2017

# An assessment of heart failure screening tools for an outpatient arrhythmia devices clinic

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Walden University
2017

Abstract

An Assessment of Heart Failure Screening Tools for an Outpatient Arrhythmia Devices

Clinic

by

Lucy J. Paul

Project Submitted in Fulfillment

of the Requirements for the Degree of

Doctor of Nursing Practice

Walden University

November 2017

Abstract

People living with heart failure (PLHF) should be screened for symptoms at every

healthcare visit since they are 3 times more likely to experience ventricular arrhythmias.

This quality improvement project (QIP) compared 3 self-administered HF symptoms

questionnaires to determine the best screening tool for a tertiary hospital arrhythmia

devices clinic. The instruments included the Minnesota Living with Heart Failure

Questionnaire (MLHFQ), the Kansas City Cardiomyopathy Questionnaire (KCCQ), and

the Self-Reported Heart Failure Symptoms (SHEFS) questionnaire. For a 30-day period,

76 people were eligible to participate in the QIP, with 55 participants included in the final

analysis (72.5% participation). The questionnaires were compared and assessed with the

gold standard laboratory test for HF (NT-proBNP) for sensitivity and specificity. For HF,

the SHEFS was the most sensitive (83%) compared to the NT-proBNP, but the MLHFQ

was most specific (89%). When compared to the MLHFQ as the standard, SHEFS was

71% sensitive, and 73% specific for HF. Similarly, when compared to the KCCQ, the

SHEFS was both, 75% specific and sensitive in identifying HF.  However, the rate of

correlation to a positive or negative NT-proBNP test results was the highest for the

SHEFS (87%). All 3 questionnaires were statistically significant in predicting admission

to hospital for HF in the past 6 months ($p = 0.02$ to $0.03$). Finally, given the shortest

length and simplicity of use, the SHEFS was selected by the stakeholders to be the

standard screening tool for the clinic. This project contributes to positive social change by

providing the first reported comparison in the literature to implement questionnaires in a

clinic to assess symptoms for PLHF attending an arrhythmia devices clinic.

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Dedication

I would like to dedicate this product of my hard work and perseverance, to my two sons, Nathan and Noah. May they always remember that learning is a life long journey.

Acknowledgments

I would like to take this opportunity to acknowledge the unending support, guidance, and encouragement I received from the faculty of nursing in the past three years. A special thank you to Dr. Palmieri for his guidance, patience, understanding, and his constant mentorship. To Dr. Minnick and Dr. Leach, my sincerest appreciation for their valuable time and support. I would also like to acknowledge my family for their unending support and love during this journey. Finally, to my dear friend, colleague, and fellow classmate Janine, who took this journey along with me: our hard work has paid off!

Table of Contents

List of Tables

Section 1: Nature of the Project

**Introduction**

Heart failure is a chronic, progressive disease with unpredictable and fluctuating stages and cycles of exacerbation. According to Centers for Disease Control and Prevention (2016), there are close to 6 million adults in the United States living with heart failure. Approximately one in four heart failure patients die within one year and 50% die within five years of initial diagnosis (Gerber et al., 2015). In the United States, approximately $40 billion is spent each year on caring for people living with heart failure (PLWHF) (Lloyd-Jones et al., 2010).

The increased risk for life threatening cardiac arrhythmias is an important heart failure complication (van Riet et al., 2016). Arrhythmias result from the left ventricular dysfunction (LVD) diagnosed in the more than 40% of PLWHF (van Riet et al., 2016). The ventricular arrhythmias are highest amongst people with LVD accompanied by a low ejection fraction (EF) (40% or less) (Buxton et al., 2002). In this subgroup of patients, an implantable cardiac device (ICD) is recommended to prevent cardiac arrest from the ventricular arrhythmias (Bennett et al., 2016). With an ICD, PLWHF require routine monitoring and maintenance in a specialty arrhythmia devices clinic. The purpose of this quality improvement project was to identify an effective screening tool for self-reported symptoms of heart failure in order to efficiently recognize those who are at an increased risk of experiencing a cardiac arrest due to ventricular arrhythmia.

# Problem Statement

## Local Context for Gap-in-Practice

The Arrhythmia Devices Clinic (ADC) is an outpatient clinic, located in an ambulatory center of a large tertiary hospital in southwestern Ontario. The ADC is responsible for the continued care of PLWHF who have an ICD as a result of experiencing an episode of ventricular arrhythmia, or because they are at risk for developing an arrhythmia. Within the ADC, there is a robust quality management program focused on assurance, control, and improvement. The arrhythmia program database is an important source of information for the ADC quality management program, and which guided this project.

At each cardiac related appointment, both the Heart Failure Society of America (HFSA), and the Canadian Cardiovascular Society (CCS) recommend a routine heart failure assessment for all people with history of heart failure or who are at risk for developing heart failure (Lindenfeld et al., 2010; Moe et al., 2015). This assessment includes review of signs and symptoms of heart failure such as orthopnea, paroxysmal nocturnal dyspnea, shortness of breath on exertion, and peripheral edema (Mayo Clinic, 2017a). These assessments are especially important for people with a documented history of heart failure, and/or those who are at risk of developing heart failure (Lindenfeld et al., 2010; Moe et al., 2015). Despite the importance of this assessment, practice in the ADC did not involve the element of evaluating patients for signs and symptoms of heart failure. As such, the missed opportunity to identify a patient at risk contributed to suboptimal care.

**Local Relevance and Practice Environment**

A recent review of the arrhythmia program database revealed that close to 15% of patients who are being followed in the ADC are admitted, or readmitted to hospital annually with the diagnosis of heart failure or ventricular arrhythmias. As such, management of heart failure in the ADC was identified as one of the leading problems in need of addressing through a quality improvement project; an implementation of a heart failure screening tool.

Although there are currently seven validated heart failure screening tools available in the literature (Dunderdale et al., 2008; Guyatt et al., 1989; Hak et al., 2004; Mannheimer et al., 2007; O'Leary et al., 2000; Spertus et al., 2015; Wiklund et al., 1987), none have been evaluated for use in an arrhythmia clinic setting (Garin et al., 2013; Garin et al., 2014) (Appendix A). As such, the validated tools needed to be evaluated for their sensitivity and specificity, as well as usability and usefulness, in identifying heart failure symptoms in arrhythmia clinic setting.

**Significance and Implications for Nursing Practice**

Given the compelling link between heart failure and arrhythmia, the need to identify an evidence-based screening tool for heart failure that is easy to use, and provides useful data in the arrhythmia clinic setting, was important to optimize patient care, and improve overall health outcomes. Nurses play an integral role in patient care and often represent the first and/or only encounter of the patient with the healthcare system. As such, optimization of care depends largely and completely on these opportunistic encounters. By implementing a heart failure screening instrument that is

feasible, suitable, and applicable to the ADC practice environment, would ensure that the nurses have the appropriate tools to optimize care, and improve patient outcomes.

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**Purpose Statement and Project Objectives**

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**Gap-in-Practice Defined**

The purpose of this evidence-based quality improvement project, or EB-QIP, was to identify the most relevant heart failure screening instrument, evaluate the instrument validity, reliability, and applicability to the population, and then recommend the best instrument for the arrhythmia clinic. Previously, patients presenting to the ADC were not screened, assessed, and/or managed for heart failure. The project objective was to identify an evidence-based quality improvement tool that would increase health care provider's awareness, knowledge, and use of evidence-based guidelines in the management of heart failure.

**Evidence-Based Practice**

Evidence-based health care combines current knowledge, up-to-date research, and expert advice in order to provide care that is consistent, effective, and efficient. Hanson et al. (2012) described how utilizing evidence-based guidelines in clinical practice led to a significant decrease in venous thromboembolic events in children after trauma. Similarly, a study done by Kudenchuk et al. (2012) showed how the use of evidence-based guidelines contributed to improved outcomes in patients who suffered an out of hospital arrest. Lastly, Farmakis et al. (2016) demonstrated how a substantial decrease in mortality from heart failure was achieved when evidence-based guidelines for heart failure were incorporated into the care process.

In order implement, promote, and ensure evidence-based practice, the research question to guide the practice must be first clearly defined. In this case, this was accomplished by utilizing the PICOT method: P (patient population/problem/place), I (intervention/test), C (comparison/current practice), O (outcomes), and T (type of project/time). Therefore, using the PICOT format, the research question was initially formulated as follows: In the population attending an outpatient ADC, which of three (two of which are evidence-based, and one of which was developed specifically for the project) self- administered heart failure symptoms instruments could best identify heart failure patients at risk for ventricular arrhythmia? The three instruments evaluated included: (a) Self-reported Heart Failure Symptoms (SHEFS) questionnaire (Appendix B), (b), Minnesota Living with Heart Failure Questionnaire (MLHFQ) (Appendix C), and (c) Kansas City Cardiomyopathy Questionnaire (KCCQ) (Appendix D).

**PICOT Process**

In order to ensure the best patient outcomes, nurses need to incorporate the latest evidence in their clinical practice (Barth et al., 2016). This is an ongoing quality improvement process beginning with a structured question to define a clinical problem, called the PICOT question (Melnyk et al., 2011). This PICOT question is derived from a well described method to guide nurses in defining a clinical problem, organizing the facts into a clear and concise problem statement, identifying the best research evidence, and evaluating the evidence for implementation into practice. The evidence is evaluated to determine what interventions work the best, in what kind of clinical setting, and for what

patient population. This method informed the development of the PICOT question that guided this project.

## PICOT Question

### P-Patient/Population/Problem/Place

Adult patients (age 18 or older) with a Cardiac Resynchronization Therapy-Defibrillator (CRT-D) or a Cardiac Resynchronization Therapy-Pacemaker (CRT-P). Problem: There was no screening being done or documented for heart failure symptoms in patients attending the ADC. Existing screening questionnaires are complex and time consuming. Place: Outpatient, ambulatory ADC located in a tertiary hospital in southwestern Ontario

### I-Intervention

The SHEFS instrument; the MLHFQ and the KCCQ instruments.

### C-Comparison

Current standard, no instrument.

### O-Outcomes Measured

The primary outcome for this project was the fit (or lack of fit) of the screening instruments for the clinical setting. Also, the sensitivity for identifying heart failure was evaluated. Secondary outcomes included a review of the rates of healthcare providers documenting the questionnaire findings in the patients' charts. Finally, the rates of readmission to hospital with symptoms of heart failure and/or ventricular arrhythmias requiring shock from the device will be evaluated after the recommended screening tool has been implemented.

**T-Type of Project/Time**

A quality improvement project with instrument evaluation. The quality

improvement project was implemented over a period of one month. In addition, in order

to evaluate the instrument's fit and suitability from a users' perspective, the Delphi

method was employed.

**Response to the Gap-in-Practice**

The quality improvement project highlighted the need for healthcare providers to

use evidence in the treatment of heart failure in the ADC setting. Secondly, by identifying

and recommending a heart failure screening instrument that is most suitable for the ADC,

this project represented the first step in changing practice behaviors.

## Nature of the Doctoral Project

**Project Sources of Evidence**

A recent review of the Planning and Analysis EP Database (unpublished,

confidential ADC document) indicated that approximately 15% of readmissions to the

hospital for patients with an implantable device are due to heart failure exacerbations, and

heart failure related ventricular arrhythmias. The current practice in the ADC does not

include screening, assessment, treatment, or documentation of patient's signs and

symptoms of heart failure.

As PLWHF are at threefold the risk of developing ventricular arrhythmias, this

was an important identified gap in practice that needed to be addressed (Cubbon et al.,

2016).

This quality improvement project proposed to establish a standardized operating procedure to effectively identify PLWHF seeking care at the ADC who are either at risk, or who are currently exhibiting heart failure signs and symptoms. The project endeavored to classify the existing heart failure screening tools as to their relevance, fit, applicability, and usability in this specialized clinical setting. Previously, there has been limited evidence as to the application of the existing heart failure screening tools within an outpatient clinic setting.

**Project Method**

Seven well-known and used instruments were identified in the literature; these were narrowed to the two most relevant for this project (Appendix A). Then, these two instruments were administered to measure the self-reported heart failure symptoms for the defined patient population. In addition, a new proposed heart failure screening tool developed especially for the clinic was administered alongside the validated tools for the purpose of comparison. Once this project data was collected and evaluated, a recommendation, as to the most appropriate tool, was presented to the stakeholders. Once the stakeholders selected an instrument, a policy and procedure with an education module will be developed to implement the instrument in the ADC.

**Project Pathway**

The purpose of this doctoral project was to trial three different heart failure screening tools (two validated tools, and one newly developed tool) in the ADC setting, and identify the tool that would be most appropriate for being used in the clinic

environment. The best tool was then recommended for implementation in the care process.

## Significance of the Project

### Statistical Evidence

With more than one million people hospitalized throughout the United States and Europe, heart failure is a global pandemic (Ambrosy et al., 2014). According to Dunay et al. (2014) about $70 billion will be spent annually on heart failure care by the year 2030. This expenditure can be reduced with wide spread implementation of the appropriate, relevant, and evidence based processes to aid in the early recognition and management of heart failure. For example, Farmakis et al. (2016) demonstrated how optimizing heart failure care through evidence-based recommendations significantly reduced morbidity and mortality from the disease.

