the parties with respect to this Agreement. No change or modification of any of the provisions of this Agreement shall be effective unless memorialized by an instrument in writing signed by the parties hereto. All notices required or permitted to be given hereunder shall be given in writing, to the
parties at their addresses set forth herein, or to such other address with respect to which notice has been given in accordance herewith. Whenever possible, each provision of this License Agreement shall be interpreted in such a manner as to be effective and valid under applicable law. If any covenant or other provision of this Agreement, or portion thereof, under circumstances not now contemplated by the parties, is invalid, illegal or incapable of being enforced, by reason of any rule of law, administrative order, judicial decision or public policy, all other conditions and provisions of this Agreement shall, nevertheless, remain in full force and effect, and no covenant or provision shall be deemed dependent upon any other covenant or provision unless so expressed herein. The parties desire and consent that the court or other body making such determination shall, to the extent necessary to avoid any unenforceability, so reform such covenant, term, condition or other provision or portion of this Agreement to the minimum extent necessary so as to render the same enforceable in accordance with the intent herein expressed.

b. This Agreement shall inure to the benefit of Licensor, its successors and assigns. Licensee shall not have the right to assign this Agreement, or delegate its duties, by operation of law or otherwise, without first obtaining the written consent of Licensor.

c. This Agreement shall be governed by and construed in accordance with the laws of the State of Missouri.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed as of the day and year first above mentioned.

Outcomes Instruments, LLC *University of Alabama- Huntsville *

By: John Spertus
Title: President
“Licensor”

By:
Title: "Licensee"

SCHEDULE A: LICENSED PROPERTIES

KCCQ – English (US)
This version of the KCCQ has been validated among English-speaking residents of the US. This zip file includes two PDF files: the KCCQ itself and scoring instructions.

SCHEDULE B: DESCRIPTION OF STUDY

Project Name
Integrating the Palliative Care Principles of Shared Decision Making and Advanced Directives into Routine Heart Failure Management

Project Type
Quality Assessment/Improvement

Project Dates
Start: 04/04/2018
End: 01/04/2019
Duration: 275 days
Enrollment

Sites: 1
Average subjects per site: 150
Total enrollment: 150

Schedule of Use

Administer to subjects thus: every 30 days
Total uses per subject: 9
Total uses: 1,350

Sponsor Name

University of Alabama in Huntsville

Sponsor Type

Other

SCHEDULE C: LICENSE FEES & PAYMENT TERMS

Payment Terms
Payable on Receipt

Total Instrument Fees

$ 115.00

Total License Fee

$ 115.00
ADVANCE DIRECTIVE FOR HEALTH CARE (Living Will and Health Care Proxy)

This form may be used in the State of Alabama to make your wishes known about what medical treatment or other care you would or would not want if you become too sick to speak for yourself. You are not required to have an advance directive. If you do have an advance directive, be sure that your doctor, family, and friends know you have one and know where it is located.

I, __________________, being of sound mind and at least 19 years old, would like to make the following wishes known. I direct that my family, my doctors and health care workers, and all others follow the directions I am writing down. I know that at any time I can change my mind about these directions by tearing up this form and writing a new one. I can also do away with these directions by tearing them up and by telling someone at least 19 years of age of my wishes and asking him or her to write them down.

I understand that these directions will only be used if I am not able to speak for myself.

If I become terminally ill or injured:

Terminally ill or injured is when my doctor and another doctor decide that I have a condition that cannot be cured and that I will likely die in the near future from this condition.
Life sustaining treatment – Life sustaining treatment includes drugs, machines, or medical procedures that would keep me alive but would not cure me. I know that even if I choose not to have life sustaining treatment, I will still get medicines and treatments that ease my pain and keep me comfortable.

Place your initials by either “yes” or “no”: I want to have life sustaining treatment if I am terminally ill or injured. ____ Yes ____ No

Artificially provided food and hydration (Food and water through a tube or an IV) – I understand that if I am terminally ill or injured, I may need to be given food and water through a tube or an IV to keep me alive if I can no longer chew or swallow on my own or with someone helping me.

Place your initials by either “yes” or “no”: I want to have food and water provided through a tube or an IV if I am terminally ill or injured. ____ Yes ____ No

If I Become Permanently Unconscious:

Permanent unconsciousness is when my doctor and another doctor agree that within a reasonable degree of medical certainty I can no longer think, feel anything, knowingly move, or be aware of being alive. They believe this condition will last indefinitely without hope for improvement and have watched me long enough to make that decision. I understand that at least one of these doctors must be qualified to make such a diagnosis.

Life sustaining treatment – Life sustaining treatment includes drugs, machines, or other medical procedures that would keep me alive but would not cure me. I know that even if I
choose not to have life sustaining treatment, I will still get medicines and treatments that ease my pain and keep me comfortable.

