Effectiveness of a telemonitoring and patient-centric health coach intervention for adult patients with heart failure: A quality improvement project

Linda Lee Tavares, MS, RN, ACNP-BC, AACC
Richmond, Virginia

BSN, Radford University, 1983
MSN, Virginia Commonwealth University: Medical College of Virginia, 2000

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Arlene Keeling, PhD, RN, FAAN _____
Signature of Chair

Dorothy Tullmann, PhD, RN _____
Signature of Member

Barbara Sorbello, PhD, RN, NEA-BC _____
Signature of Member

Shaival Kapadia, MD, FACC _____
Signature of Member

Abstract

Background: Telemonitoring interventions to prevent readmissions in patients with heart failure (HF) have shown inconsistent results in their effectiveness on HF-related and all-cause rehospitalization. Interventions geared toward early identification of HF symptoms in concert with improved care coordination and enhanced patient self-care may help to prevent unplanned hospitalizations in patients with HF. The Theory of Heart Failure Self-care provided the framework to understand and direct a combined telemonitoring and patient-centric health coach intervention (Tele-HC).

Objective: The purpose of this quality improvement project was to evaluate the outcomes of a Tele-HC intervention designed for older adult patients with heart failure in a community hospital setting.

Methods: The outcomes evaluation used a descriptive, cross-sectional observational design for the readmission rates. A one-group pretest-posttest design was used to measure self-care outcomes. Predictive models were tested using correlation and regression analysis.

Results: The 30-patients were primarily Caucasian, female with a mean age of 77.5 years. The majority of patients had HF with an ejection fraction ≤ 40%, NYHA class II or III symptoms, and received appropriate medical therapy. Health literacy was adequate in the sample. The 30-day all cause readmission rate was 6% with no patients being re-hospitalized for decompensated HF. Patient self-care scores improved with all three categories reaching statistical significance ($p < .0001$). Patients received mean of two touches daily during the first two weeks and a mean of three touches every two days

for the remainder of the study. A significant relationship existed between the number of touches during the first two weeks and improvement in self-care maintenance scores (p =.009). The number of touches moderately predicted changes in these scores (r = .426, p =.019). No direct correlation was drawn between touches and readmission rate, due to the data being skewed in favor of the intervention.

Conclusion: Strategies that engage patients as partners in their self-care and leverage technology appear to reduce readmissions and improve self-care outcomes.

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Table of Contents

Effectiveness of a telemonitoring and patient centric health coach intervention for adult patients with heart failure: A quality improvement project

Section I

Introduction and Background

Heart Failure and the Burden to Society

A perfect storm occurs when multiple factors, not one of which independently is devastating, converge thus creating a catastrophic force resulting in epic change (Emanuel & Fuch, 2008). Such a confluence of forces is as rare as it is devastating. Over time and through disconnected events, the United States (US) health care environment has evolved into a perfect storm (Emanuel & Fuch, 2008). Heart failure (HF) is at the pinnacle of the storm with the escalating combined societal public health burden and economic burden accelerated by the burden of rehospitalization in the context of a changing national health care system.

This significant public health burden affects approximately 6 million Americans, with 670,000 new cases of HF annually (Jessup et al., 2009; Lloyd-Jones et al., 2010; Roger et al., 2011). Heart failure is a clinical syndrome manifested by a constellation of diverse cardiac and non-cardiac abnormalities (Gheorghiade, Vaduganathan, Fonarow, & Bonow, 2013; Lindenfeld et al., 2010). The burden of chronic HF is associated with progressive decline in quality of life and impaired functional status characterized by suboptimal self-care behaviors and frequent hospitalizations, with up to 50% mortality within 5 years of diagnosis (Brandon, Schuessler, Ellison, & Lazenby, 2009; Rogers et al., 2012; Rose et al., 1999).

Heart failure diagnosis represents the single largest Medicare expenditure with the estimated direct and indirect annual cost of HF projected to reach $56 billion dollars in 2020 (Heidenreich et al., 2011). This staggering economic burden is accelerated by frequent hospitalization and rehospitalization in patients over the age of 65 accounting for approximately 1 million cases, 6.5 million inpatient hospital days, and 3.4 million ambulatory visits per year (Roger et al., 2011).

The Readmission Cycle

The rehospitalization burden is created by the nearly 30% readmission rate within 60 days post-discharge that accompanies the diagnosis of HF (Gheorghiade et al., 2013). The discharge from the acute care setting is a critical transition point, particularly for the elderly patient (Halasyamani et al., 2006). The causes of rehospitalization are multifactorial and often attributed to poor coordination of care transitions (Forster, Murff, Peterson, Gandhi, & Bates, 2003; Naylor et al, 1994).

The thirty-day readmission rate for Medicare patients is 25%, representing two million beneficiaries, resulting in $18 billion Medicare dollars annually for unplanned hospitalization (Centers for Medicare & Medicaid Services (CMS), 2010; Jencks, Williams, & Coleman, 2009) with rates similar in patients with either preserved or reduced ejection fraction (Fonarow et al., 2007). This burden is recognized by accreditation, regulatory, government agencies that are targeting 30-day hospital readmission as a sign of poor quality, safety, and unwarranted cost related to patient outcomes (Axon & Williams, 2011). This publicly reported data is linked to certifications, accreditations, and reimbursement with current payment adjustment including payment denial and financial penalties (Axon & Williams, 2011; CMS, 2008).

The drivers of readmission are multifactorial and often attributed to fragmented transitions from the hospital to the home or skilled facility due to a lack of communication, a lack of care coordination, and poor self-care (Bennett et al., 1998; Forster, Murff, Peterson, Gandhi, & Bates, 2003; Naylor, et al., 1994). Other behavioral factors including lack of adherence to medication, diet, and weight monitoring, combined with lack of economic resources, or lack of social support frequently contribute to rehospitalization (Jessup et al., 2009; Krumholz et al., 1997). The patients most vulnerable to readmission are often the elderly who possess a myriad of co-morbid conditions resulting in polypharmacy, functional limitations, psychosocial factors, and transportation issues embedded in a fragmented transitional process (Milone-Nuzzo & Pike, 2001; Naylor, Bowles, & Brooten 2000). Self-care deficits, lifestyle choices, and sub-optimal symptom management surrounding HF contributes to the rehospitalization burden (Bennett et al., 1998).

A New Era in Health Care

The demand for improved patient outcomes, such as readmission rates and lower health care costs are fueling a powerful change within the American health care system (Baily, Bottrell, Lynn, & Jennings, 2006; Classen et al., 2011). These changes are now legislated by the Patient Protection and Affordable Care Act (PPACA) of 2010. Goals of the act are to improve quality of care, optimize patient access, improve care coordination, reduce cost, improve efficiency, reduce unplanned hospitalizations and readmissions, modernize the health care experience, and engage the patient as an active participant in their care (Goodson, 2010; Holtrop & Jordan, 2010; Lanese, Dey, Srivastava, & Figler, 2011). These goals are promoted through positive and negative incentive programs.

For example, the *meaningful use* program involves provider and hospital use of a certified electronic medical record with a patient access portal. Currently tied to this program is approximately $30 billion dollars in incentives with the threat of reduced payments for those that fail to comply with the changes. One of the many goals of meaningful *use* is to promote patient engagement in their care by providing access to their medical information (U.S. Department of Health and Human Services (HHS, 2010). Conversely, beginning in the end of 2012, the Hospital Readmissions Reduction Program of PPACA began downward adjustment of Medicare reimbursement to penalize hospitals for readmissions (Joynt & Jha, 2012; Roger, 2013).

Transitional care deficits. The concept of transitional care as defined by the American Geriatric Society is an "asset of actions designed to ensure the coordination and continuity of healthcare as patients transfer between different locations or different levels of care" (Coleman & Boult, 2003, p. 556). Although the Institute of Medicine (IOM) (2001) heralds communication among and between caregiver teams, patients, and families as critical to providing high-quality care, a patient's transitional care experience is often poorly coordinated due to deficiencies in communications coupled with a multitude of socio-demographic and economic factors (Roger et al., 2011). This fragmentation is often due to numerous patient interactions with varied health care settings and a myriad of providers among multiple disciplines.

Patient care remains authoritarian. The PPACA address transitions of care by promoting reimbursement for care coordination and shifting the focus to the patient experience (Stone & Hoffman, 2010). PPACA attempts to place the patient at the nucleus of their health care experience by requiring providers to collaborate and integrate

care delivery ("Patient centered medical home resource center," n.d.). The patient with chronic diseases is thereby provided a continuum of care from disease prevention to treatment and palliation and ultimately end of life ("Patient centered medical home resource center," n.d.). Patient-centered care, one of the IOM characteristics of an effective health care system, is an approach whose goal is to empower patients to become active participants in their own care (IOM, 2001; Reynolds, 2009). The elements of a patient-centered approach include enhanced provider-patient communication, health literacy with clinician directed patient education, assessment of patient-centered outcomes, shared decision-making, collaborative care planning, and goal setting (IOM, 2001).

Unfortunately, despite all of these initiatives, physicians and other providers continue to use authoritarian strategies during health care interactions with patients (Frosch, May, Rendle, Tietbohl, & Elwyn, 2012). In a qualitative study of well-educated, predominately female, affluent patients, mean age 65, Frosch and colleagues (2012) discovered patients hesitated to share their opinions with providers for fear of challenging the relationship. The patient's desire to collaborate with their physicians was dependent upon the physician's willingness to participate. The participants expressed concern at being labeled as "difficult." The participants further verified the presence of an inherent power differential and that providers perpetuated an authoritarian stereotype with fear of retribution if they challenged or questioned a physician's advice or recommendation. While patient-centered care ideologically revolves around the patient, current health care interactions continue to conform to traditional socially sanctioned roles placing the provider in the authoritarian role (Frosch et al., 2012).

Patient-centric healthcare and patient generated health data. *Patient-centric healthcare* embraces elements of the patient-centered model, while systematically placing the patient at the genesis of all information and interactions often using technology as an information conduit (Scher, 2012). Placing technology in the patient's hands allows transmission of clinically relevant data in real time outside of the traditional care setting. Patient-generated health data (PGHD) refers to data that is generated and directed for distribution by the patient (Shapiro, Johnston, Wald, & Mon, 2012). PGHD, once filtered and synthesized enhances the communication experience between the patient and the healthcare provider (Scher, 2012; Shapiro et al., 2012). The provider and patient collaboratively manage the data, thereby becoming equal partners in the healthcare experience (Frosch et al., 2012; Scher, 2012). Patient-centric healthcare encourages patient self-management of their health conditions, particularly HF (Walsh et al., 2012), and highlights the importance of caregiver and community involvement (Scher, 2012).

Non-pharmacological Interventions

Several decades of research supports the importance of evidence-based medical and device therapy in management of HF patients to meet the challenges of limited health care resources in the face of the goals and limitations of PPACA (Kulshreshtha, Kvedar, Goyal, Halpern, & Watson, 2010). Additionally, the international HF guidelines highlight the importance of monitoring signs and symptoms, optimizing medications, providing education, facilitating self-care, and care coordination (Yancy et al., 2013). Currently, a mounting body of evidence suggests that non-pharmacological interventions implemented by multidisciplinary teams across the health care continuum can reduce hospitalizations and improve self-care for patients with HF (McAlister, Stewart, Ferrua,

& Murray, 2004; Naylor 2000). These include telemonitoring and encouraging patient self-care through health coaching by specialized heart failure nurses.

Telemonitoring. Telemonitoring (TM), the use of remote monitoring technology, has become an integral part of transitional care for adult patients with HF (Kulshreshtha et al., 2010; Roger, 2013). Remote TM programs acquire and securely transmit data on a patient's HF status to health care teams, alert providers to early signs of clinical decompensation, and create opportunities for timely interventions (Kulshreshtha et al., 2010). The potential secret weapon of TM is the engagement of the largest health care workforce in the world, that of the patient and their caregivers (Cleland, Lewinter, & Goode, 2009).

The data collected via TM bridges the communication gap between the patient and the health care team in an effort to improve patient outcomes (Benatar, Bondmass, Ghitelman, & Avitall, 2003; Chaudhry, Barton, Mettera, Spertus, & Krumholz, 2007). TM technology allows patients to receive care in a variety of settings and forms rather than exclusively during face-to-face interaction (Chaudhry, Phillips, et al., 2007; IOM, 2001). Additionally, the patient-generated data allows them to link behaviors with consequences, such as nonadherence to diet with weight gain (Kulshreshtha et al., 2010).

However, TM interventions to prevent readmissions in HF have shown inconsistent results in their effectiveness on HF-related and all-cause rehospitalization (Roger, 2013). This variability highlights the complexity of managing patients with HF and the challenges in readmission prevention. Today's chronically ill, vulnerable seniors have a higher acuity than in previous years at the time of hospital discharge. They often require extensive home assistance, close outpatient monitoring, skilled nursing, physical,

and occupational therapy. These vulnerable seniors are often being cared for at home by an elderly, frail, and chronically ill spouse (Milone-Nuzzo & Pike, 2001; Neal, 2004).

Self- care. Health care professionals often operate from a paradigm that knowledge translates into behaviors and thus improves clinical outcomes (Gwadry-Sridhar et al., 2005). However, reality typically heralds that treatment adherence has little relationship to knowledge (Durose, Holdsworth, Watson, Przygrodzka, 2004). Self-care programs aim to empower the patient to assume the primary role in managing their condition (Jovicic, Holroyd-Leduc, Straus, 2006).

Self-care is a decision-making process involving the choice of behaviors aimed at maintaining physiologic stability (Riegel et al., 2004). These behaviors include symptom monitoring, treatment adherence, and purposeful engagement in a behavior response to manage symptoms when they occur (Riegel et al., 2004). Self-care is a decision-making process involving the choice of behaviors such as symptom monitoring and treatment adherence, which maintain physiologic stability and engages a response to symptoms when they occur (Riegel et al., 2004).

Health coaching. Health coaching, rooted in motivation and education, is an integrative process of partnering with patients using a patient-centric approach to change behavior through an engaged, structured, and supportive partnership (Huffman, 2007). In the chronic disease population including HF, the goal is to facilitate patient self-management strategies for the purposes of preventing disease exacerbation and hospitalization (Huffman, 2007). The health coach uses motivational interviewing (MI) to activate patient self-care and confidence in their ability to change (Miller, Zweben, DiClemente, & Rychtarik, 1992).

Motivational interviewing includes expressing empathy and fostering identification of discrepancies between the current behavior and the behavior needed to achieve goals (Miller et al., 1992). Techniques used in MI include open-ended questions, affirmation of strength, reflective listening, summarizing what the listener has heard, and avoiding arguments (Miller et al, 1992; Miller & Rollnick, 2013). The health coach MI model embraces the complex interactions of motivations, cues to actions, influence of environment, culture, and values, perceptions of benefits and consequences, expectations, state of readiness, ambivalence, self-care, and implementation intentions (Linden, Butterworth, & Prochaska, 2010). The approach is not patriarchal or authoritarian, but rather patient centric and collaborative (Ossman, 2004).

Innovative technologies

Opportunities for innovative delivery models are abundant as a changing health care systems moves toward patient-centricity with patient generated health data coupled with an emphasis on transitional care coordination (Bailey et al., 2006; Chaudhry et al., 2010; Cleland, Louis, Rigby, Janssens, & Balk, 2005; Dahl & Penque, 2000; DeBusk et al; Kasper et al., 2002; Krumholz et al., 2002; Naylor et al., 2004; Scher, 2012). For the HF population, the use of technology to monitor patient clinical status at home in concert with a health-coach is a viable model to engage patients in self-care behaviors, close the patient-provider communication gap, foster patient autonomy, and enhance the patient experience (Gellis et al., 2012). Therefore, the purpose of this project was to evaluate the outcomes of a combined telemonitoring and patient-centric health coach (Tele-HC) intervention on 30-day readmission (HF and all cause) for adult patients, age 65 or greater, with HF from a community hospital setting. In addition, changes in self-care

behaviors will be assessed. The primary hypothesis of the study was that Tele-HC would result in a reduction in hospitalization rate for adult patients recently hospitalized for acute decompensated HF. The second hypothesis was that Tele-HC would result in improved Self-care of Heart Failure Index scores.

Theoretical Framework

The Theory of Heart Failure Self-care, a situation-specific theory developed and defined by Riegel and Dickson (2008), provides the framework for this quality improvement project (see Appendix A). The concept of self-care is rooted in Orem's Self- care Deficit theory with the basic idea of engaging patients in their care (Taylor & Orem, 2006). Self-care corresponds to health related behaviors performed by an individual on their behalf to maintain health, life, personal development, and well-being (Orem, 2001).

Orem (2001) further describes three types of limitations for self-care which include limitations of knowing, limitations in decision making and judgment, and limitations in engaging in results- achieving courses of action. Self-care behaviors are identified in the literature as an essential component of HF management and associated with reduction in frequent hospital readmissions and exacerbations among HF patients (Artinian, Magnan, Sloan, & Lange, 2002; Paradis, Cossette, Frasure-Smith, Heppell, & Guertin, 2010; Riegel & Dickson, 2008). Riegel and Dickson (2008) augment Orem's (2001) theory with specific application to the HF population.

Stages of the Model

The theory of heart failure self-care is a continuum composed of five stages whereby a patient moves from self-care maintenance to self-care management (Riegel &

Dickson, 2008). The authors further identify self-confidence as a mediator and /or moderator between the stages (Riegel & Dickson, 2008). Self-care maintenance is operationalized to include behaviors to maintain physiological stability such as symptom monitoring and treatment adherence (Riegel & Dickson, 2008). Self-care management reflects an active, deliberate decision making process in response to symptoms (Riegel & Dickson, 2008). Self- care maintenance and management provide the canopy for the five underlying progressive stages. Self-confidence undergirds the individual's progression, and is strengthened as the individual moves through the stages.

Stage 1, *symptom monitoring and treatment adherence*, reflects the patient's awareness of symptoms related to their condition and their adherence with the treatment plan (diet, daily weight, medication, and exercise). Stage 2, *symptom recognition*, is the first stage entering self-care management. The patient becomes aware of a status change such as increased dyspnea, weight gain, or edema. In a validation study of the theory by the Riegel and Dickson (2008), symptom recognition correlated significantly with treatment ($p = 0.003$). Stage 3, *symptom evaluation*, requires the patient to evaluate the change in status to prompt a decision to take action. The action manifests as *treatment implementation* in Stage 4, and culminates with treatment *evaluation* in Stage 5 (Riegel & Dickson, 2008).

The patient navigates the model using the experience of *naturalistic decision-making* (Lipshitz, Klein, Orasanu, & Sales, 2001). Naturalistic decision making (see Appendix B) is characterized by " (1) focusing on process rather than outcome, (2) using decision rules that match the situation and the action, (3) letting context influence decision making, and (4) basing practical decisions on empirical information available at

the moment" (Riegel & Dickson, 2008, p. 192). Thus, individuals make decisions about engaging in self- care behaviors based upon the situation influenced by their knowledge, experience, skill, and values (Riegel & Dickson, 2008).

Self-care confidence serves as both a mediator and moderator in the model. A mediator may be viewed as the "why" or the "how" (Kraemer, Wilson, Fairburn, & Agras, 2002). A moderator may be viewed as the "on whom" or "under what conditions" (Kraemer et al., 2002). For example, pipes bringing water to the sink serve as the mediator of the water and the faucet serves to moderate the water flow and temperature (Joel Anderson, PhD, 2013).

Self-confidence as a mediator and influenced by social support, improves the patient's confidence in their ability to manage HF symptoms. Self-confidence mediates and facilitates the patient's transition from self-care maintenance to more autonomous self-care management behaviors (Riegel & Dickson, 2008). Self-confidence moderates and improves as the individual transitions from self-care maintenance behaviors to self-care management behaviors (Riegel & Dickson, 2008).

Section II

Review of the Literature

A systematic review of literature and critical appraisal was conducted via EBSCOhost, using multiple databases including Ovid MEDLINE, CINAHL, Cochrane Library, the Agency for Healthcare Research and Quality (AHRQ), Google Scholar, and CardioSource®. The questions guiding the search were:

1. What is the effectiveness of telemonitoring for adult patients with HF in reducing readmissions?

2. What is the effectiveness of health coaching in the HF population?

3. What are the models being used to assess self-care in the HF population?

A series of searches was performed August 2011 through January 2013 using keywords heart failure, telemonitoring (telemedicine), transitions of care, transitional care, self-management (self-care), health coach, mobile phone (cellular phone), motivational interviewing, and patient-centered care throughout multiple disciplines. The combination of heart failure and telemonitoring yielded 335, heart failure and self-management yielded 514 articles and cellular phone, heart failure, and telemonitoring yielded 13. These combinations were reduced by inclusion criteria.

The inclusion criteria for the electronic search weremeta-analysis, randomized control trials (RCT), secondary analysis of the primary RCT, cohort studies, or pilot studies. The studies were written in English, published in peer-reviewed journals from multiple disciplines and international sources between 2002 and 2012. Criteria for the telemonitoring (TM) studies were interventions involving electronic telemonitoring compared to usual care. Interventions had to include the use of electronic monitoring

equipment to measure the patient's blood pressure (BP) and/or weight (at a minimum), and transmit the data using some form of technology to a health care provider location. Additional inclusion criteria were adult patients, over the age of 65, with HF and primary outcomes of rehospitalization or time to rehospitalization following TM intervention.

Health coach studies evaluated included the term "health coach" or "motivational interviewing" as the intervention in patients with HF or cardiovascular disease including the equivalent, diabetes. Self-care studies included use of the Self-care for Heart Failure Index (SCHFI) or other tools to assess self- management in patients with HF or chronic disease in conjunction with a health coach or TM intervention. Qualitative studies were included to provide an enriched context of self-care, health coaching, and motivational interviewing. Excluded were case studies, multiple case series, and editorial literature.

Following abstract review of the studies that met inclusion criteria, the final yield was 75 studies; each article was reviewed with 23 studies being included for analysis. Ancestral review identified three meta-analysis and six additional studies that were included in the review. Two qualitative studies evaluating of self-care in heart failure were included to help define the concept in the population of interest. Critical analysis of the quantitative studies included identifying the study design, sample, setting, independent variables, dependent variables, and outcomes. The study design, statistical analysis, and limitations were evaluated using the Consolidated Standards of Reporting Trials (CONSORT) format. Highlights of the review including intervention, outcomes, and pertinent analysis are presented in Tables 1, 2 and 3.

Telemonitoring

Telemonitoring (TM), the use of communication technology to monitor patient

clinical status, allows patients to receive care in a variety of settings and forms rather than exclusively during face-to-face interactions (Chaudhry, Phillips, et al., 2007; IOM, 2001). The term 'telemonitoring' describes a myriad of interventions from nurse-generated telephone follow-up to automated home monitoring equipment or implantable devices. These interventions measure and record blood pressure (BP), oxygen levels, heart rate (HR), EKG, and weight. Telemonitoring interventions have been developed to improve patient outcomes and reduce the high costs associated with HF. (Seto et al., 2012a).