The progressive pathology of heart failure eventually leads to left ventricular dysfunction (Gerber et al., 2015), which results ultimately in electrical conduction abnormalities such as ventricular arrhythmias (van Riet et al., 2006). To treat these life-threating conduction abnormalities, an implantable cardiac device is recommended (Beyerbach, 2016). Overall, early interventions can decrease the number and the severity of ventricular arrhythmias linked to the disease (Cubbon et al., 2016).

### Stakeholder Analysis

The stakeholder analysis was important for this quality improvement project to identify all of the parties that could potentially affect or be affected by the project and/or project outcomes. (Hodges & Videto, 2011). The topic for this project was

collaboratively selected by the clinical director, medical director, clinical manager, and the project leader. Subsequently, additional stakeholders were identified and invited to participate in the development of the SHEFS questionnaire. The purpose behind the development of the SHEFS questionnaire, was to create a simple tool that would allow for a quick assessment of heart failure symptoms in the clinic setting, given the limited current resources. The additional stakeholders included arrhythmia physicians, clinical educator, nurse clinicians, clinical nurse specialist, cardio vascular technologists, and business clerks. Furthermore, the entire stakeholder group was invited to contribute to the project design and the implementation strategy. The project stakeholders were identified through personal conversations, program meetings' discussions, and formal and informal electronic mail announcements.

Stakeholders are considered to be those individuals that could affect or be affected by decisions, behaviors, or actions related to provision of care. This project embraced the involvement of the stakeholders as a critical source of knowledge specific to improving disease management. Kountz et al. (2015) argued that enhancements to patient care require a multidimensional approach, including the involvement of diversified stakeholders. Through an analysis, the authors found three main stakeholder groups: (a) patients, (b) healthcare providers, and (c) payers. For example, the study done by Haywood et al. (2014) demonstrated how health-related quality of life, and patient reported outcomes influenced, and were influenced by, the stakeholders: patients and the general public.

**Contributions to Nursing Practice**

The purpose of the project was to create awareness among healthcare providers of the importance, relevance, and effects of evidence-based heart failure screening. Secondly, the project contributed to a meaningful modification of the arrhythmia clinic nurses' attitudes, beliefs, and behavior patterns with respect to screening for heart failure, and generated practice that will include consistent use of evidence-based heart failure screening. Finally, the project enabled and supported the nurses in consistently applying evidence in their practice.

Within the ADC setting, the role of nursing should encompass a routine interrogation of the implantable device, review and reconciliation of medications, vital signs measurement, and focused physical assessment of the patient. However, in majority of the cases, only the first two activities were completed (i.e. vital signs are not checked, and physical assessment is not performed). These omissions resulted in missed opportunities in identifying heart failure signs and symptoms. The nurses reported that time constraints, absence of management support, lack of knowledge of evidence-based guidelines, and overall lack of comfort in dealing with heart failure were the main barriers. However, as Saunders and Vehvilainen-Julkunen (2016) contended, nurses are optimally positioned to apply the best evidence to their clinical practice because of their skills, knowledge, experience, and nature of their roles. The nurses often represent the first, and sometimes the only healthcare encounter between the patient and healthcare agency. As such, nurses are best positioned to change practices and revise processes to optimize patient care.

**Transferability of Knowledge**

Knowledge transfer is the process of sharing, communicating, spreading, or diffusing knowledge (theoretical or practical) to other individuals within the organization. The purpose of knowledge transfer is to ensure that all those involved have access to this knowledge of information, data, and results in order to establish full understanding of the issue(s) at hand, and to promote optimal collaboration. Singh et al. (2015) demonstrated how knowledge transfer approach resulted in an effective implementation and dissemination of best practice guidelines for stroke, and ultimately, in improved patient care and outcomes. The authors utilized a unit-based knowledge transfer team approach to champion and encourage the use of evidence-based guidelines through bedside mentoring, informal discussions, and collaborative patient care.

Firstly, the knowledge developed by the stakeholders specific to quality improvement and evidence-based practice will be used for other projects within the ADC. Secondly, the knowledge obtained from the project implementation and evaluation has the potential of being applied in similar settings within the organization, as well as to other arrhythmia clinics in the region, province, and country. Finally, this knowledge will contribute to the development of new guidelines and protocols, and inform changes in practices.

**Implication for Positive Social Change**

Social change can be best described as any meaningful and considerable modification of behavior patterns, attitudes, and opinions, resulting in substantial social consequences or outcomes (Form & Wilterdink, 2017). For example, a systematic review and meta-analysis done by Laranjo et al. (2014) demonstrated that implementing

interventions through social networking sites resulted in significant positive effects on health behavior-related outcomes.

Implementation of a feasible, applicable, and sustainable screening tool for heart failure symptoms in outpatient, ambulatory arrhythmia clinic patient population, will allow in the future for a consistent, comprehensive, and evidence-based assessment of patients for heart failure symptoms. This in turn will enable healthcare providers in early identification of the disease, initiation of appropriate interventions and follow up, and avoidance of hospital admission. Consequently, this will result in improved quality of life for the patient as well as a decrease in the risk of adverse events.

## Summary

In summary, heart failure care continues to contribute to a significant economic and psychosocial burden. The magnitude of the problem will likely continue to rise as the population ages, and more individuals are diagnosed with heart failure. One of the fundamental solutions to this problem, is to implement standardized, consistent, and evidence-based processes and methods to enable an early recognition of the disease and hence, an early treatment. A recent evaluation of the ADC environment revealed that no such screening was being done, and since a significant portion of ventricular arrhythmias is the direct result of heart failure, screening for symptoms of the disease should be an expected and integral component of clinic assessment.

In the following section of this paper, an evidence-based practice model was defined, and the process of applying the model's concepts to develop and implement interventions addressing the above issue, was described. Background to the problem was

discussed within the context of the clinical setting, and the problem's relevance to nursing practice was explained. Finally, the role of the project leader in this quality improvement project was explored, followed by a short synopsis of the research literature.

Section 2: Review of Scholarly Evidence

**Introduction**

Despite the fact that patients with heart failure are at higher risk of developing ventricular arrhythmias, previous practice in the ADC did not include the assessment of patients for signs and symptoms of heart failure (van Riet et al., 2016). As such, the purpose of this quality improvement project was to identify an effective screening tool for self-reported symptoms of heart failure in order to efficiently recognize those who are at an increased risk of experiencing a cardiac arrest due to ventricular arrhythmia. In this section of the paper, the evidence-based model used to guide this project will be described, the project's relevance to nursing practice will be discussed, local background and context in which this project was developed will be examined, and the role of the DNP student will be outlined.

**Theories, Models, and Concepts**

According to Schaffer, Sandau, and Diedrick (2012), evidence-based practice (EBP) models assist in translating research evidence into clinical practice (Schaffer et al., 2012). Complexity of the practice problem as well as the nature of the clinical setting in which the problem is present will determine model suitability. Although there are a number of applicable EBP models available in the literature, the Stetler's model of evidence-based practice guided this project (Stetler, 2001).

**Stetler Model of Research Utilization**

Since 1976, the Stetler model of evidence-based practice has been renamed the Stetler model of research utilization (Stetler, 1994). According to Stetler, this model is

based on the assumption that the individual's use of research may or may not involve the formal organization and secondly, that lack of knowledge and skills related to the use of research can impede effectiveness of its use (National Collaborating Centre for Methods and Tools, 2011).

The model also outlines some criteria to first establish if the project/program is desirable and feasible. These criteria include: level of corroborating evidence, current practice and magnitude of need for change, suitability for the project/program in the specific clinical setting, and the feasibility of implementing the program based on availability of human and financial resources, risks and benefits, and readiness of the stakeholders (Stetler, 2001).

Stetler's evidence-based practice model is comprised of five phases or stages to guide clinicians through the process of applying research findings in clinical practice. These phases include: (a) preparation, (b) validation, (c) comparative evaluation/decision making, (d) translation/application, and (e) evaluation. The Stetler's model is appropriate for this quality improvement project as it mimics the five phases through: (a) preparation of the screening instruments, (b) validation of the instruments, (c) evaluation of suitability for the ADC, (d) application of results/knowledge, and (e) evaluation of outcomes.

The *first phase* of the model includes identification of the problem at hand, exploring all influencing factors that may contribute to the issue, and evaluating available and current research on the topic. In the *second phase* of the model, the available evidence is evaluated for credibility and relevance to the stated problem. *Third*

*phase* of the model includes the process of summarizing research findings and formulating recommendations. Translation of evidence into practice, including the incorporation of any specific or required variations, makes up the *fourth phase*. In the *fifth and final phase* of the model, implementation outcomes are evaluated, and relevance to practice is outlined. The following paragraphs will describe how the model's phases were completed throughout the Project.

The first phase of Stetler's model is designed to help the health care provider in identifying the need for change, or the need to solve a clinical problem, in the context of available and relevant evidence. In the case of the project, a review of the program's 2015 organizational data revealed that a significant portion of the ADC patients were readmitted to the hospital within 30 days of their device implantation. Majority of these readmissions were related to heart failure, and heart failure related ventricular arrhythmias. As part of quality improvement, the need to improve heart failure care within the clinic was identified. The specific characteristics of the clinic's environment and staff were explored in order to assess any potential influencing factors that may influence or hinder implementation of practice change, such as lack or limited financial, physical, or human resources.

In the second, or validation phase, each of the available sources of evidence were evaluated for credibility, relevance, and level of strength. The sources of evidence included program specific database, organizational statistics, peer hospitals, evidence-based guideline depositories, and research literature. The relationship between heart

failure screening in the ADC, and the potential decrease in the rates of re-admissions for this patient population was established.

The third phase of Stetler's model involved the process of organizing the evidence, summarizing findings, and making recommendations. The result or end product of this phase was the recommendation that a screening tool for heart failure should be implemented within the ADC. The decision was made to trial three different tools: one developed specifically for the clinic, and two other tools that were previously applied in other settings.

During the fourth, or translation phase of the model, the screening tools were evaluated as to their fit and applicability, and a formal plan for practice change was formulated.

Finally, the fifth or evaluation phase of the model evaluated if proposed change was efficient and effective, and what type of strategies needed to be implemented in order for the change to be sustained.

## Project Relevance to Nursing Practice

**Search Strategy**

Literature search was conducted using the following databases: Cochrane Systematic Reviews, MEDLINE (PubMed), CINAHL, Psych Info, Google Scholar, and Embase. The key words included in the search were as follows: heart failure, guidelines, CRTs, outpatients, screening tools, ventricular arrhythmias, and self-reported (all MeSH terms). Only articles available in the English language were assessed and/or included in the literature review for the project. All abstracts yielded from the initial search were

reviewed before being considered for further examination and subsequent appraisal. Those articles deemed relevant to the project were included in the final analysis. Literature search was limited to articles from the year 2006 to 2016, unless they contributed to further knowledge and understanding of the issue at hand, such as original source articles.

In total, 99619 articles were initially identified when the search terms *heart failure* and *screening tools* were used. The articles were narrowed down to 1495 when the above terms were used in combination with *self-administered*. These were further narrowed down to 132 articles when the term *outpatients* was added. Abstracts of all of the 132 articles were reviewed, and subsequently 12 articles were considered for the project's literature review. Summary of the articles is presented in Appendix F with levels of evidence in Appendix G.

**General Literature**

There is ample evidence in the literature on the use of heart failure screening tools in inpatient settings (Garin et al., 2014; Green et al., 2000; Spertus et al., 2015) or in outpatient cardiology clinic settings (Eurich et al., 2006; Gilbert et al., 2015; Heidenreich et al. 2006; Masoudi et al., 2004). However, there is a limited evidence as to the use of the existing heart failure screening tools within an ambulatory arrhythmia clinic setting. The purpose of this project was to classify the existing heart failure screening tools/questionnaires as to their relevance, fit, applicability, and usability in the specialized clinical setting by the nursing staff. Since nurses represent the initial and most often the only contact of the arrhythmia patients with a healthcare provider during their clinic visit,

it is essential that screening for heart failure be completed by the nursing staff. Through their knowledge, skill, and expertise, and through the use of appropriate and relevant screening tool, nurses will be in a position to provide optimal patient care to the ADC patient population.

Heart failure is associated with a high morbidity and mortality rate with approximately 50% of individuals dying of the disease within five years of diagnosis, and 25% dying within one year (Gerber et al., 2015). Those who were previously hospitalized for decompensated heart failure, are at significantly higher risk of recurrent events including death (Senni et al. 2014). Due to the frequent episodes of hospitalizations and re-hospitalizations required as a result of the disease, the economic burden of heart failure care is staggering. In 2012, the global annual cost of direct and indirect heart failure care was estimated to be nearly 108 billion dollars (Cook et al. 2014). In the United States specifically, this cost was assessed to be at over 30 million. In that same year, Canada spent close to four million on costs associated with heart failure.