Place your initials by either “yes” or “no”: I want to have life-sustaining treatment if I am permanently unconscious. ____ Yes ____ No

Artificially provided food and hydration (Food and water through a tube or an IV) – I understand that if I become permanently unconscious, I may need to be given food and water through a tube or an IV to keep me alive if I can no longer chew or swallow on my own or with someone helping me.

Place your initials by either “yes” or “no”: I want to have food and water provided through a tube or an IV if I am permanently unconscious. ____ Yes ____ No

Other Directions: Please list any other things you want done or not done.

In addition to the directions I have listed on this form, I also want the following:

_______________________________________________________________

_______________________________________________________________

If you do not have other directions, place your initials here:

____ No, I do not have any other directions.

This form can be used in the State of Alabama to name a person you would like to make medical or other decisions for you if you become too sick to speak for yourself. This person is called a health care proxy. You do not have to name a health care proxy. The directions in this form will be followed even if you do not name a health care proxy.
Place your initials by only one answer: _____ I do not want to name a health care proxy.

(If you check this answer, go to Section 3)

_____ I do want the person listed below to be my health care proxy. I have talked with this person about my wishes.

First choice for proxy: __________________________________________
Relationship to me: __________________________________________
Address: _____________________________________________________
City: ____________________________ State _______ Zip _______

Day-time phone number: ______________ Night-time phone number: __________

If this person is not able, not willing, or not available to be my health care proxy, this is my next choice:

Second choice for proxy: _________________________________________
Relationship to me: __________________________________________
Address: _____________________________________________________
City: ____________________________ State _______ Zip __________
Day-time phone number: ______________ Night-time phone number: __________

Instructions for Proxy

Place your initials by either “yes” or “no”: I want my health care proxy to make decisions about whether to give me food and water through a tube or an IV. _____ Yes
_____ No
Place your initials by only one of the following:

_____ I want my health care proxy to follow only the directions as listed on this form.

_____ I want my health care proxy to follow my directions as listed on this form and to make any decisions about things I have not covered in the form.

_____ I want my health care proxy to make the final decision, even though it could mean doing something different from what I have listed on this form.

I understand the following:

- If my doctor or hospital does not want to follow the directions I have listed, they must see that I get to a doctor or hospital who will follow my directions.

- If I am pregnant, or if I become pregnant, the choices I have made on this form will not be followed until after the birth of the baby.

- If the time comes for me to stop receiving life sustaining treatment or food and water through a tube or an IV, I direct that my doctor talk about the good and bad points of doing this, along with my wishes, with my health care proxy, if I have one, and with the following people:

________________________________________________________________________

________________________________________________________________________
Your name:

_______________________________________________________

The month, day, and year of your birth:

_________________________________                 Your signature:

____________________________________________________

Date signed: _______________________________________________________

I am witnessing this form because I believe this person to be of sound mind. I did not
sign the person’s signature, and I am not the health care proxy. I am not related to the
person by blood, adoption, or marriage and not entitled to any part of his or her estate. I
am at least 19 years of age and am not directly responsible for paying for his or her
medical care.

Name of first witness:

_________________________________________    Signature:

_________________________________________    Date:

_____________________________________________

Name of second witness: _________________________________

Signature:__________________________________________Date:_________________

________
I, ____________________________________________, am willing to serve as the health care proxy. Signature: _________________________________ Date:

_______________

Signature of Second Choice for Proxy:

I, __________________________, am willing to serve as the health care proxy if the first choice cannot serve.

Signature: ________________________________________ Date:

_______________
REFERENCES

http://dx.doi.org/10.1161/CIRCULATIONAHA.109.869123

http://dx.doi.org/10.1161/CIR.0b013e31824f2173

http://dx.doi.org/10.1016/j.jacc.2017.11.025


Implications for palliative care programs. *Journal of Palliative Medicine, 14*, 1317-1324. http://dx.doi.org/10.1089/jpm.2011.0179


85


priorities. *Journal of the American College of Cardiology, 70*, 1919-1930.

http://dx.doi.org/10.1016/j.jacc.2017.08.036

Kavalieratos, D., Kamal, A. H., Abernethy, A. P., Biddle, A. K., Carey, T. S., Dev, S., ...


Mentz, R. J., Tulsky, J. A., Granger, B. B., Anstrom, K. J., Adams, P. A., Dodson, G. C., ...


http://dx.doi.org/10.1016/j.jacc.2017.05.030


Spertus, J. (2016). *Medical device development tool (MDDT) qualification decision summary for Kansas City Cardiomyopathy Questionnaire (KCCQ)* [MDDT Qualification Decision Summary (MDDT020)]. Retrieved from Food and Drug Administration MDDT:
https://www.fda.gov/downloads/MedicalDevices/ScienceandResearch/MedicalDeviceDevelopmentToolsMDDT/UCM581761.pdf


http://dx.doi.org/10.1016/j.cardfail.2016.10.013

http://dx.doi.org/10.1161/CIR.0b013e31829e8776