Diagnosis and Management of Heart Failure: An Investigation to Evaluate a Device to Measure Jugular Venous Pressure

by

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A thesis

presented to the University of Waterloo

in fulfillment of the

thesis requirement for the degree of

Master of Science

in

Health Studies and Gerontology

Waterloo, Ontario, Canada 2015

I hereby declare that I am the sole author of this thesis.

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ABSTRACT

Diagnosing and managing heart failure (HF) can be challenging as patients sometimes present atypically with non-specific signs and symptoms. Effective management hinges upon an accurate, timely diagnosis.

An important component of physical examination, the assessment of jugular venous pressure (JVP), can assist in the diagnosis and management of HF. Clinical assessment of JVP can be performed at the bedside using the Lewis method whereby the height of the jugular venous pulse above the right atrium is measured. Reliability of the maneuver can be affected by variability related to the appropriate vein to use, reference points, and variable classification of normal versus abnormal. A non-invasive point of care device, the Mespere Venous 1000 Central Venous Pressure (CVP) System, can be used to measure JVP. It has been approved by Health Canada and the Food and Drug Agency for commercial use.

The overall aim of this study was to conduct a preliminary evaluation of the feasibility of using the Mespere Venous 1000 CVP System to measure JVP for the diagnosis and management of HF in primary care and long term care (LTC). The study involved two projects: Project i and Project ii. Project i was conducted in one primary care and four LTC settings. It sought to gather qualitative information from the physicians and nurses about their perceptions relating to: measurement of JVP, acceptability of the device, perceived ease of use, and perceived barriers of the device. Focus groups and interviews were conducted with six physicians and nine nurses in primary care, and four physicians and ten nurses in LTC. Findings showed that the device was more acceptable and feasible to use for LTC clinicians than it was for primary care clinicians, particularly if its reliability among LTC residents could be demonstrated. Project i revealed that the low acceptability of the device in primary care appears to stem in part from a lack of

understanding of the importance of the JVP and patterns of practice that favor transfers of patients to emergency department (ED) for more definitive management. Project ii of the study aimed to assess the reliability of the device in the LTC setting. Two LTC physicians, two nurses and thirty six LTC residents participated in the study. The findings showed that the reliability of the device, when used by LTC nurses, was greater than that of physicians' measures obtained with the Lewis method.

In conclusion, the study suggests that the use of the point of care (POC) Mespere Venous CVP 1000 System to measure JVP is acceptable and feasible in the LTC setting, but less so in primary care. In LTC, it provides more reliable measures of the JVP than does clinical assessment by physicians. Additional study is required to further improve the reliability of the device when used by LTC nurses. Further work is also required to develop primary care processes that promote HF management within primary care settings, and whether the device could have a role in such settings.

ACKNOWLEDGEMENTS

Foremost, I would like to express my deepest gratitude to my supervisor, Dr. George Heckman, for his continuous support, encouragement, patience and for providing me the opportunity to learn under his tutelage and guidance. The experiences are invaluable and have helped me become a more competent critical thinker.

To my committee members, Drs. Veronique Boscart, Andrew Costa, and Robert McKelvie, my profound appreciation for the invaluable technical advice and professional leadership provided in the realization of this investigation.

My sincere gratitude to my family and friends who have provided tremendous support and assistance in facilitating the successful completion of this research pursuit.

Special thanks to all the physicians, nurses, and long term care residents involved in this study and whose cooperation made this endeavor possible.

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CHAPTER 1

INTRODUCTION

HF is often misdiagnosed or undetected in primary care and LTC, thus preventing optimal management. The prevalence of HF cases is increasing with population aging. Improving the diagnosis of HF, thus facilitating more optimal management, is essential to curb its significant impact on patients and on health care resources.

The assessment of JVP is an important measure recommended in guidelines to diagnose and manage HF. The measure is underutilized and devalued among modern clinicians. In addition to the conflicting recommendations as to how the measure should be obtained, there is a paucity of experimental literature investigating utility and perceptions of the clinical sign in primary care and LTC. The Mespere Venous CVP 1000 System is a non-invasive, POC device which measures JVP. Its role in primary care and LTC to supplement the diagnostic process for HF has not been evaluated. The overall focus of this study was to explore the potential of the device in these settings. The investigation adopted two projects – Project i and Project ii.

1.1 Overview

HF is defined as a complex clinical syndrome that arises secondary to abnormalities of cardiac structure and/or function (inherited or acquired) that impair the ability of the left ventricle to fill or eject blood at a rate commensurate to meet the metabolic needs of the body (Libby, Bonow, Mann & Zipes, 2008). More than 600,000 Canadians live with HF and approximately 50,000 new patients are diagnosed each year (Blais et al., 2014; Ross et al., 2006). Its prevalence is expected to increase over the next decades due to population aging (Curtis et al., 2008) coupled with recent improvements in the survival rates of patients with coronary artery disease, a main risk factor for HF (McCullough et al., 2002). Although HF affects 1 to 2% of

Canadians (Chow, Donovan, Manuel, Johansen & Tu, 2005), it is predominantly a condition of the elderly with an incidence of 9.7% in those aged 75-84 and 17.4% in those aged 85 years and over (Bleumink et al., 2004). One in five individuals who survive to age 80 will develop HF over the remaining years of their life (Lloyd-Jones et al., 2002).

HF has been referred to as Canada's silent epidemic as it is associated with a prognosis that is markedly worse than other cardiovascular diseases. The condition has a devastating impact on an individual's quality of life by causing shortness of breath, fatigue, disability, and cognitive impairment. It is the second most responsible cause for hospitalization in those over the age of 65. These patients experience lengthy stays with up to 21% readmitted within 30 days (CIHI, 2012). Even though HF is largely an incurable condition, there are therapies that can help patients maximize their quality of life. Dietary modifications and pharmaceuticals coupled with weight loss and physical activity can alleviate symptoms. Thus, part of the solution to improve the prognosis of the condition lies in earlier, more accurate diagnosis, and effective management.

Diagnosing and managing HF can be a process wrought with challenges, particularly among geriatric populations. Symptoms may be subtle and when present, mistakenly attributed to senescence. Patients may not report symptoms until their condition becomes more severe. Atypical presentation is common in frail older adults who may present with geriatric syndromes such as functional decline or delirium. Other signs and symptoms can also occur in the setting of other conditions, such as Chronic Obstructive Pulmonary Disease (COPD). Amidst these challenges, one of the more useful clinical maneuvers for diagnosis and management of HF is the assessment of JVP.

JVP is a specific sign of HF, and can be assessed through the Lewis Method which requires measurement of the venous pulse at the patient's bedside. The Lewis Method entails the external measurement of the maximal height of jugular venous distension above the sternal angle while the patient is positioned at forty five degrees. JVP is reflective of intra-atrial pressure and volume fluid status. An elevated JVP is indicative of abnormal heart dynamics, usually implying fluid overload and the need for diuresis. Although not independently diagnostic, elevated levels are an important clinical finding as evidenced by its noteworthy value in many best practice guidelines (Maestre et al., 2009 ; Yancy et al., 2013).

Despite the potential role of JVP measurement as a component in the diagnosis and management of HF, it is often underutilized, and many erroneously perceive the JVP as not helpful. Primary care and LTC clinicians have cited a high degree of uncertainty in their clinical skills which translates to indecision in establishing a diagnosis of HF and reliance on imaging (Heckman et al., 2014). Many practitioners of varying levels of seniority and experience do not measure JVP correctly, leading to a cycle of unreliable information, lack of confidence, and underuse of this sign (Chiaco, Parikh and Fergusson, 2013).

In order to improve the reliability of the JVP measure at the POC, the non-invasive, Mespere Venous 1000 CVP System was developed for use at the bedside, and provides clinicians with a JVP measurement and its corresponding waveform. While the device has been approved by Health Canada for commercial use, its use in primary care and LTC settings has not been evaluated.

1.2 Research Objectives

The overall objective of this study was to assess the acceptability and feasibility of using the Mespere Venous 1000 CVP System in the diagnosis and management of HF in primary care and in LTC settings.

Specific objectives of Project i include:

i. Explore primary care and LTC clinicians' perceived understanding of the JVP;

ii. Describe the acceptability of the Mespere Venous 1000 CVP System to primary care and LTC clinicians;

iii. Assess perceptions of the ease of use of the Mespere Venous 1000 CVP System among clinicians in primary care and LTC; and

iv. Identify perceived barriers to implementation of the Mespere Venous CVP System to measure JVP in primary care and LTC.

Specific objectives of Project ii include:

v. Determine the inter-rater reliability of the Mespere Venous 1000 CVP System when used by LTC nurses; and

vi. Determine the inter-rater reliability of the Lewis method to measure JVP when applied by physicians in LTC.

CHAPTER 2

REVIEW OF LITERATURE

The intent of this study was to investigate the potential of a non-invasive, POC device to measure JVP in primary care and LTC. This chapter covers the following topics:

(i) Definitions of Terms

(ii) Pathophysiology of HF and JVP

(iii) Prognosis and Management of HF

(iv) Diagnostic Inaccuracy and Challenges

(v) Significance of Symptoms and Signs

(vi) Importance of JVP

(vii) Clinical Assessment of JVP

(viii) POC Devices and the Mespere 1000 CVP System

2.1 Definition of Terms

Terms commonly used in this study are defined below.

Central Venous Pressure: Measure of the filling pressure of the right ventricle and gives an estimate of the intravascular volume status. It is influenced by circulating blood volume, venous tone, and right ventricular function (Muralidhar, 2002).

Chronic Disease: Non-communicable diseases that are of long duration and generally slow progression. The four main types are cardiovascular diseases (such as heart failure), cancers, chronic respiratory diseases (such as chronic obstructed pulmonary disease and asthma) and diabetes (World Health Organization, 2015).

HF*:* A complex clinical syndrome that arises secondary to abnormalities of cardiac structure and/or function (inherited or acquired) that impair the ability of the left ventricle to fill or eject blood at a commensurate rate to meet the metabolic needs of the body (Libby, Bonow, Mann & Zipes, 2008).

JVP: The pressure within the jugular veins (Mann, 2011).

LTC homes: Facilities which provide living accommodation for people who require on-site delivery of 24 hour, 7 days a week supervised care, including professional health services, personal care, and services such as meals, laundry and housekeeping (Healthycanadians.gc.ca, 2004).

Nurse Practitioner (NP): A RN with advanced university education provides personalized, quality health care to patients. A RN can specialize in one of four areas including primary health care, adult and pediatric care, and anesthesia (RNAO.ca, 2015).

POC: Medical testing at or near the site of patient care (Kost, 1995).

Primary Care: Day-to-day healthcare given by a health care provider. Typically this provider acts as the first contact and principal point of continuing care for patients within a healthcare system, and coordinates other specialist care that the patient may need. Patients commonly receive primary care from professionals such as a primary care physician (general practitioner or family physician), a nurse practitioner or a registered nurse. Depending on the nature of the health condition, patients may then be referred for secondary or tertiary care (Hawk, 2002).

Registered Nurse (RN): A RN studies for a longer period of time, allowing for greater depth and breadth of foundational knowledge in the areas of clinical practice, decision-making, critical thinking, leadership, research utilization, and resource management (RNAO.ca, 2015).

Registered Practical Nurse (RPN): A RPN is a professional nurse. The autonomy of the RPN is influenced by the complexity of the client's condition. A RPN has greater autonomy when caring for a client with less-complex conditions. As client complexity increases, there is a corresponding increase in the need for a RPN to consult with RNs. RPNs work in clinical settings such as primary care and LTC (RNAO.ca, 2015).

Specialists: Medical specialists are physicians who have completed advanced education and clinical training in a specific area of medicine such as cardiology and geriatrics (De Jong, Heiligers, Groenewegen & Hingstman, 2006).

2.2 Pathophysiology of HF and JVP

The physiologic underpinnings of HF serve to understand the trajectory of the condition, diagnostic challenges, and need for effective management. The body's compensatory responses to HF lead to an elevation of JVP.

HF results from an initial injury affecting the cardiac muscle and subsequent systemic response. The reduced cardiac output and ensuing lack of adequate oxygen delivery begins as the consequence of any abnormality in cardiac structure or function. Depressed cardiac output arises as a result of systolic or diastolic left ventricular dysfunction, or a combination of both (Figuerora & Peters, 2006). Systolic dysfunction is commonly present in HF with Reduced Ejection Fraction (HF-REF) while diastolic dysfunction can occur in either HF-REF or HF with Preserved Ejection Fraction (HF-PEF). HF-REF is classified as a left ventricular ejection fraction less than 50% (Figuerora & Peters, 2006). On the other hand, HF-PEF is defined as left ventricular ejection fraction ≥50%) and its causes are similar to that of HF-REF with the most common being hypertension and ischemic heart disease (Figuerora & Peters, 2006).

The physiologic responses to low cardiac output act to maintain mean arterial pressure (MAP) through activation of the Frank Starling mechanism, neurohormonal cascades and ventricular remodeling. In this way, the circulatory system is able to increase stroke volume, a variable determined by contractility of the cardiac muscle, preload and afterload. Preload is defined as the amount of myocardial fiber stretch at the end of diastole while afterload is the pressure the left ventricle must overcome to expel blood. The right atrial pressure reflects the preload of the right ventricle and is represented in the jugular veins. Thus, right atrial pressure can be assessed indirectly by measuring the JVP (Mann, 2011). The normal mean jugular venous pressure is 4 to 8 cm of water (or blood) or 3 to 6 mmHg (Mann, 2011).

Neurohormonal activation begins with the release of epinephrine and norepinephrine which increases heart rate and contractility. These catecholamines allow for vasoconstriction, in turn, elevating MAP towards its normal physiologic level. Furthermore, they initiate the renin-angiotensin-aldosterone cascade. Renin is an enzyme that cleaves angiotensinogen to angiotensin I in the liver and circulates in the bloodstream until it is spliced by angiotensin converting enzyme (ACE) to its active form, angiotensin II. This hormone signals the release of aldosterone from the adrenal cortex which triggers the release of norepinephrine and vasopressin. The response will increase preload and JVP, initially providing the peripheral tissue with sufficient oxygen and explains the stabilization phase observed in the progression of HF. Over time, the response is maladaptive as prolonged activation leads to myocardial toxicity and eventual reduction in ejection fraction, tachycardia, arrhythmias and myocyte loss (Chaggar, Malkin, Shaw, Williams & Channer, 2009). The neurohormonal mechanism can be found in APPENDIX i.