The pathophysiology of heart failure contributes to left ventricular remodeling, which leads to abnormalities in the function and structure of the heart predisposing it to life-threatening arrhythmias (Jaeger, 2010). According to Jaeger, cardiac arrhythmias stemming from severe left ventricular dysfunction have the potential of resulting in sudden death. As a result, these patients most often have an implantable cardiac device inserted for primary prevention. In the case of ongoing heart failure symptoms and depressed left ventricular function, patients receive a device capable of cardiac resynchronization as well. Despite the available mechanical therapy, the goal of

optimizing heart failure, and decreasing the likelihood of ventricular arrhythmias, is to optimize medical therapy as per evidence-based guidelines.

**Specific Literature**

Guyatt (1993) argued that health-related quality of life could be measured through either a generic or a disease-specific instrument or both, as they are not mutually exclusive. The author described how each of these instruments has its strengths and weaknesses, and how one may be better over another depending on the setting and/or circumstances. Guyatt contended that the key measurement properties of an instrument were its ability to detect crucial changes (responsiveness), and its ability to measure what it was assumed to measure (validity).

Berry and McMurray (1999) reviewed the design and validation of a number of general and disease-specific questionnaires, and their performance in measuring quality of life in patients with heart failure. The authors contended that in order for any questionnaire to be useful, it must be able to assess the patient's physical, emotional as well as social status or wellbeing. Furthermore, disease-specific questionnaires, rather than generic questionnaires, provided more useful information when the effects of treatment were being measured.

Similarly, Eurich et al. (2006) looked at the responsiveness of both generic and heart failure specific questionnaires to assess change over a period of six weeks. The responsiveness was measured in terms of psychometric indices as well as outside clinical data. The authors concluded that the Kansas City Cardiomyopathy Questionnaire

(KCCQ) was the most responsive tool when attempting to assess change over a short period of time.

Garin et al. (2009) completed a systematic review with meta-analysis to evaluate heart failure specific quality of life instruments on their reliability, validity, and responsiveness. The following instruments were included in the review: Minnesota Living with Heart Failure Questionnaire (MLHFQ), Chronic Heart Failure Questionnaire (CHFQ), Quality of Life Questionnaire for Severe Heart Failure (QLQ-SHF), Kansas City Cardiomyopathy Questionnaire (KCCQ), and Left Ventricular Dysfunction (LVD-36) questionnaire. Garin concluded that the evidence showed most support for the use of MLHFQ, followed by KCCQ, and then CHFQ.

Then, five years later, Garin et al. (2014) conducted another systematic review to assess heart failure specific questionnaires. The authors identified seven such questionnaires, and evaluated them for reliability, validity, sensitivity to change, and interpretability. Overall, the authors rated the KCCQ as their first choice, followed by the MLHFQ, and the CHFQ.

Finally, Kelkar et al. (2016) conducted a systematic review on the existing patient-reported outcomes tools for heart failure. Out of 31 instruments identified in the literature, nine met the authors' initial inclusion criteria. Kelkar further assessed these nine instruments with respect to their psychometric indices and relevance to clinical practice. The authors concluded that only two out of the nine tools met all criteria: MLHFQ and the KCCQ.

**Evidence to Address the Gap-in-Practice**

Despite the overwhelming evidence in the literature that evidence-based guidelines contribute to an enhanced patient care and improved outcomes, guideline recommended therapies are often poorly followed by the healthcare providers. A systematic meta-analysis done by Gohler et al. (2006) reported that guideline suggested heart failure medications were prescribed by the providers on average 60% of the time and in as low as 10% of the cases. Although many studies in the literature define adherence as 80% compliance with recommended therapies, Vehovec et al. (2016) showed that rates higher than 80% were required to reduce the risk of death in heart failure patients.

## Local Background and Context

### Evidence to Justify the Problem

A recent review of the planning and analysis EP Database (an unpublished and confidential document developed as part of a quality improvement project for the hospital) identified that about 15% of the AP patients are re-hospitalized within 30 days of having their implantable device inserted. Although a number of causes for the readmissions were identified, heart failure constituted to be the main reason, followed by episodes of ventricular arrhythmias.

By implementing *best practice* within the ADC, the arrhythmia program will contribute to providing the best care for its patients while advancing healthcare through education and research. Furthermore, improving heart failure care within the ADC, will likely result in decreased rates of readmission to hospital, and heart failure related complications.

**Institutional Context**

The ADC is situated within a large tertiary hospital located in southwestern Ontario, Canada. The clinic is part of the arrhythmia program (AP) whose mandate is to provide assessment, treatment, and follow up care of patients with cardiac arrhythmias and/or, with implantable cardiac devices. As part of the Local Integrated Health Network, the AP is the regional referral center for patients with arrhythmias in southwestern Ontario.

A Quality Improvement Plan (QIP) published by the hospital in 2014, identified five strategic organizational goals, including the need to implement *best practices* as the means to improve the patient experience (Hospital A, 2014). In response to the publication, the AP stakeholder team identified heart failure care as an area for improvement. The stakeholder team also acknowledged that any clinical project undertaken to meet the strategic goal, had to align with the mission, vision, and values of the organization. Through respect, caring, innovation, and accountability, the hospital's mission is to "provide excellent health care for the people and communities we serve and to advance health care through education and research" (Hospital A, 2016).

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**Local Terms and Definitions**

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For the purpose of this project, the following terms were defined:

**Arrhythmia Devices Clinic (ADC)**

A specialized outpatient, ambulatory clinic providing care to patients who have an implantable cardiac device.

**Cardiac Resynchronization Therapy-Defibrillator (CRT-D)**

An implantable medical device intended to synchronize the contractions of the ventricles for optimal efficiency of the heart (Boehmer, 2004; Marzec et al., 2017). It is also capable of delivering electrical energy through the heart when a ventricular arrhythmia is detected by the device (Ellenbogen et al., 2016).

**Cardiac Resynchronization Therapy-Pacemaker (CRT-P)**

An implantable medical device intended to synchronize the contractions of the ventricles for optimal efficiency of the heart (Boehmer, 2004; Marzec et al., 2017). It is also capable of electrically pacing the heart if the patient's heart rate falls below predefined set parameters (Ellenbogen et al., 2016).

**Guidelines**

A set of evidence-based recommendations, developed by experts in the field, to guide care of a specified condition/disease including assessment, diagnosis, and treatment (National Institute for Health and Care Excellence, 2017).

**Heart Failure**

A condition in which the heart fails to keep up with the demands to provide adequate blood flow to the rest of the body (Heart and Stroke Foundation of Canada, 2017). Most commonly associated with symptoms of shortness of breath, swelling of lower extremities, and inability to lie flat (American Heart Association, 2017).

**Stakeholders**

Any and all individuals who could influence or could be affected by the project's implementation and outcomes (Hodges & Videto, 2011).

**Ventricular Arrhythmia**

An abnormal rapid heart rhythm that originates in the lower chambers of the heart. This rhythm can result from damage to the heart muscle, cardiomyopathy, or sometimes in structurally normal hearts (Mayo Clinic, 2017b). Often associated with sudden cardiac death (Ellenbogen et al., 2016).

## Role of the DNP Student

### Professional Relationship to the Project

The American Association of Colleges of Nursing (AACN) (2006), outlined the essentials, or critical elements, that are integral to define the role and responsibilities for graduates with the doctor of nursing practice (DNP). According to the AACN, a DNP program prepares students to meet these foundational elements. Subsequently, this project allowed the student to fulfill the requirements to successfully meet these essentials. Specifically, through this project the student was able to demonstrate the use of science to guide practice, incorporate organizational and systems leadership for quality improvement, analyze evidence, contribute to policy development, integrate inter-professional collaboration to improve patient outcomes, and influence population health (AACN, 2006).

### Professional Role in the Project

In the context of this evidence-based quality improvement project, the DNP student functioned as the project leader, acting as a change agent within the healthcare agency. Specifically, the project leader was responsible for defining a clinical practice problem. Then, by designing, implementing, and evaluating an evidence-based quality improvement project, the project leader improved the clinical practice. The DNP student

had also the unique advantage of having the theoretical knowledge and the practical experience/expertise to bridge the gap between theory and practice, and to produce and introduce changes that would best serve the needs of the ADC population.

**Motivation for Completing the Project**

The DNP student's motivation to complete this project stemmed from both a personal and professional desire to improve the treatment of heart failure patients at all levels of care. The student's past work experience involved caring for patients in a heart failure specialty clinic. During this time period, many bonds were made between the student and the patient as well as the patient's family members. The patients and their loved ones often referred to the clinic as their *lifeline*. However, only 2% of patients with the diagnosis of heart failure are actually followed in a specialty clinic (Howlett et al., 2015). The remaining 98% are followed by family practitioners, cardiologists, internists, or not at all. As such, the importance of identifying, treating, and optimizing heart failure at any cardiac related encounter, especially in ADC setting, was extremely high for the DNP student. By leading this change, the DNP student served as a role model and champion for the nursing profession by demonstrating commitment to evidence-based practice. Secondly, by implementing the DNP project, the student played a significant role in improving patient care, optimizing clinical outcomes, and improving efficiencies. Finally, the DNP student contributed to policy changes at all levels of care, by developing policies, and by planning, organizing, implementing, and evaluating new processes to improve delivery of care. This dedication to nursing profession and evidence-based practice was one of the strongest motivators to complete this project. On

a personal level, the DNP student's motivation to complete the project was that of feeling of a personal accomplishment by reaching one of the student's long-term life goals.

**Potential Biases**

This DNP student had previously worked with heart failure population and was strongly motivated to improve the care of these patients in any setting. However, this motivation may have been interpreted as bias towards healthcare providers who did not think that heart failure assessment was important in the ADC setting. For example, resistance to change in practice may be interpreted as indifference or lack of knowledge rather than the fact that there are insufficient resources in place to sustain the change.

Another possible bias was the fact that the project included only patients who had a CRT-D or CRT-P device, as they have a known and documented history of heart failure (an initial indication for the implantable cardiac device). However, there may be other patients with an implantable cardiac device such as Permanent Pace Maker (PPM) or Implantable Cardioverter Defibrillator (ICD) who may exhibit initial or ongoing signs and symptoms of heart failure and who did not benefit from the assessment.

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**Summary**

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The purpose of this section was to explain and define the significance of the problem as it related to the clinical practice setting. This was accomplished by exploring the local background behind the problem and the context within which the problem exists. Secondly, the role of the DNP student in the project was explained and described as it pertained to the eight essentials for the DNP practice. Following that, a brief

literature review illustrated the scope of the problem and the need for change of the current practice. The literature also identified two screening tools for heart failure, which have been previously validated, and which were used for the purposes of the project: KCCQ and MLHFQ. Finally, the Stetler's model for evidence-based practice was described in terms of the framework being chosen to support and guide the process of planning, developing, implementing, and evaluating the project. The next section of this paper will focus on outlining the study design, approach methods, data collection, and analysis of evidence.

Section 3: Collection and Analysis of Evidence

**Introduction**

Previous practice in the ADC did not include screening for the signs and symptoms of heart failure. This resulted in missed opportunities for optimization of care and potential, and avoidable, admissions to hospital due to heart failure, or ventricular arrhythmias due to exacerbation of the disease. The purpose of this evidence-based quality improvement project was to identify the most relevant heart failure screening instruments, evaluate the instrument validity, reliability, and applicability to the population, and recommend the best instrument for the arrhythmia clinic. A search of literature presented in the previous section, demonstrated that adherence to evidence based guidelines for heart failure is overall poor amongst healthcare providers (Gohler et al., 2006). Although the literature search yielded seven validated instruments for screening for heart failure, none have been evaluated in an arrhythmia clinic setting.

In order to meet the project's stated goals and objectives, a suitable and sound research methodology was applied, and data collection approaches identified. Both, methodology and study design, played instrumental roles in ensuring that the project met its stated goals and objectives. The method or approach to data collection depends on the type of data being collected, as well as the type of sources of data. For example, Hodges and Videto (2011) argued that information gathered for the purposes of program planning, should have both qualitative and quantitative components, and include primary and secondary sources. The purpose of this chapter was to highlight the study

methodology, design, approaches to data collection, and strategies for analyzing the collected evidence.

## Practice-Focused Question

About 15% of this ADC patients are admitted or readmitted to hospital annually due to exacerbation of heart failure, and/or ventricular arrhythmias.  Despite these statistics, previous practice in the ADC did not include the screening for signs and symptoms of heart failure. As such, a simple, suitable, and reliable screening instrument was needed in the ADC in order to facilitate a change this practice. In ambulatory, outpatient arrhythmia devices clinic patient population, which of the three patient self-administered heart failure symptoms questionnaires was the most suitable and feasible screening tool to be implemented in this specialized setting?

**Patient Population**

Adult patients with a Cardiac Resynchronization Therapy-Defibrillator (CRT-D) or a Cardiac Resynchronization Therapy-Pacemaker (CRT-P), who presented to the outpatient, ambulatory ADC located in a tertiary hospital in southwestern Ontario**.**

**Issue**

There was previously no screening being done or documented for heart failure symptoms in patients attending the ADC. Existing screening questionnaires were complex and time consuming.

**Intervention**

The main objective of the intervention was to compare the three questionnaires as means of establishing suitability and fit of the screening tools in this specialized setting.