In the HF population, the results from trials that examined transitional care models have been inconsistent, largely due to diverse interventions under investigation and varying study designs (Seto et al., 2012b). Inconsistencies existed in the literature regarding the fundamental components of a successful TM intervention including modality of data transmission, frequency of data transmission, which data points are most predictive in preventing hospital readmission, and who monitors the data (see Table 4). Additionally, although 30-day readmission prevention is the focus in the current American health care system, most of the research used a longer outcome window.

Components of telemonitoring. The literature lacked consensus regarding the fundamental components necessary for TM program to achieve significant outcome results. While the majority of the studies reviewed used transmitted physiologic data, variability existed regarding the additional components of the monitoring intervention. These included disease management programs, incorporating video surveillance, nurse generated calls, and self-reported responses to questions about lifestyle and treatment adherence.

The multicenter SPAN-CHF II trial compared 90-day readmission rates in

patients with NYHA class II-III HF (Weintraub et al., 2010). The control group received traditional HF disease management versus disease management plus automated TM. The TM was only 50% effective at preventing readmission in the sample of primarily white men with NYHA class II-III HF (Weintraub et al., 2010). The Home or Hospital in Heart Failure study (HHH) compared 12-month readmission rates for three groups using a combination of automatic interactive voice responses, nurse calls, vital signs and additional cardiopulmonary data (Mortata et al., 2009). No significant difference in HF rehospitalization rates was noted at the one-year endpoint.

The majority of the studies received transmitted data via a phone line to an internet server; however, several studies used a combination TM with video technology. A prospective three-part randomized trial compared usual home health care to home health plus TM with an electronic device, and a third arm adding a video component that included a digital stethoscope to the TM plus home health model (Dansky, Vasey, & Bowles, 2008). The TM and TM plus video groups had fewer hospitalizations at 60 days with significance reached after controlling for number of home care days (Dansky et al., 2008). Likewise, a study of mainly men with NYHA class III HF treated with daily TM transmission of physiologic data plus weekly video conference with the nurse, favored the video-TM intervention in reducing 90-day readmission, but did not achieve statistical significance (Woodend et al., 2008). Conversely, a RCT comparing a videophone TM intervention with physiological data monitoring to usual care, reported that video-TM had no added effect over usual home care (Bowles, Riegel, Weiner, Glick, & Naylor, 2010).

Patient response to automated questions was another strategy used to monitor HF patients. Self-reported answers to daily questions regarding medication adherence, HF

symptoms, and diet was used as the exclusive intervention in the TEHAF study of 382 HF patients (Boyne et al., 2012). Four sets of dialogue questions were customized for the patient with their answers transmitted to a nurses' desktop computer. Answers that fell outside of the parameters were automatically corrected by the device, visible to the patient, and alerted the nurse. The intervention resulted in fewer hospital readmissions at one-year, but did not reach statistical significance (Boyne et al., 2012).

Patient generated calls to an interactive system of questions about HF symptoms in addition to self-reported weight did not produce a significant reduction in 180-day hospitalization in the large Tele-HF trial (Chaudhry et al., 2010). Adherence to the program fell to 55% by the end of the study. Likewise, no significant difference in 180-day hospitalization rate was achieved in the HOME-HF study (Dar et al., 2009). This study combined simple "yes" or "no" questions with the transmission of physiological data compared with usual care (Dar et al., 2009). Conversely, significant reduction in 90-day rehospitalization was achieved with a three-part intervention combining patient responses to text questions, TM of physiologic data, and disease management in the SPAN-CHF II trial (Weintraub et al., 2010). Likewise, weekly nurse generated calls to review symptoms, adherence, lifestyle, blood pressure and weight in conjunction with transmitted EKG, achieved a significant reduction in 1-year readmit rates with curves diverging at 150 days (Giordano et al., 2009).

Frequency of data transmission. The frequency of data transmission varied in the studies with the majority using daily data transmission. The remainder of the studies used either weekly transmission or added a secondary intervention to the otherwise daily data transmission. Of the 18 studies reviewed, only three achieved statistical significance

in reducing HF hospitalization. Daily monitoring of physiologic data (blood pressure, weight, heart rate, and oxygen saturation) significantly reduced 90-day HF hospitalization in patients with NYHA class III-IV HF (Benatar, Bondmass, Ghitelman, & Avitall, 2003). Daily monitoring combined with a protocol driven disease management program reached statistical significance in reducing reduced 90-day HF hospitalization for patients with NYHA class II-III HF by 50% (Weintraub et al., 2010).

Weekly evaluation of cardiopulmonary data via TM in a cohort with 96% adherence rate, did not demonstrate significant reduction in HF readmission or hospitalization (Mortara et al., 2009). Conversely, a TM intervention of weekly nurse phone calls to assess patient self-reported BP, weight, adherence, and symptoms of HF combined with electronic EKG transmission in a predominantly male patients with New York Heart Association (NYHA) class III HF, achieved statistical significance in reducing HF readmission at 1 year (Giordano et al., 2009). Notably, the time to readmission curves remained similar until day 100, and diverged favoring TM in a relatively flat pattern (Giordano et al., 2009).

The combination of twice-weekly video review of symptoms in addition to daily transmission of physiologic data favored reduction in 60-day rehospitalization in HF patients (Dansky et al., 2008). This result reached significance after controlling for number of home care days. Conversely, neither the use of weekly video conference in addition to daily transmission of physiologic data (Woodend et al., 2008) or twice daily data transmission combined with monthly nurse phone support (Cleland et al., 2005) achieved significant reduction in HF hospitalization in two studies.

Data points. The TM data points varied throughout the literature. Two studies

focused exclusively on a single data point in the TM intervention. The remainder of the studies used multiple physiological data points or a combination of physiologic data and disease related questions. Chaudhry and colleagues (2007) identified the value of monitoring daily weight to predict HF hospitalization in their case-control study of patients with predominately NYHA class III HF. Gradual weight gain in patients with HF began 30-days prior to hospitalization with curves diverging more substantially within a week prior to hospitalization (Chaudhry, Wang, Concato, Gill, & Krumholz, 2007). In the RCT of primarily men with severe HF recently hospitalized for HF and on optimal HF therapy, monitoring of daily weight did not significantly reduce rehospitalization (Lyngå et al., 2012).

In the multicenter Tailored Telemonitoring in Patients with HF (TEHF) trial of primarily male participants with NYHA class II HF, no physiologic data were transmitted, rather answers to questions about patient symptoms, knowledge, and behavior (Boyne et al., 2012). The two groups remain congruent in 1-year HF readmission, but noted divergence of the Kaplan-Meier curves at 2 months (Boyne et al., 2012). Subgroup analysis revealed a more significant outcome in the TM group where participants had been diagnosed with HF less than 18 months (Boyne et al., 2012).

The 90-day intervention of monitoring multiple physiologic markers in predominantly African American female patients with NYHA class III-IV HF significantly decreased HF readmission rates compared with nurse home visit (Benatar et al., 2003). In the Tele-HEART study of adults mostly with HF (81%), daily TM was used to follow multiple physiologic markers (Gellis et al., 2012). The hospitalization rate at one year favored the intervention group and was significant at reducing emergency

room visits (Gellis et al., 2012). Likewise, participants in the TEMA-HF 1 study who were monitored daily for blood pressure, weight, and heart rate were less likely to be admitted for HF at 180 days (Dendale et al., 2012).

Combining telemonitoring of daily physiologic data with additional monitoring modalities achieved significance in two of the trials. The combined TM with at least two weekly video sessions with a nurse to review symptoms, and examine the patient with a digital stethoscope in addition to usual home health care significantly reduced 60-day rehospitalization in patients with HF (Dansky et al., 2008). Likewise, combining daily text messages related to symptoms, functional status and adherence with TM of physiologic data reduced 90-day HF rehospitalization in patients with NYHA class II-III HF (Weintraub et al., 2010).

A pilot randomized control trial (RCT) by Schwarz (2008) using TM of daily weights and answers to simple questions about symptoms in a predominantly-white 50% female sample, with 79% reporting NYHA class III-IV found no significant difference in HF readmit compared with the usual care group. Likewise, in a study of 82% men with NYHA class III-IV HF, Seto and colleagues (2012) found no difference in admits using transmission of daily weight, BP, and responses to simple questions. The authors attributed this finding to the under powering of the sample.

A meta-analysis of RCTs and cohort studies with over 8000 patients, defined TM to encompass phone calls, phone calls plus home visit, external monitoring devices (using a variety of modalities for transmission), and implantable devices in the TM group, found TM to be statistically significant in reducing the risk of HF readmits (Klersy, De Silvestri, Gabutti, Regoli, & Auricchio, 2009). A meta-analysis of 14 RCT with a pool of

4200 patients with chronic HF, evaluated TM compared with structured telephone support (Clark, Inglis, McAlister, Cleland, & Stewart, 2007). Although TM reduced HF admission by 20%, statistical significance was not achieved (Clark et. al., 2007). In an updated 2011 meta-analysis that added 11 studies, the same researchers noted that both TM and structured telephone support reduced HF related hospitalizations with relative risk reduction of 0.79 and 0.77 respectively (Inglis et al., 2010).

Who should monitor the data? The literature overwhelmingly uses nurses to monitor the data with favor toward nurses specially trained regarding HF (Bowles et al., 2010; Boyne et al., 2012; Chaudhry, Wang, et al., 2007; Cleland et al., 2005; Dansky et al., 2008; Dar et al., 2009; Gellis et al., 2012; Lyngå et al., 2012; Weintraub et al., 2010). Advanced practice nurses (APN) monitor the data in three studies (Benatar et al., 2003; Schwarz, Mion, Hudock, & Litman, 2008; Seto et al., 2012a), and physicians were involved in data monitoring in four studies (Giordano et al., 2009; Koehler, et al., 2011; Mortara et al., 2009; Seto et al., 2012). No correlation of superiority was noted in any of the models.

For example, of the three studies using APNs to monitor data, the model that included APN home visits proved significant in reducing rehospitalization (Benatar et al., 2003). Physician monitoring of daily transmitted BP and weights was neutral in preventing HF readmissions (medial follow up of 26 months) in the TIM-HF study (Koehler, et al., 2011). Likewise, the impact of physician involvement in monitoring TM data is unclear based on the results of two trials using a physician- nurse collaboration model. First, no significant differences were noted in outcomes of the HHH study of patients with NYHA class II-III HF (Mortara et al., 2009). Conversely, significance was

achieved with a TM intervention that included weekly review of data using a physician-nurse model (Giordano et al., 2009). A unique model of general practitioners monitoring data in collaboration with HF nurses and or cardiologists favored the TM group to decrease HF related hospitalizations, but noted no difference in all cause hospitalization in the TEMA-HF study (Dendale et al., 2012).

Therefore, the question remains what type of TM is the best, what elements are most important, who is best equipped to monitor the data, and how often should data be transmitted for evaluation, and which data points are most predictive in preventing rehospitalization? The data suggests that some type of monitoring is better than no monitoring, but what one system works most consistently to reduce rehospitalization and is easily reproducible? The current Centers for Medicare and Medicaid (CMS) endpoint for quality and penalty is 30-days for rehospitalization, while the literature endpoint windows vary from two to 18 months. The notion of the need to better identify the HF patient most likely to benefit from TM (Koehler et al., 2011) is provocative in a health care system with a limited number of resources serving a rapidly aging population. Thus, both a challenge and opportunity exists for innovations and models in to identify HF patients most likely to benefit from an intervention and to develop an intervention with reproducible outcomes in the HF patient with endpoint targets of 30-days and beyond.

Health Coaching

Heath coaching is a technique of partnering with patients to enhance self-management strategies for the purpose of preventing exacerbations of chronic illness and enhancing positive lifestyle changes (Huffman, 2007). The health coach (HC) collaborates with the patient to provide patient-centric education on what changes are

needed, skills to accomplish change, and foster confidence that change can occur (Huffman, 2007; Palmer, Tubbs, & Whybrow, 2003). In the literature, health coaching has been used with patients who have diabetes mellitus (DM), chronic illness, and cardiovascular (CV) disease. The majority of the literature involving health coaching in the cardiac populations centers on CV risk reduction and medication adherence with minimal use in the HF population.

In a large RCT of high-risk diabetic patients, the HC intervention involved patients viewing a video in DM management and identifying barriers to self-management (Sieber, Newsome, & Lillie, 2012). The study favored the intervention group for outcomes of viewing the video, 6-month primary care follow-up, and disease-relevant laboratory tests. In a small quasi-experimental study of patients with type 2 DM, a HC intervention focused on understanding of the diagnosis and treatment plan, reached significant reduction in HgbA1C at six months (Ivey et al., 2012).

Adult patients with chronic illness significantly improved their self-efficacy scores following a series of three health-coaching sessions (Linden et al., 2010). Underserved patients with chronic illness reported significant improvement in their perception of shared decision-making with their physician and engagement in their medical care following a HC intervention using community workers (Cooper et al., 2011). Unfortunately, the intervention did not improve their medication adherence.

Focusing on CV risk reduction, the first of two large RCTs, Vale and colleagues (2002) used a HC intervention of four 20-minute phone sessions focused on reduction in total cholesterol and LDL. At six months, the total cholesterol and LDL were significantly lower in the HC arm compared with usual care (Vale, Jelinek, Best, &

Santamaria, 2002). In the COACH trial, a multicenter RCT study, Vale, and colleagues (2003) coached 394 participants regarding CV risk via telephone. When compared with the usual care group of a similar size, the primary outcome of change in total cholesterol achieved statistical significance (Vale et al., 2003). Likewise, Edelman and colleagues (2006) used a HC in their multidimensional intervention targeting CV risk factor reduction. The intervention significantly reduced Framingham risk score and increased participant readiness for exercise (Edelman et al., 2006).

In a quasi-experimental study of NYHA class III-IV patients with HF, a HC program focused on patient education and nurse availability demonstrated significant improvement in self-care scores and behaviors (Jaarsma, Abu-Saad, Dracup, & Halfens, 2000). Combining a HC and TM model, participants in a small quasi-experimental study of patients with HF achieved significant outcomes in dyspnea reduction and improved activity (Wongpiriyayothar, Piamjariyakul, & Williams, 2011). Conversely, a single intervention with a HC using education sheets and 18 group meetings contacts over a one-year period did not reduce HF hospitalizations (Powell et al., 2010). The authors did note the predictive value of between NYHA class III and death or HF hospitalization. Thus, the literature recognized the value of health coaching in the cardiovascular population, but for patients with HF a gap exists in consistent outcomes.

Self-care in heart failure

Self-care is notoriously sub-optimal in individuals with HF, despite multidisciplinary efforts to educate patients about how to care for themselves (Dickson & Riegel, 2009). Heart failure self-care includes behaviors of adherence to medication, diet, daily weight monitoring, fluid and alcohol restriction, symptom monitoring,

exercise, and preventive behaviors (Riegel, Moser, et al., 2009). Self- confidence is a strong predictor of performing self-care behaviors for HF management (Paradis et al., 2010; Schnell-Hoehn, Naimark, & Tate, 2009).

Self-care in the context of self-efficacy refers to the belief that the individual has within themselves self-care ability (Schnell-Hoehn, 2009). Self- efficacy was evaluated in five of the TM studies using valid instruments (Benatar et al., 2003; Bowles et al., 2010; Boyne, Vrijhoef, Wit, & Gorgels, 2011; Dansky et al., 2008; Seto et al., 2012). The studies that measured self-efficacy reported overall improvement in scores and self-care (Benatar et al., 2003; Bowles et al., 2010; Dansky et al., 2008; Seto et al., 2012). Additionally, the authors correlated the scores as predictive for self-care management by HF patients (Benatar et al., 2003; Bowles et al., 2010; Dansky et al., 2008; Seto et al., 2012).

Bowles and colleagues (2010) incorporated the SCHFI in their RCT evaluating TM vs. usual care. The TM group had statistically significant improved SCHFI scores at 6 months. Additionally, the intervention group had a delay to time of readmission, although not statistically significant. In a later study, the SCHFI was used to evaluate a highly automated user centered TM intervention compared with usual care (Seto et al., 2012). The self-care maintenance and self-care management scores improved significantly. Unfortunately, the trial was underpowered to detect differences in hospitalization rates between the groups (Seto et al., 2012).

Paradis and colleagues (2010) studied self-efficacy using the Self-care of Heart Failure Index (SCHFI) in a quasi-experimental study. They evaluated the effect of a face-to-face motivational interviewing followed by two phone calls at day 5 and 10 on

self-efficacy of HF patients from a clinic setting. The participants chose the behavior they wanted to change. The intervention group was largely male (67%), married (80%), with NYHA class II symptoms (67%), compared with 53% NYHA class III in the control group. The SCHFI scores reflected improved self- confidence in performing HF self-care behaviors (Paradis et al., 2010).

The Tele-HF trial attempted to engage patients in self-care behaviors using a daily-automated interactive tele-prompt voice response system. The intervention did little to reduce hospital readmission or encourage self-care (Chaudhry et al., 2010). Adherence to the voice response system decreased with only 55% of the intervention patients using the TM system at least 3 times per week by the end of the study (Chaudhry et al., 2010).

In a qualitative descriptive meta-analysis, Dickson and Riegel (2009) identified the importance of skill, knowledge, experience, and consistency with values as key factors that influence decision-making. Their results revealed that experience is a powerful method of acquiring skill, and that providers often leave patients to learn from their mistakes (Dickson & Riegel, 2009). Knowledge serves as a foundation, although often insufficient, in mastering self-care (Dickson & Riegel, 2009).

These results were expanded in a later qualitative meta-analysis of three prior mixed method studies evaluating self-care management skills among patients with HF. Two major themes identified include the notion that attitudes drive a patient's self-care prioritization (Dickson, Buck, & Riegel, 2011). Secondly, that fragmented self-care instruction leads to poor patient self-care integration and ultimately self-care skill deficits (Dickson et al., 2011). Adherence to diet, symptom monitoring, and the ability to

differentiate particularly HF symptoms from other comorbid conditions were the skills most challenging to the HF patients studied (Dickson et al., 2011).

Thus, it is clear from the literature that patients with HF are complex with a myriad of factors influencing their lives and abilities to manage their disease. Based on the literature, implementation of any outpatient transitional care program in this cohort of patients should include validated tools to assess and measure self-care behaviors. The Tele-HC project will use the SCHFI to measure changes in self-care behaviors by comparing baseline scores with 30-day scores.

Summary of Literature

This systematic review demonstrates that a myriad of research studies were conducted on samples of adult patients, with a variety of types and classifications of HF in urban and rural settings, university affiliated and community-based hospitals, in the United States and Europe. The majority of studies were RCTs representing Level 1 evidence. The samples were studied to evaluate the impact of a variety of TM strategies on hospital readmission rates, HF readmission, HF mortality, all-cause mortality, lengths of stay, quality of life, functional status, self-care skills, and depression. Based on this review, TM strategies vary in type and sophistication. Some strategies included weight and BP exclusively. Other interventions captured complex physiological data using video, digital stethoscope, and implantable devices. Additionally, the components of the TM interventions varied from a physiological data only, disease management strategies, nurses calling patients, and patient responses to automated questions relating disease management. Inconsistencies exist in the literature regarding which data points are most significant in monitoring to prevent rehospitalization. This disparity highlights the

complex nature of managing patients with HF.

In summation, in the reported studies, the patient sample was predominantly male and Caucasian with NYHA Class II-IV symptoms. Independent variables most often included vital signs and weight monitoring. Biomarkers such as proBNP were used in two of the studies, and one study identified use of a morbidity index (Boyne et al., 2011; Dendale et al., 2012). Valid instruments for the quality of life, functional status, self-care, and depression were used (Benatar et al., 2003; Boyne et al., 2012; Clark, Inglis, McAlister, Cleland, & Stewart, 2007; Dansky et al., 2008; Inglis et al., 2010; Seto et la., 2012; Woodend et al., 2008). Studies where participants were on optimal HF failure therapy, outcomes of mortality and readmission were inconsistent (Boyne et al., 2012; Cleland et al., 2005; Koehler, et al., 2011; Lyngå et al., 2012).

The literature is clear that interventions to prevent readmission in the HF population have shown variable effectiveness on both HF and all- cause readmission (Inglis, Clark, McAlister, Stewart, & Cleland, 2011; Roger, 2013). This variation is largely due to diverse study interventions, variations in study designs, diverse samples, and inconsistent comorbid disease burden. The divergent outcomes highlight the complexity of managing patients with HF and the challenges of preventing unplanned hospitalizations.

Review of the literature illuminated several gaps. The first gap is defining what type of TM program is most effective in preventing readmissions in the HF population. In addition, the question remains what variables are most important to monitor, and which patient cohort is most likely to benefit? The data supports that some method and focus of monitoring is probably better than no monitoring, although may not produce

statistically significant outcomes. How important is the role of human touch in these models? In the Tele-HF trial whose intervention required patients to call their weights in to an automated voice system, dramatically lost patient engagement by the end of the study (Chaudhry et al., 2010). Furthermore, one author concluded the importance of patient selection for interventions and that a one size fits all approach may not work (Koehler et al., 2011). It is clear from the data that no one system works consistently with reproducibility across all types of HF patients. The literature overwhelmingly places nurses in key roles for TM projects that treat this patient group. Thus, a challenge and opportunity exists for customizable innovations and models with reproducible outcomes in the HF patient population.

The second gap is defining innovations whose results are significant in a medically optimized HF population. Third, since the majority of HC data in the CV population revolves around disease prevention, what is the best method to facilitate patient self-care in the chronic illness HF population? Next, a lack of evidence exists correlating the effect of HC plus TM on patient self- care development in the HF population. Finally, the literature supports using the SCHFI to describe and quantify HF patient self-care management at baseline and during an intervention process. Reviewing the literature and integrating multidisciplinary components supports the clinician to apply evidence-based care and contributes to the holistic care of this patient cohort.

Section III

Methods

Research Question

The purpose of this quality improvement project was to evaluate a combined telemonitoring device and patient-centric health-coaching intervention (Tele-HC) for adult patients with heart failure from a community hospital setting. Thirty day all cause hospital readmission was the primary outcome of interest. A secondary outcome of interest was changes in the Self-care of Heart Failure Index (SCHFI) scores at 30-days compared with time of enrollment.

The primary hypothesis was that Tele-HC intervention would result in a reduction in rehospitalization rate for adult patients recently hospitalized for acute decompensated heart failure (HF). The secondary hypothesis was that participants would have a significant change in SCHFI scores at 30-days. This project added important information to the HF literature and other TM studies by incorporating a patient-centric approach HC model.

The following questions guided the quality improvement project:

1. For adult patients, age ≥ 65, with HF, what is the 30-day all cause readmission rate when treated with a Tele-HC intervention?

2. For adult patients with HF treated with the Tele-HC intervention, what is the change in SCHFI scores at 30 days compared with time of enrollment?