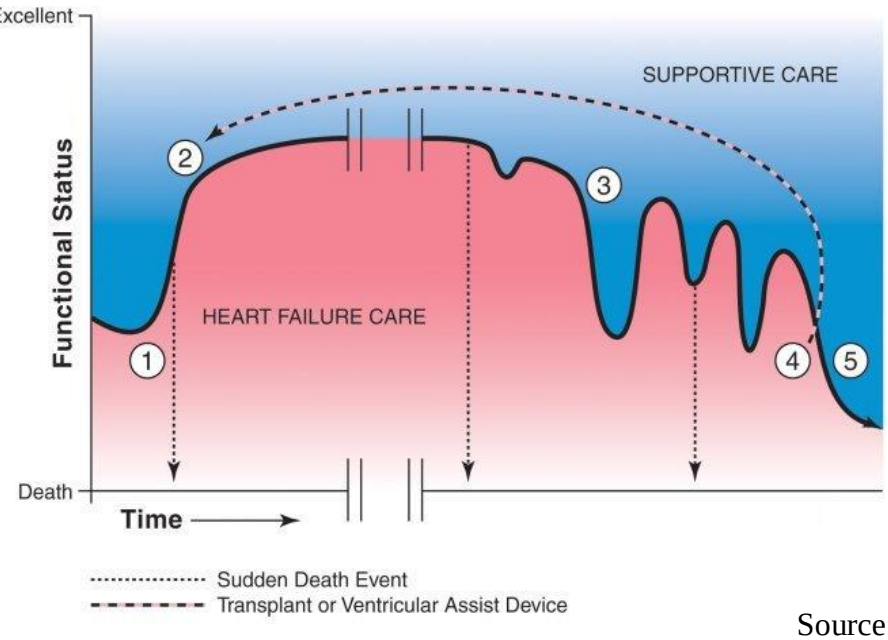
Venous compliance and volume in the jugular veins are dynamic measures which are influenced by a number of variables. Alteration of venous volume can stem from decreased cardiac output, increased blood volume, changing from the standing to supine position, arterial dilation, and contraction of skeletal muscle (particularly legs and abdomen). Alternatively, changes in compliance can result from venous constriction, forced expiration and muscle contraction. Venous constriction can be caused by circulating vasoconstrictor substances such as catecholamines which decrease compliance and increase JVP. During a forced expiration, external compression of the vena cava functionally reduces the compliance of the vein, in turn increasing JVP (Mann, 2011). Muscular contractions, particularly of the abdomen and limbs lead to compression of the veins, decreases compliance, and forces blood into the thoracic compartment, thus increasing intrathoracic blood volume and JVP.

The mechanisms activated in HF are intended to maintain homeostasis in threatening situations such as intense exercise or hemorrhage, when MAP and output are affected. In these circumstances, these pathways are successful in negating the effects of hemodynamic abnormalities and as they are part of numerous negative feedback loops, the response is eventually quelled. However, in HF, the response never turns off as these systems are constantly attempting to compensate for the heart's inability to maintain adequate output. The constantly circulating hormones exacerbate the hemodynamic problems in HF and promote further hormone release. As a result, intravascular volume and JVP will continually rise as HF progresses until a critical reduction in left ventricular ejection fraction is reached. At this point, the body will maximize its vasoconstrictive abilities to redirect blood to all vital organs. This will add to the hemodynamic burden and will incur rapid decline ending in terminal HF (Kemp & Conte, 2012).

2.3 Prognosis and Management of HF

HF is a chronic progressive condition with an unpredictable trajectory that varies widely between patients (FIGURE 1). The insults to the heart and systemic response cause a prolonged deterioration. Patients experience cycles of acute decompensation often requiring hospitalization and recovery. These cycles arise repeatedly before death which in 30% to 40% of HF patients occurs suddenly, while others occur from the progressive HF or associated comorbidities (Kannel & Belanger, 1991). HF incurs a significant overall burden on the health care system.

FIGURE 1 - HEART FAILURE TRAJECTORY



Source: Goodlin, 2009

Mortality

Despite advances in medical therapies and management, HF remains a highly lethal condition. The Framingham Heart Study followed patients between 1990 and 1999, finding that the risk of mortality significantly increased following a diagnosis of HF with 30 day, one year, and five year mortality rates being 10%, 20%-30% and 45%-65% respectively (Levy et al., 2002). The five year rate for HF is the highest adjusted mortality rate when compared to

myocardial infarction and cancers of the bowel, prostate, ovary and bladder (Stewart et al., 2001).

Hospitalization

HF is the most common cause of hospital admission for those aged sixty five and older (Defrances, Lucas, Buie & Golosinskiy, 2008). More than 33,000 Canadians (Dai et al., 2012) and 1 million Americans (Butler, Marti, Pina & DeFilippi, 2012) are hospitalized every year with a primary diagnosis of HF. These patients spend an annual average of 26.9 days in hospital (Johansen, Strauss, Arnold, Moe & Liu, 2003). Approximately 25% of patients are readmitted within 30 days (Krumholz et al., 2009; Jencks, Williams & Coleman, 2009) and 50% within one year (Johansen, Strauss, Arnold, Moe & Liu, 2003). Recurrent HF and related cardiovascular etiologies are the primary cause for half of these readmissions while the other half are due to comorbidities (Setoguchi & Stevenson, 2009).

Inconsistent findings have cited either an increase or decrease in the temporal trend of HF hospitalizations. The American National Hospital Discharge Summary found a 79% increase between 1979 and 2004 with HF as a primary diagnosis and a twofold increase when HF was listed as a discharge condition (Fang et al., 2004). Alternatively, another large scale study in the United States found a relative decline of 29.5% between 1998 and 2008 (Chen, Normand, Wang & Krumholz, 2011). Notwithstanding, adverse post discharge outcomes have remained relatively unchanged over the past two decades despite improvements in therapy (Blair et al., 2011) and policy developments in the USA to penalize 30-day HF related re-hospitalization (The Patient Protection and Affordable Care Act, 2010).

Unnecessary hospitalizations are detrimental for older adults with HF as they lead to an elevated risk of death (Solomon et al., 2008). The CHARM trials recruited 7,572 chronic HF

patients who had nonfatal hospital visits with either preserved or reduced left ventricular ejection fraction. It was found that the mortality rate increased after hospitalization even when adjusting for baseline death predictors and was highest within the first month post discharge. The length of HF hospitalization and frequency were directly related to risk (Solomon et al., 2007). Significant predictors of acute HF decompensation and high readmission rates included patients' poor compliance with therapy and diet restrictions, as well as failure to recognize early symptoms of HF deterioration (Malik et al., 2011). Following an acute episode of HF requiring hospitalization, estimated six month mortality rates range from 8% to 12% (Parikh, Felker & Metra, 2015). Hospitalization also leads to functional decline. One study found that almost one fourth of older adults with a mean age of 84 years and hospitalized for HF was discharged to LTC (Allen et al., 2011). Other estimates ranged from 13% to 18% (Jung, Yeh & Pressler, 2012).

Hospitalization and Mortality in LTC

Most LTC residents are over the age of 80 (Statistics Canada, 2007), have substantial cognitive impairment (Rovner et al., 1990) and display multifaceted behavioral issues (Zwijsen et al., 2011) causing their medical care to be complex. HF is common among LTC residents with a prevalence of 20% and is coupled with significant co-morbidities, namely dementia, diabetes mellitus and COPD (Daamen et al., 2010). LTC residents with HF incur higher annual mortality and hospitalization rates of 42% and 31% respectively, compared to 24% and 27% in the non-HF LTC population (Foebel et al., 2013). Furthermore, temporal trends show that despite a reduction in hospital length of stay and in-hospital mortality, 30 day readmission rates from LTC have increased to almost 20% between 1993 and 2006 (Bueno et al., 2010).

2.3.1 Management Challenges

Given the adverse outcomes highlighted above, timely diagnosis and appropriate management of HF have potential to optimize quality of life and reduce HF-related hospitalizations and complications. There are a number of therapies, both self-directed and pharmaceutical, which can reduce the risk of hospitalization and death. Interested readers are referred to relevant guidelines for more information (Arnold et al., 2006; Keteyian et al., 2012, Abdulla et al., 2006; McKelvie et al., 2012; Packer et al., 2001; Faris et al., 2002).

Despite the foregoing, optimal management of HF in older persons according to best practice guidelines (Hancock et. al, 2014), is impeded by a number of barriers. Notably, physicians in primary care cite a hesitancy to prescribe recommended therapies to patients who are elderly, frail and have many comorbidities and polypharmacy (Fuat et al., 2003). Additional barriers in LTC include a lack of defined inter-professional responsibilities, negative assumptions surrounding the acceptability of interventions (Close et al., 2013) as well as insufficient access to diagnostic equipment and specialists (Strachan et al., 2014). Importantly, primary care and LTC physicians often cite a lack of confidence in establishing an accurate diagnosis of the condition (Phillips, Tofler and Martin, 2014; Khunti, Hearnshaw, Baker & Grimshaw, 2002).

Low diagnostic confidence of HF among clinicians is common. A focus group study found that 95% of cardiologists, 93% of internists, 66% of general practitioners and 32% of HF nurses cited confidence in diagnosing HF-REF. For HF-PEF, confidence levels were much lower with percentages for cardiologists, internists, general practitioners and HF nurses being 58%, 43%, 7% and 6% respectively (Hancock et al., 2014).This study was conducted in the United

Kingdom where general practitioners are equivalent to Canadian family physicians who most often practice in primary care and LTC.

The Canadian Cardiovascular Society asserts that optimal management of HF is hinged upon an accurate, timely diagnosis (McKelvie et al., 2013). However, low diagnostic confidence can delay identification of the condition and thus lead to adverse outcomes.

2.4 Diagnostic Accuracy and Challenges

Accurate diagnosis by family physicians is essential as the majority of patients with HF live independently in the community and only present to the larger hospital setting when symptoms become severe (Gillespie, 2006). Low diagnostic confidence or an inaccurate diagnosis can delay the initiation of treatment and account for the poor outcomes observed in the HF population. This section seeks to quantify the impact of low diagnostic confidence on accuracy, and to present challenges in identifying HF.

2.4.1 Prevalence of Undiagnosed and Misdiagnosed HF

In primary care, HF cases often go either undetected or are misdiagnosed. A cross sectional study found that 16% of patients had previously unrecognized HF when using the European Society of Cardiology's diagnostic guidelines (van Riet et al., 2014). HF is sometimes also over-diagnosed (Sparrow, Adlam, Cowley & Hampton, 2003). A retrospective review showed that HF was unlikely in 30% of patients previously thought to have the condition. The main syndromes responsible for false positive diagnoses were obesity, unrecognized symptomatic myocardial ischemia (without HF) and pulmonary disease (Remes, Miettiene, Reunanan & Pyorala, 1991).

In LTC, diagnostic accuracy for HF is often worse. Barents et. al (2008) conducted a cross-sectional study examining the number of misdiagnosed HF cases. They showed that approximately 62.5% (15 of 24) of patients deemed to have HF were previously undetected. At the onset of the study, of 22 patients thought to have HF, 60% (13) were incorrectly diagnosed. These findings were corroborated by Bolmsjö et al. (2013) whose study explored the prevalence of HF in Swedish nursing homes with special focus on HF diagnoses. Of the 429 residents in the study, 196 had suspected HF (based upon BNP >100 ng/L) yet, only 66 had the diagnosis in their chart. The findings show that 154 of 363 residents (42%) who were deemed to not have HF had a mean BNP of 143.2 ng/L and should have undergone further examination for potential HF. As one year mortality was similar between suspected HF group and diagnosed HF, the authors surmised that this could indicate a high rate of undetected HF. The probability of appropriate pharmacotherapy increased if the correct diagnosis was in the patient record (Bolmsjö et al., 2013).

Only one study in LTC was found to clearly differentiate between HF stemming from HF-REF and HF-PEF. Hancock et. al (2012) found that half of the overall HF cases using the European Society of Cardiology guidelines was previously undiagnosed and 75% of previously diagnosed HF at the onset of the study were unconfirmed. When distinguishing between the two types, HF-PEF was previously undiagnosed in 90% of cases. Not only is HF under-diagnosed but it is often uncharacterized and medical records were found to not specify the type or severity of HF in 99% of cases (Hancock et al., 2012).

2.4.2 Diagnostic Challenges

Detection of HF early in its trajectory may be difficult as symptoms are often unreported by patients or misattributed to aging. A study conducted in LTC found that 11 of 15 de novo HF

cases were overlooked due to mild symptoms and the remaining four were missed due to multiple comorbidities leading to confusion and ascription of symptoms to non-cardiovascular causes (Barents et al., 2008). Varied symptom presentation was also noted by Hancock et. al (2012) as leg edema, dyspnea and breathlessness appeared to have little diagnostic utility in the LTC population. Furthermore, Valle et al. (2005) found that most patients were asymptomatic as only 23% cited dyspnea and/or ankle edema.

COPD presents clinically in a similar fashion to HF. If signs and symptoms are exclusively attributed to COPD, underlying HF may be undetected. A study recruited community dwelling patients who had COPD diagnosed by their general practitioner and did not have a cardiologist. The participants underwent an extensive diagnostic work-up and of the 405 patients, 83 had previously unrecognized HF (Rutten et al., 2005). In LTC, Barents et. al (2008) attributed the main reason for an incorrect diagnosis to a previous history of atrial fibrillation and COPD.

Poor clinical skill proficiency can contribute to the diagnostic difficulties involved with HF. Physicians expressed a lack of confidence in their clinical skills and inappropriately rely on echocardiography to establish a diagnosis (Heckman et al., 2014). Given the limited access to investigative tests in primary care and LTC, confidence and accuracy of diagnosing HF in part lie in improving the assessment of the JVP.

2.5 Significance of Signs and Symptoms

Clinical history and physical examination are the cornerstones of establishing a diagnosis of HF (Cubero, Rivera, Moral & Melchor, 2004), thus making the evaluation of clinical signs and symptoms crucial. This section seeks to outline the value of the signs and symptoms and how they can be used in the differential diagnostic process.

2.5.1 Medical History and Symptoms

A thorough medical history can identify the contributing factors of a suspected HF case and establish their severity. Assessments such as the Minnesota Living with Heart Failure questionnaire (APPENDIX ii) have been developed to help physicians identify disease severity or quantify changes over time. Clinical questionnaires, namely the Walma, Framingham, Boston, Goteborg, Gheorghiade, Duke and NHANES-I show good concordance and can help in attributing HF signs and symptoms to other causes as they are highly specific (range from 80% to 98%). However, their low sensitivity (35% to 65%) limit their potential in diagnosis (Fonseca et al., 2004).

The cardinal symptoms of HF are dyspnea, initially on exertion and eventually at rest, orthopnea, paroxysmal nocturnal dyspnea and peripheral edema. As previously discussed, these symptoms may be mild, and in the most subtle end of the spectrum, patients might lack symptoms altogether (Fonarow et al., 2008). Symptoms of HF are generally insensitive with varying degrees of specificity, with the exception of dyspnea. It is a commonly reported symptom among HF patients and has sensitivity, specificity and positive predictive values of 92%, 19% and 79% respectively. Patients with dyspnea at rest were 13% more likely to have HF (Ahmed, Allman, Aronow & DeLong, 2004). Although findings have been notably heterogeneous, pooled results for dyspnea cite a sensitivity of 83% and specificity of 54% (Mant et al., 2009). Orthopnea has good specificity in some instances but studies have reported varied estimates ranging from 60% to 95% while sensitivity is 44%. Similar to orthopnea, paroxysmal nocturnal dyspnea (PND) has relatively good specificity but is insensitive, though estimates are heterogeneous (Mant et al., 2009). Dyspnea on exertion, orthopnea and PND are uncommon

(Ahmed, Allman, Aronow & DeLong, 2004). Edema, classified as either a sign or symptom has a sensitivity of 53% and specificity of 73% (Mant et al., 2009).

HF patients may present with a wide assortment of other symptoms including palpitations, lightheadedness and syncope. This myriad of symptoms complicate the differential diagnostic process as they are sometimes attributed to bronchitis if in conjunction with a dry cough or asthma if wheezing is present (Mann, 2011). And, as noted previously, frail seniors with HF, such as those who reside in LTC, often present with geriatric syndromes rather than the cardinal features of HF.