Both the MLHFQ and the KCCQ have been previously validated as sensitive tools in screening for heart failure symptoms, and the SHEFS questionnaire was a new tool developed especially for the purposes of the clinic.

**Comparison**

No screening tools; previous practice.

**Outcomes Measured**

The primary outcome of this project measured the fit of the screening tool (or lack of fit) for the clinical setting as well as the sensitivity of the tool in identifying heart failure, as compared to the results of Brain Natriuretic Peptide (BNP) test—a specific blood test performed to establish presence/absence of heart failure. Two secondary outcomes have been subsequently identified one of which, was the evaluation of rates of compliance of the staff in documenting the questionnaires' results in the patient chart. The final (secondary) outcome will look at evaluating the rates of readmission to the hospital with symptoms of heart failure and/or ventricular arrhythmias requiring shock from the device, after the screening tool has been implemented. Finally, a focus group comprised of the instrument users was asked to evaluate the tools' fit and suitability for the practicum setting from their perspective, by using the Delphi technique.

According to Rowe and Wright (2011) the description of the Delphi technique/method did not appear in print until 1975 although it has been developed by the Rand Corporation sometime in the 1950s. Although initially slow in being adopted by the wider audience, it has since gained popularity over the past couple of decades. It has been used in several fields of study, and by various disciplines as a method of soliciting the

opinions of experts to obtain an agreement or compromise on an issues or a topic. As Hsu and Sandford (2007) argued, it is "well suited as a means and method for consensus-building" (p. 1). The traditional Delphi process involves four rounds of iterations (can vary anywhere from three to five) and employs the use of questionnaires as means of obtaining feedback. Each round of questionnaires asks the subjects to rate each item to establish priority or importance. However, as Goodman (2017) argued, this approach can sometimes create bias as subjects tend to rank/rate noncontroversial items higher than those that are controversial.

Subject selection for the Delphi process is one of the most important aspects of this method as the quality of results is highly dependent on the expertise of the participants. In the case of this project, the three instruments were sent to the group of end-users who were asked to rate the questionnaires using a survey monkey program. Each individual in the group was asked to rate the questionnaires based on their perception as to the usability and fit of the tool in the clinical setting as well as their individual preference. Subsequently, the results were presented to the group at one of the program's weekly meeting. Consensus was determined by majority of the individuals agreeing on one particular questionnaire as being the most suitable and preferable.

**Time**

The SHEFS questionnaire was administered in parallel to the MLFHQ, KCCQ, and BNP testing for a period of one month. The second secondary outcomes will be measured after six months of the best screening tool's implementation.

**Project Purpose and Method Alignment**

The purpose of this EB-QIP was to identify an effective screening tool for self-reported symptoms of heart failure in order to efficiently recognize those who are at an increased risk of experiencing a cardiac arrest due to ventricular arrhythmia. By comparing a newly developed tool to two already validated heart failure screening tools, the project determined what tool was the most suitable for the arrhythmia clinic setting as a screening instrument.

**Key Operational Definitions**

**Characteristics of interest.** Screening tool's ability to identify and recognize heart failure symptoms.

**Measuring instrument.** The measuring instruments were the three different self-reported heart failure symptoms questionnaires.

**Method of test.** Three questionnaires, assembled in a random order, were administered to all consecutive patients meeting the pre-determined criteria.

**Decision criteria.** Each questionnaire's score predicting a likelihood of heart failure, as compared to the other two questionnaires and to BNP results (if done), was deemed to be a sensitive tool for screening.

**Statistical Package for the Social Sciences (SPSS), Version 19.0.** A computer statistical software used to perform statistical analysis of the outcomes data.

**Univariate regression analysis.** A statistical method used to explore for a potential association between a single variable and a particular outcome of interest.

**Sources of Evidence**

The possible sources of evidence were acquired from statistical data, evidence-based guidelines for heart failure and best nursing practice (CCS, HFSA, AHA, RNAO guidelines), literature review, benchmarking to other like-organizations, existing hospital policies/procedures, stakeholder input, national clinical guidelines review, program specific databases, and evidence-based practice models. These sources of evidence helped in identifying the magnitude of the practice problem as compared to other-like organizations, the extent of use (or lack of use) of evidence based guidelines for heart failure in the arrhythmia clinic setting, as well as any currently available screening tools that have been previously validated.

**Archival and Operational Data**

This doctoral project involved in part, an analysis of the organization's operational data that is routinely collected as a component of its quality improvement measurement. Specifically, the rates of admission and readmission to hospital with the diagnosis of heart failure, amongst ADC patients, will be measured and compared between pre-implementation, and six-month post-implementation of the recommended screening tool.

The organization currently collects routine data on all hospital admissions including the cause for admission, and diagnosis at discharge. The EP program data analyst extracts the data that pertains specifically to the patients who are being followed in the ADC. The analysis is subsequently presented to the senior administration members of the program in database format.

**Description of Data Collection**

The data for this project was collected through a retrospective review of the patients' health records with respect to the content and results of the questionnaires that were completed as part of the patient's recent visit to the ADC. This included a review of the BNP blood results if they were completed.

**Participants**

The parties that contributed evidence to address the practice-focused question were all those individuals who had completed the three questionnaires. As part of the EB-QIP, all patients who had either a CRT-P, or CRT-D were identified prior to their clinic visit, and subsequently asked to complete the questionnaires as part of their clinic visit. A participation of total of 50-60 patients was initially planned in order to provide meaningful data for analysis.

**Procedures**

For this project, two existing and validated tools (KCCQ-12 and MLHFQ) were used to collect the evidence, along with a newly created tool (SHEFS questionnaire).

The KCCQ was initially developed by John Spertus and colleagues as a 23-item questionnaire to quantify "physical limitations, symptoms, self-efficacy, social interference and quality of life" in patient with congestive heart failure (Green et al, 2000, p. 1245). The tool has been subsequently validated in a number of different conditions and settings (Joseph et al., 2013; Spertus et al., 2008; Tucker et al., 2016)

The KCCQ was subsequently reduced by Spertus and Jones (2015) to a 12-item questionnaire (KCCQ-12) which demonstrated a preserved "validity, reliability,

responsiveness, prognostic importance, and interpretability of the original instrument"
(Cardiovascular Outcomes Inc., 2016, p. 1). Spertus and Jones (2015) argued that the
shorter version of the original KCCQ was more feasible to be implemented without
compromising the psychometric properties of the original instrument. The KCCQ-12
measures the reported frequency of symptoms, physical and social limitations, and
alteration in quality of life because of heart failure. The score is calculated out of 70, and
the lower the score, the worse are the predicted outcomes including highest risk for
mortality and morbidity.

The MLHFQ was originally developed in 1984 at the University of Minnesota by
Thomas Rector, as a self-administered method of measuring the effects of heart failure
on an individual's quality of life (Pietri et al., 2004). The tool has been since validated
through several research studies for validity and reliability in various settings, under
different conditions, and in different languages (Ahmeti et al., 2016; Bilbao et al., 2016;
Garin et al., 2009; Supino et al., 2009)

The questionnaire is composed of 21 questions, asking individuals to rate their
heart failure symptoms, functional limitations, and psychological responses, on a scale
from zero to five (zero representing no limitations, and five representing severe
limitations). The maximum possible score is 105, with the lower score representing little
or no effect on the individual's quality of life, and higher score representing significant
limitations to quality of life.

The SHEFS questionnaire was initially developed by the DNP student in
conjunction with the medical director of the arrhythmia service. A draft of the

questionnaire was distributed to heart failure specialists in the organization for input and comments (as experts in the field) prior to finalization. The final format of the instrument is composed of five questions deemed by the heart failure experts to be the *minimum* elements required in the assessment for symptoms of heart failure.

## Analysis and Synthesis

The following paragraphs will outline this project's approach with respect to project design and collection methods. Description of the study patient population will follow, containing details about inclusion and exclusion criteria. Finally, data collection methods will be explained followed by description of the evaluation plan.

### Data Systems and Procedures

The project followed a prospective cohort design (Sedgwick, 2013). This type of design follows a group of similar individuals over a period of time. The patients with CRT-P or CRT-D device were identified the day prior to their clinic appointment and they were flagged for the study. The questionnaires were given to patients after they had registered and while awaiting clinic appointment. The package of questionnaires included a cover sheet (Appendix E) and the three questionnaires (SHEFS, KCCQ, and MLHFQ). The order of the questionnaires in the package was assigned a randomization sequence to prevent selection bias. The patients were asked to hand in their package to the healthcare provider that physically checked their device. Copies of the questionnaires were scanned into patient's permanent electronic medical record, as per hospital policy for all documents pertaining to patient's visit. These records were then accessed to review the completed questionnaires. The questionnaires were evaluated as to percentage

of completion, measured heart failure prognostic score, and their ability to successfully predict/identify heart failure as compared to the BNP results obtained during their clinic visit. All data was entered into an Excel spreadsheet, and subsequently exported to an SPSS (Version 19.0) program for analysis.

**Population and Sampling**

Inclusion criteria for the study was defined as adult patients (18 years or older) who presented to the ADC of the hospital, who had either a CRT-D or a CRT-P device in situ, and who were English speaking. Exclusion criteria was applied to patients who were less than 18 years of age, to those who did not have a CRT-D or a CRT-P device, who did not speak English, or those who refused to fill out the questionnaire.

Sampling method was defined as the inclusion of consecutive patients who met the above criteria, over a period of one month.

**Data Integrity**

The patients were asked to fill out the questionnaires while waiting for their appointment with the clinic staff. The questionnaires were then collected and results of each tool entered onto patient's ADC electronic record. Copies of the questionnaires were then scanned (as per hospital's protocol) to be included in permanent electronic record. Prior to scanning into the hospital record, the questionnaires were reviewed to ensure that they were correctly documented in the ADC's electronic record. Subsequently, the questionnaire data was retrieved at a later date to perform secondary analysis. Any incomplete data was identified, recorded, and documented in the analysis.

**Data Analysis**

The purpose of this quality improvement project was to assess for the most
suitable and appropriate screening tool to be used in this clinical setting, in order to
improve the management of heart failure in this patient population and subsequently, to
decrease the rates of readmission for heart failure and heart failure-related ventricular
arrhythmias. As such, the primary outcome for this study was the performance of the
three different questionnaires' scores/results in their ability to predict or identify heart
failure as compared to the bedside blood test for brain natriuretic peptide (BNP). For this
project, both descriptive and inferential statistic were utilized to describe the basic
features of the data elements, and to analyze the relationship(s) (if any) between the
variables.

The purpose of descriptive statistics is to provide/present a summary of the
features of variables in the study, usually in the format of actual numbers (*n*), means,
percentages, and distribution across quartiles. In this study, descriptive statistics were
used to illustrate the quantitative characteristics of the data elements including age,
gender, type of device (CRT-D or CRT-P), method of EF measurement, degree of left
ventricular dysfunction, type of cardiomyopathy, previous history of heart failure,
evidence of admission to hospital for heart failure in the past six months, and most
responsible physician for heart failure care.

Inferential statistics were used to determine if there was a difference between
elements/groups, and if the observed difference was dependent rather than accidental.
For this study, the three questionnaires were compared to the results of the BNP blood

test (as the gold standard) to determine a relationship (or lack of) between the questionnaires and the BNP. Secondly, the SHEFS questionnaire was compared to the MLHFQ and then to the KCCQ to determine if there was an association (a *p*-value of <0.05 was considered to show statistical significance). Finally, univariate regression analysis was performed to determine the association between the questionnaires' scores, including the BNP results, and other elements such as admission to hospital in the past six months, NYHA functional class, medication class optimization, and ejection fraction.

The final secondary outcomes will look at rates of readmission to hospital with symptoms of heart failure and/or ventricular arrhythmias requiring a shock from the device, after the recommended screening tool has been implemented.

**Project Evaluation Plan**

The evaluation plan had fourfold objective: to analyze and determine the sensitivity (or lack of) of the newly development SHEFS questionnaire in identifying heart failure as compared to the KCCQ, the MLHFQ, and the BNP, to determine which questionnaire was most suited for the ADC patient population given the current resources and environment, to determine the rates of compliance by staff in documenting results of the questionnaires, and to determine if rates of readmission to hospital with heart failure among this clinic's patients has improved six months after implementing the recommended screening tool.

## Summary

In this section of the paper, the project question was outlined and stated in terms of patient population, intervention, control, observation, and time line. Subsequently, the

study design and methods were explained with respect to the method of data collection, type of participants, and mode of implementation procedures. Subsequently, the organization's archival and operational data was identified as the main source of information required for project evaluation. In the following section, project findings and resultant recommendations will be presented and discussed.

Section 4: Findings and Recommendations

**Introduction**

Despite the best available treatments, heart failure remains a major cause of morbidity and mortality worldwide. Half of the individuals diagnosed with heart failure will die within five years of the initial diagnosis, and one quarter will die within one year (Gerber et al., 2015). In 2012, the global economic burden of the direct and indirect costs associated with heart failure care were estimated at $108 billion for that year, and these costs will likely continue to rise as the population ages (Cook et al., 2014).