3. Does a relationship exist between touches (health coaching) and rate of lack of hospital readmission?

4. Does a significant relationship exist between touches (health coaching)

favorable changes in SCHFI scores at 30-days compared to baseline?

Definitions

All cause readmission was operationalized by the time (in days) between index hospital discharge with a primary or secondary diagnosis of HF and the occurrence date of readmission for any reason.

The *advanced practice nurse* (APN) was a registered nurse board certified as a nurse practitioner. The APN worked collaboratively with the patient and their caregivers, the cardiologist, the staff at the project site, and C3Nexus. The APN provided staff, patient, and family education on disease process, served as a clinical and quality resource for the C3Nexus staff, performed research, established metrics, and assisted with data interpretation.

Body Guardian Remote Monitoring System (RMS)® (Minneapolis, MN) is a three-part system including a wearable monitoring device, an electronic BP cuff and scale, and a pre-configured smart phone for data transmission (see Appendix C). The device system containing a microprocessor, memory, and Bluetooth chip (Preventice, 2013), interfaced with the dedicated cell phone to transmit physiological data through the cellular network into a HIPPA protected cloud. Classified as a class 2 medical device, the BodyGuardian RMS® transmitted biometric information including; heart rate, heart rate variability, single lead rhythm strip, respiratory rate, blood pressure, weight, body position, and activity levels (Preventice, 2013) to LifeStat.

C3Nexus is a healthcare solutions company designed to transform the patient healthcare experience by delivering high touch (hi-touch) healthcare using high technology (hi-tech) interventions.

Cardiovascular team (CV) included the cardiologist, advanced practice nurses (APN), and registered nurses on the cardiology care team.

Food reconciliation, a process, developed by the author, by which the nutrition and wellness clinician (NWC) assisted the patient and caregiver in identifying foods using a stoplight color-coding system. Red equated to " danger" and " avoid- too much sodium," yellow signals "caution" eat just occasionally and in small amounts, and green means " go" and make these foods a first choice. The danger foods contained ≥ 150 mg of sodium per serving, the "caution" foods contain 85-150 mg of sodium per serving, and the " go" foods contain ≤85 mg sodium per serving, with foods ≤ 20 mg being an excellent choice (see Appendix D). The total daily sodium content desired was 1500 mg (Apple et al., 2011).

Health coaching (HC) was operationalized to include tools of patient education and health promotion to enhance patient well-being and achievement of their health-related goals using techniques of motivational interviewing (MI) (Palmer, Tubbs, & Whybrow, 2003; Rollnick, Mason, & Butler, 1999).

Health literacy was defined as the ability of the patient to obtain, process, and understand the basic health information needed to make appropriate decisions regarding their health ("About Health Literacy," n.d.; Reeves, 2008). Health literacy was measured using the Newest Vital Sign tool (see Appendix E).

Heart failure (HF) included either a primary or a secondary diagnosis in the 428 cohort of ICD-9 codes (see Appendix F).

Heart failure with preserved ejection fraction (HFpEF) was defined as HF with ejection fraction greater than 40% (Yancy et al., 2013).

Heart failure with reduced ejection fraction (HFrEF) was defined as HF with an ejection fraction less than or equal to 40% (Yancy et al., 2013).

High touch (hi-touch), the philosophy of the intervention team, was conceptualized as points of contact and communication between the patient and the team.

LifeStat was custom designed and built software cloud-based mHealth platform developed by the C3Nexus founders. Life- Stat is a sensory and management platform that collected real-time data, evaluated the data via programmable algorithms, and stored the data.

Meaningful visit, a term developed by the author, was defined as home visits that provide face-to-face interaction between the patient-centric health coach (PCHC) and the patient to cover content and issues that were meaningful to the patient and caregiver.

Motivational interviewing (MI), the foundation for the health coach intervention, is a technique developed by Miller and Rolnick (1990), uses the OARS technique coupled with a transactional model of communication (Breen et al., 2009). This strategy acronym strategy stands for: ***O****pen-ended questions*, ***A****ffirmation* of the person's strengths, ***R****eflective listening*, ***S****ummary* whereby the HC summarizes key points (Miller & Rollnick, 2013). The transactional communication model recognizes contributions from both parties in the areas of knowledge, interest, and willingness to participate during the encounter (Breen et al., 2009).

Patient-centric care included the elements of patient-centered care defined as "the experience (to the extent the informed, individual patient desires it) of transparency, individualization, recognition, respect, dignity, and choice in all matters, without exception, related to one's person, circumstances, and relationships in health care"

(Berwick, 2009, p. w560). This model acknowledged that the patient was the genesis of all information and interactions and promoted patient-generated data.

The *patient-centric health coach* (PCHC), a conceptual term, represented the team led by a registered nurse (RN) and composed of a nutrition and wellness clinician (NWC), patient care liaison, and support staff. The RN developed a collaborative partnership with the patient and caregiver. The NWC, trained and certified in nutrition and wellness, collaborated with the RN and the patient in identifying nutrition and wellness goals. The liaison, trained in social work, served as the connection between the patients, hospital staff, and C3Nexus staff. She provided case management, coordination, and oversight of the patient experience. The support staff offered a personal human interface when needed by the patient.

Re- admission or *rehospitalization* was identified by the time (in days) between index hospitalization with a primary or secondary discharge diagnosis of HF and the occurrence date of readmission for any cause. Emergency room visit and observation visits were not included.

Self-care was defined as the "naturalistic decision-making process involving the choice of behaviors that maintain physiologic stability (symptom monitoring and treatment adherence) and the response to symptoms when they occur" (Riegel et al., 2004, p. 350). Heart failure self-care included behaviors of adherence to medication administration, diet, weight monitoring, fluid and alcohol restriction, symptom monitoring, exercise, and preventive behaviors (Riegel, Moser, et al., 2009). Self-care was measured using the Self-care for Heart Failure Index.

Teach back was an iterative process that involved asking patients to restate

information that has been presented (White, Garbez, Carroll, Brinker, & Howie-Esquivel, 2013). The technique allowed the educator to assess understanding, identify lapses in learning, tailor, and reinforce teaching in a manner to engage the patient (White et al., 2013).

Teachable moment was a moment when the patient is ready to accept new information for use (Leist & Kristofco, 1990).

Telemonitoring was operationalized as the transmission and evaluation of data obtained from the Body Guardian Remote Monitoring System (RMS), TM a wearable electronic monitoring device to the algorithm-supported cloud based LifeStat Platform (see Figure 3). Real time data collected via Bluetooth was transmitted to HIPPA (Health Information Patient Protection Act) mHealth cloud via Wi-Fi. ("BodyGuardian ® How it works," (2013); Elrod, 2012).

Tele-HC was a combined intervention using the BodyGuardian RMSTM and patient-centric health-coach program developed by the author to improve symptom recognition, monitoring, management, and care transition from hospital to home.

Touches were any direct patient interaction with a C3Nexus team member. Touches were bidirectional interactions with face-to-face, verbal, or digital contact and included phone calls, test messages, or emails.

Design

This quality improvement project used a descriptive, cross-sectional observational design for the readmission rates. A one-group pretest-posttest design was used to measure self-care outcomes.

Setting

This quality improvement project was conducted at a 130-bed suburban community hospital that was part of a 19- hospital system on the east coast. The hospital has two cardiac catheterization labs, one electrophysiology (EP) lab, performed diagnostic and interventional cardiac catheterizations, EP studies, and device implantations. The acute care setting had a six-bed interventional care unit (IVCU), 10 bed medical-surgical intensive care unit (ICU), 21 bed progressive care unit (PCC), 20 additional remote telemonitoring beds, and a 26 bed ED. The Tele-HC project was offered to patients who met criteria prior to being discharged from the IVCU, ICU, PCC, or remote telemetry units.

Sample

A single setting was used and participants were identified and recruited using a convenience-sampling plan. Thus, each potential participant meeting inclusion criteria was eligible to participate (Wood & Ross-Kerr, 2011). The sample included adults treated at St. Francis Medical Center, with a primary or secondary diagnosis of HF as identified by ICD-9 codes in the 428 (congestive heart failure) cohort. Inclusion and exclusion criteria are listed below.

Inclusion criteria:

1) Adults over the age of 65 or greater with either a primary or a secondary diagnosis of heart failure (systolic and/or HFPEF) related to ICD-9 codes

2) English speaking

3) Living at home, with or without a caretaker

4) Ambulatory

5) Discharged from the acute care setting

6) Be under the care of a single multi-provider cardiology practice

Exclusion criteria:

1) Diagnosis of dementia or disabling psychiatric disorder

2) Discharged to a skilled facility or rehabilitation center

3) Irreversible or terminal medical conditions likely to affect 6-month survival or ability to participate in the project

4) End stage renal disease requiring dialysis

5) Lack of willingness to participate

Recruitment occurred during the in-patient hospital visits. Registration occurred in a rolling fashion between June 1, 2013 and November 30, 2013, and followed for 30 days. Enrollment was concluded when a sample of 30 patients was obtained (Vaughan, 1998). Potential patients were identified by the CV team and presented in daily rounds.

Program Description

The program was designed to reduce rehospitalization and facilitate self-care management behaviors in patients with HF. Remote TM and access to a HC with daily interactions were the methods of influencing self-care behaviors.

A multidisciplinary team provided the functional infrastructure for the quality improvement project. The team consisted of the project facilitator (author) in collaboration with the C3Nexus medical director, an additional cardiology APN, case management, nursing, referring cardiologists, hospitalists, and patient-centric health coach (PCHC) team.

Prior to implementation, the team was educated on the goals of the program. The

team members were also involved in developing, evaluating, and refining the process. The APN provided the team with current research on the telemonitoring and health coaching strategies. The team was educated by the APN on motivational interviewing (MI), the use of teach back methodology, and administration of the SCHFI and Newest Vital Sign tools. Additionally, the APN served to collect and interpret data, refine processes as a liaison between the hospital, the providers, and the C3Nexus team. The PCHC team met regularly with the APN to review cases using an integrative model of evidence based practice, nursing science, anatomy, physiology, and disease management.

The Tele-HC program combined the hi-tech of the Body Guardian RMS® (Preventice, Minneapolis, MN) using the LifeStat algorithm in concert with a hi-touch PCHC. The participants were provided with wearable BodyGuardian ® system, including an electronic blood pressure (BP) cuff and scale, in addition to usual care. These devices were compatible with pacemakers and implantable cardioverter-defibrillators. The weight, EKG tracings, BP readings, and activity levels were automatically transmitted wirelessly via Bluetooth to a mobile phone (Samsung galaxy, Ridgefield Park, NJ). The custom-designed and built software application on the phone was used to display, store and transmit data to *LifeStat*, the data management platform.

Standard care included heart failure education by the specialized cardiac nurses in the hospital. Standard care also included follow up visits to the clinic five to seven days following hospital discharge and then every one to three months depending on severity of illness.

LifeStat displayed algorithm-mediated data for the PCHC and provider to review via a web portal or secure tablet. Biometric data were available continuously with

monitor protocols capturing data points every hour. Additional patient-generated data were initiated based on patient-reported symptoms. The live data evaluation by the PCHC occurred daily from 7am – 7 pm. The PCHC did additional monitoring and evaluation of the transmitted data on an as needed basis for calls generated outside of the 12-hour monitoring window.

The PCHC, a conceptual term for hi-touch component of the intervention, started in the hospital when the C3Nexus liaison interviewed the patient (see Appendix G) to assess level of engagement, eligibility, and establish the relationship between the patient and C3Nexus. The RN who was the primary contact for the patient experience championed the PCHC intervention. The RN focused on areas of disease management including symptom recognition, adherence to treatment strategies, care coordination, and medication matters. Medication matters included initial medication reconciliation and organizing resources to obtain medications for patients who had socioeconomic challenges. The liaison became part of the PCHC team when patients had socioeconomic challenges. The NWC become the PCHC when collaborating on issues related to nutrition, food preferences, lifestyle, and exercise.

The PCHC established a patient-centric relationship using Miller and Rollnick (1990) OARS technique of MI coupled with a transactional model of communication. A patient-centered approach was maintained by first assessing health literacy with the Newest Vital Sign tool. By maintaining a patient-centric focus, the PCHC and team worked to close knowledge gaps, validate life-experience, values, and honor cultural diversity in communication and shared decision-making (Breen et al., 2009; Walsh et al., 2012).

Topics included the patient's understanding of their disease, treatment strategies, establishing goals of health, and therapy expectations. As the PCHC and team identified knowledge deficits, they customized the education and employed the teach-back methodology to address the gaps. The PCHC engaged the patient in collaborative care planning and goal setting to insure interventions were congruent with the patient's readiness for change, needs, values, culture, desires, and health goals. Patient empowerment and self-care management were measured with the SCHFI in a pre-test – post-test fashion (see Appendix H).

The APN educated the team on motivational interviewing (MI), the use of teach back methodology, administration of the SCHFI and Newest Vital Sign tools. The NWC focused on food reconciliation, nutrition assessment, and establishing wellness goals with the patient. The hi-touch personal interactions included one face-to-face encounter in the home, daily contact with the PCHC for the first14 days with a patient-driven tapering schedule thereafter. Following patient identification and enrollment, the intervention used a three-phase approach: *pre-visit phase, the calibration phase, and the maintenance phase*.

Procedure

Human subject protection. Institutional Review Board (IRB) exemption was obtained with classification of the project as a quality improvement initiative (see Appendix I).

Patient identification and enrollment. Participants were selected from a convenience sample at St. Francis Medical Center using a 5-month rolling enrollment process. The participants were hospitalized with a primary or secondary diagnosis of

heart failure beginning June 1, 2013 through November 30, 2013. Subjects were identified by the cardiovascular team. The author validated the diagnosis of HF with chart review of the cardiology team's impressions, related signs and symptoms of decompensated HF, diagnostic testing including documentation of ejection fraction, echocardiogram within the past 6 months, and pro-BNP. While making daily rounds, the APRN informed the potential participants of the intervention and gained oral permission to contact C3Nexus. If they agreed to participate, C3Nexus was notified via transmitted order. The author reviewed the electronic medical record to obtain clinical data and completed the LACE and CORE- HF scores.

Pre-visit. Once C3Nexus received the order, the liaison, serving as the PCHC, met with the patient and caregiver in the hospital to establish the initial phase of the patient-centric relationship. During a semi-structured interview, the program was discussed and the patient was assessed for willingness to participate and basic use of technology. The PCHC obtained data on the patient's mental status, caregiver support, and lifestyle. The interview concluded with completion of the partnership agreement (see Appendix J) and property agreement (see Appendix K). The partnership agreement outlined the essence of the program and patient and PCHC roles and responsibilities. The property agreement included health information release (HIPPA) authorizing C3Nexus to collect de-identified data with anticipated publication of results. The patient was provided written materials about the device and the program. Finally, the liaison interfaced with the hospital case manager to coordinate timing and elements of hospital discharge.

Calibration phase. Following hospital discharge, the PCHC contacted the patient

and caregiver to establish the time of the first face-to-face meeting in the patient's home. The *initial meaningful visit* occurred within 24-48 hours of hospital discharge at a time when the caregiver can be present. During this relationship focused visit, participants were provided with the BodyGuardian® system, scale, and BP cuff. Patients and caregiver, if available, received education on use of the BodyGuardian® system, and given access to technical support. They were asked to wear the monitor 24 hours per day except when bathing, transmit weight and BP data, and communicate with their coach daily.

Additionally, the patient was evaluated for health literacy by completing Newest Vital Sign tool. Self-care behaviors were assessed using a semi-structured interview format to complete the SCHFI tool. The patient participated in medication reconciliation by comparing the discharge medication list with the discharge summary and the actual medications on hand. The PCHC contacted the provider for any discrepancies. Next, using techniques of MI and teach back to maintain patient-centeredness, the PCHC performed brief food reconciliation, categorizing harmful foods, and collaborated with the patient to identify basic diet-appropriate alternatives. The PCHC identified areas of educational deficits regarding disease management and used those as a *teachable moment*.

This two-week *calibration phase* established the fundamental elements of the hi-touch patient relationship with the PCHC and set the stage for building patient self-confidence and improving self-care. Additionally, this phase allowed time to establish a baseline for the patient's health status, goals of care, and self-care ability. This resource intense phase consisted of two hi-touch meaningful home visits by members of the PCHC

team and at least daily touches with the patient.

The second *meaningful visit*, facilitated by the NWC as the PCHC, occurred within ten days following hospital discharge. Prior to this visit, the NWC met with the RN to discuss the results of the first meaningful visit. During the second meaningful visit, the PCHC performed a comprehensive assessment of the patient's current diet, eating habits, food preferences, and exercise practices. The NWC reviewed current foods in the patient's home and helped the patient to identify foods high in sodium. Based on a proprietary protocol, the PCHC employed teach back techniques and MI, to assist the patient in developing nutrition goals, meal planning, and shopping list to meet the American Heart Association guidelines of 1500mg diet.

During the calibration phase, the first two weeks of the intervention, the PCHC communicated with the patient at least daily using a pre-established method of communication (text, phone, or email). During these touches, the PCHC reviewed biometric data from the previous 24 hours, and continues to build on the trusting relationship. Following a proprietary algorithm the PCHC assessed the patient's understanding of care, adherence to medication and diet, and reviewed symptoms. Optimizing teachable moments, the PCHC provided education and reinforced success the patient had made in their self-care. Additionally, the PCHC coordinated care for the patient to follow up with their healthcare team. Hi-touch 24-hour bidirectional access to the PCHC was provided to the patient for the course of the program. The APRN served as a resource to the PCHC and provided case and disease based education to the C3Nexus staff.

Maintenance phase. Following the initial 14 days, the PCHC continued to monitor daily patient data, but PCHC initiated communication was tapered based on patient need. By this phase, the patient and PCHC team had a trusting relationship, and the patient was encouraged to initiate contact with the PCHC for any perceived changes in clinical status. The PCHC maintained hi-touch by providing at least weekly feedback to the patient regarding changes in biometrical data, health goal achievement, and successful behavior change. The bidirectional communication allowed the PCHC to assess the patient's progress and understanding of treatment and goals, address any current needs, and facilitate problem solving. The PCHC closed the communication gap through contact with the patient's attending care team to discuss any changes in clinical status or medication plan. Following day 30 in the program, a second SCHFI was completed. The entire program continued for an additional 60 days in a similar manner. Upon completion of the entire 90-day program, a final SCHFI tool was completed, the equipment was returned, and a follow-up satisfaction survey was mailed to the patient.

Instruments and Measures

Instruments. The LACE (see Appendix L) and the CORE- HF calculator (see Appendix M) were used to illustrate sample characteristics more precisely. The Newest Vital Sign (see Appendix E) was used to describe participant health literacy at baseline. The Self-care of Heart Failure Index (see Appendix H) was used to describe participant self-care management skills.

The *LACE* index identified patients at high-risk for unplanned hospital readmission by quantifying comorbidity burden and reflecting the patient's level of outpatient disease management as indicated by the ED use (van Walraven et al., 2010).

In their study, van Walraven and colleagues (2010) identified four variables independently associated with 30-day mortality or hospital readmission after a hospitalization. These variables form the acronym and included **L**ength of stay, **A**cuity of admission, **C**omorbidity measured with the Charlson comorbidity index, and **E**mergency department use 6 months prior to index hospitalization (van Walraven et al., 2010). Validation of the LACE tool proved accurate (Hosmer-Lameshow goodness-of-fit statistic 14.1, p=.059) and moderate discrimination (c statistic 0.68; 95% CI, 0.65-0.71) at predicting hospital readmission (van Walraven et al., 2010).

The *CORE calculator*, developed in conjunction with the Centers for Medicare and Medicaid Services, consisted of three models: HF, acute myocardial infarction, and pneumonia (Krumholz, Normand, Desai, et al., 2008; Krumholz, Normand, Keenan, Desai, et al., 2008; Krumholz, Normand, Keenan, Lin, et al., 2008). The tools were based on hierarchical condition categories grouped related to comorbidities to predict hospital readmission (Kansagara et al., 2011). The CORE-HF model predictability carried a *c*-statistic = 0.61 (Krumholz, Normand, Keenan, Lin, et al., 2008). The actual predictability of the score is unclear, and its developers recommend using the data at the institution level to establish meaningfulness (Krumholz, personal communication, January 17, 2013). The choice for this tool was to describe morbidity within the study sample.

The *Newest Vital Sign* (NVS) tool (Weiss et al., 2005), was used to describe the health literacy level of the sample. Health literacy has been the foundation of the self-care programs and a prominent component of patient centered care (Walsh et al., 2012). The NVS included a nutritional label available in English and Spanish took three minutes

to administer (Weiss et al., 2005). Respondents were scored on answers to six yes-no questions related to the label (see Figure 12). The NVS demonstrated reliability (Cronbach's $\alpha > .76$) (Weiss et al., 2005), high sensitivity and moderate specificity for detecting limited literacy (Osborn et al., 2007). In a comparison study with Rapid Estimate of Adult Literacy in Medicine (REALM) tool and the short Test of Functional Health Literacy in Adults (S-TOFHLA), the authors noted the NVS might misclassify those with adequate literacy based upon the REALM and S-TOFHLA (Osborn et al., 2007).

The *Self-care of Heart Failure Index* (SCHFI pronounced "skiffy") was used in a pre-test post- test format to measure self-care. This instrument, developed by Riegel and colleagues with most recent revision in 2009, was a measure of self-care decision-making process involving choices between behaviors that maintain physiological stability and the management response to symptoms when they occur (Riegel, Lee, Dickson, & Carlson, 2009). The SCHFI used a quantitative, ordinal, self-reported, performance-rating scale to measure three subscales including self-maintenance, self-management, and self-confidence (Riegel, Lee, et al., 2009).

The subscales consisted of 10, 6, and 6 Likert questions, respectively. A score of 70 or greater was the suggested cut-point to judge self-care as adequate (Riegel, Lee, et al., 2009). A change in score greater than one-half of a standard deviation was noted to be clinically relevant (Riegel, Lee, et al., 2009). The SCHFI v.6, published in 2009 had a coefficient α of less than 0.6 for the self-care maintenance and self-care management scales, and an α greater than 0.8 for the self- confidence scale (Riegel, Lee, et al., 2009).

Construct validity was tested by confirmatory factor analysis and correlations

between subscales (Riegel, Lee, et al., 2009). The 2009 index scoring update recommended the three scores be viewed separately rather than obtain a composite score. Additionally, Riegel and colleagues (2009) verified that no learning effect was associated with repeated administration. The SCHFI, available in eight languages, takes approximately 5 minutes to complete, and can be completed directly by the patient or indirectly using interview technique (Riegel et al., 2004).

Measures. The EMR was queried by the author at enrollment for demographic and HF variables. Demographic variables included age, gender, and marital status. Heart failure variables included type of HF (HFrEF or HFpEF), etiology of HF (ischemic, nonischemic), ejection fraction (EF), duration of HF diagnosis < 6 months, and New York Heart Association (NYHA) class. The number of touches recorded in LifeStat quantified coaching. The days to readmission were recorded in LifeStat.