2.5.2 Physical Examination

The purpose of the physical examination is to aid in identifying the presence of disease, determining the cause and severity, hemodynamic profile, response to therapy, and prognosis. The majority of HF signs have good sensitivity but poor specificity with the JVP being a notable exception. For example, tachycardia has poor sensitivity and widely varying estimates of specificity (92%, 82% and 40%) (Mant et al., 2009).

A third heart sound (S3) is audible in some patients at the apex of the heart and could be indicative of volume overload, restrictive filling, aortic and mitral regurgitation (Tribouilloy et al., 2001). It is a very specific sign at 99% but not sensitive at 24% (Shamsham & Mitchell, 2000; Mant et al., 2009). Thus, if the sign is present, it helps to rule the disease in but if absent it does not rule the disease out. In combination with jugular vein distension, a third heart sound portends an especially poor prognosis (Drazner, Rame, Stevenson & Dries, 2001) and disease progression (Drazner, Rame & Dries, 2003).

Auscultation of the pulmonary system may uncover the presence of crackles. However, in spite of pulmonary congestion, crackles may be absent because of increased lymphatic drainage

and compensatory changes in the perivascular structures that have occurred over time. In some cases, wheezing may be the only manifestation of pulmonary congestion and this leads to asthma or COPD being frequently and erroneously diagnosed in patients who actually have HF (Shamsham & Mitchell, 2000). Lung crackles are associated with 51% sensitivity and 81% specificity (Mant et al., 2009).

2.6 Importance of JVP

The majority of studies investigating JVP have reported heterogeneous results or inadequate descriptions of how the measure was obtained to allow for comparisons. Systematic reviews cite poor sensitivity and moderate specificity of JVP with values of 52% and 70% respectively. However, only one study (of seven) reported how the JVP was quantified and reported a specificity of 99% and sensitivity of 24% (Fonseca et al., 2004). Furthermore, 3 items from history (age, coronary artery disease, and loop diuretic use) in addition to 6 from physical examination (pulse rate and regularity, displaced apex beat, crackles, heart murmur, and increased JVP) showed high independent diagnostic value for HF (Kelder et al., 2011). The signs that best predicted the diagnosis of HF were JVP greater than 6 cm with hepatic enlargement and edema, S3 gallop, a heart rate greater than 110 bpm and crackles. Finally, the JVP has prognostic utility with elevated levels being associated with HF related hospitalizations and increased probability of death (Drazner, Rame, Stevenson & Dries, 2001). Accordingly, assessment of the JVP figures prominently in numerous guidelines and diagnostic criteria for HF.

European Society of Cardiology

The guidelines acknowledge that the diagnosis of HF especially in the early stages may be difficult, due to signs resulting from sodium and water retention, obesity, advanced age, and even chronic lung disease. To establish “suspected HF”, relevant symptoms and signs, one of

which being elevated JVP, need to be present. The guidelines do not indicate a specific cutoff to quantify "elevated JVP".

American College of Cardiology

The 2013 American College of Cardiology/American Heart Association Recommendations state that an elevated jugular venous pressure is the most useful sign of congestion (Yancy et al., 2013).

Canadian Cardiovascular Society

For acute HF, the 2012 CCS guidelines prefer the PRIDE scoring system (APPENDIX iii) or Boston criteria to establish the likelihood of HF. The PRIDE score does not utilize JVP, which figures prominently in the Boston criteria. It is important to note that the guidelines emphasize basic evaluations that are widely available and place less value on advanced tests which should be reserved for selected, medically complex patients. Although not explicitly mentioned, the CCS criteria categorized the assessment of JVP under the volume status component of physical examination found in APPENDIX iv.

Framingham criteria

The Framingham criteria (TABLE 1) require a minimum of two major or one major and two minor criteria be present concurrently. The Framingham criteria treat an elevated CVP defined as greater than 16 centimeters of water or neck vein distention as major criteria (Maestre et al., 2009).

TABLE 1 – FRAMINGHAM DIAGNOSTIC CRITERIA FOR HEART FAILURE

Major Criteria	Minor Criteria
Paroxysmal nocturnal dyspnea or orthopnea	Bilateral ankle edema
Neck-vein distention	Nocturnal Cough
Rales	Dyspnea on ordinary exertion
Cardiomegaly	Hepatomegaly
Acute pulmonary edema	Pleural Effusion

S3 gallop	Vital capacity decreased one third from maximum
Increased central venous pressure (> 16 cm H_2O)	Tachycardia (heart rate >120/min)
Circulation time (> 25 seconds)	
Hepatojugular reflux	
Weight loss (> 4.5 kg in 5 days in response to treatment)	

Source: (Maestre et al., 2009)

Boston

The Boston criteria (TABLE 2) utilize a scoring scheme whereby elements of the clinical history, physical examination and chest radiograph are scored and then classified under the categories of "Definite HF" for total scores including and between 8 and 12 points, "Possible HF" if between 5 and 7 points and "unlikely HF" if ≤ 4 points. A JVP of greater than 6 centimeters of water in isolation is associated with two points, and three points in the presence of edema or hepatomegaly. Considering that the range of possible HF is from 5 to 7 and definite HF from 8 to 12, an elevated JVP is one of the most influential signs from the physical examination contributing to the HF diagnosis (Marantz et al., 1988).

TABLE 2 – BOSTON CRITERIA

Category	Criteria		Score
Clinical History	Dyspnea	At rest	4
		On level ground	2
		While climbing	1
	Orthopnea		4
	Paroxysmal nocturnal dyspnea		3
Physical Examination	Heart rate	91-110 beats/min	1
		110 beats/min	2
	Jugular Venous Pressure (> 6 cm H_2O)	Alone	2
		Hepatomegaly or edema	3
	Rales/Crackles	Basilar Crackles	1
		More than Basilar Crackles	2
	Wheezing		3

	S3 Gallop	3
Chest Radiograph	Alveolar pulmonary edema	4
	Interstitial pulmonary edema	3
	Bilateral pleural effusion	3
	Cardiothoracic ratio > 0.5 (posteroanterior projection)	3
	Upper flow Distribution	2

Source: (Mann, 2011)

2.7 Clinical Assessment of JVP

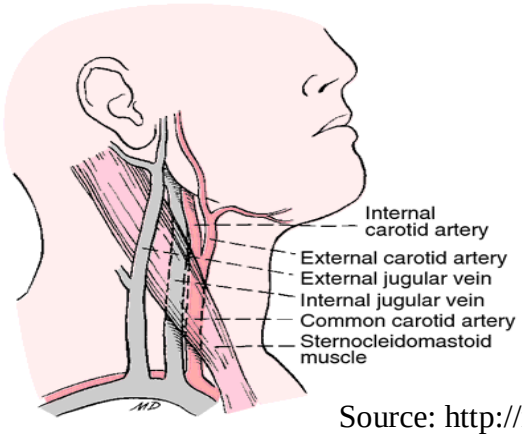
CVP can be measured invasively at the junction of the superior vena cava and right atrium by insertion of a catheter. Alternatively, it can be measured non-invasively by approximating the height of the JVP above the chosen landmark (Izakovic, 2011). It should be noted that there is considerable variability in clinical recommendations of the technique, cut off values, and classification used to assess JVP.

2.7.1 Anatomical Considerations

Internal versus External Veins

There is a difference in opinion among medical educators and clinicians whether the internal or external jugular vein is best suited for observation of JVP. Both have specific strengths and weaknesses and there appears to be little consensus as to which supersedes the other in terms of importance. Some clinical researchers have exclusive preferences while others agree that using either vein is sufficient. The position of the two veins can be visualized in FIGURE 2 below.

FIGURE 2 - INTERNAL AND EXTERNAL JUGULAR VEINS



Source: http://medical-dictionary.thefreedictionary.com

The above figure shows that the internal jugular vein (IJV) runs more medially than the external jugular vein (EJV). It travels down the inside of the neck and outside the internal and common carotid arteries, uniting with the subclavian vein to form the brachiocephalic vein. Traditionally, the internal vein is most often recommended in medical textbooks and literature as it forms a direct conduit with the superior vena cava and contrary to the EJV, does not undergo two right angle turns (Constant, 2000). It is believed that this allows for a more accurate estimation of JVP. However, as the IJV is located deep beneath the sternocleidomastoid muscle, it is often difficult to see and differentiate from the carotid artery (Vinayak et al.,2006).

Alternatively, the EJV is lateral to the IJV and superior to the sternocleidomastoid muscle, traveling to the base of the neck where it joins the subclavian before emptying into the superior vena cava. Proponents of the IJV state that the EJV is similarly just as difficult to visualize and unhelpful in detailed examinations (Constant, 2000; Ahmed, Jones and Hays, 2008). In other cases, the external jugular vein has been noted as being significantly more easily observed than its internal counterpart and can differentiate between low and high levels of CVP (Vinayak et al., 2006).

Braunwald's eighth edition of cardiovascular medicine contends that the IJV is preferred as the EJV contains valves and is not directly in line with the superior vena cava and right atrium (Libby, Bonow, Mann & Zipes, 2008). However, the IJV also has competent valves which may in fact, obscure accurate estimations of the JVP by preventing reflux of venous blood from the right atrium (Silva, Deen, Fernando & Sheriffdeen, 2002). There is considerable anatomical variability and the physiologic impact of these variables remain unconfirmed (Valecchi et al., 2010)

An overview article pertinent to the JVP in acutely ill patients found a high level of agreement between physical examination of JVP and catheterization regardless of whether the internal or external vein was observed (Garg & Garg, 2000).

Right versus Left Sided Veins

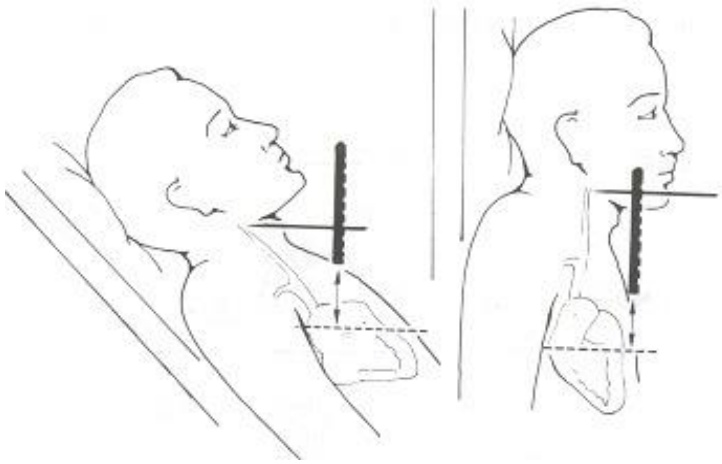
Another anatomical consideration relates to whether the jugular vein on the left or right side of the neck provides the best option for observation. During periods of modest inspiration, the descending diaphragm and aorta relieve the partial compression of the left brachiocephalic vein making the pressure within the two internal jugular veins equal. However, partial compression of the left brachiocephalic vein by the aorta may occur, particularly in older patients, impairing transmission of the accurate right atrial pressure to the left brachiocephalic vein. This is the most common cause of unequal pressures. As the right brachiocephalic vein and IJV are in a direct line with the superior vena cava, it is believed that there is better transmission of right atrial pressure. Therefore, examination of the right jugular venous pulse is preferred for assessing the hemodynamic changes in the right side of the heart (Post, 2015).

2.7.2 Lewis Method

The Lewis method is used to non-invasively measure JVP at the bedside. The first step requires identification of the jugular vein with the patient at a 45^0 upward tilt. The jugular pulse should be located by observation. Sometimes, extension of the patient's chin might be needed to enhance the observation but care is necessary not to tense the sternocleidomastoid muscle excessively as this will compress the external and internal jugular veins, concealing their pulsations (Mann, 2011).

Following identification of the jugular vein, the height of the mean JVP is measured in cm of water above the midpoint of the right atrium, the standard reference point for hemodynamic measurements in the catheterization laboratory. To determine the mean JVP, the height of the venous column on inspiration and the crest of the column on expiration should be noted. The patient should be encouraged to avoid exaggerated breathing or holding their breath as this may exacerbate the pulse. A horizontal line should be drawn from the estimated height of the pulse to intersect a vertical line which is estimated to protrude from the sternal angle. The distance should be measured and when the obligatory 5 cm is added, this value represents the mean JVP (Mann, 2011). The addition of 5 cm represents a simple estimation often used to represent the distance between the sternal angle and the right atrium. The process can be accomplished with the use of two rulers as in depicted in FIGURE 3.

FIGURE 3 - MEASUREMENT OF THE JVP USING THE STERNAL ANGLE



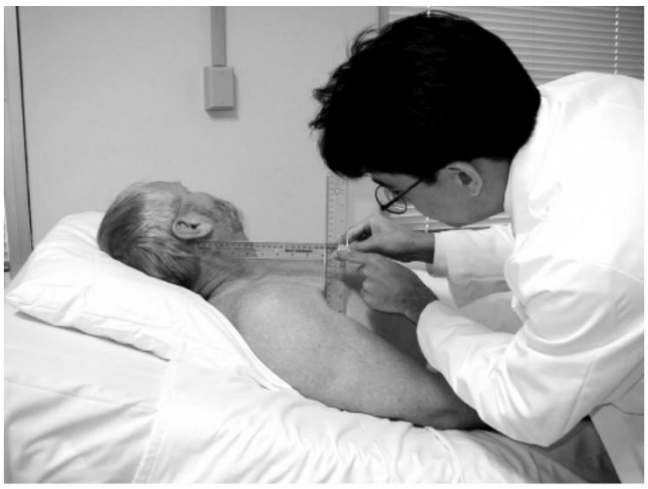
Source: (Walker, Hall & Hurst, 1980)

The clinician should observe the rise and fall of the venous pressure during normal inspiration and expiration. To confirm the measurement or if the jugular veins cannot be identified, the clinician should apply firm but persistent pressure over the liver for 10 seconds while observing the mean JVP, a maneuver known as the hepatojugular reflux (Mann,2011). In healthy individuals, this will incur a modest or no rise in mean JVP but, a positive reflux involves an increase in JVP of more than 3 cm H_2O that are sustained for longer than 15 seconds. Although termed the hepatojugular reflux, pressure is not necessary directly upon the liver and thus is also referred to as the abdominojugular reflux (Karnath, Thornton & Beach, 2002). After determining the mean JVP, the clinician should attempt to determine the venous pulse contour by observing the venous pulse in right side of the neck (Mann, 2011). The hepatojugular reflux significantly increases the specificity of JVP (Libby, Bonow, Mann & Zipes, 2008).

A variation of the Lewis method involves having the patient in a supine position on a bed elevated such that the peak of the right jugular pulsation can be observed. The angle of inclination is usually between 30^0 and 45^0. The physician should begin by placing the zero mark of the centimeter ruler at the midaxillary line and fourth intercostal space, a landmark known as

the phlebostatic axis which acts as an alternate reference point to the sternal angle. This axis is considered a true external reference point for the right atrium (Potger & Elliott, 1994). Using this landmark as the reference point places the zero mark at the level of right atrium, and the height of the jugular venous pulse should be measured vertically from this point. The ruler should be held perpendicularly to the floor. The JVP is the measured distance between the zero mark of the ruler and an imaginary line running parallel to the floor and extending from the highest point of pulsation of the right jugular vein as shown in FIGURE 4.