Advanced or ongoing heart failure leads to a progressive left ventricular remodeling which subsequently contributes to abnormalities in the cardiac structure and function, resulting in the development of ventricular arrhythmias requiring treatment from an ICD. Despite the direct link between heart failure and ventricular arrhythmias, the ADC did not previously screen patients for symptoms of the disease.

A recent review of the EP program database showed that close to 15% of the ADC patients are admitted and readmitted to hospital on annual basis with the diagnosis of heart failure and/or ventricular arrhythmias. As a result of this data, the program's executive team identified heart failure care as the priority for their program quality improvement initiative.

Evaluation of existing practice identified that ADC nurses did not assess patients for heart failure. Given that heart failure and arrhythmia are inter-related, this poor approach to patient care acknowledged a significant gap in practice. As such, screening for heart failure symptoms within the ADC was identified as an area in need of

improvement. As a result, a quality improvement project was developed and designed to identify and determine the most appropriate, suitable, and feasible screening tool for heart failure in the ADC setting. The core of the practice-focused question was which self-administered heart failure screening tool was most suitable in this specialty setting. Subsequently, two previously validated tools and one newly developed tool were administered to a select patient population within the ADC to evaluate their effectiveness in predicting heart failure. The purpose of this doctoral project was to evaluate all three tools and recommend the one that would be most appropriate in this clinical setting.

Evidence for this project was obtained from the results of three self-administered questionnaires that were given to patients as part of their visit to the ADC. The questionnaires were initially administered as part of a quality improvement project to promote heart failure screening within the ADC. Subsequently, the information obtained from each of these questionnaires was accessed for analysis as to their predictive characteristics and feasibility of use in the ADC. An approval from the site's Research Ethics Board (REB) (Appendix H) as well as the Walden University's Institutional Review Board (IRB) (Appendix G) was obtained prior to implementation of the project.

**Findings and Implications**

**Demographics and Descriptive Data**

Over a period of one month, a total of 76 patients were identified for the study. Out of the total, 14 patients were identified as *missed opportunity* as they did not receive the package of questionnaires at the time of the clinic registration and therefore, were not included in the study. Out of the remaining 62 patients who did receive the package of

questionnaires, two did not speak English and therefore were unable to complete the questionnaires resulting in the two questionnaire packages being excluded from analysis. Subsequently, 60 questionnaire packages were analyzed. Questionnaire packages that were incomplete (either one or more of the questionnaires in the package was not completed) were also excluded, resulting in 55 patients being included in the final study analysis.

Of the 55 patients, 14 (25%) were female, and 41 (75%) were male. The average age of study patient was 69 years with a range between 41 and 85 years of age. Forty-three (78%) of the 55 patients had previously documented history of heart failure, and 12 (22%) did not. Approximately 10% of patients ($n = 5$) have had documented history of admission to hospital with heart failure in the past six months.

Distribution of patients with respect to device type, type of cardiomyopathy, New York Heart Association (NYHA) functional class, the degree of left ventricular (LV) dysfunction, and method of ejection fraction (EF) measurement is represented in Table 1 (Distribution of patients), and the degree of LV function is represented in Table 2 (Left ventricular function).

Table 1

*Distribution of patients*

| Variable | n | % | |
|---|---|---|---|
| Device type | | | |
| CRT-P | 9 | 16.4 | |
| CRT-D | 46 | 83.6 | |
| Type of cardiomyopathy | | | |
| Ischemic | 25 | 45.5 | |
| Non-ischemic | 30 | 54.5 | |
| NYHA class | | | |
| I | 3 | 5.5 | |
| II | 21 | 38.2 | |
| III | 19 | 34.5 | |
| IV | 0 | 0 | |
| Not documented | 12 | 21.8 | |
| Degree of LV dysfunction | | | |
| Normal | 1 | 1.8 | |
| Mild | 10 | 18.2 | |
| Moderate | 7 | 12.7 | |
| Severe | 34 | 61.8 | |
| Not documented | 3 | 5.5 | |
| Method of EF measurement | | | |
| Echo | 38 | 69.0 | |
| RNA | 8 | 14.6 | |
| Angiogram | 4 | 7.3 | |
| Not documented | 5 | 9.1 | |

Table 2

*Left ventricular function*

| | Ejection fraction % |
|---|---|
| Normal | 50% and > |
| Mild dysfunction | 40-50% |
| Moderate dysfunction | 30-49% |
| Severe dysfunction | <30% |

The study patients reported that the most responsible physicians (MRPs) for their heart failure care were as follows: general practitioner ($n = 6$, 11%), cardiologist ($n = 47$, 75%), internist ($n = 1$, 2%), and heart function clinic specialist ($n = 1$, 2%).

With respect to heart failure medications, the CCS (2015) recommends that three main classes of medications be prescribed for patients with the disease: angiotensin-converting enzyme inhibitors (ACEIs), beta blockers (BBs), and mineralocorticoid receptor antagonists (MRAs). Out of the 55 study patients, 45 (82%) were on some type of ACEI, 50 (91%) were on a BB, and only 24 (44%) were on MRA. Only 20 (36%) were on all three recommended medications, and merely one individual was on optimal doses of all three classes of recommended medications.

**Results for the Heart Failure Screening Tools**

Because heart failure is a collection of signs and symptoms, none of the questionnaires could confidently predict heart failure based on one measurement alone. As such, the diagnosis of heart failure could only be stated as "likely" or "unlikely."

The average KCCQ score was 51.1, ranging from 27 to 67, with a score of 35 of less corresponding to "likely" heart failure (Green et al., 2008). Eight patients (14.5%) met the criteria of "likely" having heart failure i.e. scoring 35 or less on the questionnaire.

The average MLHFQ score was 24.5 with a range of 0 to 68, with a score of 53 or greater corresponding to patients "likely" having heart failure (Rector et al., 1987). Seven patients (13%) met the criteria of "likely" having heart failure (i.e. scoring 53 or greater on the questionnaire).

The average SHEFS questionnaire score was 0.5, ranging from 0 to 5, with a score of 1 or greater corresponding to "likely" heart failure. Therefore, as per this criterion, 18 patients (32.7%) "likely" had heart failure.

The average NT-proBNP (BNP) result was 1216, with a range between 62-3556 pg/ml. Approximately 30% of the study patients ($n = 15$) had BNP test completed. Out of these patients, 6 (40%) "likely" had heart failure. Confirmation of heart failure was based on the BNP reference range presented in Table 3 (Mangla, 2014).

Table 3

*Brain-type natriuretic peptide (BNP) reference range*

| Heart failure unlikely | Heart failure likely |
| --- | --- |
| <300 pg/ml | age <50 years, NT-proBNP >450 pg/ml<br>age 50-75 years, NT-proBNP >900 pg/ml<br>age >75 years, NT-proBNP >1800 pg/ml |

In the 15 study patients who had NT-proBNP blood test completed, 13 (87%) of the results (heart failure likely or heart failure unlikely) corresponded to the SHEFS results, as compared to 11 (73%) corresponding to the MLHFQ results, and 11 (73%) corresponding to the KCCQ results. Of the 15 study patients who had all of the four test results available (NT-proBNP, SHEFS questionnaire, MLHFQ, and KCCQ) 10 (67%) were all in agreement with respect to heart failure being "likely" or being "unlikely."

Comparison within the group of three (SHEFS questionnaire, MLHFQ, and KCCQ) showed that SHEFS matched the MLHFQ results 72% ($n = 40$) of the time, and the KCCQ 75% ($n = 41$) of the time. MLHFQ results matched the KCCQ results 87% ($n = 48$) of the time. Comparison within the four groups is presented in Appendix J.

All three questionnaires identified symptoms of heart failure. However, both the KCCQ and the MLHFQ took considerably longer to complete as they were composed of 12 and 21 questions respectively, as compared to SHEFS questionnaire, which had only five questions. Secondly, both the KCCQ and the MLHFQ had a larger scale (1-7 and 0-5 respectively) of rating which could result in under or over reporting of symptom severity. SHEFS questionnaire on the other hand, required only YES/NO answers and the questions were easy to understand.

With regards to the domains measured, both the KCCQ and the MLHFQ measured elements in the physical and emotional domains whereas the SHEFS questionnaire focused entirely on measuring physical symptoms.

Finally, the SHEFS questionnaire had the higher rates of agreement with the NT-proBNP results for presence or absence of heart failure than either the KCCQ or the MLHFQ. When comparing the SHEFS questionnaire, the MLHFQ, and the KCCQ to the NT-proBNP results, SHEFS had the highest percentage of sensitivity and it was as specific as the KCCQ but less specific than the MLHFQ. When comparing the SHEFS questionnaire to both the MLHFQ, and the KCCQ individually, the SHEFS had similar percentage of sensitivity and specificity for both groups.

**Documentation and Follow up Results**

With respect to the health care providers (HCP) reviewing questionnaires with the patient, only 40 (73%) commented that they reviewed the results. Two of the 40 questionnaires reviewed by the HCPs resulted in a referral to a heart function clinic, four in a referral to the Nurse Practitioner (NP), six in a referral to the MRP, and 27 in *no*

*action taken*. None of the patient charts showed evidence of documentation that the questionnaires were completed or reviewed, what the results of the questionnaires were, or what was the follow up of positive results.

**Unanticipated Limitations or Outcomes and Their Potential Impact on the Findings**

One of the major limitations of the project that may have a potential impact on the findings was the fact that only 15 (27%) patients had NT-proBNP blood tests done. This test is very expensive to perform and only a select group of patients have it completed. The decision to have the NT-proBNP done or not is made by the MRP at the time of patient encounter, and it is based on a number of factors such as the patient's condition at the time, patient's past health history, presence of other comorbid diseases that may mask heart failure, and/or the MRP's clinical judgment.

Another unanticipated limitation that may have a potential impact on the findings was the fact that both the organization and the ADC are currently undergoing many operational and system changes including changes in staffing complements and staffing models. The arrhythmia program's previous *all registered nurse (RN) model* has shifted recently to a *majority cardiovascular technologist (CVT) mo*del. The two roles have different job descriptions, different scopes of practice, different practice standards, and different level of knowledge. Hence, the emphasis on physical assessment may be lower among the CVTs. Secondly, their level of understanding of the implications of positive screening findings may differ significantly. This may contribute to under reporting of patient symptoms and subsequently, to under- identify of these patients for further follow up.

**Ethical, Legal, and Economic Implications**

Within the ethical context, screening of all appropriate patients for heart failure ensures that patients are receiving fair, equal, and equitable care and services, which falls within the ethical principal of justice. Self-reporting of symptoms also allows for a degree of autonomy and self-determination whereas patients may choose to under or over report their symptoms or choose not to fill out the questionnaire at all. Implementing the heart failure screening tool within the ADC setting is also beneficent and non-maleficent, as there is a clear benefit of screening all appropriate patients for heart failure, and it does not cause harm.

From legal perspective, the questionnaire is not mandatory and therefore patients are not legally obligated to complete it. However, if and when patients complete the questionnaire/screening tool, it becomes a legal part of their medical record which is protected by privacy laws. Therefore, there are minimal legal implications for this project.

Within the economic context, implementing a heart failure screening tool will result in better heart failure management in the ADC. Early symptom identification may delay or completely avoid an admission to hospital with heart failure, resulting in substantial direct and indirect cost savings. Implementation of the tool itself, will require minimal resources as it is self-administered.

**Implications in Terms of Individuals, Communities, Institutions, and Systems**

The implications resulting from the project findings have multi-level effects. In terms of individuals, the findings showed that close to half of the ADC patient population was experiencing one or more symptoms of heart failure at the time of their clinic visit.

Without a screening tool, these patients would be potentially not identified and/or missed to follow up. This could subsequently result in these patients requiring an unplanned admission to hospital with heart failure, or in these patients experiencing a decreased quality of life because of their symptoms.

From the community perspective, the ADC provides expert care to all patients living within its local integrated health network—a geographically defined regional area. As such, it has the obligation to ensure that it is providing the best care to all of its members within the region. The best care includes a comprehensive management of heart failure in those who have a history of the disease, as well as those who are at risk for developing the disease.

From institution point of view, the implication of not implementing any screening tool at all creates the risk that the current practice will continue to maintain poor standards of care, and fail to meet professional practice standards. This approach will also contribute to underutilization of best evidence, research, and expert knowledge.

Documentation of findings and follow up on positive screening results is crucial to the success of the project (i.e. why screen if nothing is going to be done about the results?). In fact, the next step of this project is to develop a policy and procedure on how to deal with positive findings.

Finally, from the systems perspective, the implication resulting from the project findings is that it will require an involvement and a coordinated effort between all members of the ADC staff to make this change a success. For example, the business clerks must supply all ADC patients with the questionnaire at the time of registration, the

CVTs and RNs must review and document the results of the screening tool as well as refer for appropriate follow up, and the NP and/or the MRP must ensure that an appropriate heart failure management is initiated. Finally, the manager of the clinic as well as the program director must support and enforce these activities, and the educator must be available as a resource for heart failure education.

**Implication to Positive Social Change**

Within the social context, the project findings have the potential of bringing about a positive social change not only within the culture of the clinic itself, but also within the organization, and overall in the nursing profession. By changing behaviors, attitudes, values, patterns, and norms, the project findings will likely challenge, drive, modify and adjust current structures and arrangements.