The author calculated LACE and CORE-HF scores at baseline. The PCHC documented homebound status, caregiver presence, medication classification, and administered the Newest Vital sign on during the first meaningful visit. PCHC also administered through patient interviews, the SCHFI at baseline and 30-days. The APRN scored these tools.

Outcomes

The primary outcome variable explored and described was the occurrence and time from hospital discharge to readmission for any reason. Hospital readmission was measured in days from index hospitalization discharge to readmission and occurrence of readmission within 30-days for any cause readmission during the 30-day follow-up period. The 30-day readmission rate for the sample was calculated by dividing the

number of participants who were readmitted within 30-days by the total number of participants in the sample. A sub-group analysis of 30-day HF readmission rates was calculated by dividing the total number of heart failure readmissions within 30 days by the total number of participants.

The secondary outcome of self- care scores were measured with the SCHFI tool at baseline and at 30 days. The tools was scored and interpreted according to guidelines published by Riegel and colleagues (2009). A score of 70 or greater was congruent with adequate self-care. The delta for the tool was measured by subtracting the second score for each section individually from the initial score in each section. Correlation models were tested to identify relationships between touches and outcomes.

Data Collection

Data were collected during the June through December 2013 period. All data were de-identified prior to statistical analysis and stored in an Excel ® spreadsheet. Data collection included demographic data, information about disease etiology, burden, treatment, and scores on assessment tools. Age, gender, race, marital status, caregiver presence, and homebound status, were examined to investigate differences within the sample. Heart failure etiology, NYHA classification, comorbidities, and the number of medications illustrated the disease burden. Medications used to treat HF were recorded to illustrate disease management. Scores on the LACE, Core-HF, and the Newest Vital Sign tool helped to describe severity of illness, outpatient management, and the capacity for basic understanding of health.

The outcome measure of rehospitalization was based upon status of readmission and the number of days from index hospitalization until rehospitalization. Since patients

were followed electronically by the PCHC, all 30-day hospitalizations were identified. Improvement in patient self-care was measured using the SCHFI with scores recorded at baseline and 30-days. As recommended by the author of the tool, each section was scored individually. Individual scores as well as the changes in scores were used for analysis.

Data Analysis

Descriptive and comparative analysis was performed using SPSS, Version 21 (SPSS, Inc., Chicago, IL). Data from the 30-day follow-up period was recorded and analyzed for each participant. This was an intention-to-treat analysis and all patients completed the 30-day program. Baseline continuous-level sample characteristics were expressed as mean and standard deviation, and categorical-level characteristics as frequency and proportion. All participants completed the 30-day intervention. The number of touches was expressed as mean and standard deviation. The primary outcome measure of all cause readmission rates was computed for the sample and reported as a percentage. The sample SCHFI scores were analyzed in a pre-test-post-test fashion using dependent t-tests, as the data were evenly distributed. Tests were two-tailed, and statistical significance was set at alpha = 0.05. Associations between variables were analyzed using Pearson's correlation.

Ethical Issues

Ethical issues surrounding this quality improvement (QI) project were minimal. The leadership of the institution sanctioned and supported the QI project. Through a contractual agreement, the hospital provided C3Nexus a flat fee per patient to cover the cost of the program. Thus, no additional cost to the patient was incurred. The

investigative team were hospital employees. The lead cardiologist was also a principal of C3Nexus. No patient identifiers were used and anonymity was maintained. All patients meeting criteria were approached. The risk to the participants was minimal

Products

The QI products will be shared with C3Nexus and the hospital system at the local, regional, and national levels. The results will be disseminated through publication and at local, regional, and national conferences. A condensed manuscript will be submitted to the *Journal of Cardiovascular Nursing.* The editor of this journal developed the Self-care of Heart Failure Index. A content of the journal frequently includes innovations and updates for the care of patients with heart failure.

Section IV

Results

Participant Profile

Demographic characteristics. Thirty-two adult patients over the age of 65 with heart failure who met criteria for enrollment were approached for enrollment. Two patients declined enrollment for reasons related to use of technology. The final sample of thirty participants was enrolled starting June 1, 2013 through November 30, 2013. Demographic characteristics are displayed in Table 5. The mean age of the entire sample was 77.5 years with a range from 69 to 86 years. Fifty-seven percent (n= 17) were female, and 80% Caucasian. The group was evenly split between married and single, which included divorced or widowed. Ninety percent were not homebound and the majority listed the presence of a caregiver.

Medical characteristics. Medical characteristics are displayed in Table 6. At the time of enrollment, 40% of the participants had a new diagnosis of heart failure (HF). Sixty percent of the participants had an ejection fraction (EF) equal to or less than 40%. Of those with reduced EF, 33% were of an ischemic etiology. The majority of majority of participants had NYHA class II or III symptoms at the time of enrollment with each group accounting for 43% of the group, respectively. The mean length of stay was four days with 70% of the patients falling at or below that mark.

The participants had an average of four of the comorbid conditions recorded. Greater than 50% had three to four comorbidities. The most frequently occurring comorbid conditions included hypertension (93%), coronary artery disease (77%), and atrial fibrillation (60%). Less than half had chronic kidney disease, and approximately

one third had diabetes and sleep apnea. Ten percent of the patients were noted to have a diagnosis of depression.

Patients were on a mean number of 12 medications with ranges from seven to seventeen. Medical therapy, included beta-blockers, angiotensin converting enzyme – inhibitors (ACE-I) or angiotensin receptor blockers (ARBs), diuretics, potassium sparing diuretics, potassium supplements, statins, aspirin, and diabetes therapy. The entire patient subgroup with a reduced EF (n=18) were all treated with beta-blockers, and 78% with either an ARB or ACE-I.

Instruments. All patient records were reviewed for calculation of a *LACE* and *CORE- HF* score prior to hospital discharge. Both the LACE and CORE-HF scores were evenly distributed (see Table 7).

The mean LACE score was nine out of a possible 19 with scores ranging from six to twelve. The mean CORE-HF score was 25% with scores ranging from 20 to 30%. Analysis of the relationship between the LACE and CORE-HF scores revealed a significant medium strength correlation ($r = .391$, $p = .016$). In terms of predictability, the CORE-HF score did not significantly predict the LACE score ($R^2 = .153$, $p = .033$).

Three participants refused to complete the *Newest Vital Sign* with state reason due to simplistic nature of the tool. For the 27 who completed the tool, the mean score was five out of a top score of six. The scores ranged from three to seven with a mean of five (see Table 6). Adequate health literacy is defined by scores of four or greater (Weiss et al., 2005). Seventy eight percent scored four or greater.

Outcomes. The primary outcome of rehospitalization was six percent for all cause, and zero for heart failure (see Table 7). Since the readmission data were skewed due to the low readmit number, no pattern was identified. Of the two patients readmitted, one was readmitted at day 22 with a small bowel obstruction. The second patient was readmitted on day 13 with non-sustained ventricular tachycardia during exercise. This potentially life-threatening arrhythmia was picked up as a result of the intervention. Due to concern for ischemia, he underwent a cardiac catherization and was treated medically. Neither patient had decompensated heart failure as a component of their rehospitalization.

The Self-care for Heart Failure Index (SCHFI), composed of three separate scores, reflected patient behaviors in the areas of self-care maintenance, self-care management, and self-confidence related to their HF. Baseline and 30-day scores for each section of the SCHFI are presented in Tables 7, 8. A score of 70 or greater indicated adequate self-care (Reigel, Lee et al., 2009). A change in score greater than one-half of a standard deviation was noted to be clinically relevant (Riegel, Lee, et al., 2009). The mean baseline scores for each of the three sections fell below the 70 mark. A dependent-*t* test was conducted to assess changes in scores for each section by comparing baseline scores to scores at 30-days. Predictive models were tested using regression analysis.

Patient self-care maintenance behaviors significantly improved by day 30 compared with baseline ($p < .0001$). Seventy percent of participants (n=21) scored 70 or higher on the 30-day assessment. Of the remaining nine patients, eight had scores consistent with clinically relevant improvement in their self-maintenance behaviors. Thus, 97% of patients had improved self-care maintenance scores by the end of the 30-

days.

Assessment of self-care management behaviors was done based upon HF symptoms within the past 30-days. Ninety six percent of patients (n=29) answered "yes" to the presence of HF symptoms in the prior 30-days. The remaining patient did not identify "trouble breathing" or "ankle swelling" as his HF symptoms. The baseline mean score was 34, indicating suboptimal management. At 30-days, 56% (n=17) of patients answered "yes" to symptoms of HF within the past month. The baseline and 30-day scores of this subgroup were compared and found to be significant for improvement ($p < .0001$). Nine patients (53%) in the subgroup reported adequate self-care maintenance behaviors by day 30. Of the remaining eight who scored less than 70, seven had score changes meeting criteria for clinical relevance. So, for self-care management behaviors, a combined 94% of this subgroup scored 70 or greater or had a clinically relevant score improvement by the end of the observation period.

Patient self-confidence behaviors were generally suboptimal at baseline with a mean score of 49. However, closer evaluation of the confidence intervals revealed that 23% of the patients (n=7) had scores reflecting adequate self-confidence. The mean self-confidence score at 30-days improved significantly ($p <.0001$), with 53% (n=16) having scores > 70. Of the remaining 14 patients, eight had score changes clinically significant for self-confidence behaviors. Thus, 80% of patients had either statistically or clinically significant improvement in their self-confidence scores.

Relationships between touches and score changes were evaluated using Pearson's correlation to determine the influence of touches on the outcomes (see Table 8). The number of touches the patients received measured the health-coaching component of the

intervention. Touches included any form of communication with the patient including telephonic, texting, email, or a face-to-face visit. The relationship between touches and SCHFI scores was examined by section, with a sub-group analysis done on those participants who answered "yes" to Section B in at both baseline and 30-days. Additionally, since the calibration phase of the program was more resource intensive, sub-group analysis was done relating score changes to the number of touches within the first two weeks, and then at 30-days

The mean number of touches during the 30-day trial period was 47. Eighty seven percent of patients (n=26) received an average of more than one touch per day during the program. Evaluation of touches during the first two weeks showed a similar pattern. However, subgroup analysis of the patients who reported HF symptoms during the program (n=17), received twice as many touches during the first two weeks, and 50% more touches at 30-days compared with those who did not have HF symptoms during the observation period.

There was a moderate positive linear relationship between touches during the 30-days and the change in self-care maintenance scores. This relationship was not found to be significant (r = .3, p = .054). The model explained only 9% of the change in scores for the group. The 30-day touches did not significantly explain changes in self-care maintenance scores. However, subgroup analysis revealed a significant relationship between the number of touches within the first two weeks, and improvement in self-care maintenance scores (r=.426, p = .009). In terms of predictability, the number of touches moderately predicted changes in self-care maintenance scores (R=.426, p = .019).

At the completion of the observation period, 17 patients answered "yes" to the

question in Section B indicating symptoms of HF during the past month. For those 17 patients, there was no significant correlation between touches at two weeks (r =.315, p =.109) or 30-days (r =.118, p = .326), and changes in self-care management scores. As well, there was no significant relationship between touches at both intervals and self-confidence scores at the end of the project (r = .164, p = .193; r = .947, p = .403). No predictive patterns were identified in the models.

Discussion

This primary purpose of this project was to evaluate readmission rates for the sample of adult patients with heart failure (HF) from a community hospital treated with a combined telemonitoring and patient-centric health coach intervention (Tele-HC). The secondary purpose was to evaluate changes in patient self-care scores in the areas of self-care maintenance, self-care management, and self-confidence as these behaviors relate to their HF. Remote telemonitoring (TM) and access to a patient-centric health coach (PCHC) were the methods of influencing self-care behaviors. The outcomes of the study reflect the synergy of a hi-tech monitoring with a hi-touch nursing intervention. The advanced practice nurse (APN) served as the resource implementing many of the doctorate of nursing practice (DNP) essentials for the project.

The results of this project show a group of elderly patients with HF in addition to multiple medical conditions. Similar to other studies, these patients were treated with optimal medical therapy for their HF (Boyne et al. 2012; Chaudhry et al., 2010; Cleland et al., 2005; Dar et al., 2009; Giordano et al., 2009; Koehler et al, 2011; Mortara et al., 2009; Seto et al., 2012; Weintraub et al., 2010).

The overwhelming majority had poor self-care skills at baseline. These baseline

findings echo the notion that patients with multiple chronic conditions are vulnerable to poor self-care (Dickson, Buck, & Riegel, 2011). The participants, similar to those in other studies, had experience with decompensated HF, but lacked skills to recognize early signs of a HF exacerbation, manage their HF, and participate in self- care maintenance behaviors (Bentara et al., 2003; Bowles et al, 2010; Danskey, Vasey & Bowles, 2008; Riegel et al., 2009; Seto et al, 2012).

The Tele-HC intervention provided a platform by which to monitor, manage, and educate these patients. The patient-centric model provided the framework for care delivery by fostering trusting relationships with the PCHC. The hi-tech telemonitor provided the biometrical data needed to drive evidence based care. Self-care behaviors were measured using the Self-care of Heart Failure Index (SCHFI). The APN role was pivotal in identifying patients, collecting, analyzing, and interpreting data, educating staff, and providing project leadership.

The sample was primarily Caucasian females with a mean age of 77.5. This demographic differed from most of the samples in the literature, which were generally male and less often Caucasian. Most of the patients were not home bound, which is again contrary to most tele-monitoring programs. Eighty percent had a caregiver involved, and half were married. Heart failure was a new diagnosis for 40% of the patients. Sixty percent had an ejection fraction less than 40%, and NYHA class II or III functional status. Of those with left ventricular systolic dysfunction, medical care was evidence based with all participants taking a beta-blocker and 70% on either and ACE-I or an ARB. Participants were receiving an average of seven medications and had at least three cardio-renal or pulmonary comorbid conditions.

The sample had adequate health literacy. The mean LACE score of nine correlated with a 10.3% probability of death or rehospitalization within 30-days following discharge (van Walraven et al., 2010). Subgroup analysis of those with a score greater than nine, 43% had scores suggesting 12-20% risk of 30-day rehospitalization or death. The authors of the CORE-HF tool recommended applying the results uniquely to the institution of study to determine predictability and significance of the results (Krumholz, personal communication, January 17, 2013).

The mean CORE-HF result for this project was 25%. Correlation analysis of the LACE and CORE-HF scores showed a moderate correlation, but the CORE-HF score did not predict the LACE score. The lack of predictability may be because the CORE-HF reflected disease burden and comorbidities. The LACE incorporated a morbidity scale, but also indicated the individual's success with managing their health as an outpatient.

The results of this project are noteworthy in terms of both primary and secondary outcomes. The readmission rate for the group was six percent for all cause and zero for heart failure. These results are staggering considering the publically reported readmission rates for the hospital are similar to the 23% national average for both all cause readmission and HF readmission ("Hospital compare," 2014). The month prior to implementation of the Tele-HC project, the actual hospital readmission for HF was 20%. The hospital HF readmission rates over all fell to 10% during the study period. The interpretation of these results is difficult due to the small sample size and distribution of data.

Perhaps more important and lasting was the secondary outcome of improved patient scores reflecting positive behavior change. Patient self-care management, self-

care maintenance, and self-confidence in dealing with their HF was evaluated using the SCHFI tool. The Self-care of Heart Failure Theory also provided the foundational for this project. The mean scores for each section of the tool at baseline were well below the score of 70 needed to indicate optimal self-care behaviors. Following the Tele-HC intervention, significant improvement in scores was noted throughout the group. Most outstanding were the percentage of patients who achieved either statistically significant or clinically relevant improvement in their scores. By the end of the project, 97% had improved self- care maintenance behaviors, 94% had improved self-care management behaviors, and 80% improved self-confidence in managing their HF. Although empirical evidence correlating HF self- care to readmissions is limited, improvement in self-care is implied as a factor for the reduction in hospitalization (Dickson, Buck, & Riegel, 2011). This lack of evidence highlights the complexity of managing HF patients (Dickson, Buck, & Riegel, 2011), and suggests the presence of other variables.

The PCHC intervention was quantified as the number of touches the patient received during the project. The touches provided opportunity for patients education and reinforcement of self-care maintenance behaviors. Participants were educated on the importance of daily weights and diet and medication adherence. Additionally, they were coached on ways to monitor and recognize HF symptoms, improve their diet, increase their physical exercise, and solve daily problems related to their medical conditions.

Most patients had an average of two touches per day for the first two weeks, and three touches every two days for the remainder of the program. The touches during the first two weeks were moderately related and significant to the improvement in self-care maintenance behaviors. The number of touches did not collectively explain the changes

in 30-day SCHFI scores.

Through the touches, the coach gained subjective assessment of the patient's engagement in the process. During each touch, the coach customized the interaction to facilitate patient self-care. The touches also provided opportunity for teachable moments and encouragement for goals achieved. Although patient engagement was not specifically measured, it was identified as a variable of interest for future study.

Several providers were initially hesitant to enroll their patients due to perceived increased workload and alteration in office workflow. The PCHC was able to translate continuous biometric data into meaningful information by identifying trends and correlating the data with patient assessments. The data were synthesized and presented in a *Smart Report* document. This document accompanied the patient to their office visits and provided the clinician with a more robust picture of patient's progress following their hospitalization. This paved the way for medication adjustments and advancement of treatment plans.

Based upon PCHC reports and patient evaluations, several themes emerged with regards to the Tele-HC intervention. Patients reported feeling a sense of satisfaction knowing that the PCHC was available at any time to mediate between the provider and the patient, facilitate problem solving, trouble shoot, and listen. The patient-centric care model, built on relationship-centered care, became the foundation whereby the patient was coached to find their strengths (Gellis et al, 2012). These strengths translated into self-confidence in self-care maintenance, symptom recognition, problem solving, and management of their HF. Providers reported a better sense of their patient's progress between office visits post-hospitalization.

Limitations

This project has several limitations. The design was that of a QI project with historical comparison. Future study should include case comparison or control design. In addition, the lack of rigorous design raises questions about selection, process, and additional variables. Selection bias existed, as participants were hand selected by the CV team and chosen based on perceived level of engagement. Since participants were chosen within a selected radius of the hospital, those from areas that are more rural were disqualified. Patients received HF education from a variety of sources while in the hospital. Since relationships are key to a patient –centric model, a better understanding of patient engagement and the components of behavior change may help identify those patients most likely to benefit from the Tele-HC program.

The interpretation of these results is difficult due to the small sample size and distribution of data. The findings are limited to patients who are primarily Caucasian females with the presence of a caregiver, and NYHA class II or III functional status. Data on education level and socioeconomic status was not collected and may have been helpful in developing predictive models of required touches. The length of time the device was worn was also not collected and could provide insight into adherence. Patients with both types of HF, reduce and preserved EF, were included, but not analyzed as separate groups. Future study comparing these groups may provide unique data related to outcomes.

Since the touches represented the health-coaching intervention, definition of the type and quality of touches was identified as an opportunity for future exploration. Specifically, describing the modality, content, intensity, and frequency of the touches

may help to further customize the intervention. This data may also help with future resource allocation and cost analysis.

In addition, although patients reported medication adherence, an automated recording device was not used. Information about number of medication changes and clinic visits was not collected. Economic data evaluating the cost analysis of the program with actual and projected return on investment was not collected. This data would be beneficial in the future, as the program increases and broadens its reach to other health care settings and systems. Finally, data were recorded for a 30-day period although patients remained in the program for 90-days. Future study should include assessment of self-care behaviors and hospitalization trends for 90-days and up to one year given the burden that HF syndrome poses on patients and society. Finally, additional investigation is needed to address the sustainability and replication of these results across diverse patient cohorts.

Nursing Practice Implications

The Tele-HC intervention was a nurse driven intervention based upon nurses practicing to the full extent of their training and education (IOM, 2010). The intervention placed nursing as partners with patients and providers in redesigning healthcare delivery for this sample. The APRN incorporated the essentials of science, inter-professional collaboration, scholarship, and evidence based practice in this QI project. Finally, this QI project demonstrates the leadership role that APRNs can play using information systems and patient care technology to improve and transform healthcare (“The essentials of DNP education for the advanced practice nurse,” 2006).

Conclusion

The Tele-HC intervention significantly reduced rehospitalization and improved self-care behavior scores for the sample of adult patients with HF. This project added to the current literature that evaluates interventions aimed at preventing rehospitalization for patients with HF. Over the past two decades, a plethora of telemonitoring interventions and protocols with diversity in study designs, patient samples, and outcomes have been published (Clark et al., 2007; Inglis et al., 2010; Inglis et al., 2011). Previous studies involving patients with HF that incorporated a measure of self- care such as the SCHFI, related successful self-care as a predictor of self-care management and subsequent reduction in rehospitalization (Benatar et al., 2003; Dansky, Vasey, & Bowles, 2008; Bowles et al., 2010).

This project echoes the notion that patients with multiple chronic conditions are vulnerable to poor self-care (Dickson, Buck, & Riegel, 2011). Although the primary goal of the project was to prevent rehospitalization in this group, a potentially lasting, and life-changing outcome was imparting skills of self-care to this sample. Self-care skills were developed and nurtured through the patient-centric Tele-HC intervention. As the patient bore responsibility for self-management, the TM system evolved from a crisis detection mechanism to a health maintenance system (Dendale et al. 2012). The intervention facilitated all nurses to practice within their broad scope of practice. It also incorporated many of the essentials of the DNP for the APRN.

The absence of a sustainable and reproducible home-based program heralds to the complexity of treating aging patients with the HF syndrome (Dickson, Buck & Riegel, 2011) in ways that change behavior, and prevent hospitalizations. As the perfect storm of

an aging population, rising chronic disease burden, and reduction in financial reimbursements rages, strategies to enhance self-care management of HF and improve outcomes are critical. Research is needed to develop tools to better identify those patients most likely to engage and benefit from a Tele-HC program (Koehler et al., 2011). In addition, data on the sustained behavior change and the economic saving to the healthcare system will be paramount. In the end, strategies that develop relationships to engage patients as participants in their self-care, leverage technology, and continue to deliver health care with the human touch will transform the healthcare experience and quell the storm.