FIGURE 4 - MEASUREMENT OF THE JVP USING THE PHLEBOSTSTIC AXIS



Source: (Karnath, Thornton & Beach, 2002)

As some patients with elevated CVP need to be raised more than 45^0 for the pressure to be estimated, clinicians frequently underestimate the value and it has been recommended that they simply determine whether the CVP is elevated or not, without attempting to make a specific measurement (Karnath, Thornton & Beach, 2002).

2.7.3 Reliability

JVP measures can be inaccurate leading to poor reliability (Stevenson & Perloff, 1989). This is because many practitioners of varying levels of seniority and experience do not measure it correctly, leading to a cycle of unreliable information, lack of confidence, and underuse. To this end, astute technique and a keen eye have been noted as vital to produce a reliable measure of the JVP (Chiaco, Parikh and Fergusson, 2013). When correlated to direct measurement, the bedside clinical estimation of CVP has been merely fair (McGee, 1998). Differing standards of reference, clinicians, numeric or categorical classification, and variable definitions of the normal range have limited comparison between previous studies (Libby, Bonow, Mann & Zipes, 2008).

Variability in measure has been a long standing concern in the bedside estimate of CVP. Agreement has been found to be greatest in the medical student to resident ratio ($\kappa = 0.65$) than student to attending physician ($\kappa = 0.56$) and resident to attending physician ($\kappa = 0.30$) (Cook, 1990). Inter-observer variation and even intra-observer variation is substantial with discrepancies as large as 7 cm of H_2O (Cook, 1990). A recent review study comparing physical examination to catheterization in acutely ill hospitalized patients found that clinicians were accurate in 50% of cases when classifying CVP as low, normal or high based on their JVP measure. Importantly however, accuracy was much better if the venous pressure was predicted to be high (77- 80% accuracy) as opposed to low (3- 38% accuracy) (Garg & Garg, 2000).

Assessing the JVP using the phlebostatic axis is thought to confer greater reliability owing to smaller degrees of variation in measurements caused by the patient's posture. On comparing measurements performed in the emergency room to those in hospital, disparities were as great as 11.8 cm H_2O when the sternal angle was used, compared to 9.1 cm H_2O with the phlebostatic axis (Haywood, Joy & Camm, 1991).

In establishing the clinical criteria for the Framingham recommendations to establish a diagnosis of HF, inter-rater reliability between clinicians was assessed. The inter-rater reliability of neck vein distension classified dichotomously as high or low conferred fair to good reliability at 0.71 (Maestre et al., 2009).

The literature on the reliability of JVP measures is limited. The need for more rigorous investigations with clear descriptions of how the variable was measured with standard cutoffs (if categorically classified) has been acknowledged (Sankoff & Zidulka, 2008).

2.7.4 Assessment Challenges

The poor reliability of JVP measurements may persist because of multiple misconceptions among physicians and clinicians as outlined by Ahmed, Jones & Hays (2008). The first is the belief that only the internal jugular veins are useful in the estimation of JVP. As previously outlined, the internal jugular veins are difficult to observe as they lie behind the largest group of muscles in the neck, the sternocleidomastoids. These muscles can obscure an accurate observation of the vein leading to an underestimate or inability to obtain a measure altogether (Curtis et al., 2005). Research findings have shown that the EJV is indeed easier to visualize than the IJV and depicts strong agreement with low and high CVP (Vinayak et al., 2006).

Secondly, there is a mistaken belief that patients must be positioned at a 45^0 incline and that the distance between the right atrium and sternal angle should always be 5 centimeters regardless of body position. A visible jugular pulsation in the neck at 45^0could be misleading as it is rendered useless when the pressure is too high (top of the jugular pulsation behind the angle of jaw) or too low (top of the jugular pulsation behind the clavicle). Thus, it is recommended that patients be either in a supine position, sitting position or any other position in between that

allows for the observation of the height of the pulse. Ideally, if the top of the jugular pulsation is above the level of the sternal angle, that distance should be added to the estimated distance between the sternal angle and right atrium. On the other hand, if the top of the jugular pulsation is below the level of the sternal angle, this distance should be subtracted from the estimated distance between the sternal angle and right atrium (Ahmed, Jones and Hays, 2008).

The addition of 5 centimeters to the raw measure has been questioned. The sternal angle or notch is an anatomical landmark and depending on the position of the patient, can be a variable number of centimeters above the approximate location of the right atrium. At the recommended 45^0 upward tilt from the horizontal, the distance in vertical height can range from 5 to 10 centimeters. If the patient is tilted progressively upward towards 90^O, the distance can be as great as 12 centimeters. A recent study using computed tomography (CT) scan measurements in 160 patients to determine the distance between the sternal angle and the level of the right atrium, found the median value for the vertical distance was 5.4 cm in the supine position. However, when the CT images of the torso were rotated to 30^0, 45^0 and 60^0, the median vertical distances were 8, 9.7, and 9.8 cm, respectively (Seth, Magner, Matzinger & Walraven, 2002). Patients have been known to display wide variations in height at respective degrees with a range of 5 to 13 cm at 30º for example. It has been recommended that 10 cm should be added if the torso is elevated greater than 45^0 (Devine, Sullenberger, Bellin & Atwood, 2007). These differences highlight the exactness required to reproduce precise measures.

Other notable factors contributing to the poor reliability of the measure include variations in the positioning of patients, poor ambient lighting, difficulty in differentiating carotid from venous pulse, biologic variation in CVP with projects of respiration and the effects of vasoconstrictive medication and diuretics (Cook, 1990). Although the Lewis method suggests

that the measure be quantified numerically, studies have posited that normal JVP levels can be defined when the blood column is not visible. However, this classification is imprecise and slight elevations of JVP would be inaccurately labeled as "normal". It has been postulated that this categorization could account for apparent low sensitivity of elevated JVP for diagnosing HF (Laar, 2003).

Despite the possibility of using JVP measures to diagnose HF as evidenced above, the assessment of JVP has been devalued by the European and Dutch societies of cardiology mainly because the method is difficult, requiring substantial training and experience (Laar, 2003). This suggests that relying solely on improving clinical skills may be impractical in busy primary care and LTC settings. The following section reviews the use of POC devices to assess the JVP in primary care and LTC.

2.8 POC Devices and the Mespere Venous 1000 CVP System

2.8.1 POC Devices

POC testing is defined as medical testing at or near the site of patient care. These tests can vary from simple medical blood tests to urine test strips, ECGs, O_2 saturation, heart rate measurement and imaging such as with a portable ultrasound device (Kost, 1995). Family physicians in the UK, USA, Netherlands, Belgium and Australia have endorsed the use of POC devices to aid diagnosis, although the focus was mainly on acute conditions (Howick et al., 2014).

POC testing offers many benefits and reduces the turnaround time from testing to results, allowing for more effective patient triage and improved care. Some POC tests have been shown to simplify test procedures, reduce the chance of operator error, and utilize a blood sample that does not require pretreatment (Chan et al., 2013). Already deemed equivalent to traditional

laboratory tests in diagnosing type 2 diabetes (Lovrenčić et al., 2013), POC tests provide the potential of rapid diagnosis, risk stratification and management of patients presenting with symptoms consistent with HF (Christenson, Collinson, deFilippi and Christenson, 2014).

Mini-echocardiograms, smaller in size than traditional devices and used at the bedside, have been identified as a comparable measure to the clinical assessment of JVP. Although it requires less instruction, use of the device necessitates clinician interpretation as well as evaluation and assessment of its use (Rizkallah et al., 2014). Furthermore, a study comparing two different techniques for measuring JVP byway of ultrasonography performed at the bedside found a high degree of inter-rater reliability in emergency room patients (Socransky et al., 2009).

To date, no other POC device or technique has been used to measure the JVP. Despite the fact that the Mespere Venous 1000 CVP System was approved by Health Canada and the Food and Drug Agency for commercial use, its role in primary care and LTC remains unexplored.

2.8.2 Mespere Venous 1000 CVP System

The Mespere Venous 1000 CVP System outputs a JVP measure and plethysmographic waveform in real time. It utilizes near-infrared spectroscopic light through an adhesive patch which is placed on the external jugular vein. As shown in FIGURE 5, a reference patch is placed at the phlebostatic axis.

FIGURE 5 - PATCH PLACEMENT FOR THE MESPERE VENOUS 1000 CVP SYSTEM

Source: (Mespere LifeSciences Inc., 2013)

The system also consists of the handheld component, docking stand and cable. The handheld is compact and has a battery which provides eight hours of continuous use. The docking stand serves as a charging and calibration station. The handheld is depicted in FIGURE 6.

FIGURE 6 - HANDHELD COMPONENT FOR THE MESPERE VENOUS 1000 CVP SYSTEM

Source: (Mespere LifeSciences Inc., 2013)

The device allows for output in either centimeters of water or millimeters of mercury. To measure JVP, the patch has to be placed on the external jugular at the height of the pulse. To facilitate for this, once the patches are placed on the patient, the device will prompt the clinician to either incline or recline the patient. If on a mechanical bed, this can be done automatically. In other instances, positioning the patient may need to be manually performed. A comprehensive step by step device protocol can be found in APPENDIX v.

Previous studies have shown a strong correlation between JVP measured by the device and right heart catheterization (Correlation $r = 0.89$, $p<0.001$; Accuracy 2.17 mmHg). The study recruited HF or pulmonary hypertension patients at a tertiary medical centre receiving catheterization as part of their usual care (Hoyt & Koelling, 2013). Another study found that the Mespere device detected greater variation in right atrial pressures in comparison to 2D

transthoracic echocardiography in a hospital based population (Levitt, Evangelista & Chow, 2014).

The prognoses of HF patients can be significantly improved if a diagnosis is timely and accurate. However, significant barriers inherent to HF, the older adult population, and primary care clinicians exacerbate the diagnostic accuracy of the condition. One of the most specific signs, an elevated JVP is underutilized or often incorrectly measured. Interventions to improve clinical skills among primary care and LTC physicians, particularly with respect to the JVP, are certainly a consideration but may be impractical in such busy settings. The Mespere Venous 1000 CVP System is a non-invasive, POC device which measures JVP. It is important to establish the acceptability and feasibility of using the device in primary care and LTC.

CHAPTER 3

METHODOLOGY

Accurate and timely diagnosis of HF is essential for its effective management. An elevated JVP is one of the most useful signs for diagnosing and managing HF, but is underused or used inaccurately in primary care and LTC settings. The Mespere Venous1000 CVP System has the potential to improve that assessment of HF in these settings.

3.1 Research Questions

This investigation followed an exploratory design. The aim of the study was to assess the acceptability and feasibility of using the Mespere Venous 1000 CVP System to measure JVP for diagnosing and managing HF in primary care and LTC. Specific questions included:

1. What is the perceived understanding of the JVP among primary care and LTC clinicians?
2. How do clinicians in primary care and LTC perceive the acceptance of the Mespere CVP 1000 System to measure JVP?
3. How do clinicians in primary care and LTC perceive the ease of use of the Mespere CVP 1000 System to measure JVP?
4. What do clinicians in primary care and LTC perceive as barriers to the implementation and use of the Mespere Venous 1000 CVP System?

Based on emerging findings during the assessment of the acceptability and feasibility of using the Mespere Venus CVP 1000 System in LTC during the first project (Project i) of the investigation, the following two questions were added in a second project (Project ii):

5. What is the inter-rater reliability of the Mespere Venous CVP 1000 System when used by LTC nurses?
6. What is the inter-rater reliability of the Lewis method to measure JVP when applied by physicians in LTC?

3.2 Project i Design

This project employed an exploratory, descriptive design. The concepts of acceptability, ease of use and perceived barriers stem from the Technology Acceptance Model (TAM). This model suggests that when users are presented with a new technology, a number of factors influence their decision about how and when they will use it, perceived usefulness and perceived ease of use. Perceived usefulness is defined as the degree to which a person believes that the use of a system will improve performance while perceived ease of use refers to the degree to which a person believes that the use of a system will be effortless (Hauser & Shugan, 1980). The overarching goal of TAM is to predict acceptability. The model postulates that the use of a device is determined by the behavioral intention, but on the other hand, that the behavioral intention is determined by the person's attitude towards the use of the system and also by his perception of its utility (Davis, 1986).

Acceptability and perceived barriers are not distinct and acceptability may to a significant degree be influenced by the number and magnitude of perceived barriers. Acceptability is defined as the general view or attitude towards treatment operationalized in terms of judgment (Lebow, 1987). Participants' perceptions of the device could have derived from many factors

including but not limited to: personal values and beliefs, professional orientation, role, theoretical knowledge, practical training acquired through formal and continuing education, experience, availability and use of best practice guidelines (Sidani & Braden, 2011). Assessing acceptability was crucial as participants who perceived the device as acceptable would develop enthusiasm for it, offer it to peers, utilize it on patients assigned to their care, encourage and support its use and deliver it with fidelity. These are positive outcomes that would ensure that the device will be used effectively if implemented (Sidani & Braden, 2011). Alternatively, if clinicians perceived the device as less acceptable, they might not adopt it even if it were proven to be effective (Severy, Tolley, Woodsong & Guest, 2005). Acceptability is distinct from but precedes concepts of satisfaction and continued use. In lieu of these factors, the aim of an acceptability analysis in the context of this study was to focus on how the targeted audience, nurses and physicians in primary care and LTC would react to the prospect of integrating the device into their care setting (Sidani & Braden, 2011). This conceptualization allowed acceptability to be assessed at the time of potential implementation design and decision making, prior to actual device implementation. Acceptability is also distinct but related to concepts of appropriateness and usefulness. Participants may accept the device due to perceived intended purposes of use.

Perceived ease of use is defined as the degree to which a person believes that using a particular system would be free from effort and is a component of a usability analysis (Sidani & Braden, 2011). Its acknowledgement is a key component in human factor engineering science and research suggests that new technologies should be easy to use for end users. It has been observed that technology usability and ease of use are recognized as necessary components to

ensure that new technologies are used effectively; as evidenced by the number of recent publications on the topic in the healthcare literature (Karsh, 2004).

The consultative deductive approach was considered appropriate to achieve the objectives of this project as it allowed for input of key stakeholders (LTC and primary care nurses and physicians) to be obtained in regards to the appropriateness, relevance and usefulness of newly developed interventions or in this case, a novel device. The methodologies put forth by Sidani & Braden (2011) recommended group or individual interviews involving an interactive discussion. The following steps provided the basis upon which the training module and focus groups were structured:

1) Review the clinical problem requiring intervention;
2) Provide an overview of the selected intervention including its components, mode of delivery and dose;
3) Describe in detail, potential aspects of the intervention, setting and timing of delivery;
4) Ask interviewees to comment on the relevance of the device to their practice;
5) Request interviewees to appraise the overall device for appropriateness and usefulness in addressing the preset problem and its suitability to the target population; and
6) Ask interviewees to suggest ways of modifying the intervention and/or additional content, activities or techniques to enhance comprehensiveness and acceptability of the intervention.

Some components outlined in the above steps were not relevant to the device. For example, instead of the interviewer describing the mode of delivery, setting and timing of the intervention, those views were elicited from the participants in order to elicit previously

unconsidered implementation ideas. The impact of adopting the device into routine practice can be tested in a future efficacy and effectiveness intervention, for which the acceptability study would serve as a foundational layer.

The study was submitted to and received ethics clearance from a Research Ethics Board of the University of Waterloo.