From the ADC staff perspective, the findings will conceivably result in a change of the individual member's values, beliefs, and opinions with respect to the significance and importance of screening for heart failure. The recommended interventions will also potentially change the staff members' previous habits, behaviors, and practice routines. This in turn will both, generate and facilitate better patient care and, improve health outcomes.

From the organizational and systems perspective, the project findings will likely force a change in the existing policies and procedures with respect to management of heart failure in the ADC. By establishing and applying practice standards that meet the requirements of the profession, and ensuring that the latest research is incorporated in the organization's policies and procedures, will lead to positive social change.

Finally, from the nursing profession perspective, the project findings will lead to improved patient care by nurses in other like-settings. For example, by effectively and efficiently identifying those who are at risk, the screening tool can be implemented by other nurses in family practice settings, in cardiology outpatient offices, or in any other outpatient clinics.

## Recommendations

The SHEFS questionnaire met the basic requirements for screening for heart failure in the ADC population: quick to complete, easy to understand and answer, able to identify the main physical symptoms of heart failure, and shown to be more predictive of heart failure in this setting as compared to the previously validated heart failure screening tools (KCCQ and MLHFQ). Secondly, when compared to the other two heart failure screening tools, the SHEFS questionnaire was determined by the end users to be a more suitable screening tool for this patient population. As such, the first recommendation is to implement the SHEFS questionnaire as the tool of choice for heart failure screening in the ADC.

The second recommendation is to ensure that heart failure screening is a mandatory and standard element of patient's medical record completed by the staff during a patient visit to the ADC. This approach will ensure that all patients, regardless of the type of device or risk factors, are appropriately assessed, identified, and referred for further appropriate heart failure care. Development of organizational policy and procedure for this new practice would be highly recommended to prevent missed opportunities and avoided complications of heart failure and/or admission to hospital.

The third recommendation is to mandate that an appropriate education on heart failure be completed by each of the staff as part of their orientation to the clinic. Being able to recognize not only the importance of screening for heart failure in this particular patient population, but also the most common signs and symptoms, would assist the HCPs in identifying those who are at risk and subsequently, intervening and/or implementing appropriate therapies.

The fourth recommendation is to implement an appropriate and concrete documentation tool that would promote and encourage heart failure screening in the ADC. Currently, the rudimentary, and very basic, documentation process is not user friendly, includes only the health care provider's subjective interpretation of patient's condition, and does not address the essential components of physical assessment.

The fifth recommendation is to develop policy and procedure with respect to follow up of positive heart failure screening tool findings. Because of the multitude of different providers involved in patient's care, it is often difficult to ascertain who is most responsible or most appropriate to address the heart failure symptoms. A proposed decision tree for HCPs who find positive results on the screening tool is included in Appendix K.

## Strengths and Limitations of the Project

One of the limitation of the project was that it included only patients who had a CRT-D or CRT-P device, as they have a known and documented history of heart failure (an initial indication for the implantable cardiac device). However, there may be other patients with an implantable cardiac device such as Permanent Pace Maker (PPM) or

Implantable Cardioverter Defibrillator (ICD) who may exhibit initial or ongoing signs and symptoms of heart failure and who have not been included in the screening.

Another limitation of the project was the fact that the HCPs were not ready for this practice change, as evidenced by the lack of documentation of the questionnaires, or its outcomes, in the patient's clinic chart by the HCPs. As McEntee, Cuomo, and Dennison (2009) contended, barriers to adherence to guidelines at the provider level are often related to practice environment constraints, time limitations, attitudes and beliefs of those involved, as well as the provider's level of knowledge of guidelines, and his/her comfort with recommended treatment.

One of the strengths of this project was that the tools contributed to an additional knowledge of the patient's status/condition. For example, the provider's review of the patient's self-reported symptoms, may have provided the opportunity in offering additional information that may perhaps not be normally elicited during a typical patient encounter. This information could have altered the course of treatment or therapy.

Secondly, this type of screening can be applied in instances/settings where time resources are limited, and therefore self-report of symptoms can avert addition of extra resources required to collect the information. This type of screening tool therefore, is versatile and universal, and subsequently, can be applied in other like-settings.

Finally, the strength of the project is the fact that it specifically addresses nursing practice and contributes to further professional knowledge. As such, nurses in other specialties can apply this project's findings in their own areas of practice or draw on the finding to implement their own projects.

## Recommendations for Future Projects

One of the main recommendations for similar future projects is to actively involve the clinic staff in the development and evaluation of the project through small steps approach in order to maintain the momentum, and to retain their interest and enthusiasm.

Secondly, the value and the significance of having the relevant and applicable background education on the disease being assessed (heart failure), cannot be underestimated. Without the basic knowledge of the pathophysiology of the disease, its prevalence, incidence, prevailing signs and symptoms, it may be difficult for the HPCs/stakeholders to understand why screening is important.

Thirdly, it is important to ensure that the time elapsed between project design and implementation is short. As mentioned above, some of the staff's interest in the project declined over time, and it was difficult to re-engage them.

Fourthly, it is crucial that the researcher is familiar and comfortable with the different research methodologies and approaches, even prior to determination of study goals and objectives. Knowing what to look for (outcomes), and how to look for it (methods) can make a significant difference. This knowledge plays an especially important role in the interpretation of findings.

Section 5: Dissemination Plan

**Dissemination Plan**

As Forsyth et al. (2010) contended, it is crucial that all new knowledge gained through evidence-based projects be disseminated. According to Hampton et al. (2011) presenting program results/outcomes in a public forum allows for exposure of the issue to the greater audience which can help in raising awareness and drawing in and mobilizing additional support. Bringing attention to the issue at hand may not only help in obtaining added financial and human resources, but also in generating and guiding future policies.

**Institution Experiencing the Problem in Practice**

In order to disseminate the results of this work to the organization in which this project was completed, a number of different approaches and methods will be utilized.

First of all, an executive summary of the project and project findings delivered to the senior management of the program, will identify the clinical issue/problem in question (as supported by organizational data), describe the methods of addressing this problem (project), present the outcomes/results, and list the suggested recommendations. The focus of this summary will be to identify strategies that will bring the changes forward, and to generate the necessary support needed for these strategies. Secondly, the purpose of this program level presentation will be to inform the administration of the current status of the program and the changes needed for improvement.

A power point presentation will be subsequently delivered to all of the stakeholders (including the arrhythmia clinic staff) at an arrhythmia grand rounds, and/or at cardiology grand rounds held on weekly basis in the organization. Through this venue,

the project results can inform others within the organization of the quality improvement

work that is being done within the program.

**Broader Nursing Profession**

With respect to the broader nursing profession, the results of the program will be

presented in the format of scientific poster at local, provincial, and/or national nursing

conferences. Sharing the results of the project as well as the challenges and successes,

may help other nurses in implementing similar projects within their own clinical settings.

One of the conferences in particular that may be most appropriate for this project's result

dissemination is the annual Canadian Cardiovascular Society Congress meeting which

includes the Canadian Council of Cardiovascular Nurses (CCCN) chapter. This particular

national association's vision aligns with my own professional and personal goals: to

advance "cardiovascular nursing through leadership, advocacy, research and knowledge

translation" (CCCN, 2017).

Finally, submission of a manuscript to a peer-reviewed national or international

nursing journal will help in disseminating the knowledge and ideas to a broader audience.

A good quality professional journal with an international recognition and reputation, will

ensure that the results are read by other nurses with a keen interest in advancing the

nursing profession.

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**Analysis of Self**

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**As a Scholar**

By completing the DNP program, I will achieve the terminal degree for my

profession. However, now more than ever I realize that the learning will never end, nor

should it end. The journey of discovery will continue in my daily practice and I hope to instill this enthusiasm for learning to the nursing students I mentor, and to the nurses I work with. By providing leadership and role modeling to other nurses and nursing students through completion of this advance degree, will put me in a position where I can support them and offer advice.

Completing the DNP program will also signal the realization of my life long goal. It will symbolize the accomplishment of a very arduous, but rewarding personal journey to fulfill a personal challenge I set out for myself. It will also give me the opportunity to prove to myself, my colleagues, my family, and my friends that I could do this.

As the move towards DNP degree as the entry into advanced practice approaches, it is also imperative that as a practicing nurse practitioner, I am prepared and hold the necessary qualifications.

Thirdly, completion of the DNP program will provide me with the necessary skills, knowledge, and competencies to contribute to the exploration of nursing practice issues and subsequently, to translation of applicable and relevant research findings to address these issues in order to advance nursing both as a profession, and as a science.

**As a Practitioner**

According to one of the American Association of Colleges of Nursing's (2006), essentials of Doctoral Education for Advanced Nursing Practice (essential II) the DNP program prepares its students to employ the "principles of business, finance, economics, and health policy to develop and implement effective plans for practice-level and/or system-wide practice initiatives that will improve the quality of care delivery" (p. 11).

Development, implementation, and evaluation of the DNP project has definitively prepared me to lead future projects and actively participate in continuous quality improvement within the organization, the program, and my profession. The DNP experience has given me the confidence, the knowledge and the skills as a practitioner, to develop further projects that will influence and affect not only individuals, groups, communities, and populations, but also the nursing profession.

As a practitioner, I will be better equipped to promote and model the use of evidence at patient, provider, and system levels. I will have the background to actively contribute to positive changes in the clinical practice.

**As a Project Developer**

The most difficult role to play in this project was that of the project developer. It was very challenging to initially get the buy-in from the nursing staff, and I constantly struggled with ensuring that the project was implemented accordingly. Numerous email reminders as well as individual meetings were necessary for the project to be completed.

On a more positive note, as a project manager I had the opportunity to apply gained knowledge and skills to design, implement, and evaluate a clinical program within the organization on my own. The prospect of leading the entire project, rather than being a passive participant, was initially quite daunting. However, given that the project was going to influence outcomes and contribute to best care, the experience was very rewarding. Finally, by recommending innovative approaches to improving patient care, in view of the resource constraints, I felt that I was really making a difference.

## Challenges, Solutions, and Insights

Overall, my experience of completing this DNP project has been a very positive one. There has been no major glitches, interruptions, or setback. It has been a very challenging but also a rewarding experience that required a tremendous physical and emotional commitment. However, to see the project progress from mere notions and ideas to a finished product, was both exciting and gratifying.

One of the biggest challenges of completing my DNP project was the time interval that was required to complete the different stages of the project, starting with the proposal, through the IRB process, and finally implementation and evaluation. However, each stage of the project was a crucial component that needed to be completed in order to naturally proceed to the next stage. Nevertheless, this time lag played a key role when the time for implementation came about. Having heard about the project months ago, the clinic staff forgot about the project details, and also lost some of their enthusiasm when the time came to implement. To address this challenge in future projects, it would be worthwhile to bring all of the stakeholder together again before implementation, in order to generate a renewed interest and enthusiasm about the project.

What I learned most about this scholarly journey, is that it takes a lot of time and planning to get things rights. In my previous experience, projects that were rushed through, or ones that took shortcuts, failed either before implementation, or before evaluation was completed.  As such, a well-designed project/study requires the ongoing commitment from the project leader, and continuous attention to details.

**Summary**

Heart failure continues to pose a significant burden on the society due to its resource-intensive requirements and resultant financial costs. As such, the need to quickly and effectively identify those who have heart failure or who are at risk for heart failure, is of the highest priority, regardless of the clinical setting. Screening tools which employ patient administered self-reported symptoms of heart failure questionnaires, allow for an efficient and effective method of identifying those at highest risk. This is especially true in an ADC setting where resources are limited, and the mandate does not incorporate full physical assessment and focused history taking into clinic visit. This doctoral project allowed for the examination, evaluation, and recommendation of the most appropriate and suitable screening tool for the ADC.

After a comprehensive and detailed analysis of the project data, the project leader concluded that the best heart failure screening tool for the ADC setting was the SHEFS questionnaire. It was the simplest tool to complete with the least amount of resources required. The tool also performed better with respect to identifying those who are more *likely* to have heart failure, when compared to the other heart screening tools such as the KCCQ and the MLHFQ, based on the concordance to the gold standard test for heart failure: the NT-proBNP blood test. As a result of these findings, a number of recommendations were made.

First of all, the project leader recommended that the SHEFS questionnaire be implemented as the screening tool of choice for the ADC. Secondly, that the screening for heart failure in the ADC become an expected standard. Thirdly, that a mandatory

education on heart failure be provided to all new staff members to the ADC. Fourthly, that a comprehensive documentation tool be implemented in place of the existing tool. Finally, that a policy and procedure be developed with respect to follow up care of patients with positive heart failure screening results.

The purpose of this doctoral project was to translate the knowledge, skill, and experience acquired through the process of designing, implementing, and evaluating a quality improvement project, in order to guide and direct nursing practice changes reflective of latest research and evidence. Ultimately, the project outcomes resulted in recommendations for the practice setting, as well as organizational system changes, in order to improve the quality of healthcare delivery whilst meeting the needs of the individuals and the community in question.