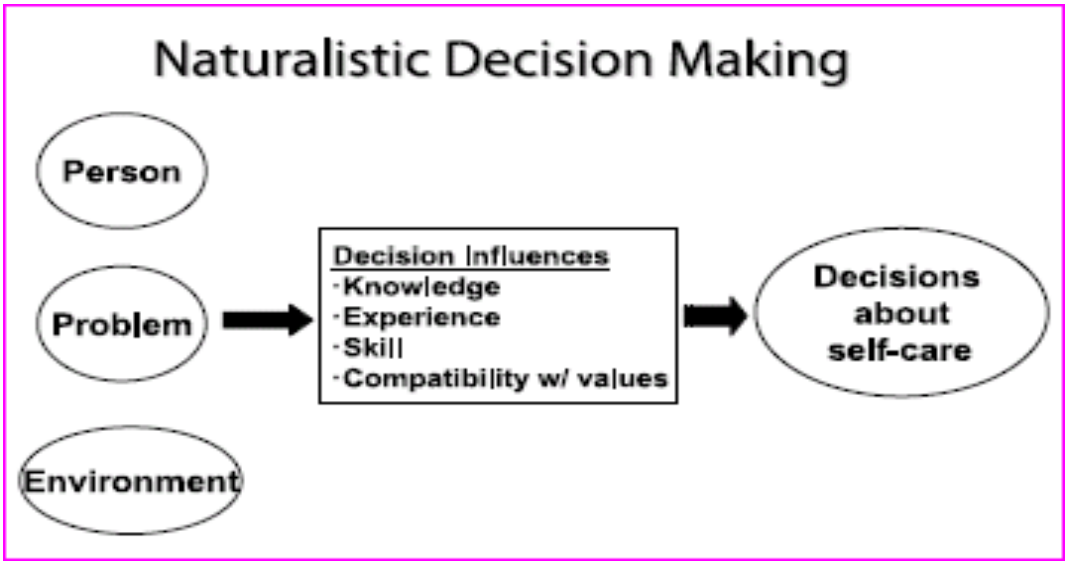
Appendix A

Self-care of Heart Failure Theoretical Model

Appendix A. Riegel, B. & Dickson, V. (2008) A situation-specific theory of heart failure self-care. *Journal of Cardiovascular Nursing. 23(3), p. 192.* Reprinted with permission

Appendix B

Naturalistic Decision Making Model



Appendix B. Riegel, B. & Dickson, V. (2008). A situation-specific theory of heart failure self-care. *Journal of Cardiovascular Nursing. 23(3), p. 193.* Reprinted with permission.

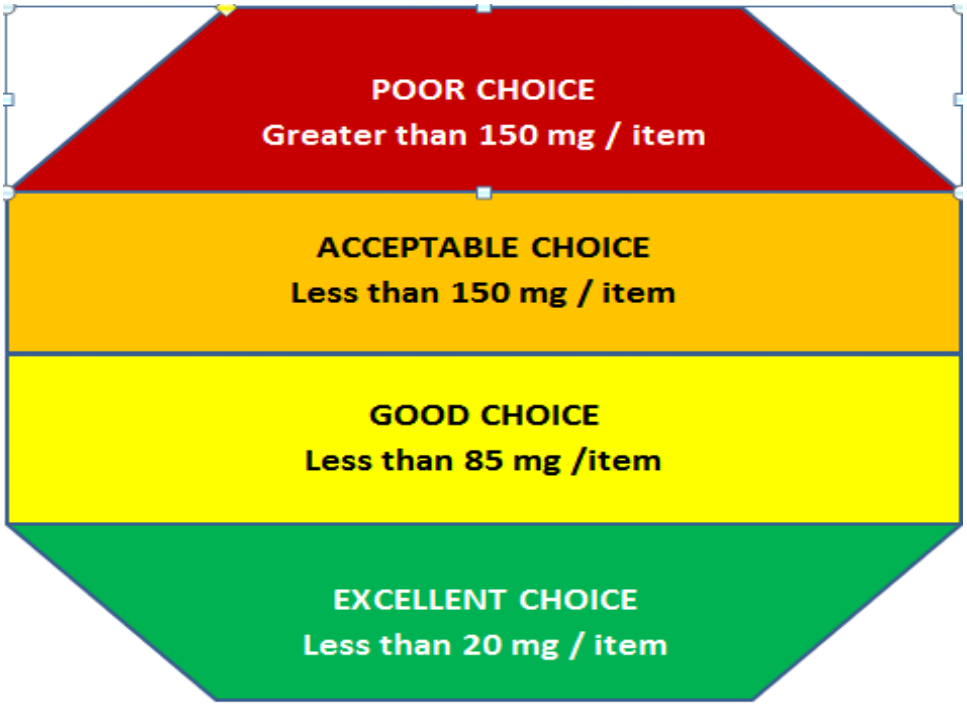
Appendix C

BodyGuardian Remote Monitoring System®

Appendix D

Sodium Warnings

Maximum Sodium Total per Day 1,500 mg
Maximum Sodium Total per Meal 500 mg



Appendix E

The Newest Vital Sign (Part I and II)

Part I.

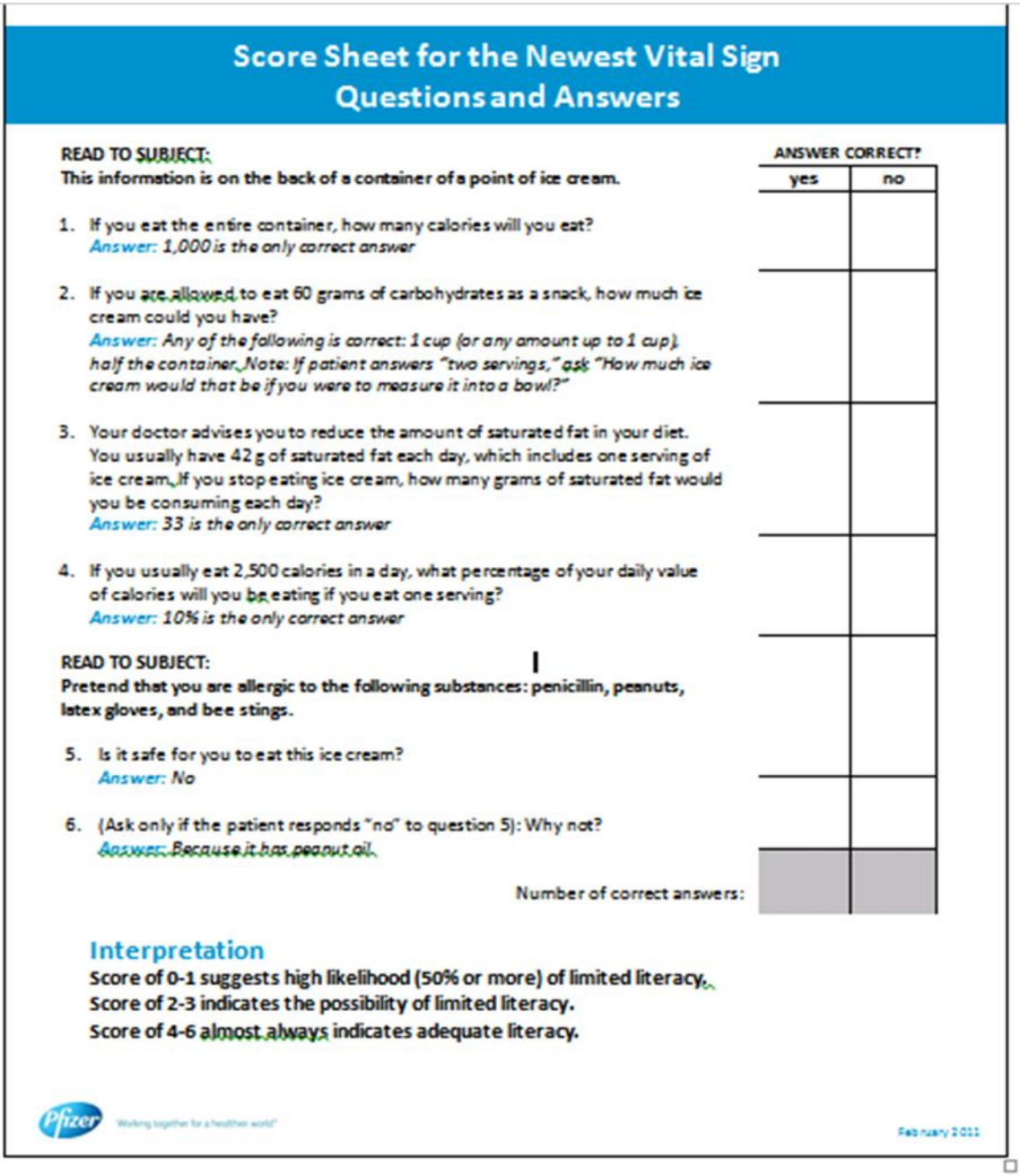
Nutrition Facts

Serving Size	½ cup
Servings per container	4
Amount per serving	
Calories 250	Fat Cal 120
	%DV
Total Fat 13g	20%
Sat Fat 9g	40%
Cholesterol 28mg	12%
Sodium 55mg	2%
Total Carbohydrate 30g	12%
Dietary Fiber 2g	
Sugars 23g	
Protein 4g	8%

*Percentage Daily Values (DV) are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.

Ingredients: Cream, Skim Milk, Liquid Sugar, Water, Egg Yolks, Brown Sugar, Milkfat, Peanut Oil, Sugar, Butter, Salt, Carrageenan, Vanilla Extract.

Part II.



Score Sheet for the Newest Vital Sign
Questions and Answers

READ TO SUBJECT:
This information is on the back of a container of a pint of ice cream.

	ANSWER CORRECT? yes	no
1. If you eat the entire container, how many calories will you eat? *Answer: 1,000 is the only correct answer*		
2. If you are allowed to eat 60 grams of carbohydrates as a snack, how much ice cream could you have? *Answer: Any of the following is correct: 1 cup (or any amount up to 1 cup), half the container. Note: If patient answers "two servings," ask "How much ice cream would that be if you were to measure it into a bowl?"*		
3. Your doctor advises you to reduce the amount of saturated fat in your diet. You usually have 42 g of saturated fat each day, which includes one serving of ice cream. If you stop eating ice cream, how many grams of saturated fat would you be consuming each day? *Answer: 33 is the only correct answer*		
4. If you usually eat 2,500 calories in a day, what percentage of your daily value of calories will you be eating if you eat one serving? *Answer: 10% is the only correct answer*		
READ TO SUBJECT: Pretend that you are allergic to the following substances: penicillin, peanuts, latex gloves, and bee stings.		
5. Is it safe for you to eat this ice cream? *Answer: No*		
6. (Ask only if the patient responds "no" to question 5): Why not? *Answer: Because it has peanut oil.*		
Number of correct answers:		

Interpretation

Score of 0-1 suggests high likelihood (50% or more) of limited literacy.
Score of 2-3 indicates the possibility of limited literacy.
Score of 4-6 almost always indicates adequate literacy.

Pfizer Working together for a healthier world

February 2011

Figure 12. The Newest Vital Sign developed for public use by Pfizer. Adapted from "The Newest Vital Sign," 2011, obtained from www.pfizerhealthliteracy.com.

Appendix F

ICD-9 Codes for Heart Failure

Heart failure 428 code definition:

- "inability of the heart to pump blood at an adequate rate to fill tissue metabolic requirements or the ability to do so only at an elevated filling pressure
- inability of the heart to pump blood at an adequate rate to meet tissue metabolic requirements or the ability to do so only at an elevated filling pressure" (www.ICD9 Data.com, 2012).

428 Heart failure

- 428.0 Congestive heart failure, unspecified
- 428.1 Left heart failure
- 428.2 Systolic heart failure
  - 428.20 Unspecified
  - 428.21 Acute systolic heart failure
  - 428.22 Chronic heart failure
  - 428.23 Acute on chronic systolic heart failure
- 428.3 Diastolic heart failure
  - 428.30 Unspecified
  - 428.31 Acute diastolic heart failure
  - 428.32 Chronic diastolic heart failure
  - 428.33 Acute on chronic diastolic heart failure
- 428.4 Combined systolic and diastolic heart failure
  - 428.40 Unspecified
  - 428.41 Acute combined systolic and diastolic heart failure
  - 428.42 Chronic combined systolic and diastolic heart failure
  - 428.43 Acute on chronic combined systolic and diastolic heart failure
- 428.9 Unspecified

(www.icd9data.com, 2012)

Appendix G

In-Hospital Visit Questionnaire

Adm. **To** Hosp.: _____Adm. **To** C3: _____DNR_____

Kit: _____Ext. ID: _____Patient: _____ Preventice ID: _____

PCP: _____Cardiologist:_____

Health Partner Name: _____ Location: _____

Home Health: _____O2:_____Cardiac Rehab: _____HX of Smoke/ETOH: _____

First Name: _____ Last Name: _____

Preferred name to be called: _____

Home #:_____Cell #:_____

E-mail:_____

Address: _____

Birthdate: _____ Age: _____ Weight: _____ Height: _____

Health Insurance: _____

Are you employed? _____

Source of Income: _____

How do you plan to cover your expenses while off work? _____

Applied for disability, Medicaid and Care Card? _____

Do you currently have any financial concerns? _____

Are you on a food budget? _____

Pharmacy: _____

Are you Compliant with your medications? If no explain: _____

Mental Status Assessment:

Independent: _____Ambulatory:_____Transportation:_____

Rate Activity Level: Active _____; Moderate _____; Sedentary _____

Alert to Person, Place, Health Condition: _____

Affect: Appropriate_____; Flat_____; Dramatized_____; Weepy_____

Memory Functions: Intact _____; Short-term _____; Long-term _____

Degree of Tech savvy: Maximum _____; Minimum_____

Caregiver: (Spouse? Yes/No) Other: _____

First Name: _____ Last Name: _____

Cell #:_____ E-mail:_____

Family Member #1: relation_____

First Name: _____ Last Name:_____

Home #:_____ Cell #:_____

E-mail:_____ City/State: _____

Family Member #2: relation_____

First Name: _____Last Name:_____

Home#:_____Cell #:_____

E-mail:_____ City/State: _____

Are you currently a caregiver? _____

Is patient interested in C3 or patient driven by caregiver? _____

Do you have any pets? _____

Do you have any problems with reading or writing? _____

How do you obtain information best? Are you a visual, audio, or hands on learner?

Interests:

Profession: _____Status/Retired: _____

Religion: _____ Church: _____

Who or where do you find your strength: _____

Interests/Sports: _____

_____

Born and raised: _____

Appendix H

Self-Care of Heart Failure Index (SCHFI)

SELF-CARE OF HEART FAILURE INDEX

All answers are confidential.

Think about how you have been feeling in the last month or since we last, spoke as you complete these items.

SECTION A:

Listed below are common instructions given to persons with heart failure.

How routinely do you do the following?

	Never/ rarely	**Some-times**	**Frequent**	**Always/ daily**
1. Weigh yourself?	1	2	3	4
2. Check your ankles for swelling?	1	2	3	4
3. Try to avoid getting sick (e.g., flu shot, avoid ill people)?	1	2	3	4
4. Do some physical activity?	1	2	3	4
5. Keep doctor or nurse appointments?	1	2	3	4
6. Eat a low salt diet?	1	2	3	4
7. Exercise for 30 minutes?	1	2	3	4
8. Forget to take one of your medicines?	1	2	3	4
9. Ask for low salt items when eating out or visiting others?	1	2	3	4
10. Use a system (pillbox, reminders) to help you remember your medicines?	1	2	3	4

SECTION B:

Many patients have symptoms due to their heart failure. Trouble breathing and ankle swelling are common symptoms of heart failure.

In the past month, have you had trouble breathing or ankle swelling? (Circle one).

0) No

1) Yes

11. If you had trouble breathing or ankle swelling in the past month…
(circle 1 number)

	Have not had these	**I did not recognize**	**Not Quickly**	**Somewhat Quickly**	**Quickly**	**Very Quickly**
How quickly did you recognize it as a symptom of heart failure?	N/A	0	1	2	3	4

Listed below are remedies that people with heart failure use. If you have trouble breathing or ankle swelling, how likely are you to try one of these remedies? (circle 1 for each)

	Not Likely	**Somewhat Likely**	**Likely**	**Very Likely**
12.Reduce the salt in your diet	1	2	3	4
13. Reduce your fluid intake	1	2	3	4
14. Take an extra water pill	1	2	3	4
15.Call your doctor or nurse for guidance	1	2	3	4

16. Think of a remedy you tried the last time you had trouble breathing or ankle swelling,

	I did not try anything	**Not Sure**	**Somewhat Sure**	**Sure**	**Very Sure**
How sure were you that the remedy helped or did not help?	0	1	2	3	4

SECTION C:

In general, how confident are you that you can:

(Circle 1 for each)

	Not Confident	**Somewhat Confident**	**Very Confident**	**Extremely Confident**
1. Keep yourself free of heart failure symptoms?	1	2	3	4
2. Follow the treatment advice you have been given?	1	2	3	4
3. Evaluate the importance of your symptoms?	1	2	3	4
4. Recognize changes in your health if they occur?	1	2	3	4
5. Do something that will relieve your symptoms?	1	2	3	4
6. Evaluate how well a remedy works?	1	2	3	4

Appendix I

IRB Approval

BON SECOURS RICHMOND HEALTH SYSTEM

Bon Secours Virginia Health System

June 19, 2013

Linda Tavares, DNP(c), MS, RN,
ACNP-BC, AACC Bon Secours
Heart and Vascular Institute

13700 St. Francis Blvd., Suite 606

Midlothian, VA 23114

Re: DNP Capstone Project: Effectiveness of a Telemonitoring and Patient-Centric Health Coach Intervention for Adult Patients with Hemi Failure: A Quality Improvement Project

Dear Ms. Tavares,

Thank you for your submission of the above-referenced capstone project for your Doctor of Nursing Practice degree at the University of Virginia. The project entails the use of the FDA- approved Body Guardian Remote Monitoring System (RMS)T" in combination with a patient- centric health coach to evaluate and improve outcomes of older (age 65 or greater) hemi failure patients at Bon Secours St. Francis Medical Center. Pursuant to this office's review of the proposal and our conversation today, this letter is to confirm that your proposal is determined to be a quality improvement project and not a human subjects research study, and therefore does not require review or oversight by the Bon Secours Richmond Health System Institutional Review Board (!RB).

If the project's goals or purposes change so as to characterize it as human subjects research, please contact me for further discussion or complete and submit the IRB's initial submission study forms.

Please do not hesitate to contact me at 804-627-5157 or mmk_leep@bshsi.org if you have any questions.

Best regards,

Mark F. Leep, JD, MBA, CIP

Director, Institutional Review Board

Appendix J

Partnership Pledge

C3NEXUS Partnership Pledge

Welcome to the C3NEXUS family. Your road to better health starts today.
C3Nexus is an organization dedicated to improving the health and wellness of patients worldwide. Through the use of state-of-the-art technology and your own personal healthcare partner, you'll receive paramount customer service and expertise in developing a health and wellness plan tailored to meet your specific needs.
Our personal healthcare partners serve as trusted liaisons between doctor and patient. You'll receive your own personal healthcare partner to work with you and your family to monitor your daily vitals, schedule regular home visits, and assist in carrying out the designated health routine aimed at effectively addressing your health needs and improving the quality of life for you and your family.
Establishing a strong relationship and partnership is essential to achieving success. And, we need your help. We're asking you to partner with us so we can provide a comprehensive service that covers your healthcare needs. By signing this pledge, you acknowledge that you are ready to work with C3NEXUS on the journey to a healthier you.

C3NEXUS Partnership Pledge

I, _____, pledge to give 100 percent participation and effort in working with my family, my personal healthcare partner and my physician to create a healthier life for me.

Appendix K

Data Collection and Property Return Agreement

Data Usage and Property Return Agreement

I, _____ (Customer), hereby accept responsibility for all property issued to me throughout my course of treatment with C3NEXUS. I understand that I am required to return all Company property upon request or at the end of my 90 day treatment with C3NEXUS in working condition.

I understand that my individual health information data will be collected through C3NEXUS. This data is protected by law as explained in the Bon Secours Privacy Notice. My information will only be used or shared in accordance with this notice. C3NEXUS may use my information in a population study only after my information has been de-identified of all personal indicators.

By: _____

Appendix L

Modified LACE Tool

Modified LACE Tool

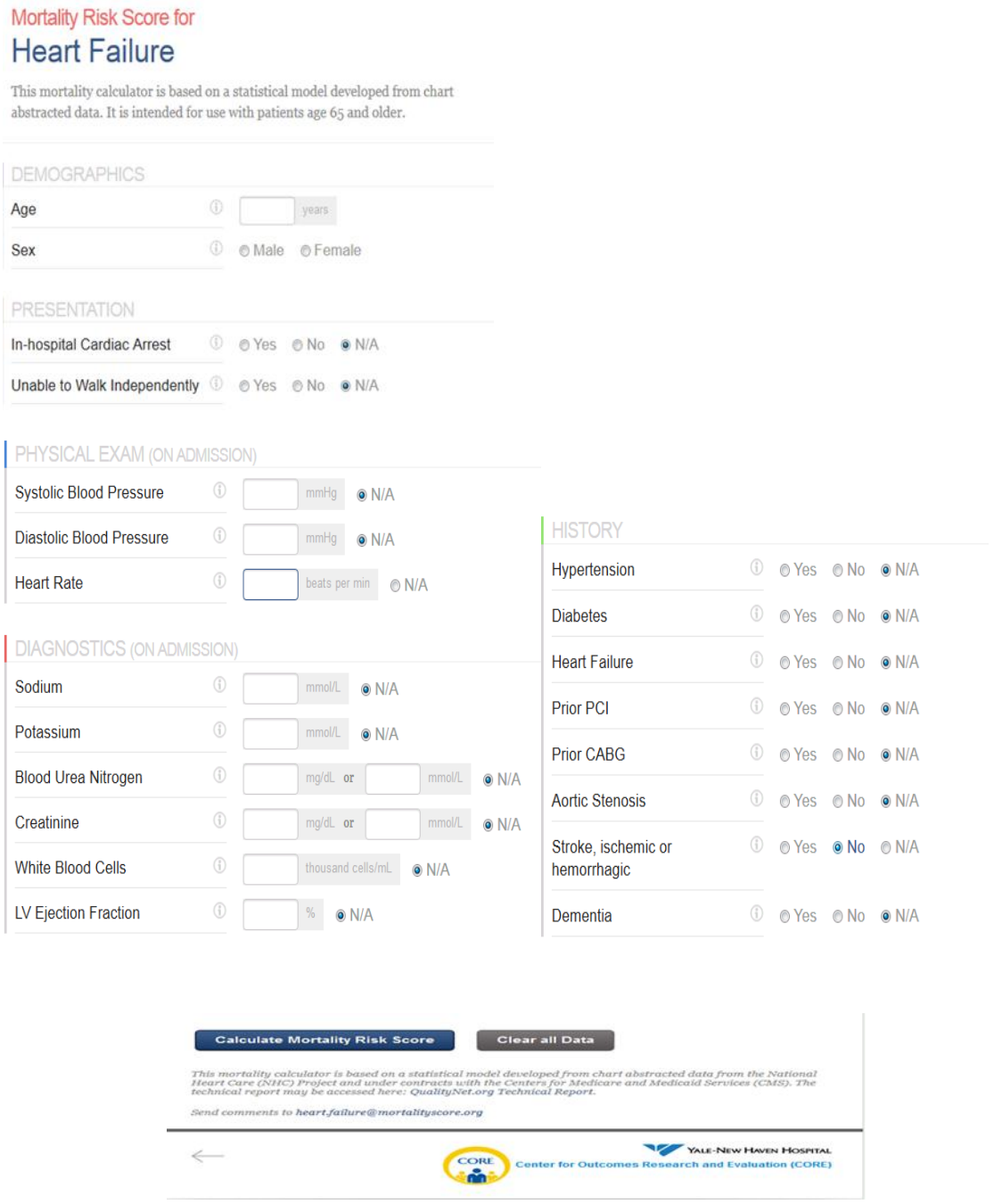
Attribute	Value	Points	Prior Admit	Present Admit
Length of Stay	Less 1 day	0		
	1 day	1		
	2 days	2		
	3 days	3		
	4-6 days	4		
	7-13 days	5		
	14 or more days	6		
Acute admission	Inpatient	3		
	Observation	0		
Comorbidity: (Comorbidity points are cumulative to maximum of 6 points)	No prior history	0		
	DM no complications, Cerebrovascular disease, Hx of MI, PVD, PUD,	1		
	Mild liver disease, DM with end organ damage, CHF, COPD, Cancer, Leukemia, lymphoma, any tumor, cancer, moderate to severe renal dz	2		
	Dementia or connective tissue disease	3		
	Moderate or severe liver disease or HIV infection	4		
	Metastatic cancer	6		
Emergency Room visits during previous 6 months	0 visits	0		
	1 visits	1		
	2 visits	2		
	3 visits	3		
	4 or more visits	4		
	Take the sum of the points and enter the total ➔			

17

Appendix L. The LACE tool consolidated to include all elements in a modified format. Adapted from Use *of modified LACE tool to predict and prevent hospital readmission (Power point),* by R. Kreilkamp, n.d. retrieved from http://www.raadplan.com/yahoo_site_admin/assets/docs/Use_of_Modified_LACE_Tool_to_Predict_and_Prevent_Hospital_Readmissions.209175219.ppt; *Derivation and validation of an index to predict early death or unplanned readmission after discharge from hospital to the community* by Carl van Walraven et al., 2010, *Canadian Medical Association Journal,* 182, 6, p. 553. Reprinted with permission.