3.2.1 Recruitment and Setting

For the primary care nurses and physicians, the selected setting was the New Vision Family Health Team as it allowed for optimal convenience. The researcher coordinated the study with one lead physician and one NP. Those individuals disseminated information letters, consent forms as well as logistic information such as focus group location and times to their fellow staff members. Primary care nurses and physicians were recruited from this facility.

The recruitment of LTC physicians commenced with the researcher emailing executive directors in the local region with information letters, consent forms and a detailed explanation of the study. It was requested that they disseminate details of the study to their staff physicians. Interest on the part of executive directors was minimal. Even when disseminated, few physicians expressed a desire to participate. Due to the size and structure of LTC in the Kitchener-Waterloo region, most homes staffed two to three physicians. This made a single site focus group impractical as even with maximum participation, there would still be fewer participants than was recommended. To recruit from multiple sites would require the alignment of a number of logistic variables, namely convenience of scheduling and location. Therefore, instead of one focus group, the research student individually interviewed four LTC physicians who had voluntarily responded to a time, and location that were at their convenience.

The recruitment of the LTC nurse participants commenced with the research student contacting the executive directors of LTC homes in the Kitchener-Waterloo area. The selection of the setting was based upon the interest expressed by the administration of the home and ease of facilitation. Parkwood Mennonite home was the selected location and nurses were recruited in a convenient manner.

The researcher coordinated the scheduling of focus groups with the facility directors and administrative staff to ensure that logistics such as location and time were at the convenience of the nurses. This was done in an effort to minimize barriers to participation. Recruitment and consent letters were sent to the nurses by the executive director of the home, inviting them to participate in the study two weeks prior to the scheduled data collection date. Recruitment and consent letters can be found in APPENDIX vi. In an effort to respect privacy and confidentiality, only the executive director was contacted for recruitment purposes. No communication was made with the nurses prior to the focus group. The research student followed up with the director to ensure that the materials had been disseminated and provided answers to any questions which had arisen. This helped to reduce the risk of a low participation rate.

3.2.2 Data Collection Procedures

The primary collection method employed for this component of the study was focus groups. Focus group design and format were adopted from the recommendations put forth by Krueger and Casey (2000). The authors defined a focus group as "a carefully planned series of discussions designed to obtain perceptions on a defined area of interest in a permissive, nonthreatening environment" (Krueger & Casey, 2000, page 5). Focus groups offer many advantages and are well suited to encourage participation from those who are reluctant to share information in one on one interview settings. This technique allowed the researcher to observe

interpersonal communication and to highlight cultural values and norms within the group (Kitzinger, 1995). Focus groups were chosen to address the first four research objectives. Verbal, qualitative dialogue allowed for the participants to offer their perceptions and insight addressing ease of use and barriers to implementation. Using focus groups to explore perceived acceptability a priori to device implementation is supported by Sidani & Braden (2011).

Focus groups consisted of homogenous participants of characteristics relevant to the context of the study. A double-layer design was used. The first included two different personnel groupings: nurses and physicians. The second strata related to clinical setting: primary care and LTC. Focus group segregation was key to allow for the assessment of views towards other professional groups in that setting and professional scope of care. Krueger and Casey (2000) recommended that three to four focus groups should be conducted with each homogenous group until data saturation is reached. Data saturation is defined as the point at which additional data collection reveals no novel themes or patterns. However, due to limited resources and time constraints, one focus group per homogenized group was conducted. As the objectives and results of the focus group present minimal risk or harm to individual participants or care facilities, it was deemed adequate to have fewer than recommended focus groups (Krueger & Casey, 2000). Given these provisos, it was safe to conclude that data saturation was reached when no new idea or suggestion was posed by the second group (physicians or nurses) in the same care setting and relevant to the same concept. If different themes continually emerged, additional focus groups and data collection would have been required. It was found, however, that this was not the case and four focus groups were sufficient for data saturation.

A sample size of six to eight individuals per focus group was considered appropriate by similar studies and literature assessing staff perceptions (Kitzinger, 1995). This number of

participants allowed for ample opportunity to share experiences and opinions, while at the same time being large enough to allow for a diverse range of perspectives (Krueger & Casey, 2000).

The focus group questions were developed iteratively having consulted medical and qualitative research experts in the field. Additionally, questions development was based on principles found in Creswell's Qualitative Inquiry and Research Design (2007) and similar qualitative studies in the field found through PubMed (Ayala & Elder, 2011). An outline of the focus group questions can be found in APPENDIX vii.

In the context of this study, acceptability was guided by the participants' views on how the device addressed any difficulty in measuring JVP to diagnose and manage HF. In order to elicit these views, a thorough understanding of the device attributes was needed. Participants required knowledge of the nature of the device components, method of use, benefits or effectiveness in addressing the present problem and risks involved (Sidani & Braden, 2011). For this reason, a training module detailing the device protocol was delivered to each focus group and individual interview. The module was designed by the research student and manufacturers of the device, Mespere Life Sciences Inc. The module lasted approximately 30 minutes. It included a PowerPoint presentation which provided a step-by-step guide on how to operate the device, a definition of JVP, the Lewis method and how elevated levels can indicate HF among other conditions. The presentation was accompanied by a demonstration of how to use the device to measure JVP. The training module and demonstration were performed by the researcher. The aim of the module was to provide an overview of the device and brief introduction to the measure. Following this, the participants had an opportunity to practice using the device either on themselves or other focus group members who volunteered. An experimentation period was essential to allow for the observation of participants' behavior while using the device and to

allow for informed opinions on device usability. This period lasted approximately thirty minutes. Immediately after completion, the focus group began with an outline of the study objectives, focus group length, recording, transcription, and confidentiality (Creswell, 2007). The total average time for the training module, experimentation period, and focus group was two hours. At the end of the focus group, participants were provided a feedback letter found in APPENDIX viii.

The one-on-one interviews followed a similar protocol. The LTC physicians had an opportunity to practice using the device on a volunteer or the research student.

Collected data were in the form of observational field notes taken by a research assistant as well as transcribed focus group dialogues. The combination of observational notes and transcripts allowed for data source triangulation and increased validity. During the focus group and experimentation period, a research assistant observed nonverbal communication and took field notes while the facilitator guided the participants through the questions (Creswell, 2007).

3.2.3 Method of Data Analysis

Qualitative data obtained through the focus groups and individual interviews were converted to transcripts by the research student. Analyses of the transcripts and field notes were conducted using recommended procedures (Rabiee, 2004; Creswell, 2007) and began with the printing and thorough review of data sources. Concepts were identified using emergent and directed coding (Guest, MacQueen & Namey, 2012). Coded data were organized according to major categories and subcategories reflecting more specific perceptions. Categories of codes were color coordinated to group similar concepts and to organize the data, creating themes (Rabiee, 2004). Transcripts were analyzed with a particular focus on clusters of information relating to: i) perceived understanding of the JVP; and ii) ease of use, acceptability and perceived

barriers of the POC device. Throughout the qualitative data analysis, consideration was given to: words and their meaning, the context of comments made, frequency of comments, intensity of remarks, word use, and body language (Krueger, 1994). The transcripts were twice reviewed to ensure emergent codes were substantiated. If found to be unsupported, codes were disregarded. Each transcript was coded and analyzed before the next focus group was conducted. This allowed the research student and facilitator to develop emergent prompts and points of emphasis during subsequent focus groups.

To increase inter-coder consistency, a few initial transcripts were coded and discussed by the research student and assistant. The research student then proceeded to code the remaining transcripts. All codes and themes were reviewed and confirmed by a second coder. The researcher discussed any discrepancies and collaboratively agreed upon the final codes, categories, and identified themes for each group (Saldaña, 2013). The intent of the second coder was to reduce bias through subjectivity of the researcher's interpretation.

3.3 Project ii – Reliability Study

Project ii was conducted in order to determine the reliability of the device and to compare it to the reliability of measurements obtained by LTC physicians using the Lewis Method, thus addressing research questions 5 and 6.

3.3.1 Measurement of Reliability

The significance of a measured variable is largely dependent on the extent to which clinicians and researchers can rely on the indicator being meaningful (validity) and accurate (reliability) of the physiologic or behavioural attribute. Reliability is the extent to which a measurement is error free and validity is the degree to which the measure quantifies or describes what it intends to measure.

Reliability estimates stem from the variability or differences among measured quantities within a sample. Total variability is a composite of between subject variability and measurement error. These components can be estimated and a measure is thus considered reliable if a greater proportion of the total observed variability is represented by subject variability,

$$\text{Reliability} = \frac{\text{Subject Variability}}{\text{Subject Variability} + \text{Measurement Error}}$$

Measurement errors are subdivided into systematic or random error. Systematic errors can be corrected for with the addition or subtraction of a constant value (Portney & Watkins, 2009). Random error however, can vary greatly in unpredictable ways as it stems from a multitude of sources including fatigue, inattention, mechanical inaccuracy or simple mistakes in administration (Portney & Watkins, 2009). Statistically, variability is quantified by variance, making the formal definition of reliability,

$$\text{Reliability} = \frac{\sigma_S^2}{\sigma_S^2 + \sigma_E^2}$$

where, the subscript ***S*** and ***E*** denote subject and error respectively. As the denominator is always larger than the numerator, reliability is expressed as a coefficient ranging from 0 to 1 where 1 represents minimal error and a perfectly reliable test.

Although it is recommended that establishing both intra-rater and inter-rater reliability be a minimum to establish a good test (Portney & Watkins, 2009), this may not be required. If inter-rater reliability contains all sources of error contributing to intra-rater reliability in addition to any differences that may arise between observers, then a demonstration of high inter-rater reliability would be sufficient to satisfy both concepts. However, if proven to be low, it is unclear whether this arises from differences between or within observers (or both), necessitating an

intra-rater analysis (Streiner & Norman, 2008). For this reason, among others, an inter-rater analysis was chosen to be the focus of this project as it may prevent the need for a separate intra-rater investigation.

There are multiple correlation coefficients to indicate reliability but the Intraclass Correlation Coefficient (ICC) and Cohen's weighted kappa were utilized in this study as they best addressed the research objectives. The ICC was utilized as its calculation is based upon estimates obtained through an analysis of variance, reflecting both the degree of correspondence and agreement among raters. Numerous additional benefits of using the ICC include the ability to assess reliability among two or more ratings, flexibility as it does not require the same number of raters per subject and, although ideal for use with interval data, can be applied to ordinal. The ICC also supports the generalizability model proposed by Cronbach as an excellent approximation of reliability (Portney & Watkins, 2009). The generalizability theory states that variance in observed scores results as a myriad of factors including raters, subjects, testing conditions, administration of the test under specific conditions among others. These factors all impact variance and can be distinguished from random error, whereas classic reliability is undifferentiated and incorporates all sources of measurement error.

The Pearson product-moment correlation coefficient also known as Fisher's Interclass correlation coefficient is a measure based on regression analysis and used to describe the extent to which two variables can be described by a straight line. It is intended to convey association between two different classes of variables such as shoe size and height (Streiner & Norman, 2008). However, correlation does not always convey agreement although it can provide insight into relative position and consistency of ranked scores. For this study, as is the case in many clinical scenarios, it was necessary to establish that both raters agreed on the measurements and

not just that they were proportionally consistent (Portney & Watkins, 2009). A Pearson correlation coefficient of 1.0 can indicate a perfect fit despite a non-zero intercept and slope not equal to 1.0. Alternatively, an ICC will yield a value of 1.0 if all measures on each subject are identical, indicating a slope and intercept of 1.0. Thus, the Pearson coefficient can be susceptible to providing a liberal and inappropriate estimate of reliability although in practice, it should coincide with the ICC if a large proportion of total error is considered to be random (Streiner & Norman, 2008).

Some clinicians have a preference for the categorical classification of JVP as opposed to numerically quantifying it. There have been a number of studies which have treated the variable dichotomously as elevated or normal while others have stated that it may be low, medium or high. For these reasons, data analysis for this project entailed a calculation of a weighted kappa using the 3 level classification of JVP. The weighted kappa as opposed to the traditional kappa allows for partial agreement. Weights are routinely arbitrarily assigned but it has been recommended that unless there are strong and previous justifications, the commonly used quadratic weighting scheme should be implemented (Streiner & Norman, 2009). With this scheme, the weighted kappa is exactly identical to the ICC that would be computed if the 3 levels were treated as numeric data points (Streiner & Norman, 2009).

3.3.2 Sample Size

The sample size calculation followed recommendations put forth by Fleiss (1981), Cicchetti and Sparrow (1981) and Streiner and Norman (2009). An ideal sample would be large enough to ensure that the standard error of the 95% CI is 0.1 or ± 0.05.

$$Z_R = \frac{1}{2}\log_e\left[\frac{1+(k-1)R}{1-R}\right] \text{ and } Z_{R-} = \frac{1}{2}\log_e\left[\frac{1+(k-1)R^-}{1-R^-}\right]$$

Using the hypothesized reliability of R = 0.7, standard error of 0.1,

R^- = 0.7 - 0.1 = 0.6 and with two raters per subject (K= 2),

$$Z_R = \frac{1}{2}\log_e\left[\frac{1+(k-1)R}{1-R}\right] = \frac{1}{2}\log_e\left[\frac{1.7}{0.3}\right] = 0.8673$$

$$Z_{R-} = \frac{1}{2}\log_e\left[\frac{1+(k-1)R^-}{1-R^-}\right] = \frac{1}{2}\log_e\left[\frac{1.6}{0.4}\right] = 0.6931$$

Standard error = Z_R - Z_{R-}= 0.8673 - 0.6931 = 0.174

From this, the sample size equation can be utilized,

$$n = 2 + \frac{k}{2(k-1)(Z_R - Z_{Ri})^2} = 2 + \frac{2}{2(1)(0.174)^2} = 2 + 33 = 35$$

For this study, 35 patients were required based on the hypothesized reliability of 0.7 and standard error of 0.1.

3.3.3 Recruitment and Setting

The study was submitted to and received ethics clearance from two separate committees, the University of Waterloo and the LTC home. The search for a suitable LTC home began with an environmental scan of homes in the Kitchener-Waterloo-Cambridge region. Emails were sent out to executive directors whose contact information was elicited from public websites. The homes were required to currently employ two or more physicians who were willing to volunteer their time either before or after their rounds at the home. Similar to Project i, the executive directors acted as the conduit through which information letters were passed on to physicians.

The research student conducted one-on-one meetings with physicians and executive directors to explain the study in detail if requested to do so. The two nurses were recruited from a local nursing school. The selected LTC home was People Care Hilltop Manor in Cambridge.

Prior to patient recruitment, a courtesy call was sent out to all family members of residents in the home explaining the study and that the research student would be approaching residents. The study was advertised in elevators and hallways. A brief description was included in the monthly newsletter of the home. The research assistant also held information sessions which residents or families were invited to attend.

Residents were recruited as a convenience sample. The research student only approached residents who could have cognitively provided consent (Cognitive Performance Scale - CPS - score of 2 or less) and whose cognitive status was confirmed by the nurses. There was no other exclusion criteria and for three potential patients, the information letter and consent forms were translated to Portuguese and Romanian by nurses who volunteered their time.

3.3.4 Method of Data Collection

The two nurses underwent a one hour training module designed by the research student. The aim of the training was to teach the nurses how to use the device. It included a PowerPoint presentation with a step-by-step pictorial protocol for the device as well as suggestions on how to troubleshoot any errors which may occur during data collection. The nurses were also shown a five minute video on how to locate the anatomical landmarks required for device use. Following this, the two nurse raters had an opportunity to observe a demonstration of how to use the device. The demonstration was performed by a research assistant on a volunteer. Lastly, the nurses had an opportunity to practise using the device on volunteers. As data collection commenced a week

after the training, the nurses had additional practice trials immediately before collection to avoid confounding by a warm up effect.