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Appendix A: Heart Failure Screening Tools

| Tool/Instrument Name | Description | Reference |
|---|---|---|
| KCCQ | -Domains assessed: physical limitations, symptoms, self-efficacy, social limitations, quality of life<br>-23 item questionnaire<br>-Scoring ranges from one to seven (one representing severe limitations or high frequency of symptoms, and seven representing no limitations or rare occurrence of symptoms)<br>-Maximum possible score is 150, with lower scores representing significant effect on quality of life, and higher score representing little or no effect on quality of life | Green et al., 2008 |
| KCCQ-12 | -12 item questionnaire<br>-scoring as per KCCQ<br>-Maximum possible score is 70 with lower scores representing significant effect on quality of life, and higher score representing little or no effect on quality of life | |
| MLHFQ | -Domains assessed: physical, emotional<br>-21 item questionnaire<br>-Scoring scale ranging from zero to five (zero representing no limitations to activities and five representing limitations at all times)<br>-Maximum possible score 105, with lower scores representing no effect on quality of life, and higher scores representing significant effect | Rector et al., 1987 |
| Chronic Heart Failure Questionnaire | -Domains assessed: dyspnea, fatigue, emotional<br>-16 item questionnaire<br>-scoring from worst to best with scores ranging between 16 and 112 | Guyatt et al., 1989 |

| | -measures longitudinal change over time | |
|---|---|---|
| Quality of Life Questionnaire in Severe Heart Failure | -Domains assessed: psychological, physical activity, life-dissatisfaction, somatic symptoms<br>-26 item questionnaire<br>-scoring from best to worst with scores ranging between 0 and 130<br>-self-assessment of health related quality of life in severe heart failure | Wiklund et al., 1987 |
| Left Ventricular Dysfunction (LVD-36) | -Domains assessed: not clear<br>-36 item questionnaire<br>-scoring from best to worst with scores ranging between 0 and 100<br>-measures the impact of LVD on quality of daily life and overall well-being | O'Leary et al., 2000 |
| Cardiac Health Profile Congestive Heart Failure | -Domains assessed: not clear<br>-10 item visual analog scales to determine patient's perception of how heart failure influences physical, psychological, and social well-being | Mannheimer et al., 2007 |
| Chronic Heart Failure Assessment Tool | -Domains assessed: symptoms, activity levels, psycho-social, emotions<br>-46 items measured through a variety of scales to assess patient's perspective of quality of life in heart failure | Dunderdale et al., 2008 |

Appendix B: **S**elf-Reported **He**art **F**ailure **S**ymptoms (SHEFS) Questionnaire

## Arrhythmia Devices Clinic Questionnaire

**Please take a  few minutes to let us know how you have been feeling since we last saw you in our clinic:**

|  | YES | NO | DON'T KNOW |
|---|---|---|---|
| ↓ Since we last saw you, have you been more short of breath than usual? | ☐ | ☐ | ☐ |
| ↓ Since we last saw you, have you had to sleep on more pillows than usual to help with your breathing? | ☐ | ☐ | ☐ |
| ↓ Since we last saw you, have you been awakening at night feeling short of breath? | ☐ | ☐ | ☐ |
| ↓ Since we last saw you, have your feet or abdomen been more swollen? | ☐ | ☐ | ☐ |
| ↓ Since we last saw you, did you require adjustment of your water pill? | ☐ | ☐ | ☐ |
| ↓ Is there anything you would like to ask about your device today? | ☐ | ☐ | ☐ |

Please specify:_____

↓ Who looks after your heart failure, or adjusts your water pill? (please circle)

Cardiologist          Family Doctor          Heart Function Clinic          Don't know

Appendix C: Minnesota Living with Heart Failure Questionnaire (MLHFQ)

MINNESOTA LIVING WITH HEART FAILURE® QUESTIONNAIRE

The following questions ask how much your heart failure (heart condition) affected your life during the past month (4 weeks). After each question, circle the 0, 1, 2, 3, 4 or 5 to show how much your life was affected. If a question does not apply to you, circle the 0 after that question.

| Did your heart failure prevent you from living as you wanted during the past month (4 weeks) by - | No | Very Little | | | | Very Much |
|---|---|---|---|---|---|---|
| 1. causing swelling in your ankles or legs? | 0 | 1 | 2 | 3 | 4 | 5 |
| 2. making you sit or lie down to rest during the day? | 0 | 1 | 2 | 3 | 4 | 5 |
| 3. making your walking about or climbing stairs difficult? | 0 | 1 | 2 | 3 | 4 | 5 |
| 4. making your working around the house or yard difficult? | 0 | 1 | 2 | 3 | 4 | 5 |
| 5. making your going places away from home difficult? | 0 | 1 | 2 | 3 | 4 | 5 |
| 6. making your sleeping well at night difficult? | 0 | 1 | 2 | 3 | 4 | 5 |
| 7. making your relating to or doing things with your friends or family difficult? | 0 | 1 | 2 | 3 | 4 | 5 |
| 8. making your working to earn a living difficult? | 0 | 1 | 2 | 3 | 4 | 5 |
| 9. making your recreational pastimes, sports or hobbies difficult? | 0 | 1 | 2 | 3 | 4 | 5 |
| 10. making your sexual activities difficult? | 0 | 1 | 2 | 3 | 4 | 5 |
| 11. making you eat less of the foods you like? | 0 | 1 | 2 | 3 | 4 | 5 |
| 12. making you short of breath? | 0 | 1 | 2 | 3 | 4 | 5 |
| 13. making you tired, fatigued, or low on energy? | 0 | 1 | 2 | 3 | 4 | 5 |
| 14. making you stay in a hospital? | 0 | 1 | 2 | 3 | 4 | 5 |
| 15. costing you money for medical care? | 0 | 1 | 2 | 3 | 4 | 5 |
| 16. giving you side effects from treatments? | 0 | 1 | 2 | 3 | 4 | 5 |
| 17. making you feel you are a burden to your family or friends? | 0 | 1 | 2 | 3 | 4 | 5 |
| 18. making you feel a loss of self-control in your life? | 0 | 1 | 2 | 3 | 4 | 5 |
| 19. making you worry? | 0 | 1 | 2 | 3 | 4 | 5 |
| 20. making it difficult for you to concentrate or remember things? | 0 | 1 | 2 | 3 | 4 | 5 |
| 21. making you feel depressed? | 0 | 1 | 2 | 3 | 4 | 5 |

## Appendix D: Kansas City Cardiomyopathy Questionnaire (KCCQ)

### *Kansas City Cardiomyopathy Questionnaire (KCCQ-12)*

The following questions refer to your **heart failure** and how it may affect your life. Please read and complete the following questions. There are no right or wrong answers. Please mark the answer that best applies to you.

1. **Heart failure** affects different people in different ways. Some feel shortness of breath while others feel fatigue. Please indicate how much you are limited by **heart failure** (shortness of breath or fatigue) in your ability to do the following activities <u>over the past 2 weeks</u>.

| Activity | Extremely Limited | Quite a bit Limited | Moderately Limited | Slightly Limited | Not at all Limited | Limited for other reasons or did not do the activity |
|---|---|---|---|---|---|---|
| a. Showering/bathing | O | O | O | O | O | O |
| b. Walking 1 block on level ground | O | O | O | O | O | O |
| c. Hurrying or jogging (as if to catch a bus) | O | O | O | O | O | O |
| | 1 | 2 | 3 | 4 | 5 | 6 |

2. Over the <u>past 2 weeks</u>, how many times did you have **swelling** in your feet, ankles or legs when you woke up in the morning?

| Every morning | 3 or more times per week but not every day | 1-2 times per week | Less than once a week | Never over the past 2 weeks |
|---|---|---|---|---|
| O | O | O | O | O |
| 1 | 2 | 3 | 4 | 5 |

3. Over the <u>past 2 weeks</u>, on average, how many times has **fatigue** limited your ability to do what you wanted?

| All of the time | Several times per day | At least once a day | 3 or more times per week but not every day | 1-2 times per week | Less than once a week | Never over the past 2 weeks |
|---|---|---|---|---|---|---|
| O | O | O | O | O | O | O |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 |

4. Over the <u>past 2 weeks</u>, on average, how many times has **shortness of breath** limited your ability to do what you wanted?

| All of the time | Several times per day | At least once a day | 3 or more times per week but not every day | 1-2 times per week | Less than once a week | Never over the past 2 weeks |
|---|---|---|---|---|---|---|
| O | O | O | O | O | O | O |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 |

5. Over the <u>past 2 weeks</u>, on average, how many times have you been forced to sleep sitting up in a chair or with at least 3 pillows to prop you up because of **shortness of breath**?

| Every night | 3 or more times per week but not every day | 1-2 times per week | Less than once a week | Never over the past 2 weeks |
|---|---|---|---|---|
| O | O | O | O | O |
| 1 | 2 | 3 | 4 | 5 |

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

| It has **extremely** limited my enjoyment of life | It has limited my enjoyment of life **quite a bit** | It has **moderately** limited my enjoyment of life | It has **slightly** limited my enjoyment of life | It has **not limited** my enjoyment of life at all |
|:---:|:---:|:---:|:---:|:---:|
| O | O | O | O | O |
| 1 | 2 | 3 | 4 | 5 |

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

| Not at all satisfied | Mostly dissatisfied | Somewhat satisfied | Mostly satisfied | Completely satisfied |
|:---:|:---:|:---:|:---:|:---:|
| O | O | O | O | O |
| 1 | 2 | 3 | 4 | 5 |

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

| Activity | **Severely** Limited | Limited **quite a bit** | **Moderately** limited | **Slightly** limited | **Did not** limit at all | Does not apply or did not do for other reasons |
|---|:---:|:---:|:---:|:---:|:---:|:---:|
| a. Hobbies, recreational activities | O | O | O | O | O | O |
| b. Working or doing household chores | O | O | O | O | O | O |
| c. Visiting family or friends out of your home | O | O | O | O | O | O |
| | 1 | 2 | 3 | 4 | 5 | 6 |

# Arrhythmia Devices Clinic

**Dear patient:**

**We are continuously finding new ways to improve the quality of care we provide to our patients, such as you. As part of this quality improvement process, we would like to ask you to complete the attached questionnaires while you are waiting for your appointment with our clinic staff.**

**The purpose of these questionnaires is to help us identify any changes in your health as it relates to your visit today.**

**There are three questionnaires. Once you complete them, please give the package to one of the health care providers you see during your appointment.**
**Thank you,**

Appendix F: Literature Review Matrix

| Summary Table of Analyzed Articles | | | | | | |
|---|---|---|---|---|---|---|
| **Citation (in APA style with doi or link)** | **Conceptual Framework / Theory** | **Main finding** | **Research method / Sample size /** | **Strengths of the study** | **Weaknesses of the study** | **Level of Evidence** |
| Guyatt, G. H. (1993). Measurement of health-related quality of life in heart failure. *Journal of American College of Cardiology, 22*(4 Suppl A), 185A-191A. | Not identified /not used | Only MLHFQ showed disease-specific responsiveness in context of clinical trials. | Descriptive method utilized. No sample size identified. | Description of generic and specific approaches to measuring quality of life were outlined. An example of disease-specific measures in heart failure was provided. | Comparison of different questionnaires based only on outcomes of single studies. | VI |
| Guyatt, G. H. (1995). A taxonomy of health status instruments. *Journal of Rheumatology, 22*(6), 1188-1190. | Not identified /not used | Health related quality of life questionnaires should be used to inform care and guide policy development. There are | Descriptive method utilized. No sample size identified. | A taxonomy of different instruments was listed—generic and specific-- which provided the reader with | Listing of all of the available instruments but no comparison between the instruments. | VII |

| | | generic instruments and specific instruments—each has strengths and weakness. Depending on the focus, one may be better over the other. | | options as to what is available. | | |
|---|---|---|---|---|---|---|
| Berry, C., & McMurray, J. (1999). A review of quality-of-life evaluations in patients with congestive heart failure. *Pharmacoeconomics, 16*(3), 247-271. | Not identified /not used | Best disease-specific QOL questionnaires are the MLHFQ and the CHFQ. | Review of the design and validation process of generic and disease specific quality of life (QOL) questionnaires. | Detailed description of the various elements measuring the instruments' validity and ability to discriminate between changing levels of severity of the disease. | Conclusions were drawn based on results of single studies only. | VI |

| Eurich, D. T., Johnson, J. A., Reid, K. J., & Spertus, J. A. (2006). Assessing responsiveness of generic and specific health related quality of life measures in heart failure. *Health and Quality of Life Outcomes, 4*(89). http://doi.org/10.1186/1477-7525-4-89 | Not identified /not used | KCCQ was the most responsive health quality of life questionnaire to assess change over a 6-week period of time | Cohort study design with sample size of 298 subjects with heart failure. Three different questionnaires were administered and patients' change was measured using three external indicators. | Subjects were recruited from 14 medical centers across Canada and the United States (allows for generalizability) | Some of the external indicators used to measure change are subjective (NYHA class). Small sample size. Unclear as to sampling method: possible sampling bias? | VI |
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| Garin, O., Ferrer, M., Pont, A., Rue, M., Kotzeva, A., Van Ganse, E., & Alonso, J. (2009). Disease-specific health-related quality of life questionnaires for heart failure: A systematic review with meta-analyses. *Quality of Life Research, 18*(1), 71-85. http:// | Not identified /not used | Evidence showed that the MLHFQ was most reliable, valid, and responsive tool among those tested, followed by the KCCQ, then CHFQ. | Systematic review with meta-analysis. Full text reviews were performed on 421 studies. | High level of evidence and large sample size. The study tested for the most important/desirable components in a clinical tool: reliability, validity, and | Did not address the administrative burden on the patients when completing the questionnaires. Study did not identify the effect of the different settings (hospital, | I |