Appendix M

CORE-HF Calculator



Appendix M. Centers for Outcomes and Research Evaluation (CORE) calculator to estimate readmission risk for patients with heart failure. Adapted from "Heart failure: hospital 30-day readmission measure.," by H. Krumholz, S. Normond, P. Keenanm, M. Desai, Z. Lin, E. Dryer, et. Al, 200.

Tables

Table 1.
Analysis of telemonitoring studies for outcome of hospitalization and self-care

Author/ Date	**Design Level**	**Sample HF class**	**End point-months**	**Telemonitoring (TM) Type**	**Self-Efficacy/ self-care**	**Results**
Benatar, Bondmass, Ghitelman, & Avitall (2003)	RCT Retro-spective Level 1	N = 216 Female 63% AA > 80% NYHA III-IV	3	TM vs home visit TM: electronic device transmits BP, HR, wt., O2 sat	Heart Failure Self-efficacy Scale 30	↓ heart failure readmit ($p \leq .001$) ↑Self-efficacy improved in both treatment groups. ($p < 0.01$)
Cleland, J. et al. TEN-HMS study (2005)	RCT Level 1	N= 426 Male 80% NYHA IV 50% Optimal medical therapy	8	TM vs UC <u>2 TM arms</u>: -Home TM-2x/day self-measure wt., BP, HR, rhythm -Nurse telephone support-monthly calls + available by phone for pt		Readmit similar. TM shorter LOS, and mortality.
Chaudhry, Wang, Concato, Gill, & Krumholz (2007)	Nested case-control-matched Level 3	N = 268 Female 55% NYHA III 97%	18	TM vs UC pts w/ HF hospitalized vs HF w/o hospitalization Weight only		Weight change began within 30-d of admit and predictive 1 week prior to admit ($p < .001$)

Clark, Inglis McAlister, Cleland, & Stewart (2007)	Meta-analysis Level 1 b	N = 4262 14 studies	Varied	TM vs structured telephone support 9 trials readmit Transmit: variable TM- variable		All-cause mortality less w/ TM, although not statistically significant. ↓HF admit - all trials relative risk reduction- 21% tx group – pooled trials favored TM
Dansky, Vasey, Bowles (2008)	Prospective randomized	N =284 NYHA II-III	4	TM vs home health <u>2 TM arms:</u> -TM (electronic device transmits BP, HR, weight) + home health -TM (#1+video w/ digital stethoscope) + home health	Omaha System Problem Rating Scale for Outcomes	TM ↓ probability of hospitalization (video OR .35 $p < .05$; monitor only OR .69, $p < .10$). Basic TM ↑ self-reported sx related to diet ($p = .043$) and meds ($p = .001$).
Schwarz, Mion, Huddock, Litman (2008)	Pilot RCT Level 1	N = 102 Female 50% White 80% NYHA II or III 69%	3	TM (APN) vs UC TM: weight, Y/N questions about sx + adherence		Did not ↓ 90-day readmit (p =.90) or ED use ($p = .73$)
Woodend et. al. (2008)	RCT Level 1	N = 249 Male 74% NYHA III-IV 66%	3	TM vs UC TM: daily (electronic device transmits BP, HR, weight) + Weekly video conference w/ nurse + periodic EKG transmitted		↓ 90 day readmit- not statistically significant (p NR)

Dar et al (2009) HOME-HF	RCT Level 1	N= 182 Male 68% NYHA II-IV HF New dx: 41% Optimal medical therapy	6	TM vs UC TM: electronic BP, HR, weight pulse ox		No significant difference in readmit between groups (p = .30)
Giordano et al. (2009)	RCT Level 1	N= 460 Male 84% NYHA II-IV Optimal med therapy	12	TM vs UC TM: weekly or q 15 days based on NYHA class and prn Self-measure BP, wt, reported s/sx, adherence to diet, wt monitoring, meds. EKG trace prn		↓HF readmit (p=.0001)
Klersy et.al (2009)	Meta-analysis Level 1B 54% (RCT) 83% (Cohort studies)	N = 8612 Male 62% NYHA III-IV	Varied	TM vs UC <u>2 TM arms</u>: -Structured telephone strategy w/wo home visit -TM (electronic device or implantable device)		TM ↓ risk of HF hospitalization (p=.03)
Mortara et al. (2009) The HHH study	RCT Level 1	N = 461 Male >80% NYHA II-III Optimal medical	12	TM vs monthly calls TM: <u>3 arms</u> - Monthly phone call-interactive voice response		TM did not reduce readmit, or hospitalization. (p NR)

		therapy		-Call + weekly vital signs (wt, HR, BP) + sx -Call + weekly vital signs + monthly non-invasive CV-pulmonary data(EKG, activity, resp rate) + sx		
Bowles, Riegel, Weiner, Glick & Naylor (2010)	RCT Level 1	N= 218 Female 64% NYHA not indicated	6	TM vs home visits TM: video phone, Daily BP, weight, pulse ox, and glucometer	Self-care Heart Failure Index	TM did not ↓readmit rate significantly *(p*=.5) ↑SCHFI @ 6 mos ($p < .001$) for both groups in all 3 categories
Chaudhry et al. (2010) Tele-HF study	RCT Level 1	N =1653 Male 60% White 50% NYHA I-IV NYHA II-III-86% Optimal medical therapy	6	TM vs usual care TM: structured automated voice activated system w/ questions about symptoms and weight (weight single data point)		TM did no ↓ readmit rate significantly ($p = .75$) Adherence low w/ about 50% sending info 3x/week
Weintraub et al. (2010) SPAN-CHF II Trial	RCT Level 1	N = 188 Male 66% White 93% NYHA II-III Optimal medical therapy	3	TM vs disease management TM: device to transmit BP, HR, weight + disease management		TM ↓ readmit ($p= .05$)

Inglis et al (2011)	Meta-analysis	N = 8323	Varied	Structured telephone support vs TM TM varied	Self-care	TM ↓ HF hospitalization (*p*=.008) ↑Self- care (*p* NR)
Koehler et al. (2011) TIM-HF study	RCT Level 1	N = 710 Male 80% NYHA II-III Optimal medical therapy	12	TM vs usual care TM: 24/7 TM, BP, HR, weight, EKG		HF hosp @ 6 mos (*p* = .38) @ 12 mos (*p*=.28) All cause hospitalization (*p* =.29)
Boyne, Vrijhoef, Crijns et al (2012) TEHAF trial	Prospective RCT Level 1	N= 382 Male 59% NYHA II-IV Optimal medical therapy	12	TM vs usual care TM: tablet connected to phone line w/ questions about sx, knowledge, behavior No physiological data transmitted	European self-care behavior scale	No significant difference in readmit or HF admit (p =.15)
Dendale et al. (2012) TEMA-HF 1	RCT Level 1	N = 160 Male 65% NYHA III	6	TM vs UC TM: BP, HR, wt		↓HF hosp (*p*=.056) All cause hospitalization no difference (*p* = .93)
Gellis et al (2012) Tele-HEART	RCT	N =102 Female 63% White 82% 81% HF	12	TM vs UC + education TM: Electronic scale, BP cuff, pulse ox Y/N questions		TM ↓ all-cause rehospitalization (*p* = .06)

intervention (mixed COPD and HF)						
Lynga et al (2012) WISH trial	RCT Level 1	N= 344 Male 76% NYHA III-IV	12	TM vs self-reported manual weight TM: electronic scale		No significant difference in CV (*p*=.54) or all-cause hospitalization (*p=.24)*
Seto et al (2012)	RCT Level 1	N = 180 Male 82% White 78% NYHA II-IV Optimal medical therapy		Mobile phone based TM + UC vs UC TM: Weight, BP (daily) EKG (weekly) Sx questions y/n through phone (daily) Alerts sent and modified – email	Self-care Heart Failure Index	No difference in # hosp, LOS, or ED visits Sample size small TM group ↑ Self-care maintenance (*p*= .004) ↑ Self-care management (*p* =.02), no change in self-confidence (*p* =.7)

Table 2.
Health Coach and Self-Care Studies

Health Coach							
Author/Date	**Design Level**	**Sample HF class**	**End point (months)**	**Telemonitoring (TM) Type**	**Health Coach Type**	**Self-Efficacy/ self-care**	**Results**
Vale et al (2002)	RCT Level 1	N = 245	6	-	Phone 20 min x 4 sessions	-	↓ total cholesterol /LDL (p< .001)
Vale et al (2003) COACH study	RCT Level 1	N = 793	6	-	Nurse led DM Telephone + mail	-	Coaching significant for primary biomarker outcomes (p < .001)
Edelman, D et al (2005)	RCT Level 1	N = 154	10	-	Personalized health plan	-	↓cardiovascular risk (Framingham) (p = .04) ↑readiness to exercise (p = .02)
Wongpiriyayothar et al (2007)	Quasi exper Pre-test/ post test Level 2	N = 22 NYHA II-III	3	TM- phone 2x/week x 3weeks (30-60 min)	Face-to-face 30-45 min	-	↓dyspnea (p<.001), ↑activity (p<.001)
Linden, Butterworth, & Prochaska (2010)	Observational Level 3	N= 336	8	-	3 sessions 20-45 min	Self-efficacy for chronic illness	↑ self-efficacy (p = .01)

Paradis et al (2010)	Quasi-experimental Level 2	N= 30 NYHA II: 67%-I 47% C NYHA III: 26% I 53% C Male: 74%	4	-	Motivational interviewing vs UC Patients chose behavior they wanted to change	SCHFI	Improved SCHFI scores Intervention group more class II , control group more class III
Cooper et al (2011)	RCT Level 1	N = 279 HTN	12	-	Physician + Community worker	-	Med adherence did not differ, insignificant ↓BP
Ivey, et al. (2012)	Quasi experimental Level 2	N = 92 Diabetes	6	-	In office coaching	-	↓HgA1C (p = .048)

None "-"

Table 3.
Qualitative Studies

Qualitative			
Author	**Design**	**Sample**	**Themes and Outcomes**
Dickson, Buck, Riegel (2012)	Qualitative Meta-analysis from 3 prior studies	N = 99 66% male NYHA III 53%	-Attitudes drive self-care prioritization -fragmented self-care instruction leads to poor self-care integration and self-care skill defects
Seto, E; Leonard, Cafazzo et al (2012)	Qualitative Semi-structured interviews	N = 180 82% Male NYHA III or IV 46%	TM group ↑ Self-care maintenance (p= .004) ↑ Self-care management (p =.02), no change in self-confidence (p =.7) - ↑awareness and knowledge of HF condition - ↑ reassurance/ ↓anxiety - ↑empowerment/confidence - ↑ self-care motivation

Table 4.
Telemonitoring studies analyzed for components and additional outcomes

Author/Date	Design/Level	Transmission modality	Components of intervention	Compared to	Frequency of data transmission	Data points	Data monitor	Outcome
Benatar et at (2003)	Prospective RCT 2 arms	Internet via phone line	TM (APN) Electronic scale, auto BP cuff, pulse ox	APN HH visit	Daily	BP, weight, HR, O2 sat	APN	90-day ↓ HF hospitalization TM group ($p \leq .001$)
Cleland, Louis et al TEN-HMS (2005)	RCT 3 arms Good diagram of process	Internet via phone line	TM Electronic scale, auto BP, single lead EKG (wrist bands) + nurse phone support	2 arms: Nurse telephone support or UC	BID (TM) Monthly (nurse support)	BP, weight HR, rhythm	Nurse	240-day hospitalization -similar rates TM shorter LOS UC associated w/ adverse prognosis and higher mortality ($p = .032$)
Chaudhry, Krumholz et al (2007)	Nested case control	Internet via phone line	TM Electronic scale	Matched cases w/o HF hospitalization	Daily- pts contacts if missed 2 days	Weight	Nurse-specially trained by monitor company	Hospital admit Difference in weight changes w/in 30-days of admit ($p \leq .001$)
Dansky, Vasey, Bowels (2008)	Prospective RCT 3 arms	Internet via phone line Video	TM + HH 2 arms TM1-electronic scale, auto BP,	HH	Daily Video	Weight, BP, pulse, Prn glucose,	Nurse	60- day ↓hospital admit TM group (OR .98) and

			pulse, wt- nurse reviewed daily and called if abnormal TM2- added video + digital stethoscope		sessions 2-3 x/week	pules ox Sx review, heart and lung assessment via digital stethoscope		TM+ video (OR .76) (p <.01) after controlling for # home care days
Schwarz et al (2008)	Pilot RCT 2 arms	Internet via phone line	TM (APN) Caregiver present (tool to measure) Electronic scale + Y/N questions about sx, meds, Na intake	UC Caregiver present	Daily	Weight, sx, med use, Na intake	APN	90-day readmit Similar in both groups
Woodend et al (2008)	RCT N = 121	Internet via phone line Video	TM Video conference (VC)	UC	Daily- wt/BP EKG prn VC weekly	Wt, BP, EKG Conference	Not indicated	90-day readmit No significant difference in rate, although 28% shorter LOS
Dar et al (2009) HOME-HF	RCT N = 182	Internet via phone line	TM Electronic scale, BP cuff , pulse ox, control box	UC	Daily	BP, HR, weight, pulse ox 4 yes/no sx questions	HF Nurse	180-day admit no significant difference between 2 groups ↑ ER HF admits in UC (p = .01)
Giordano et al (2009)	RCT N=460	Internet via phone line Phone calls	TM- EKG transmission + phone follow up 2 arms	UC f/u PCP 2 weeks, and cards @ 12	Weekly and prn	Self-reported BP, weight Sx,	Nurse and physician	1 year HF readmit lower in TM group (p = .0001)-

			1. Scheduled TM: q week or q 15 days 2. PRN TM signs decompensation	mos		Adherence, lifestyle EKG transmitted		curves diverged at 150 days
Mortara et al (2009) The HHH study	RCT N= 461	Internet via phone line	TM-3 arms 1. Voice interactive answering machine + monthly nurse call 2. #1 + Nurse call + weekly vital signs 3. #2 + NICRAM (non-invasive cardioresp and activity monitoring)	UC	Weekly (arm 2,3) Monthly	BP, HR, weight, sx scores Clinical status	Nurse or physician	1year no significant differences in HF hospitalization or readmit
Bowles, et al Riegel… Naylor et al (2010)	RCT N = 218	Internet via phone line Video	TM Electronic scale, BP cuff, video phone	UC: HH 1-3 x/week x 8 weeks	Daily Video-intermittent at least 4	BP, weight, pulse ox, glucometer	Nurse	60-day Readmit rate less in TM group but no significant (p =.5)

Chaudhry et al (2010) Tele-HF trial	RCT N=1653	Phone call	TM Pt generated call to Voice interactive system	UC	Daily	Weight-self reported Questions about HF sx, health	Site co-ordinator Staff- not specified	180-day hospitalization No significant reduction (*p*=.45) Readmit similar in both groups (*p*=.81)
Weintraub et al (2010) SPAN-CHF II Trial	Prospective RCT N=188	Internet via phone line	TM + disease management per protocol Electronic scale, BP cuff, text messages	UC- disease management	Daily	BP, weight, HR Questions related to sx, functional status, adherence	Nurse	90-day readmit HF readmit rate favored TM (RR = .5, *p* = .05) All cause readmit > TM not significant (*p*=.3)
Koehler et al (2011) (TIM-HF) Telemedical Interventional Monitoring in Heart failure Study	RCT N=710	Bluetooth	TM Electronic scale and BP cuff, EKG machine	UC	Daily	BP, Weight, HR, EKG (3 lead)	Physician	180- day hospitalization ↓ (*p* =.38)

Boyne, Vrijhoef, Crijns et al (2012) TEHAF trial	RCT N = 382	Internet via phone line	TM- no physiological data Monitor w/ questions about sx, knowledge, behavior	UC	Daily	Answer to questions	HF Nurse	1 year HF admit Time to readmit less in TM group (p=.151)
Dendale et at (2012) TEMA-HF 1	RCT N = 160	Bluetooth	TM Caregiver involved	UC	Daily	BP, weight, heart rate	Not indicated Auto email alerts sent to GP and HF clinic Nurse/ cardiologist	180 days HF admit favored TM (p=.056)
Gellis et al (2012) Tele-HEART intervention Mixed COPD, HF	RCT N =102	Internet via phone line	TM Electronic scale, BP cuff, pulse ox	UC	Daily	BP, weight, heart rate, pulse ox, temp Answers to Y/N questions	Nurse	1 year admit favored TM (p= .06)

Lynga et al (2012) WISH trial	RCT N = 344	Internet via phone line	TM Electronic scale	Control-self-reported manual weight	TM: Daily UC: 3x/week	Weight	Nurse-monitored M-W-F	Readmit Cardiac (*p*=.54) Hospitalization All cause (*p=.24)*
Seto et al (2012)	RCT N = 180	Cell phone	TM Electronic scale and BP cuff	UC	Daily Weekly	Weight BP Y/N answers EKG	APN MD-Cardiologist	No significant difference in hospitalization