The nurses did their measures in the evenings between 8:00PM and 10:00PM on Tuesday, Thursday and the occasional Monday. Those times were selected so as to minimize the inconvenience of having residents transition in and out of bed during the day. The nurse measures were in immediate succession. The maximum time between physician and nurse measures was forty eight hours.

The two physicians were shown an eight minute video on how to assess JVP using the Lewis method. The goal of the session was to serve as a reminder of the maneuver specifics and was conducted by the researcher. Due to scheduling constraints, the physicians measured patients' JVP after their regular rounds at the facility. For one physician, those times were on Monday, Tuesday and Thursday between 10:00AM and 11:00AM. For the second physician, collection times were on Tuesday and Thursday between 8:30AM to 10AM. The number of patients measured per day ranged from 0 to 6. Due to residents sometimes leaving the home for hospital visits or special tests, the maximal time between physician measures was forty eight hours.

Clinical data was abstracted from resident charts in order to characterize the sample.

3.3.5 Method of Data Analysis

The intraclass correlation coefficient model 2,1 or ICC2(A,1) was used to measure inter-rater reliability. A weighted kappa was used for the categorical classification of JVP and was calculated by using quadratic weights. The normal interval for JVP is from 4 to 8 cm H_2O and the range can be from 2 to 25 cm H_2O (Socransky et al., 2010). Intervals of 0 to 3, 4 to 8 and 8 to 25 cm H_2O represented the low, normal and high classifications respectively. All analyses

were conducted in SAS V.9.2 (The SAS Institute). The ICC2 (A,1) was calculated using a macro found in APPENDIX ix.

3.4 Assumptions

In the study, the following assumptions were made a priori to the data collection projects. At the onset of data collection, it was assumed that primary care and LTC clinicians were aware of the JVP measure as a clinical sign. It was assumed that the focus group questions would have been able to collect information free from bias. During Project ii, it was assumed that the JVP of otherwise stable LTC residents did not inherently change over the 48 hour interval of the data collection.

CHAPTER 4

RESULTS

4.1 Project i

Three focus groups were held with 25 primary care nurses, physicians and LTC nurses while four individual interviews were conducted with LTC physicians. Sample sizes for the focus groups and interviews were as follows: Group 1 of LTC nurses (7 RPNs, 3 RNs), Group 2 of primary care nurses (6 RPNs, 3 NPs), Group 3 of primary care physicians (6 MDs), and Group 4 of LTC physicians (4 MDs). Results of the focus groups and interviews were categorized into 4 distinct groups by care setting and professional role. This was done due to the unique experiences and impressions expressed by each group despite some overlap. Demographic information for the sample can be found below in TABLE 3.

TABLE 3 - FOCUS GROUP PARTICIPANT DEMOGRAPHICS

Characteristic	Primary care physicians (n=6)	Primary care nurses (n=9)	Long term care nurses (n=10)	Long Term Care Physicians (n =4)	Total
Gender					
Male	3	-	-	2	5
Female	3	9	10	2	24
Age					
< 20	-	-	-	-	
20-29	-	2	-	-	2
30-39	2	2	3	-	7
40-49	3	1	3	-	7
50-59	1	3	3	1	8
>60	-	1	1	3	5
Occupation					
Registered Practical Nurse	-	6	7	-	13
Registered Nurse	-	-	3	-	3
Nurse Practitioner	-	3	-	-	3
Physician	6	-	-	4	10
Physician Trainee	-	-	-	-	-
Nurse Trainee	-	-	-	-	-
Educator	-	-	-	-	-

Years of experience					
<1	-	-	2	-	2
1-3	2	-	4	-	6
3-5	-	3	-	-	3
>5	4	6	4	4	18
Years in current care setting					
<1	-	1	1	-	2
1-3	2	2	4	-	8
3-5	-	2	-	-	2
>5	4	4	5	4	17

4.1.1 Main Findings of Project i

Research Question 1: What is the perceived understanding of the JVP among primary care and LTC clinicians?

In primary care, two of six physicians assessed JVP by visually observing either the internal or external jugular vein. One of the nine primary care nurses, a NP, assessed JVP by visual observation of either the external or internal jugular vein and used a dichotomous classification of the measure.

> *"So I'll look at the JVP but I don't need a number. If it's bounding, if it's elevated, I can tell it's elevated. I look, you can see the earlobe jiggle, and you know you have an elevated JVP." – Primary Care NP*

In LTC, three of four physicians assessed JVP. All used visual observation and dichotomously classified the measure as elevated or not. One participant expressed concern as to whether any physicians other than cardiologists use the Lewis method. One of the ten LTC nurses who had assessed JVP had done so only on one patient during clinical exposure in nursing school. In this instance, the participant used visual observation and dichotomous classification of the variable. The other nine nurses stated that they do not measure JVP and had forgotten skills involved with the assessment.

"This one was really easy for us, we didn't have to assess or anything….you can just look and it's right there (vein distension)" – LTC RN

"(RN1) just graduated…..she (RN1) is the only one that knows. The rest of us have all forgot." – LTC RN

Overall, twenty three of twenty nine participants stated that they never assessed JVP in their respective care settings. Of those who did, visual observation using either the external or internal vein seemed to be the technique of assessment.

Research Question 2: How do clinicians in primary care and LTC perceive the acceptance of the Mespere CVP 1000 System to measure JVP?

The six primary care physicians would rarely consider using the device on patients in their care setting, if at all.

"I think it (device use) would be rare, I can think of one patient in the last year…..forty five year old guy that was short of breath and very fatigued. I assumed he had pneumonia, he was actually in congestive heart failure…no MI, no setup….biventricular, severe heart failure. I didn't look at his JVP, who knows what a JVP is? (Laughter) If we had strapped it (the device) on, because he was short of breath so the nurses would have done it as part of his triage and his JVP was twelve, that would have gotten my attention…..once I looked up what the normal range should have been for JVP." – Primary Care Physician

The physicians stated that they were satisfied with their current strategy of volume status assessment to manage HF. One participant highlighted that in the case of new onset or worsening HF, the device would not alter the decision to transfer patients to the ED. Overall, primary care physicians perceived little need for the device to measure JVP.

None of the nine primary care nurses appeared willing to readily accept the device for JVP assessment. The numeric device measure was perceived as confirmation of visual estimation. On enquiring of the perceived role of the device in primary care, the response was:

"I don't think so – if it's not going to make any difference to your course of action then I don't see why it would." - Primary Care NP

NPs also perceived that the care of HF was a role for the ED and thus their acceptance of the device was also limited,

"Would a number change the disposition of the patient or how I manage them? No…..if he or she has acute heart failure, I'm going to send them into emerg because I don't know why the patient is in acute heart failure."

– Primary Care NP

"If I see it clinically that she has a bounding JVP, she is going to emerg regardless of the number that I get." –Primary Care NP

"When we get someone here with active CHF or having an exacerbation…..it's 9-1-1….off to the ER."- Primary Care RPN

Acceptance of the device by LTC clinicians was in marked contrast to that of primary care clinicians. All 4 LTC physicians indicated that they would like to use the device for the assessment of JVP for their patients. One physician stated that this device would be helpful to assess the JVP and that the use of the device would be similar to the use of an oxygen saturation meter, that is, correctly positioning the device and recording the value.

"What I compare it to is the technology of oxygen saturation which has changed in the past ten years, where I now carry around an oximeter with me that costs

seventy dollars. Having that little piece of information is now something that I just take for granted, it's like having a blood pressure or a pulse rate, and I just take it for granted that is going to be part of the data set a nurse is going to present to me if she has to call me about a patient. So I can see this device being something that you can just count on." – LTC Physician

The LTC nurses expressed acceptance for the device and were enthusiastic about its potential implementation. They recognized that the device could provide an additional objective measure to assist in the care of older adults,

"Well, this can become a vital sign. Not for emergency uses or anything like that, but as another vital sign for those of our residents who we're changing medications for."- LTC RPN

LTC physicians were confident in the nurses' ability to learn how to use the device effectively. One participant mentioned that most of the RNs in LTC were senior clinicians who understood the complexities of medically caring for older adults. With more objective measures available, such as the JVP, care would inevitably improve. As seen in the following quote, it was believed that POC investigative testing is best suited for nurses as opposed to physicians,

"You know, an RN who gets trained on this is going to be good. RNs are sometimes better than physicians at this kind of thing because they are very rule bound people, in terms of their personality dimensions and their goals. They are usually very empathic, we physicians tend to be more analytical but nurses are very good at doing something that has an algorithm with it."- LTC Physician

Research Question 3: How do the clinicians in primary care and LTC perceive the ease of use of the Mespere CVP 1000 System to measure JVP?

All the primary care physicians perceived that the device was easy to use, and that its guided prompts were appealing. Among the primary care nurses, there were varying views on the perceived ease of use of the device. Four of the nine nurses perceived that the device could be easily used, though interpretation of the recorded value was not clear.

"It's easy enough to use…..just the interpretation"- Primary Care RPN

"It's user friendly, but it's more…What do you do with the measure?"

– Primary Care NP

Five primary care nurses perceived that the device was not easy to use. Nurses seemed to find the process of inclining and reclining the patient cumbersome,

"On a scale of 1 to 10….5."- Primary Care RPN

"I wouldn't feel comfortable with the device – doing it myself and verbally telling the doctor what I see. If he's in the room with me and I do it, that's fine but I wouldn't feel comfortable." – Primary Care RPN

All the LTC physicians perceived that the device was easy to use and that after one or two in-service sessions, they would feel comfortable operating it in the home. Of the ten LTC nurses, all perceived that the device was easy to use. It was pointed out that the features that made the device easy to use included the clear labels, simple instructions, appropriate size, and the prompts. As highlighted by the nurses, the device was simpler to use than expected,

"*It tells you what to do, I don't have to guess."- LTC RN*

Research Question 4: What do clinicians in primary care and LTC perceive as barriers to the implementation and use of the Mespere Venous 1000 CVP System?

Perceived barriers according to primary care physicians

(i) Patient Centric Factors

Primary care physicians perceived patients' intimidation about medical technology as a barrier to the implementation of the device. Furthermore, patients' mobility in terms of positioning themselves onto the examination table was reiterated as a common barrier to using the device. Physicians were also concerned about nurses' ability to accurately locate the anatomical landmarks for the device patches. The participants noted that locating these markers could be difficult in their HF patients as the majority of them may be older, sometimes obese with large mammary glands which can further make location of the 4th intercostal space challenging, if using the nipple line.

(ii) Time Constraints

Time was perceived as another barrier. Physicians stated that the target time per patient visit of ten minutes could deter use of the device. They further suggested that medical devices would have to provide useful information to be worth the extra time. They seem to prefer devices that have scanning mechanisms rather than patches used by the Mespere device.

(iii) Cost

Cost was raised as a potential barrier by two of the six participants. The device was thought to be expensive.

Perceived barriers according to primary care nurses

(i) Location of the Anatomical Landmarks

All primary care nurses perceived as a barrier, the ability to locate the mid axillary line, external jugular, and fourth intercostal space, as stated,

> *"this intercostal thing I find very hard….feel like I have probe for it."*
>
> *- Primary care RPN*
>
> *"So underneath the clavicle, is that the first intercostal?"- Primary care RPN*
>
> *"You can't feel number four….it's one, two and then to twelve and use the nipple line….where the nipple should be." – Primary Care NP*

Fewer nurses had difficulty locating the mid-axillary line compared to the fourth intercostal space. This barrier was perceived to be exacerbated when the device has to be used on obese patients, who are short of breath or uncomfortable,

> *"again, the placement.... we tried it on a healthy, young person yesterday who is anatomically….it should be easy and yet, the placement of the thing, we couldn't get it….imagine trying to do it on someone who is obese and not comfortable."*
>
> *– Primary Care NP*

(ii) Health System Resources

Primary care nurses anticipated that lack of mechanical medical beds would be a barrier for implementation of the device. The device prompts require inclining or reclining the patient when the patches are on to ensure that the height of the pulse can be detected and having to perform this manually on the non-mechanical beds in their clinic would require significant strength,

"You really have to push it in and pull it up (referring to bed)….you need muscles." – Primary Care RPN

(iii) Time constraints

Similar to the primary care physicians, primary care nurses perceived time constraint as a barrier for device use and implementation. NPs stated that their standard time allotment for patient assessment was between two to three minutes. They stated that incorporation of the device may not be feasible without extending patient assessment time. One NP suggested that RPNs do the measure on the basis that,

"Nurses don't really have time to do that (use the device)….the RPNs might because they see patients separately but we've got to get the patient in the room and out in two or three minutes so unless there is more time allotted, I can't see the nurses doing it." – Primary Care NP

However, one RPN noted that the longer allotted assessment time may still be insufficient to acquire the measure.

"it might take you 15 minutes to get them up and undressed and do the physical assessment…if we're going to spend 10 of that doing this, it will eat up a lot of time."-Primary Care RPN

NPs agreed with the RPNs that undressing and transferring a patient onto the examination bed might take up to 10 minutes. It was perceived that this would be especially problematic in older, frail patients and the time constraints could be a barrier to using the device to measure JVP, as evidenced in the following quote,

"Nobody is going to take that thing into a room to measure JVP…realistically speaking I doubt it…because of timing issue and because you are probably going to rely on other means to diagnose it at a specific time so uh, maybe on some patients in the heart failure clinic it will be useable but if you leave it there, nobody is going to grab it and check the JVP."- Primary care NP

Perceived barriers according to LTC physicians

(i) Dementia and Resident Co-operation

The LTC physicians perceived that the inability of some residents, especially those with dementia, to remain still to place the patches could be a barrier for the device use.

"A lot of demented residents cooperate if they are apathetic, and a lot of others are agitated so they pull off everything, so it's hard to estimate but it's a big number." – LTC Physician

However, a physician pointed out that the device use would only be impeded in specific dementia cases, and emphasized the medical importance of identifying and managing HF,

"You know for most dementia people, that's not going to be a huge problem. It might be a problem for people who have frontal temporal or people who have atypical frontal Alzheimer's but you're going to worry less about that than their heart failure." – LTC Physician

Although estimates of the severity of barrier varied, all four physicians perceived that only in a subset of residents, using the device may not be easily possible due to the severe agitation and lack of cooperation by residents.

(ii) Nurse Accuracy

A significant potential barrier noted by all four physicians was concern surrounding the nurses' ability to locate the anatomical landmarks needed to obtain a precise measure,

> *"I would have concerns about whether the nurses are positioning the patients properly, going through the maneuvers and using it appropriately."*
>
> *– LTC Physician*

The physicians posited that in older, obese adults with droopy skin, locating the phlebostatic axis and external jugular could be even a greater challenge. Skillful use of the device also seemed to be a point of apprehension for the physicians as they perceived that the nurses may not be using them often enough for adequate practice.