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| doi.org/10.1007/s11136 -008-9416-4 | | | | responsiveness . | clinic, etc.). | |
| Garin, O., Ferer, M., Pont, A., Wiklund, I., Van Ganse, E., Vilagut, G., …Alonso, J. (2013). Evidence on the global measurement model of the Minnesota Living with Heart Failure Questionnaire. *Quality of Life Research, 22*(1), 2675-2684. http://doi.org/10.1007/s11136 -013-0383-z | Not identified /not used | The total MLFHQ score was the most commonly used score in heart failure patients. | Merged data from eight studies and 21 countries. Sample size: 3847 patients. | The reliability and validity of the MLHFQ was shown to be consistent among different countries. | The effectiveness of the instruments was evaluated using different criteria/ elements among the different countries. | VI |
| Garin, O., Herdman, M., Vilagut, G., Ferre, M., Ribera, A., Rajmil, L., …Alonso, J. (2014). Assessing health-related quality of life in patients with heart failure: A systematic, standardized comparison of available measures. *Heart Failure Reviews,* | Not identified /not used | The instruments identified as best with respect to reliability, validity, sensitivity, and interpretability were: KCCQ and MLHFQ. | Systematic review of all of the available health-related quality of life instruments. Seven tools were identified specifically for heart failure. | Each of the heart failure questionnaires were evaluated based on several different aspects such as: validity, sensitivity, reliability, and interpretability | None identified. | I |

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| *19*(3), 359-367. http:// doi.org/10.1007/s10741 -013-9394-7 | | | | | | |
| Kelkar, A. A., Spertus, J., Pang, P., Pierson, R. F., Cody, R. J., Pina, I. L., …Butler, J. (2016). Utility of patient-reported outcome instruments in heart failure. *Journal of American College of Cardiology, 4*(3), 165-175. http:// doi.org/10.1016/j.jchf.2 015.10.015 | Not identified /not used | Only two patient-reported outcome (PRO) instruments for heart failure met the study evaluation criteria: KCCQ and MLHFQ. | A systematic review of research studies that measured PRO instruments in heart failure. 31 instruments were identified, and nine met all inclusion criteria, and two met all evaluation criteria. | The study used detailed criteria for measuring the properties of the PROs. | The study did not examine the efficiency of implementing /administering these questionnaires. Therefore, unable to evaluate feasibility of applying these instruments in clinical practice of varying settings. | I |
| Gilbert, A., Sebag-Montefiore, D., Davidson, S., & Velikova, G. (2015). Use of patient-reported outcomes to measure symptoms and health | Not identified /not used | Clinical care may benefit from integration of patient-reported-outcomes | Review of other articles utilizing patient-reported-outcomes (PROs). No | The benefits of using PROs are identified, including frequency and timing of administration. | Not a systematic review of data. Only case studies presented. | IV |

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| related quality of life in the clinic. *Gynecologic Oncology, 136*(2015), 429-439. http://doi.org/10.1016/j.ygyno.2014.11.071 | | (PROs) instruments in assessments. | sample size available, no method identified. | The best methods of collecting this data is proposed. | | |
| Spertus, J. A., & Nassif, M. E. (2016). Screening health questionnaires and patient-reported outcomes: Will shortened versions overcome the barriers to their implementation. *Journal of Cardiac Failure, 22*(2), 1080109. http://doi.org/10.1016/j.cardfail.2015.11.010 | Not identified /not used | Shortened versions of screening instruments may under-report or under-recognize significance of symptoms. | No specific method or sample size identified. | Highlights the importance of inclusive assessment of all aspect/ components of the patient's status including cognitive status. | Opinion only. No specific data was presented. | VII |
| Psotka, M. A., von Maltzahn, R., Anatchkova, M., Agodoa, I., Chau, D., Malik, F. I., … Teerlink, J. R. (2016). Patient-reported | Not identified /not used | None of the chronic heart failure patient-reported outcome (PRO) instruments met the FDA | A systematic literature review of all of the available articles identifying the | Exhaustive literature review of all available articles over the span of five years | Only the PROs that met the FDA recommended guidelines were reviewed and analyzed. | I |

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| outcomes in chronic heart failure: Applicability for regulatory approval. *Journal of American Colleges of Cardiology, 4*(10), 791-804. http://doi.org/10.1016/j.jchf.2016.04.010 | | recommended guidelines. | use of PROs. 2,552 articles and 2,334 abstracts were identified. 19 were chosen for review. | (inclusiveness). | | |
| Heidenreich, P. A., Spertus, J. A., Jones, P. G., Weintraub, W. S., Rumsfeld, J. S., Rathore, S. S., …Williams, R. E. (2006). Health status identifies heart failure outpatients at risk for hospitalization or death. *Journal of American College of Cardiology, 47*(7), 752-756. http://doi.org/10.1016/j.jacc.2005.11.021 | Not identified/not used | A low score obtained on Kansas City Cardio-myopathy Questionnaire (KCCQ) was association with a poor prognosis for patients with heart failure. | The sample size consisted of 505 patients with heart failure, from 13 outpatient clinics. Consecutive patients who met the study criteria were included (ejection fraction <40%). | The sensitivity of a tool (independent of other clinical data) was utilized to predict heart failure prognosis. | Only one questionnaire was used (KCCQ) to evaluate for predictors of prognosis independent of other clinical data. | III |

Appendix G: Levels of Evidence

| Level of Evidence | Description |
|---|---|
| I | Evidence from a systematic review or meta-analysis of all relevant RCTs |
| II | Evidence obtained from well-designed RTC. |
| III | Evidence obtained from well-designed controlled trials without randomization |
| IV | Evidence from well-designed case-control and cohort studies |
| V | Evidence from systematic reviews of descriptive and qualitative studies |
| VI | Evidence from single descriptive or qualitative studies |
| VII | Evidence from the opinion of authorities and/or reports of expert committees |

Ackley, B. J., Swan, B. A., Ladwig, G., & Tucker, S. (2008). *Evidence-based nursing care guidelines: Medical-surgical interventions.* (p. 7). St. Louis, MO: Mosby Elsevier.

Appendix H: Research Ethics Board Approval

**Paul Lucy**

| | |
|---|---|
| From: | Sancan Janice |
| Sent: | Thursday, April 06, 2017 3:24 PM |
| To: | Paul Lucy |
| Subject: | RE: re: QI project |

Hello Lucy,

Thank you for both your phone call and the attached summary of your project. From what you have outlined, this is clearly quality improvement activity, whereby you seek to improve a localized clinic's practice in its management of heart failure patients, in order to meet current evidence-based guidelines.

It is certainly appropriate to obtain patient feedback and involvement; also it is permissible to access patient files from the specified clinic in order to both evaluate current functioning and to implement the changes necessary for practice improvement. Please note that the collected patient data will be de-identified (not anonymous) and maintained as de-identified in analyses and reports, which is expected in this type of activity.

You may publish or present your findings; simply acknowledge that any manuscript or poster represents quality improvement activity and not research.

The initiative that you have presented is considered quality improvement, and as per the TCPS2 (2014), Article 2.5, ethics approval by the HiREB is not required.

Janice

**Janice Sancan**
**Research Ethics Officer**
**Hamilton Integrated Research Ethics Board (HiREB)**
**Suite 102 - 293 Wellington Street North**
**Hamilton, ON L8L 8E7**

Tel: 905-521-2100 x 44574
Fax: 905-577-8378
Email: sancan@hhsc.ca
Web: www.hireb.ca

Appendix I: IRB Approval

**From:** IRB <irb@mail.waldenu.edu>
**Sent:** Friday, May 26, 2017 4:54 PM
**To:** Lucy Paul
**Cc:** Patrick A. Palmieri
**Subject:** IRB Materials Approved - Lucy Paul

Dear Ms. Paul,

This email is to notify you that the Institutional Review Board (IRB) confirms that your study entitled, "Heart Failure Screening Tools: Assessment for an Outpatient Arrhythmia Devices Clinic," meets Walden University's ethical standards. Our records indicate that you will be analyzing data provided to you by Hamilton Health Sciences as collected under its oversight. Since this study will serve as a Walden doctoral capstone, the Walden IRB will oversee your capstone data analysis and results reporting. The IRB approval number for this study is 05-26-17-0542764.

This confirmation is contingent upon your adherence to the exact procedures described in the final version of the documents that have been submitted to IRB@mail.waldenu.edu as of this date. This includes maintaining your current status with the university and the oversight relationship is only valid while you are an actively enrolled student at Walden University. If you need to take a leave of absence or are otherwise unable to remain actively enrolled, this is suspended.

If you need to make any changes to your research staff or procedures, you must obtain IRB approval by submitting the IRB Request for Change in Procedures Form.  You will receive confirmation with a status update of the request within 1 week of submitting the change request form and are not permitted to implement changes prior to receiving approval.  Please note that Walden University does not accept responsibility or liability for research activities conducted without the IRB's approval, and the University will not accept or grant credit for student work that fails to comply with the policies and procedures related to ethical standards in research.

When you submitted your IRB materials, you made a commitment to communicate both discrete adverse events and general problems to the IRB within 1 week of their occurrence/realization.  Failure to do so may result in invalidation of data, loss of academic credit, and/or loss of legal protections otherwise available to the researcher.

Both the Adverse Event Reporting form and Request for Change in Procedures form can be obtained at the IRB section of the Walden website:http://academicguides.waldenu.edu/researchcenter/orec

Researchers are expected to keep detailed records of their research activities (i.e., participant log sheets, completed consent forms, etc.) for the same period of time they retain the original data.  If, in the future, you require copies of the originally submitted IRB materials, you may request them from Institutional Review Board.

Both students and faculty are invited to provide feedback on this IRB experience at the link below:

**http://www.surveymonkey.com/s.aspx?sm=qHBJzkJMUx43pZegKlmdiQ_3d _3d**

Sincerely,
Libby Munson
Research Ethics Support Specialist
Office of Research Ethics and Compliance
Walden University
100 Washington Avenue South, Suite 900
Minneapolis, MN 55401
Email: irb@mail.waldenu.edu
Phone: (612) 312-1283
Fax: (626) 605-0472

Information about the Walden University Institutional Review Board, including instructions for application, may be found at this link:http://academicguides.waldenu.edu/researchcenter/orec

## Appendix J: Comparison Between Heart Failure Screening Groups

**1. SHEFS, MLHFQ and KCCQ compared to BNP:**

| | | **Numbers** | | | **Percentage** | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| | | BNP | | | BNP | | |
| | | Yes | No | | Yes | No | |
| SHEFS | Yes | 5 | 1 | 6 | **83.3%** | | Sensitivity |
| | No | 1 | 8 | 9 | | **88.9%** | Specificity |
| | | 6 | 9 | 15 | | | |
| MLHFQ | Yes | 2 | 0 | 2 | **33.3%** | | Sensitivity |
| | No | 4 | 9 | 13 | | **100.0%** | Specificity |
| | | 6 | 9 | 15 | | | |
| KCCQ | Yes | 3 | 1 | 4 | **50.0%** | | Sensitivity |
| | No | 3 | 8 | 11 | | **88.9%** | Specificity |
| | | 6 | 9 | 15 | | | |

Chi square comparison:  $p < 0.001$

**2. SHEFS compared to MLHFQ:**

| | | **Numbers** | | | **Percentage** | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| | | MLHFQ | | | BNP | | |
| | | Yes | No | | Yes | No | |
| SHEFS | Yes | 5 | 13 | 18 | **71.4%** | | Sensitivity |
| | No | 2 | 35 | 37 | | **72.9%** | Specificity |
| | | 7 | 48 | 55 | | | |

Chi square comparison:  $p < 0.001$

**3. SHEFS compared to KCCQ:**

| | | **Numbers** | | | **Percentage** | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| | | KCCQ | | | BNP | | |
| | | Yes | No | | Yes | No | |
| SHEFS | Yes | 6 | 12 | 18 | **75.0%** | | Sensitivity |
| | No | 2 | 35 | 37 | | **74.5%** | Specificity |
| | | 8 | 47 | 55 | | | |

Chi square comparison:  $p < 0.001$

**4. Univariate regression analysis of SHEFS, KCCQ, MLHFQ and BNP, and admission to hospital in last 6 months**

Dependent variable = Admission to hospital

|  | p value |
|---|---|
| SHEFS | 0.023 |
| MLHFQ | 0.030 |
| KCCQ | 0.025 |
| BNP | 0.310 |

Appendix K: Decision Tree for Follow Up of Positive Screening Results