Table 5. Demographic Characteristics

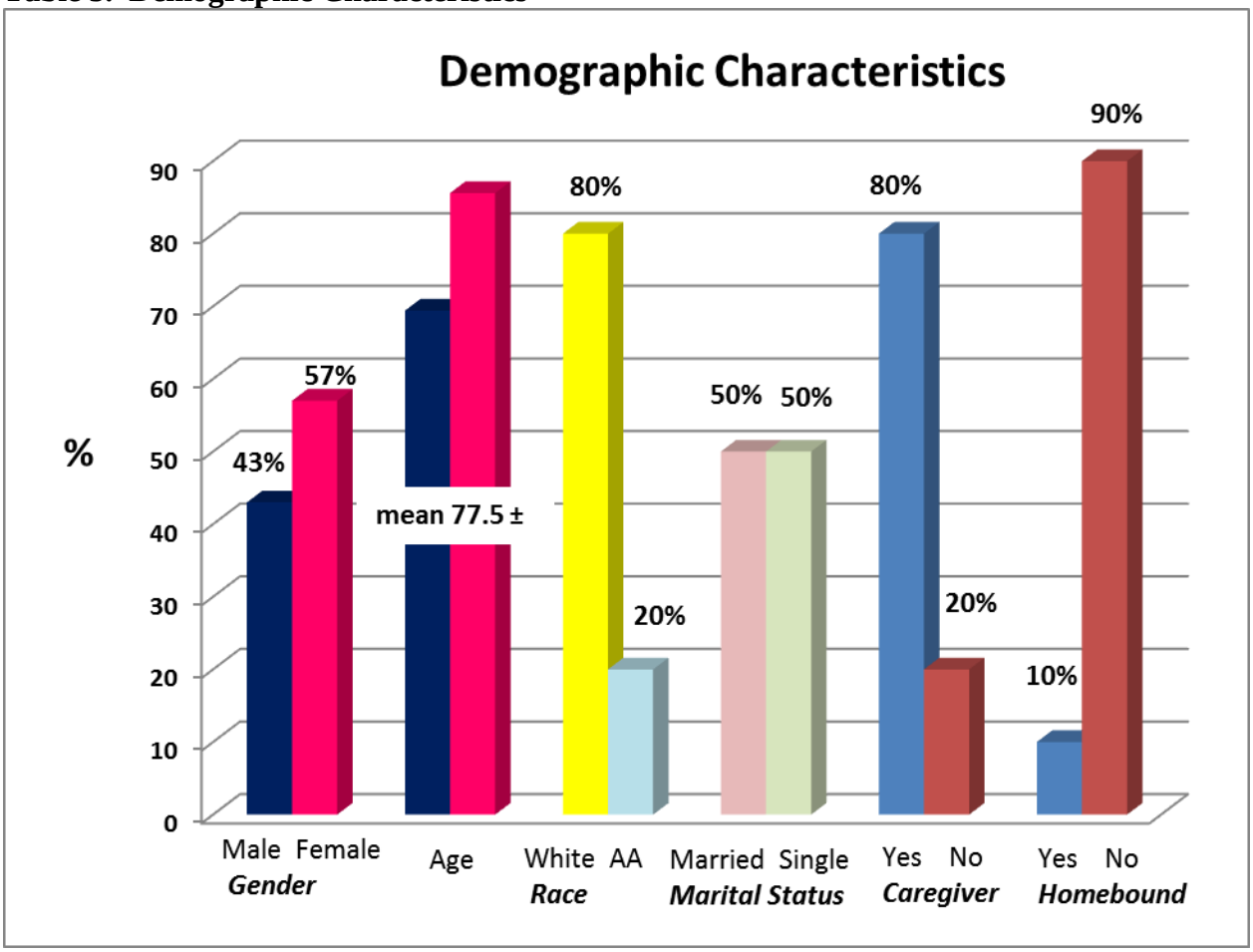


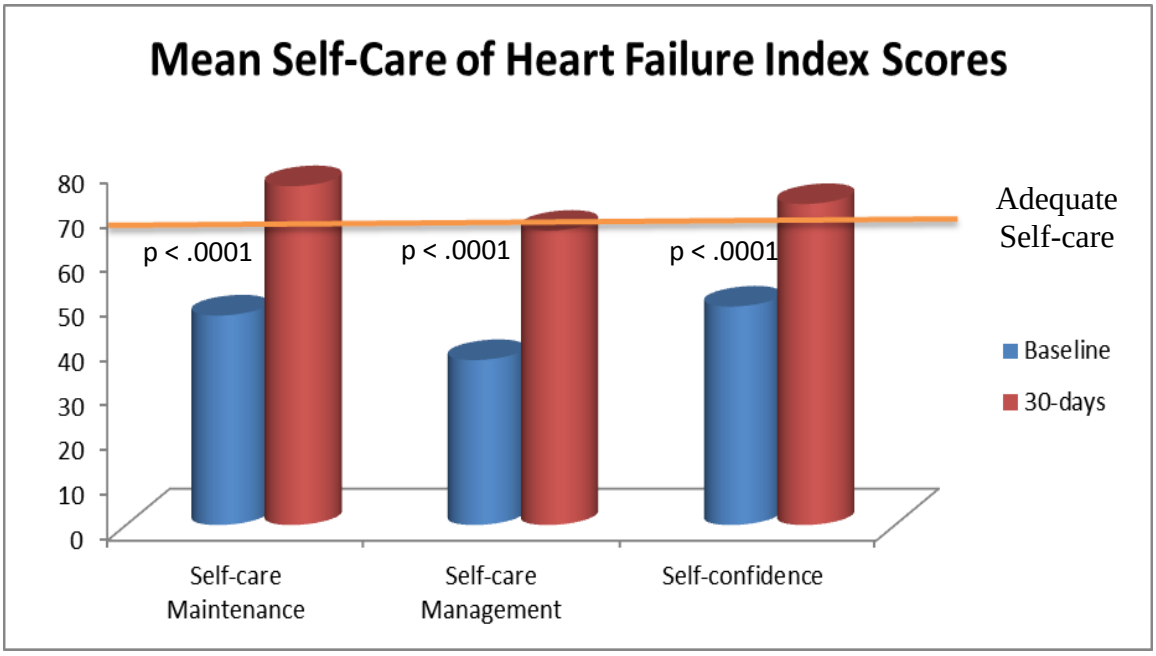
Table 6. Medical Characteristics

Characteristic	Total Sample (n =30)
Length of Stay	4 days ±2
≤48 hours	8 (27%)
3-5 days	18 (60%)
6-10 days	4 (13%)
Ejection Fraction	
Reduced (EF ≤40%)	18 (60%)
Preserved (EF > 40%)	12 (40%)
Etiology of Reduced EF (n=18)	
Ischemic	10 (33%)
Non-ischemic	8 (27%)
Date of Diagnosis	
< 6 months	12 (40%)
>6 months	18 (60%)
NYHA class	
I	3 (10%)
II	13 (43%)
III	13 (43%)
IV	1 (3%)
Comorbid Conditions	4±2
Coronary artery disease	23 (77%)
HTN	28 (93%)
Atrial fibrillation	18 (60%)
Diabetes	11 (37%)
CKD	14 (47%)
COPD	9 (30%)
OSA	11 (37%)
Depression	3 (10%)
Medication (total number)	12 ±5
Medication Class	
Beta-blockers total group	28 (93%)
Beta-blockers for reduced EF ≤ 40% (n=18)	18 (100%)
ACE-I or ARB total group	21 (70%)
ACE-I or ARB for reduced EF ≤ 40% (n=18)	14 (78%)
Diuretics	25 (83%)
Potassium sparing diuretics	8 (27%)
Potassium supplements	5 (17%)
Aspirin	24 (80%)
Statin	22 (73%)
Diabetes medications (n=11)	8 (73%)
AICD	6 (20%)
Health Literacy (n=27)	5 ± 2 (78%)(data skewed right)

Table 7. Correlation Analysis of Variables

VARIABLE	MEAN±SD	p-VALUE	PEARSON'S *r*	R^2	B
Readmit Rate					
All Cause	6%				
Heart failure	0				
LACE	9±3	.003	.391	.153	.243
CORE-HF	25±5				
Self-care maintenance (n=30)					
At baseline	47 ± 17				
At 30-days	76 ± 13				
Delta	29±16	<.0001			
Touches @ 2 weeks	26±10	.009	.426	.182	.737
Touches @ 30-days	47 ±14	.054	.300	.090	.361
Self-care management (n=17)					
At baseline	37 ±19				
At 30-days	66 ±13				
Delta	29±18	<.0001			
Touches @2 weeks	25±9	.218	.315	.099	.694
Touches @ 30-days	46 ±12	.558	.118	.014	.183
Self-confidence					
At baseline	49 ± 25				
At 30-days	72±23				
Delta	22±19	<.001			
Touches @ 2 weeks	26±10	.385	.164	.027	.304
Touches @ 30-days	47±14	.806	.047	.002	.6

Table 8. Mean Self-Care of Heart Failure Index Scores



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Section V

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Abstract

Background: Telemonitoring interventions to prevent readmissions in patients with heart failure (HF) have shown inconsistent results in their effectiveness on HF-related and all-cause rehospitalization. Interventions geared toward early identification of HF symptoms in concert with improved care coordination and enhanced patient self-care may help to prevent unplanned hospitalizations in patients with HF.

Objective: The purpose of this quality improvement project was to evaluate the outcomes of a patient-centric telemonitoring (Tele-HC) intervention designed for elderly adult patients with heart failure in a community hospital setting.

Methods: The outcomes evaluation used a descriptive, cross-sectional observational design for the readmission rates. A one-group pretest-posttest design was used to measure self-care outcomes. Correlation analysis was performed to determine relationships between the intervention and outcomes.

Results: The 30-patients were primarily Caucasian, female with a mean age of 77.5 years. The majority of patients had HF with an ejection fraction ≤ 40%, NYHA class II or III symptoms, and received appropriate medical therapy. Health literacy was adequate in the sample. The 30-day all cause readmission rate was 6% with no patients being re-hospitalized for HF. Patient self-care scores improved with all three categories reaching statistical significance ($p < .0001$). A significant relationship existed between the number of touches during the first 2 weeks and improvement in self-care maintenance scores ($p = .009$). The number of touches moderately predicted changes in these scores ($p = .019$).

No direct correlation was drawn between touches and readmission rate, due to the data being skewed in favor of the intervention.

Conclusion: Strategies that engage patients as partners in their self-care and leverage technology reduce hospital readmissions and improve self-care outcomes.

KEY WORDS: heart failure, self-care, health coach, telemonitoring

Effectiveness of a telemonitoring and patient-centric health coach intervention for adult patients with heart failure: A quality improvement project

BACKGROUND

Heart failure (HF) is at the pinnacle of a perfect storm with the escalating combined societal public health burden and economic burden. These are accelerated by the burden of rehospitalization in the context of a changing national health care system.

This significant public health burden affects approximately 6 million Americans, with 670,000 new cases of HF annually.[1,2,3] As the single largest Medicare expenditure, the estimated direct and indirect annual cost of HF is projected to reach $56 billion dollars by 2020.[4] The burden of chronic HF is characterized by suboptimal self-care behaviors and frequent hospitalizations.[5,6,7]

The Readmission Cycle. The rehospitalization burden is created by the nearly 30% readmission rate within 60 days post-discharge that accompanies the diagnosis of HF.[8] The drivers of readmission are multifactorial and often attributed to fragmented transitions from the hospital to the home or skilled facility due to a lack of communication, a lack of care coordination, and poor self-care.[9,10,11] Other behavioral factors including lack of adherence to medication, diet, and weight monitoring, combined with scarcity of economic resources, or insufficient social support frequently contribute to rehospitalization.[12,13] The patients most vulnerable to readmission are often the elderly who possess a myriad of co-morbid conditions resulting in polypharmacy, functional limitations, psychosocial factors, and transportation issues embedded in a fragmented transitional process.[14,15] Sub-optimal symptom management, self-care deficits, and lifestyle choices surrounding HF contributes to the rehospitalization burden.[9]

Currently, a mounting body of evidence suggests that non-pharmacological interventions implemented by multidisciplinary teams across the health care continuum can reduce hospitalizations and improve self-care for patients with HF.[16, 17] These include telemonitoring and encouraging patient self-care through health coaching by specialized heart failure nurses.

Telemonitoring. Telemonitoring (TM), the use of remote monitoring technology, has become an integral part of transitional care for adult patients with HF.[18,19] However, TM interventions to prevent readmissions in HF have shown inconsistent results in their effectiveness on HF-related and all-cause rehospitalization.[19] This variability highlights the complexity of managing patients with HF and the challenges in readmission prevention. Today's chronically ill, vulnerable seniors have a higher acuity than in previous years at the time of hospital discharge.[14] These vulnerable seniors are often being cared for at home by an elderly, frail, and chronically ill spouse.[14, 20]

Self- care. Health care professionals often operate from a paradigm that knowledge translates into behaviors and thus improves clinical outcomes.[21] However, reality typically heralds that treatment adherence has little relationship to knowledge.[22] Self-care programs aim to empower the patient to assume the primary role in managing their condition.[23] Self-care is a decision-making process involving the choice of behaviors aimed at maintaining physiologic stability.[23] These behaviors include symptom monitoring, treatment adherence, and purposeful engagement in a behavior response to manage symptoms when they occur.[24]

Health coaching. Health coaching, rooted in motivation and education, is an integrative process of partnering with patients using a patient-centric approach to change

behavior through an engaged, structured, and supportive partnership.[25] The goal of health coaching is to facilitate patient self-management strategies for the purposes of preventing disease exacerbation and hospitalization.[25] The health coach uses motivational interviewing (MI) to activate patient self-care and confidence in their ability to change.[26]

For the HF population, the use of technology to monitor patient clinical status at home in concert with a health-coach is a viable model to engage patients in self-care behaviors, close the patient-provider communication gap, foster patient autonomy, and enhance the patient experience.[27] Therefore, the purpose of this project was to evaluate the outcomes of a Tele-HC intervention on 30-day readmission (HF and all cause) for adult patients, age 65 or greater, with HF from a community hospital setting. The outcomes included 30-day rehospitalization rate and changes in self-care scores.

Methods

The purpose of this quality improvement (QI) project was to evaluate a combined telemonitoring device and patient-centric health-coaching intervention (Tele-HC) for adult patients with HF from a community hospital setting. Thirty day all cause hospital readmission was the primary outcome of interest. A secondary outcome of interest was changes in the Self-care of Heart Failure Index scores at 30-days compared with time of enrollment.

Design/Sample

This QI project used a descriptive, cross-sectional observational design for the readmission rates. A one-group pretest-posttest design was used to measure self-care outcomes. A single community hospital provided the setting of study. The convenience

sample included recently hospitalized adults ≥ 65 years old with a primary or secondary diagnosis of HF as identified by ICD-9 codes in the 428 (congestive heart failure) cohort. Participants spoke English as their primary language, lived at home, were ambulatory, and were under the care of a single multi-provider cardiology practice. Exclusion criteria included patients discharged to a skilled nursing or rehab facility; those with dementia or disabling psychiatric disorder; end stage renal disease on hemodialysis; those with a terminal illness; or lack of willingness to participate.

Program Description

A multidisciplinary team provided the functional infrastructure for the quality improvement project. The team consisted of the project facilitator (author) in collaboration with the medical director for C3Nexus (a privately held transitional care company), an additional cardiology advanced practice nurse (APN), case management, nursing, referring cardiologists, hospitalists, and the patient-centric health coach (PCHC) team.

The Tele-HC program combined the hi-tech of the Body Guardian RMS® (Preventice, Minneapolis, MN) using proprietary algorithms in concert with a hi-touch PCHC. The patient-centric health coach (PCHC) was a conceptual term for hi-touch component of the intervention, led by a registered nurse. The participants were provided with wearable BodyGuardian ® system, including an electronic blood pressure (BP) cuff and scale, in addition to usual care. These devices were compatible with pacemakers and implantable cardioverter-defibrillators. The weight, EKG tracings, BP readings, and activity levels were automatically transmitted wirelessly via Bluetooth to a mobile phone (Samsung galaxy, Ridgefield Park, NJ). The custom-designed and built software

application on the phone was used to display, store and transmit data to *LifeStat,* the C3Nexus data management platform.

Standard care included HF education by the specialized cardiac nurses in the hospital. Standard care also included follow up visits to the clinic 5-7 days following hospital discharge and then every 1-3 months depending on severity of illness.

LifeStat displayed algorithm-mediated data for the PCHC and provider to review via a web portal or secure tablet. Biometric data was available continuously with monitor protocols capturing data points every hour. Additional patient-generated data was initiated based on patient-reported symptoms. The live data evaluation by the PCHC occurred 7 days per week from 7am – 7 pm. The PCHC did additional monitoring and evaluation of the transmitted data on an as needed basis for calls generated outside of the 12-hour monitoring window.

The PCHC intervention started in the hospital when the C3Nexus liaison interviewed the patient to assess level of engagement, eligibility, and establish the relationship between the patient and C3Nexus. The RN who was the primary contact for the patient experience championed the PCHC intervention. The RN focused on areas of disease management including symptom recognition, adherence to treatment strategies, care coordination, medication matters, and problem solving. Medication matters included initial medication reconciliation and organizing resources to obtain medications for patients who had socioeconomic challenges. The liaison became part of the PCHC team when patients had socioeconomic challenges. A nutrition and wellness clinician (NWC) becomes the PCHC when collaborating on issues related to nutrition, healthy lifestyle, and exercise. The NWC focused on food reconciliation, nutrition assessment,

food preferences, and establishing wellness goals with the patient.

The PCHC established a patient-centric relationship using techniques of motivational interviewing coupled with a transactional model of communication.[28,29] Patient-centeredness was maintained by first assessing health literacy with the Newest Vital Sign tool.[30] Topics included the patient's understanding of their disease, treatment strategies, establishing goals of health, and therapy expectations. As the PCHC team identified knowledge deficits, they customized the education and employed the teach-back methodology to address the gaps. The PCHC engaged the patient in collaborative care planning and goal setting to insure interventions were congruent with the patient's readiness for change, needs, values, culture, desires, and health goals. Patient empowerment and self-management were measured with the SCHFI in a pre-test –post-test fashion.[31]

The hi-touch personal interactions included at least one face-to-face encounter in the home, daily contact with the PCHC for the first14 days with a patient-driven tapering schedule thereafter. Following patient identification and enrollment, the intervention used a three-phase approach: *pre-visit phase, the calibration phase, and the maintenance phase*.

Patient identification and enrollment. Subjects were identified in the hospital by the cardiovascular team. The author validated the diagnosis of HF with chart review of the cardiology team's impressions, related signs and symptoms of decompensated HF, diagnostic testing including documentation of ejection fraction, echocardiogram within the past 6 months, and pro-BNP. While making daily rounds, the APN informed the potential participants of the intervention. The author reviewed the electronic medical

record to obtain clinical data and completed the LACE and CORE- HF scores.[32, 33]

Pre-visit. The C3Nexus liaison, serving as the PCHC, met with the patient and caregiver in the hospital to establish the initial phase of the patient-centric relationship. During a semi-structured interview, the patient was assessed for willingness to participate and basic use of technology. The interview concluded with completion of the partnership and property agreements. The property agreement included health information release (HIPPA) authorizing C3Nexus to collect de-identified data with anticipated publication of results.

Calibration phase (Day 1 through 14). The *initial meaningful visit* occurred within 24-48 hours of hospital discharge at a time when the caregiver can be present. During this visit, participants were provided with the BodyGuardian® system, scale, and BP cuff. Patients and caregiver, if available, received education on use of the BodyGuardian® system, and were given access to technical support. Patients were asked to wear the monitor 24- hours per day except when bathing, and transmit biometrical data, and communicate with their coach daily.

Health literacy was evaluated using Newest Vital Sign tool.[30] Self-care behaviors were assessed using a semi-structured interview format to complete the SCHFI tool.[31] The patient participated in medication reconciliation. The PCHC contacted the provider for any discrepancies. Next, using techniques of MI and teach back to maintain patient-centeredness, the PCHC performed brief food reconciliation, categorizing harmful foods, and collaborated with the patient to identify basic diet-appropriate alternatives. The PCHC identified areas of educational deficits regarding disease management and used those as a *teachable moment*.

This two-week *calibration phase* established the fundamental elements of the hi-touch patient relationship with the PCHC and set the stage for building patient self-confidence and improving self-care. Additionally, this phase allowed time to establish a baseline for the patient's health status, goals of care, and self-care ability. This resource intense phase consisted of 1-2 hi-touch meaningful visits by members of the PCHC team and at least daily touches with the patient.

The second *meaningful visit*, facilitated by the NWC as the PCHC, occurred within 10 days following hospital discharge. Prior to this visit, the NWC met with the RN to discuss results of the first meaningful visit and identify nutrition goals. During the second meaningful visit, the PCHC performed a comprehensive assessment of the patient's current diet, eating habits, food preferences, and exercise practices. The NWC reviewed current foods in the patient's home and helped the patient to identify foods high in sodium. Based on a proprietary protocol, the PCHC employed teach back techniques and MI, to assist the patient in developing nutrition goals, meal planning, and shopping list to meet the American Heart Association guidelines of 1500mg diet.

During the *calibration phase*, the PCHC communicated with the patient at least daily using a pre-established method of communication (text, phone, or email). During these touches, the PCHC reviewed biometric data from the previous 24 hours. Following a proprietary algorithm, the PCHC assessed the patient's understanding of care, adherence to medication and diet, and reviewed symptoms. Optimizing teachable moments, the PCHC provided education and reinforced success the patient had made in their self-care behaviors. Additionally, the PCHC coordinated care for the patient to follow up with their healthcare team.

Maintenance phase (Day 15-30)**.** Daily patient data continued to be monitored. However, the primary responsibility for communication was transitioned to the patient. The PCHC maintained hi-touch by providing at least weekly feedback to the patient regarding changes in biometrical data, health goal achievement, and successful behavior change. The bidirectional communication allowed the PCHC to assess the patient's understanding of treatment and goals, address any current needs or issues, and perceived level of engagement. The PCHC closed the communication gap through contact with the patient's attending care team to discuss any changes in clinical status or medication plan. Following day 30 in the program, a second SCHFI was completed. The entire program continued for an additional 60 days in a similar manner.

Instruments and Measures

Instruments. The LACE and the CORE- HF calculator were used to illustrate sample characteristics more precisely.[32, 33] The Newest Vital Sign was used to describe participant health literacy at baseline.[30] The Self-care of Heart Failure Index (SCHFI pronounced "skiffy") was used to describe participant self-management skills.[32] The author calculated LACE and CORE-HF scores at baseline.[32, 33] The PCHC administered the Newest Vital Sign at baseline. The SCHFI was administered at baseline and 30-days. The APRN scored these tools.

Measures. The EMR was queried by the author at enrollment for demographic and HF variables. Demographic variables included age, gender, and marital status. Heart failure variables included ejection fraction (EF), type of HF (reduced EF or preserved EF), etiology of HF (ischemic, nonischemic), duration of HF diagnosis < 6 months, and New York Heart Association (NYHA) class. The number of touches recorded in LifeStat

quantified the coaching intervention. The days to readmission were recorded in LifeStat. The PCHC documented homebound status, caregiver presence, and medications.

Outcomes

The primary outcome measure was the occurrence and time from hospital discharge to readmission for any reason. Hospital readmission was measured in days from index hospitalization discharge to readmission and occurrence of readmission within 30-days for any cause readmission during the 30-day follow-up period. The 30-day readmission rate for the sample was calculated by dividing the number of participants who were readmitted within 30-days by the total number of participants in the sample. A sub-group analysis of 30-day HF readmission rates was calculated by dividing the total number of heart failure readmissions within 30 days by the total number of participants.

The secondary outcome of self- care scores were measured with the SCHFI tool at baseline and at 30 days. The tools was scored and interpreted according to guidelines published with a score of 70 or greater being congruent with adequate self-care.[31] Standard deviations were calculated, and used to assess for clinical relevance.[31] The delta for the tool was measured by subtracting the second score for each section individually from the initial score in each section. Correlation models were tested to identify relationships between touches and outcomes.

Data Collection

Institutional review board approval as a QI project was received prior to the commencement of the project. Data were collected during the June through December 2013 period. All data were de-identified prior to statistical analysis and stored in an Excel ® spreadsheet. Data collection included demographic data, information about

disease etiology, burden, treatment, and scores on assessment tools. Age, gender, race, marital status, caregiver presence, and homebound status, were examined to investigate differences within the sample. Heart failure etiology, NYHA classification, comorbidities, and the number of medications illustrated the disease burden. Medications used to treat HF were recorded to illustrate disease management. Scores on the LACE, Core-HF, and the Newest Vital Sign tool helped to describe severity of illness, outpatient management, and the capacity for basic understanding of health.

The outcome measure of rehospitalization was based upon status of readmission and the number of days from index hospitalization until rehospitalization. Since patients were followed electronically by the PCHC, all 30-day readmissions were identified. Improvement in patient self-care was measured using the SCHFI with scores recorded at baseline and 30-days. As recommended by the author of the tool, each section was scored individually. Individual scores as well as the changes in scores were used for analysis.

Data Analysis

Descriptive and comparative analysis was performed using SPSS, Version 21 (SPSS, Inc., Chicago, IL). Data from the 30-day follow-up period was recorded and analyzed for each participant. This was an intention to treat analysis, and all patients remained in the program at the end of the 30-days. Baseline continuous-level sample characteristics were expressed as mean and standard deviation, and categorical-level characteristics as frequency and proportion. All participants completed the 30-day intervention. The number of touches was expressed as mean and standard deviation. The primary outcome measure of all cause readmission rates was computed for the sample

and reported as a percentage. The sample SCHFI scores were analyzed in a pre-test-post-test fashion using dependent t-tests, as the data were evenly distributed. Tests were two-tailed, and statistical significance was set at alpha = 0.05. Associations between variables were analyzed using Pearson's correlation.

Results

Demographic characteristics. Demographic data are displayed in Table 1**.** Thirty-two adult patients over the age of 65 with heart failure who met criteria for enrollment were approached for enrollment. Two patients declined enrollment for reasons related to use of technology. The final sample of 30 participants was enrolled starting June 1, 2013 through November 30, 2013. The sample was primarily Caucasian, female, with a mean age of 77.5. Most of the patients were not home bound, had a caregiver involved, and half were married.

Medical characteristics. Medical characteristics are displayed in Table 2. The mean length of stay was 4 days with distribution favoring a shorter length of stay. Further analysis revealed that 70% of the patients had a length of stay of 4 days or less. The participants had an average of 4 of the comorbid conditions recorded. Greater than 50% had 3-4 comorbidities. The most frequently occurring comorbid conditions included hypertension, coronary artery disease, and atrial fibrillation.