(iii) Cost and Size of Device

Cost and size of the device were cited as potential barriers to device implementation and use. The LTC physicians thought that the price of the device was too high and could be the main factor to impede its implementation. One physician who was medical director of a LTC home stated:

> *"Cost isn't always a problem. These homes have sort of slush funds for devices so they will have $500 for an ultrasound so $10,000 is crazy money and you have to get everyone to ok it.....so if you could get the cost down under $1,000, that would be ideal." – LTC Physician*

One of the four LTC physicians noted that the device was slightly too large and perceived that to a lesser extent, size of the device could be a barrier. This view pertained to both the docking stand and the handheld component. Participants also pointed out a few additional minor

barriers including: adequate availability of consumables, for example, disposable patches; and storage procedures for easy accessibility in a timely manner by the nurses.

Perceived barriers according to LTC nurses

(i) Resident Centric Barriers

The LTC nurses perceived that dementia and resident cooperation could be barriers to device use. Another nurse pointed out that the residents might tug and pull on the neck strap or not comply with requests to lie in bed, making an accurate measure impossible to elicit and hence a barrier to the device use.

> *"They wouldn't let us touch them even. We can't apply the blood pressure apparatus." – LTC RPN*

Pulling at patients' skin when removing the adhesive patches was also seen as a barrier to the device implementation. A final barrier perceived was resident's fear for technological devices. The nurses described that medical technology could intimidate LTC residents as they become worried that they are severely ill,

> *"Even checking their vitals, they are asking 'am I fine?' and 'why are you doing this?"– LTC RPN*

This concern was anticipated to be highly individualized and not prevalent but could extend to resident families as well.

> *"It may worry the resident or they might go to bed and not remember the next day, it's really quite individualized. It might worry the family members for those who do remember.....a resident might say to them 'they hooked me up, I must have been really sick yesterday'. "- LTC RN*

It was believed that this might lead to frantic family members requesting information and highlights the importance of the nurses being able to explain why the test was performed and its significance.

(ii) Solutions to Resident Centric Perceived Barriers

LTC nurses provided solutions to the resident centric barriers. They stated that residents' cooperation as a barrier also arose during routine assessment of vitals. In such instances, the nurses have existing solutions which could also be applied to use of the device,

> *"We just approach several times in order to get the right number and reading."*
>
> *– LTC RPN*

In light of this suggestion, other nurses noted that obtaining vitals was sometimes impossible by referencing a recent resident who was not cooperative and vitals could not have been measured.

The participants also suggested a solution to the second barrier surrounding resident skin. In the care setting, skin on the neck was believed to be highly elastic, lending towards possibility of a tear when removing the adhesive patches. However, the nurses suggested that this barrier may be negated with careful and slow removal,

> *"Well if she had skin like (resident), it might not work so well, it did pull a bit. It would have to be like everything else, just need to be careful." – LTC RPN*

Some nurses addressed the concern of residents' fear by drawing similarities to vital sign assessment, stating that the barrier might be overcome once residents become familiar with the device as was the case with sphygmomanometers. They also stated that offering the resident reassurance would help.

(iii) Clinician Factors

Nurses perceived difficulty locating the anatomical landmarks. Differentiating the carotid artery from the external and internal jugular was initially challenging but once shown how to palpate the vein by gently pressing down on the clavicle, identification improved although this was an unsystematic observation. Nurses noted difficulty locating the phlebostatic axis. Locating the fourth intercostal space was perceived to be more challenging.

(iv) Cost

The LTC nurses perceived cost of the device as a barrier to the device implementation. One nurse suggested that a cost benefit analysis of the device could address this barrier.

4.1.2 Secondary Findings of Project i

Analysis of Project i data identified additional findings to those which addressed the research questions.

Primary Care Physicians

Theme I: Perceived Ability to Diagnose and Manage HF

This theme focuses on the management and diagnostic decision making of HF among physicians in primary care. It captures aspects of the diagnostic process and can be organized into the following subthemes: i) Perceived Diagnostic and Management Confidence; and ii) Time Constraints and Availability of Investigative Tests.

Subtheme (i): Perceived Diagnostic and Management Confidence

The physicians expressed a high degree of confidence in their ability to diagnose new onset HF. Participants acknowledged that HF was a clinical diagnosis coupled with supporting investigative tests in a relatively straightforward process:

"I think it's [HF] easy to identify…just finding why it is that way and making that conclusion….and start the treatment…it's not difficult to do."

– Primary Care Physician

For acute HF, one participant acknowledged that a large differential exists especially when a patient is short of breath but having gone through the physical examination and clinical history, they stated that one should be able to narrow it down to HF,

"Certainly there are lots of cases where you see someone come in with shortness of breath, your differential is quite large but based on your clinical exam and history…you should be able to narrow it down." – Primary Care Physician

Other physicians noted transferring acute cases of HF to the ED based upon symptoms such as shortness of breath. The severity of the condition appeared to dictate management disposition and interestingly, lack of confirmatory investigative tests was linked to low confidence of management in primary care,

"*If they are in what you hope is a little bit of failure, maybe you can medically manage them and send them home. If they are in overt failure, they may need to go to emerg because we can't probably work them up."*

– Primary Care Physician

Subtheme (ii): Diagnostic Time Constraints and Availability of Investigative Tests

Despite their expressed high confidence in establishing a HF diagnosis, participants noted that time was a significant diagnostic and management barrier,

"It just takes some time to assess fully for heart failure because it involves physical examination, history and then some investigation and all these are

needed before the diagnosis at the end…..this is not something you can diagnose within one session."– Primary Care Physician

There was an overall reliance on chest X-rays and echocardiograms to aid in the diagnosis of HF and the limited availability of these investigative tests might contribute to the diagnosis requiring multiple visits. However, there were additional intermittent factors involved including frailty,

"So it depends on when we see the patient. We have a x-ray and lab next door so if the patient is not too frail to go over there and do it, then that's what most of us will do but we wouldn't get those results back until tomorrow….so it will be helpful but not immediately. Echocardiogram is usually weeks down the road if you want to actually get an anatomical look and get a measurement of ejection fraction….you can't do that quickly. If it's after hours in the evening or on the weekend, we don't have lab or x-ray……" – Primary Care Physician

Theme II: Perception and Confidence in Assessing JVP

This theme describes knowledge of and perceptions towards the JVP measure among primary care physicians. Three subthemes were identified: i) Devaluation of JVP; ii) Skill and Confidence in Assessment; and iii) Barriers to Assessment.

Subtheme (i): Devaluation of the JVP

The majority of primary care physicians perceived the JVP as adding little value to the clinical picture of the patient in comparison to the other clinical signs. A physician elaborated upon this thought, citing a preference for shortness of breath, peripheral edema, and an increase in weight.

"I don't think it would change my management..... if I've got a known heart failure patient, I'm looking at shortness of breath, ankles swollen and if their weight has gone up….I'm not going to be measuring to see if JVP is ten or twelve millimeters." – Primary Care Physician

A numeric JVP value was viewed as being unimportant as one participant stated that patients are managed clinically rather than according to numbers,

"You treat clinically, not necessarily with numbers." – Primary Care Physician

Subtheme (ii): Confidence in Assessment

Five of the six physicians were not confident in their ability to assess the JVP. For one physician, lack of confidence and technique began during medical training and never improved.

"I have not checked JVP since residency and that was cause I had to…and even then I don't think it was accurate...you make it up." – Primary Care Physician

"So JVP, I'd say I do not check it because I'm not good at it and I don't think it's helpful for me but the other things in the exam will be more helpful in my opinion for me for what I'm comfortable doing so I don't know if other people check JVP but I do not check it." – Primary Care Physician

Another participant stated that unless a trainee was on an internal medicine rotation during clerkship, checking JVP would be rarely requested and was of the impression that it was not an emphasized skill in medical training.

Subtheme (iii): Barriers to Assessing JVP

The two physicians who attempted to assess JVP were unable to do so mainly because frail, older patients could not lift themselves onto the examination table. One participant stated that this was a significant proportion of the patients,

"I do try to do JVP on my patients that I know I'm monitoring for failure unless they are so frail that they can't get up on the table which is many of them."

– Primary Care Physician

Other factors which impeded regular assessment related to patient body type. The physicians said it was difficult to locate the jugular veins on individuals with shorter necks or in those who were obese. Long, slimmer physiques were said to lend towards easier identification of the internal jugular vein.

Theme III: Device Potential as a Teaching Tool

Despite physicians rarely assessing JVP and the belief that it adds little to the clinical picture of the patient, a few group members thought that the device could be used as a teaching tool for medical trainees. One participant explained how the device could aid in bedside teaching,

"I think I would use it if I was going to use it here with students and residents as a teaching tool…..I would use it to say 'Tell me what the JVP is' on your clinical assessment and then double check it with this as a way to teach them how to do it clinically…..a study can look at 'are we teaching our residents how to properly do a JVP? can we back it up with this machine?' and then they can move forward using their eyes." – Primary Care Physician

Theme IV: Device Potential in a Primary Care Heart Function Clinic

The New Vision Family Health Team offers a heart function clinic with one physician who took part in the focus group and one NP. The clinic presents a unique environment as it

caters only to cardiac patients including those with HF. This physician was one of two who cited trying to measure JVP in clinic.

> *"In the heart function clinic we do try to measure JVP if the patient is able to get on the bed and recline at forty five degrees, but sometimes we can't do it because you know we have some patients who are never come to the clinic. Others are ninety years old, they come in a wheel chair and we can't get them on the bed so it's very valuable but on average, I would say probably fifty percent of cases get their JVP checked." – Primary Care Physician*

The physician explained that patients in the heart function clinic were attended to for thirty minutes or longer as opposed to ten minutes allocated in standard clinic. The physicians revealed that even with more time, infrequent visits and limited mobility prevented the regular assessment of JVP in up to 50% of patients. The physicians said they were content with their current practices with respect to the JVP.

Primary Care Nurses

Theme I: Clinical and Physiologic Knowledge of JVP

Knowledge of the clinical and physiologic meaning of JVP appeared to be limited in this group, more so than among the LTC nurses. One NP who did not assess JVP emphasized the need to understand the significance of increased and decreased levels. It was also viewed as key to look at how this information can be woven into clinical practice and this was seen as more imperative than the knowledge surrounding how to use the device,

> *"It's not more so the device, it's understanding if you have a JVP that is elevated or decreased. I think that's the biggest thing, understanding the physiology behind that because you'll learn the placement of putting on the probes. It's*

actually understanding what's happening with the JVP, I think that's the most important thing. To get that number is fantastic, so if it's a quicker way of actually getting that number, even better but to actually understand it, I think that's where the training of anybody would be needed. As long as you understand why we are putting the probes on there, why do we need that number? Why is that useful?" – Primary Care NP

In addition to an evident knowledge gap, the NP who cited assessing JVP had an underlying belief that the measure would differentiate between right sided and left sided failure.

LTC Physicians

Theme I: Diagnosis and Management of HF

This theme focuses on the diagnostic decision making for HF among physicians in LTC. It captures different aspects of the diagnostic process and was organized into the following subthemes: i) Diagnostic Confidence; and ii) Diagnostic and Management Challenges.

Subtheme (i): Diagnostic Confidence

In contrast to physicians in primary care settings, diagnostic confidence of the LTC physicians for HF was low. Some participants said that most times, the diagnosis of HF could just as likely be another condition and a lot of guesswork was done in identifying the presence of the syndrome. In general, LTC participants tried to avoid sending patients to outpatient clinics due to lack of mobility which often times required transportation facilitated either by the family or an external care provider. They noted that it would be an upsetting experience for residents with dementia to leave their familiar surroundings in the LTC home to be sent out for a test. Another practical concern was finding someone to accompany the resident to the clinic. These factors acted to deter LTC physicians from requesting external investigative tests.

Subtheme (ii): Diagnostic and Management Challenges

Evaluating patients for new onset or acute HF was a process fraught with multiple barriers in LTC. One barrier to physical examination was resident compliance with instructions such as when a physician requests a resident to take a deep breath to listen for chest sounds. Also, physicians stated that a thick chest wall would interfere with their ability to hear chest sounds and being unable to physically move residents due to frailty or obesity made physical examination a cumbersome process. The physicians admitted that a large differential diagnosis with numerous etiologies exists for LTC residents who are short of breath.

> *"You might not think of it (heart failure) immediately unless they have great big swollen feet. There is a big differential for shortness of breath in long term care……it can be anything from heart attack, exacerbation, COPD, pulmonary embolism or heart failure. So you're relying a lot on your clinical exam which is sometimes difficult." – LTC Physician*

Further compounding the large differential was the potential for the co-existence of multiple conditions. One physician described difficulty in determining whether the symptoms and signs, peripheral edema for example, stemmed from a lung or cardiac condition and in the most some cases, both might be coexisting. Specific examples included an established HF patient who had developed pneumonia or vice versa. Referring to diagnostic uncertainty, one participant stated that,

> *"The acutely short of breath patient, you don't know, is it pneumonia? or is it heart failure? You know what I do now is treat both, I'll put them on antibiotic and diuretic which is pretty meatball medicine....and then ship them up to emerg if they don't get better. Plus it depends on the family, like some families demand*

that they go to the hospital, and others you can say 'let's just try to deal with it at the nursing home' so you have to get a feel for the family." –LTC Physician

The barriers to accurately diagnosing HF are more pronounced in those with dementia,

"The people I see in long term care, 60 to 80% of them have dementia. Shortness of breath has to be an observed thing once the staff get to know them then they can tell me that and it depends on the skill of the staff person. I'm not going to observe it directly as I only go in the mornings so I'm not there in the late evening. Most of the time staff is absolutely amazing at reporting these things, they are very good and I really do rely on them." –LTC Physician

Nurses' stress and their workload were concerns expressed by the LTC physicians. One participant said that requesting too many resident assessments might result in nurses' frustration and hence a premature transfer to hospital to alleviate the strain. As alluded to previously, physicians are very wary of this and stated that because of this feeling, residents' weights were infrequently obtained making it an unreliable measure in the event of acute illness,

"They're all very busy (nurses) so weighing a significant number of people every day is difficult so we don't do that with most people…..heart failure may come on really quickly so we might not have a weight that's really recent or a couple of weights taken recently…..and if they are acutely ill, can't weigh them."

–LTC Physician

One participant expressed difficulty in educating families about older adult care and also highlighted the many negatives if a physician were to discourage a family from transferring a loved one to hospital,

> *"Hospitals are terrible for old people....it's old people unfriendly but it takes a lot of work with families to get over that. For example, yesterday I have a resident who was dying and I said 'we should just keep him comfortable and do nothing' and they family freaks out, it's like 'you're killing my dad'. Well, he's dying, everyone dies and I can say, 'I will be there three times a week, keep a close eye, give you a call' a lot of work on my behalf, it's a lot easier to punt to the ER. And there's no reward for it and tremendous consequences if you get an angry family.....you got 10 years of grief at the college and law suits and the newspaper....so there is tremendous downside, no upside so most doctors and nurses just get rid of them to the hospital, we're trying to educate people to it and it's slow change in thinking but it's really tough." –LTC Physician*

There was a widespread feeling among the LTC physicians that hospitals were steadily offloading a higher proportion of older adults to LTC homes,

> *"We see the hospitals downloading everything on us because the hospitals are so pressed. I just got an email from the hospital saying they are overloaded, I just wrote back to the president of the hospital saying 'I'm really tired of these bed alerts, I get them 365 days of the year, I'm just ignoring them now'....so there is this constant pressure to get everybody out of the hospital, I had a guy yesterday who got sent to the home on intravenous and we do dialysis. So we're becoming a*

hospital, traditional hospital are getting less and less beds while nursing homes are getting more but there is that feeling there of dumping on us."