Heart failure was a new diagnosis for 40% of the patients. Sixty percent has an EF ≤40%, and NYHA class II-III functional status. Of those with left ventricular dysfunction, medical care was optimized with all participants taking a beta-blocker and 70% on either and ACE-I or an ARB. Participants were receiving an average of 7 medications and had at least 3 major comorbid conditions.

Health Literacy. Three participants refused to complete the *Newest Vital Sign* due to simplistic nature of the tool. For the 27 who completed the tool, health literacy was adequate (see Table 2). The mean LACE score of 9 correlated with a 10.3% probability of death or rehospitalization within 30-days following discharge.[31]

LACE and CORE-HF Scores. All patient records were reviewed for calculation of a *LACE* and *CORE- HF* score prior to hospital discharge. Both the LACE and CORE-HF scores were evenly distributed (see Table 3). The mean LACE score was nine out of a possible 19 with scores ranging from 6-12. The mean CORE-HF score was 25% with scores ranging from 20 to 30%. Correlation analysis between the LACE and CORE-HF scores showed a moderate correlation (p = .016), but the CORE-HF score did not significantly predict the LACE score (p =.033). The lack of predictability may be because the CORE-HF reflected disease burden and comorbidities. The LACE incorporated a morbidity scale, but also indicated the individual's success with managing their health as an outpatient.

Rehospitalization. The primary outcome of rehospitalization was 6% for all cause, and zero for heart failure (see Table 3). Since the readmission data were skewed due to the low readmit number, no pattern was identified. Of the two patients readmitted, one was readmitted at day 22 with a small bowel obstruction. The second patient was readmitted on day 13 with non-sustained ventricular tachycardia during exercise. This potentially life-threatening arrhythmia was picked up on the BodyGuardian® monitor. The patient underwent cardiac catherization, due to concern for ischemia, and was treated medically. Neither patient had decompensated heart failure as a component of their rehospitalization.

Self-care for Heart Failure Index Scores. The Self-care for Heart Failure Index (SCHFI), composed of three separate scores, reflected patient behaviors in the areas of self-maintenance, self-management, and self-confidence related to their HF. Baseline and 30-day scores for each section of the SCHFI are presented in Table 4. A score of 70 or greater indicated adequate self-care.[31] A change in score greater than one-half of a standard deviation was noted to be clinically relevant.[31] The mean baseline scores for each of the three sections fell below the 70 mark. A dependent-*t* test was conducted to assess changes in scores for each section by comparing baseline scores to scores at 30-days. Predictive models were tested using regression analysis.

Patient self- maintenance behaviors significantly improved by day 30 compared with baseline ($p < .0001$). Seventy percent of participants (n=21) scored 70 or higher on the 30-day assessment. Of the remaining nine patients, eight had scores consistent with clinically relevant improvement in their self-maintenance behaviors. Thus, 97% of patients had improved self-maintenance scores by the end of the 30-days.

Assessment of patient self-management behaviors towards their HF symptoms was done based upon HF symptoms within the past 30-days. Ninety six percent of patients (n=29) answered "yes" to the presence of HF symptoms in the prior 30-days. The baseline mean score was 34, indicating suboptimal management. At 30-days, 56% (n=17) of patients answered "yes" to symptoms of HF within the past month. The baseline and 30-day scores of this subgroup were compared and found to be significant for improvement ($p < .0001$). Nine patients (53%) in the subgroup reported adequate self-maintenance behaviors by day 30. Of the remaining 8 who scored less than 70, seven had score changes meeting criteria for clinical relevance. In terms of self-management, a

combined 94% of this subgroup scored 70 or greater or had a clinically relevant score improvement by the end of the observation period.

Patient self-confidence behaviors were generally suboptimal at baseline with a mean score of 49. However, closer evaluation of the confidence intervals revealed that 23% of the patients (n=7) had baseline scores reflecting adequate self-confidence. The mean self-confidence score at 30-days improved significantly (p <.0001), with 53% (n=16) having scores > 70. Of the remaining 14 patients, 8 had score changes clinically significant for self-confidence behaviors. Thus, 80% of patients had either statistically or clinically significant improvement in their self-confidence scores.

Relationship between touches and SCHFI scores. Relationships between touches and score changes were evaluated using Pearson's correlation determine the influence of touches on the outcomes see Table 3. The number of touches the patients received measured the intervention of the telemonitoring patient centric health coach (Tele-HC). Touches included any form of communication with the patient including telephonic, texting, email, or a face-to-face visit. The relationship between touches and SCHFI scores was examined by section, with a sub-group analysis done on those participants who answered "yes" to Section B in at both baseline and 30-days. Additionally, since the calibration phase of the program was more resource intensive, sub-group analysis was done relating score changes to the number of touches within the first two weeks, and at 30-days

The mean number of touches during the 30-day trial period was 47. Eighty seven percent of patients (n=26) received an average of more than one touch per day during the program. Evaluation of touches during the first 2 weeks showed a similar pattern.

However, subgroup analysis of the patients who reported HF symptoms during the program (n=17), received twice as many touches during the first 2 weeks, and 50% more touches at 30-days compared with those who did not have HF symptoms.

There was a moderate positive linear relationship between touches during the 30-days and the change in self- maintenance scores, but not found to be significant (p= .054). The model explained only 9% of the change in scores, and touches did not significantly explain changes in self-care maintenance behaviors. However, there was a significant relationship between the number of touches within the first 2 weeks, and improvement in self-care maintenance scores (p = .009). These touches during the first 2 weeks moderately predicted changes in self-maintenance scores (p = .019).

Seventeen patients answered "yes" to the question in Section B indicating symptoms of HF in the past month. For those 17 patients, there was no significant correlation between touches at 2 weeks or 30-days, and changes in SCHFI scores. Likewise, no predictive patterns were identified in the model. As well, there was no significant relationship between touches at both intervals and self-confidence scores at the end of the project (r = .164, p = .193; r = .947, p = .403). No predictive patterns were identified in the model.

Discussion

The Tele-HC was designed to reduce rehospitalization and facilitate self-management behaviors in adult patients with HF. Remote telemonitoring (TM) and access to a patient-centric health coach (PCHC) with daily interactions were the methods of influencing self-care behaviors. The APN served as the project manager and resource implementing many of the doctorate of nursing practice (DNP) essentials for the project.

The results of this project show a group of elderly patients with HF on optimal medical therapy, most of whom had poor self-care skills at baseline. The participants, similar to those in other studies, had experience with decompensated HF, but lacked skills to recognize early signs of a HF exacerbation, manage their HF, and participate in self- care maintenance behaviors.[31, 34-37] Absence of these skills is common in this patient population often resulting in frequent hospitalizations.[31]

The Tele-HC intervention provided a platform by which to monitor, manage, and educate these patients. The patient-centric model provided the framework for care delivery by fostering trusting relationships with the PCHC. The hi-tech telemonitor provided the biometrical data needed to drive evidence based care. Self-care behaviors were measured using the Self-care of Heart Failure Index (SCHFI). The APN role was pivotal in identifying patients, collecting, analyzing, and interpreting data, educating staff, and providing project leadership.

The results of this project are noteworthy in terms of both primary and secondary outcomes. The readmission rate for the group was 6% for all cause and zero for heart failure. These results are staggering considering the reported readmission rates for the project hospital are similar to the 23% national average for both all-cause readmission and HF readmission.[38] The month prior to implementation of the Tele-HC project, the hospital readmission for HF was 20%. The hospital HF readmission rates over all fell to 10% during the study period.

Perhaps more important and lasting was the secondary outcome of improved patient scores reflecting positive behavior change. The Self-care of Heart Failure Theory provided the foundation for this project. Patient self-care management, self- care

maintenance, and self-confidence in dealing with their HF was evaluated using the SCHFI tool. The mean scores for each section of the tool at baseline were well below the score of 70 needed to indicate optimal self-care behaviors. Following the Tele-HC intervention, self-care scores improved with all three categories reaching statistical significance ($p < .0001$). Most outstanding were the percentage of patients who achieved either statistically significant or clinically relevant improvement in their scores. By the end of the project, 97% had improved self- care maintenance behaviors, 94% had improved self-care management behaviors, and 80% improved self-confidence in managing their HF. Improvement in self-care is implied as a factor for the reduction in hospitalization, although limited empirical evidence exists correlating the two.[39] This lack of evidence highlights the complexity of managing HF patients, and suggests the presence of other variables.[39]

The PCHC intervention was quantified as the number of touches the patient received during the project. The touches provided opportunity for relationship building, reinforcement of self-care behaviors, and education. Participants were educated on the importance of daily weights and diet and medication adherence. Additionally, they were coached on ways to monitor and recognize HF symptoms, improve their diet, increase their physical exercise, and solve daily problems related to their medical conditions.

Most patients had an average of 2 touches per day for the first 2 weeks, and 3 touches every 2 days for the remainder of the program. The touches during the first 2 weeks were moderately related and significant to the improvement in self-care maintenance behaviors. The number of touches did not collectively explain the changes in 30-day SCHFI scores.

Through the touches, the coach gained subjective assessment of the patient's engagement in the process. During each touch, the coach customized the interaction to facilitate patient self-care. The touches also provided opportunity for teachable moments and encouragement for goals achieved. Although patient engagement was not specifically measured, it was identified as a variable of interest for future study.

Several providers were initially hesitant to enroll their patients due to perceived increased workload and alteration in office workflow. The PCHC was able to translate continuous biometric data into meaningful information by identifying trends and correlating the data with patient signs and symptoms. The data were synthesized and presented in a *Smart Report* document that accompanied the patient to their office visits. The provider was able to have a more robust picture of patient's progress following their hospitalization. This paved the way for medication adjustments and advancement of treatment plans.

Based upon PCHC reports and patient evaluations, several themes emerged concerning the Tele-HC intervention. Patients reported feeling a sense of satisfaction knowing that the PCHC was available at any time to mediate between the provider and the patient, facilitate problem solving, trouble shoot, and listen. The patient-centric care model, built on relationship-centered care, became the foundation whereby the patient was coached to find their strengths.[28] These strengths translated into self-confidence in self-care maintenance, symptom recognition, problem solving, and management of their HF. Providers reported a better sense of their patient's progress between office visits post-hospitalization.

Limitations

This project has several limitations. The design was that of a QI project with historical comparison. Future study should include case comparison or control design. In addition, the lack of rigorous design raises questions about selection, process, and additional variables. Selection bias existed, as participants were hand selected by the CV team and chosen based on perceived level of engagement. Since participants were chosen within a selected radius of the hospital, those from areas that are more rural were disqualified. Patients received HF education from a variety of sources while in the hospital. Since relationships are key to a patient –centric model, a better understanding of patient engagement and the components of behavior change may help identify those patients most likely to benefit from the Tele-HC program.

The interpretation of these results is difficult due to the small sample size and distribution of data. The findings are limited to patients who are primarily Caucasian females with the presence of a caregiver, and NYHA class II or III functional status. Data on education level and socioeconomic status was not collected and may have been helpful in developing predictive models of required touches. The length of time the device was worn was not recorded. Patients with both types of HF, reduce and preserved EF, were included, but not analyzed as separate groups. Future study comparing these groups may provide unique data related to outcomes.

Since the touches represented the health-coaching intervention, definition of the type and quality of touches was identified as an opportunity for future exploration. Specifically, describing the modality, content, intensity, and frequency of the touches is thought to better customize the intervention. This data may also help with future

resource allocation for the intervention.

In addition, although patients reported medication adherence, an automated recording device was not used. Information about number of medication changes and clinic visits was not analyzed. Economic data evaluating the cost analysis of the program with actual and projected return on investment was not collected. This data would be beneficial in the future, as the program increases and broadens its reach to other health care settings and systems. Finally, data were recorded for a 30-day period although patients remained in the program for 90-days. Future study should include assessment of self-care behaviors and hospitalization trends for 90-days and up to one year given the burden that HF syndrome poses on patients and society. Finally, additional investigation is needed to address the sustainability and replication of these results across diverse patient cohorts.

Nursing Practice Implications

The Tele-HC intervention was a nurse driven intervention based upon nurses practicing to the full extent of their training and education.[40] The intervention placed nursing as partners with patients and providers in redesigning healthcare delivery for this sample. The APRN incorporated the essentials of science, inter-professional collaboration, scholarship, and evidence based practice in this QI project. Finally, this QI project demonstrates the leadership role that APRNs can play using information systems and patient care technology to improve and transform healthcare.[41]

Conclusion

The Tele-HC intervention significantly reduced rehospitalization and improved self-care behavior scores for the sample of adult patients with HF. This project added to

the current literature that evaluates interventions aimed at preventing rehospitalization for patients with HF. Over the past two decades, a plethora of telemonitoring interventions and protocols with diversity in study designs, patient samples, and outcomes have been published.[42-44] Previous studies involving patients with HF that incorporated a measure of self- care such as the SCHFI, related successful self-care as a predictor of self-care management and subsequent reduction in rehospitalization.[34-35]

This project echoes the notion that patients with multiple chronic conditions are vulnerable to poor self-care.[45] Although the primary goal of the project was to prevent rehospitalization in this group, a potentially lasting, and life-changing outcome was imparting skills of self-care to this sample. Self-care skills were developed and nurtured through the patient-centric Tele-HC intervention. As the patient bore responsibility for self-management, the TM systems evolved from a crisis detection mechanism to a health maintenance system.[46] The relationship-based intervention facilitated all nurses to practice within their broad scope of practice. It also incorporated many of the essentials of the DNP for the APN.

The absence of a sustainable and reproducible home-based program heralds the complexity of treating aging patients with the HF syndrome in ways that change behavior, and prevent hospitalizations.[45] As the perfect storm of an aging population, rising chronic disease burden, and reduction in financial reimbursements rages, strategies to enhance self-care management of HF and improve outcomes are critical. Research is needed to develop tools to better identify those patients most likely to engage and benefit from a Tele-HC program.[47] In addition, data on the sustained behavior change, and the economic saving to the healthcare system will be paramount. In the end, strategies that

develop relationships to engage patients as participants in their self-care, leverage technology and continue to deliver healthcare with the human touch will transform the healthcare experience and quell the storm.

Appendix

Table 1. Demographic Characteristics

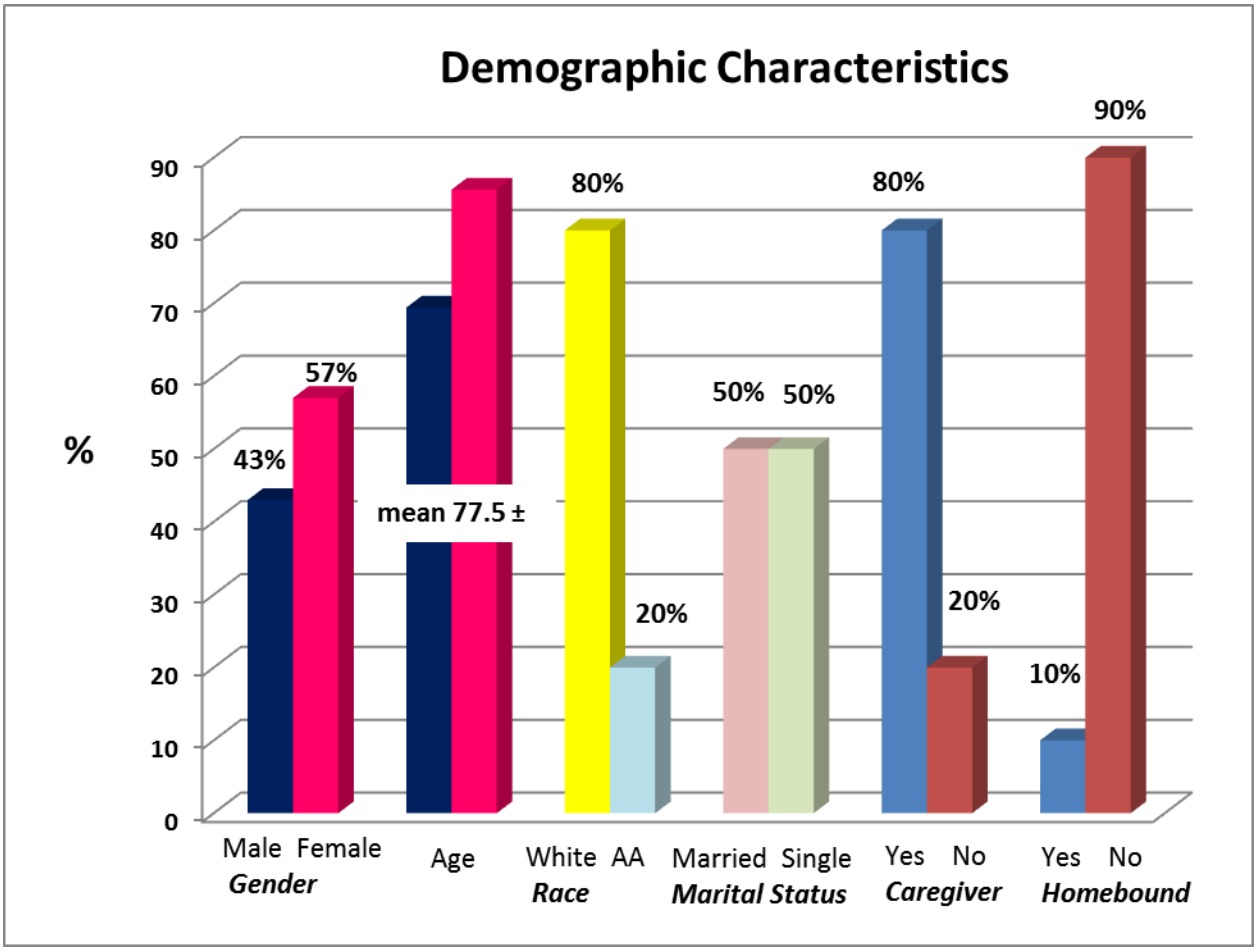


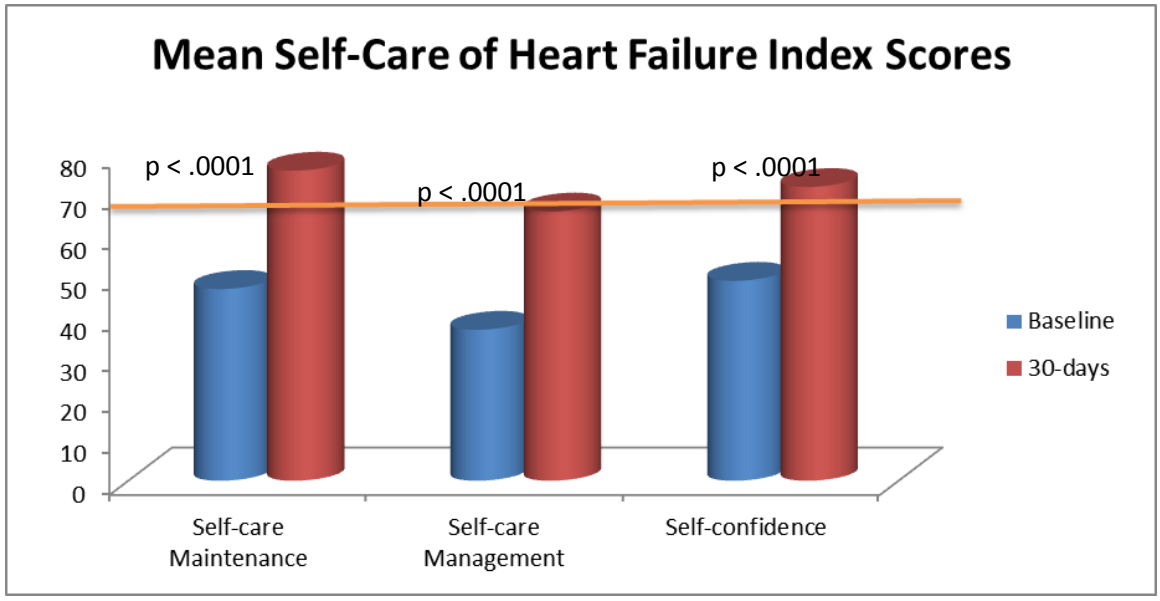
Table 2. Medical Characteristics

Characteristic	Total Sample (n =30)
Length of Stay	4 days ±2
≤48 hours	8 (27%)
3-5 days	18 (60%)
6-10 days	4 (13%)
Ejection Fraction	
Reduced (EF ≤40%)	18 (60%)
Preserved (EF > 40%)	12 (40%)
Etiology of Reduced EF (n=18)	
Ischemic	10 (33%)
Non-ischemic	8 (27%)
Date of Diagnosis	
< 6 months	12 (40%)
>6 months	18 (60%)
NYHA class	
I	3 (10%)
II	13 (43%)
III	13 (43%)
IV	1 (3%)
Comorbid Conditions	4±2
Coronary artery disease	23 (77%)
HTN	28 (93%)
Atrial fibrillation	18 (60%)
Diabetes	11 (37%)
CKD	14 (47%)
COPD	9 (30%)
OSA	11 (37%)
Depression	3 (10%)
Medication (total number)	12 ±5
Medication Class	
Beta-blockers total group	28 (93%)
Beta-blockers for reduced EF ≤ 40%	18 (100%)
(n=18)	21 (70%)
ACE-I or ARB total group	14 (78%)
ACE-I or ARB for reduced EF ≤ 40%	
(n=18)	
Diuretics	
Potassium sparing diuretics	25 (83%)
Potassium supplements	8 (27%)
Aspirin	5 (17%)
Statin	24 (80%)
Diabetes medications (n=11)	22 (73%)
	8 (73%)
AICD	6 (20%)
Health Literacy (n=27)	5 ± 2

Table 3. Outcome Variables and Correlation

VARIABLE	MEAN±SD	p-VALUE	PEARSON'S *r*	R^2	B
Readmit Rate All Cause Heart failure	 6% 0				
LACE CORE-HF	9±3 25±5	.003	.391	.153	.243
Self- maintenance (n=30)					
At baseline At 30-days Delta Touches @ 2 weeks Touches @ 30-days	47 ± 17 76 ± 13 29±16 26±10 47 ±14	 <.0001 .009 .054	 .426 .300	 .182 .090	 .737 .361
Self- management (n=17)					
At baseline At 30-days Delta Touches @2 weeks Touches @ 30-days	37 ±19 66 ±13 29±18 25±9 46 ±12	 <.0001 .218 .558	 .315 .118	 .099 .014	 .694 .183
Self-confidence					
At baseline At 30-days Delta Touches @ 2 weeks Touches @ 30-days	49 ± 25 72±23 22±19 26±10 47±14	 <.001 .385 .806	 .164 .047	 .027 .002	 .304 .6

Table 4. Change in Mean Self-Care of Heart Failure Index Scores



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What's new and important?

1. Relationships are the cornerstone in the development of patient-centric care.

2. Nurses are partners in redesigning health care delivery models in patients with heart failure by focusing on self-care behaviors.

3. This project provides evidence that patient-centric health coaching improves self-care behaviors.

4. Doctoral prepared APRNs are well equipped to lead programs using information systems and patient care technology to transform health care.