–LTC Physician

Despite increasing care demands, the physicians observed that there was not a proportional increase in resources, namely, staff, medical devices, and tools to better diagnose and manage residents in LTC care setting.

Theme II: Confidence and Barriers to Assessing JVP

The physicians who assessed JVP were not confident in their ability to obtain an accurate measure. As one physician stated, there appears to be a disconnect in physicians' perceived ability and actual proficiency in measuring the pressure,

"I think it's (JVP) one of those things that's poorly done and everyone thinks they can do it. It's terrible, they literally can't do it, you do need a machine. It's like trying to estimate your blood pressure by looking at your arm, it's that stupid, like we never guess on blood pressure, never guess on pulse. I mean you have to do the pulse and look at the clock, it is really stupid that we rely on clinical judgment because we measure everything else....it's crazy isn't it?" –LTC Physician

The physicians were not confident in their ability to measure JVP but this did not appear to deter them from assessing the measure,

"I try, I look at it, I make a comment about it but I'm never confident that's really that's going on." –LTC Physician

Contributing factors to this are obese residents with fatty necks which was cited as common in LTC. One physician added that obese individuals render the JVP measure useless.

Older adult conditions, such as kyphosis and scoliosis lead to postural issues, making it difficult to observe the neck clearly as well as to appropriately position the patient. One physician stated that when the JVP was assessed, the resident was rarely, if ever at forty five degrees. Being unable to conveniently move residents, and erosion of skill were the greatest barriers cited by the one physician who did not incorporate the JVP in diagnostic or management decisions,

> *"I guess I've gotten out of the habit of it because usually when I'm assessing people, they are sitting either in their wheel chair or they are laying in bed so you get away from finding that forty five degree angle and getting your rulers out is cumbersome.*" *–LTC Physician*

One physician expressed the view that minimal assessment of JVP eventually causes this maneuver to be abandoned over time.

LTC Nurses

Theme I: Clinical and Physiologic Knowledge

These participants appeared to be unaware of the clinical significance of an elevated or low JVP measure. Nurses expressed interest into which values warranted management from a physician,

> *"So what's the number when we would want to immediately call the doctor?"*
>
> *– LTC RN*

If the JVP was high, the nurses were aware that resident's illness could be fluid related. Interpretation of the JVP waveform was outside of the nurses' purview but many participants appeared receptive to additional training and educational aids if needed,

"I personally wouldn't be comfortable reading the waveform – I would be happy with the number but for the waveform, I'm not comfortable reading ECGs either." – LTC RPN

The nurses expressed the need for sufficient knowledge to explain to the resident and family, the meaning of the test and measure.

Overall, JVP was not assessed by the majority of participants in this study and those who did used visual observation and categorical classification. The clinicians in LTC appeared to have a higher level of acceptance of the POC device and intended to use it to assess patients assigned to their care. The device was perceived as easy to use by the majority of clinicians. Barriers common to both settings included cost and ability to accurately locate the anatomical landmarks. Time constraints in primary care and patient centric factors such as elastic skin and patient cooperation in LTC were outlined as unique barriers. Secondary findings relating to clinical knowledge, diagnostic confidence of HF, and perceptions of JVP were also identified.

4.2 Findings of Project ii

Of the 59 residents who were approached to participate in this Project, 36 consented. This accounted for a response rate of 61%. Participant characteristics are shown in TABLE 4.

TABLE 4 - LONG TERM CARE RESIDENT DIAGNOSES AND MEDICATIONS

	Number of Patients (n=36)
Average Age	83.2
Sex	
Female	23 (66%)
Male	13 (33%)
Diagnoses	
Hypertension	26 (72%)
Arthritis	17 (47%)
Alzheimer's and Related Dementias	**14 (39%)**
Diabetes	13 (36%)

Osteoporosis	13 (36%)
Depression	9 (25%)
Atherosclerotic heart disease	**8 (22%)**
Anemia	8 (22%)
Heart Failure	**6 (17%)**
Chronic Obstructive Pulmonary Disease	**6 (17%)**
Hyperlipedemia	5 (14%)
Macular Degeneration	5 (14%)
Atrial Fibrillation	**4 (11%)**
Co-Morbidities	
10 + conditions	8 (22%)
8 - 9 conditions	7 (19%)
6 - 7 conditions	7 (19%)
3 - 5 conditions	13 (36%)
1- 2 conditions	1 (3%)
Medications	
Pain Reliever	32 (89%)
Statin	15 (42%)
Proton Pump Inhibitor	12 (33%)
Selective Serotonin Reuptake Inhibitor	11 (31%)
Diuretic	11 (31%)
ACE Inhibitor	11 (31%)
Laxative	9 (25%)
Anti-Diabetic	9 (25%)
Anti-Diarrhea	8 (22%)
Calcium Channel Blocker	7 (19%)
Beta Blocker	7 (19%)
Anticoagulant	6 (17%)
Cholinesterase Inhibitor	5 (14%)
Nitrates	5 (14%)
Corticosteroid	4 (11%)
Antihistamine	4 (11%)

Results of the JVP assessments are shown in TABLE 5.

TABLE 5 - MEASURES OF JUGULAR VENOUS PRESSURE

Resident ID	Physician 1 (cm H_2O)	Physician 2 (cm H_2O)	Physician Difference (cm H_2O)	Nurse 1 (cm H_2O)	Nurse 2 (cm H_2O)	POC Device Difference (cm H_2O)
001	8	7	1	15	14	1
002	8	5	3	16	16	0
003	8	8	0	2	2	0
004	9	7	2	5	0	5
005	8	7	1	16	16	0
006	9	6	3	6	5	1
007	10	6	4	0	3	3
008	8.5	5	3.5	5	2	3
009	8	6	2	5.5	12	6.5
010	8	5	3	3	11	8
011	11	6	5	3	10	7
012	13	7	6	5	10.5	5.5
013	7	8	1	6.5	0	6.5
014	12	5	7	5	3.5	1.5
015	5	8	3	6	7.5	1.5
016	8	6.5	1.5	2	14	12
017	9.5	6	3.5	9	11	2
018	11	6.5	4.5	13	19	6
019	8	5	3	7	9.5	2.5
020	8	5	3	5	2	3
021	7.5	5	2.5	4	4	0
022	8	6.5	1.5	13	15	2
023	8.5	5	3.5	10	17	7
024	10	5	5	2	0	2
025	7.5	7	0.5	10	10	0
026	9	5	4	2	1	1.5
027	9	5	4	7	14.5	7.5
028	9.5	7.5	2	5	11	6
029	8	5	3	0	2	2
030	9	5	4	6	2	4
031	8	5	3	6.5	3	3.5
032	9.5	5	4.5	1	2	1
033	7.5	5.5	2	2	9.5	7.5
034	8.5	8	0.5	7	8	1
035	10	9.5	0.5	11	11.5	0.5
036	8	5	3	1.5	2	0.5
Mean	8.74	6.08	2.875	6.19	7.79	3.361

TABLE 6 shows that the inter-rater reliability of nurse assessments using the device was greater than that of the physicians.

TABLE 6 - INTRACLASS CORRELATION COEFFICIENTS

	ICC2 (A,1) (95% CI)
Nurses	0.63 (0.38 - 0.79)
Physicians	- 0.02 (-0.34 - 0.31)

The interaction plots for the nurses and physicians can be found in FIGURES 7 and 8 respectively as shown below.

FIGURE 7 - INTERACTION PLOT FOR NURSE MEASURES

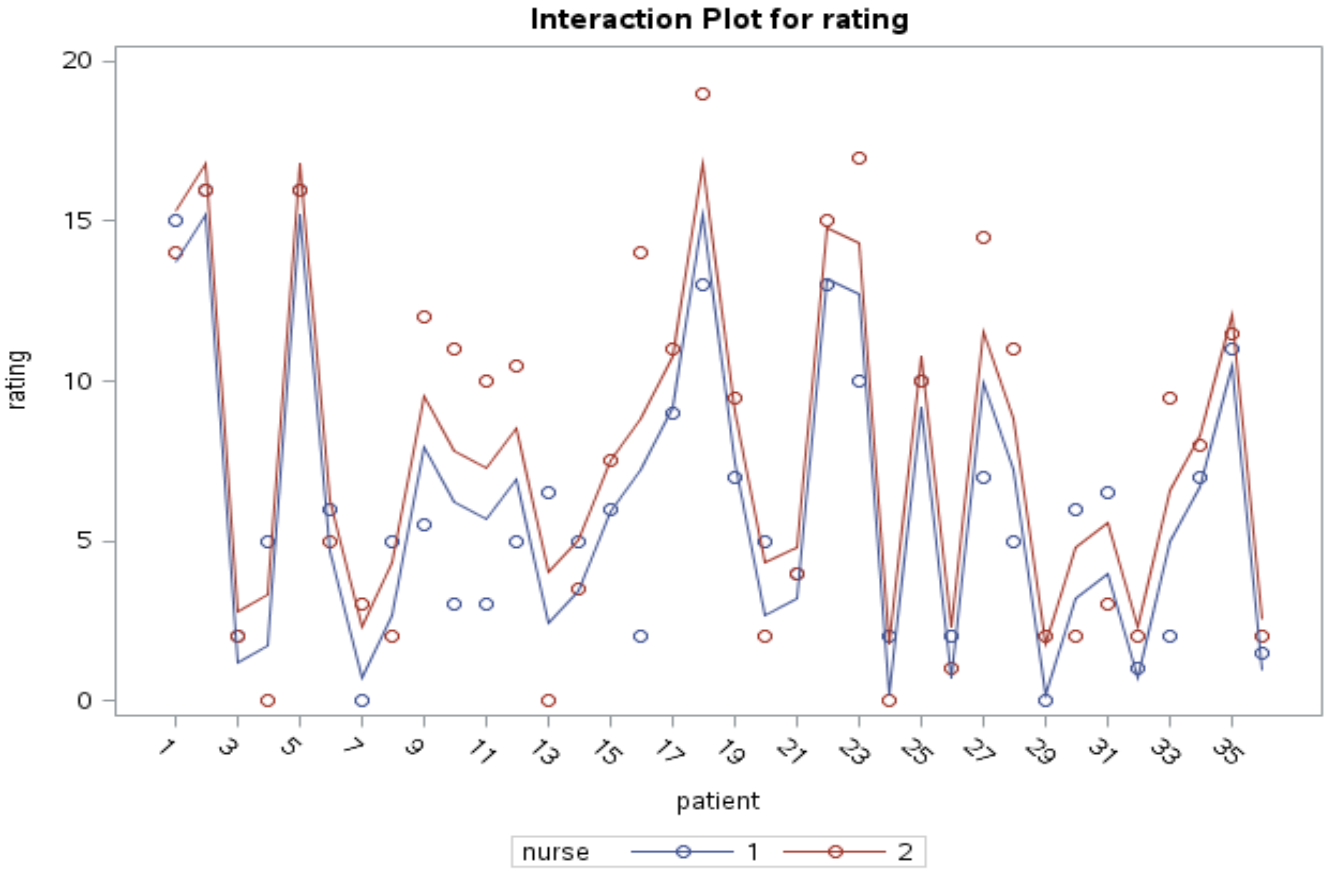
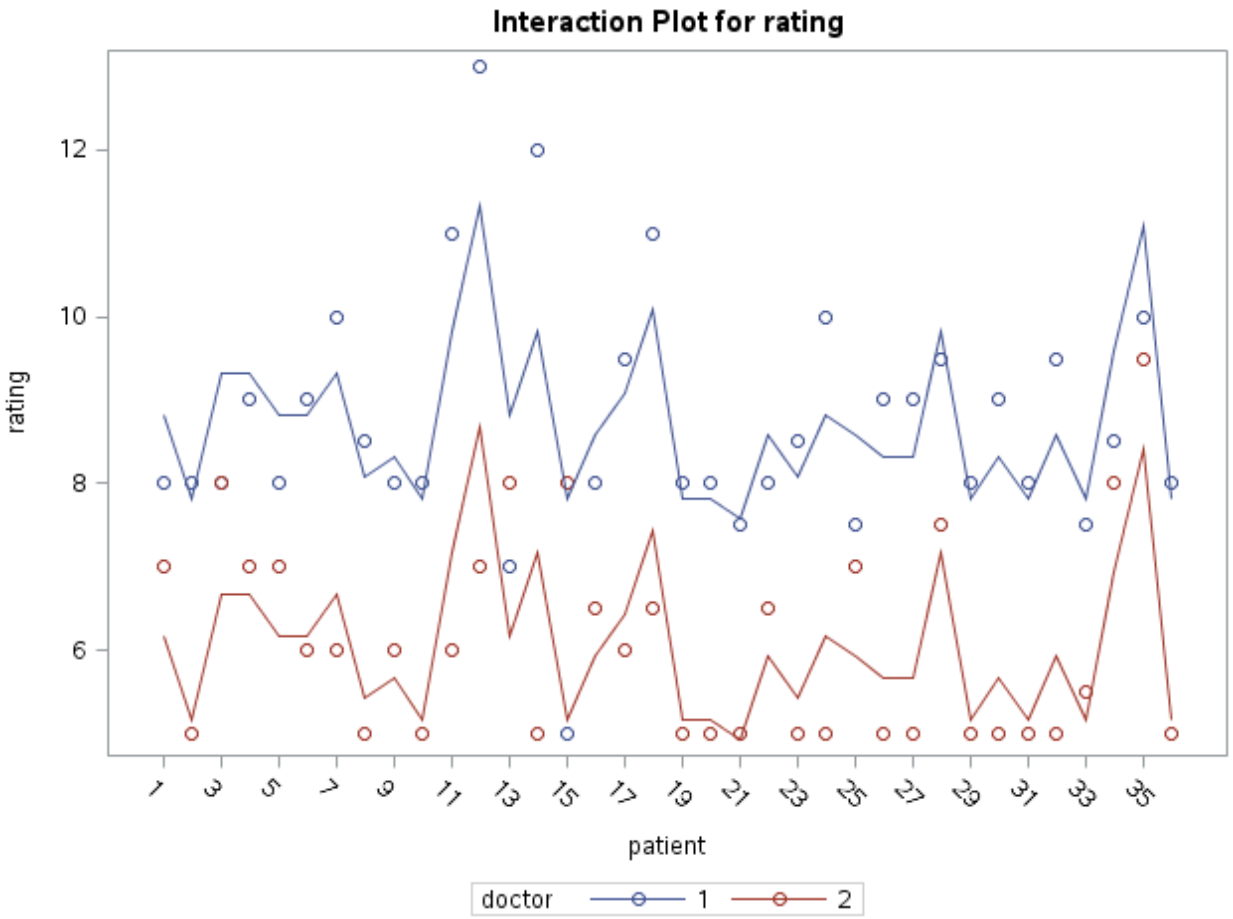


FIGURE 8 - INTERACTION PLOT FOR PHYSICIAN MEASURES



The plot lines found in the interaction plots above do not intersect at any point. Thus, one rater in both groups consistently under or overrated the JVP of the residents.

As previously outlined, some clinicians expressed a preference for a categorical classification of JVP. The normal interval for JVP is from 4 to 8 cm H_2O (Socransky et al., 2010) and from this, the interval created for low, medium and high levels are $0 <$ to ≤ 3, $4 \leq$ to ≤ 8 and ≥ 9 respectively. In this case, the reliability of the variable by physicians and nurses can also be analyzed using the level of agreement and a weighted kappa as shown is TABLE 7 and 8 respectively.

TABLE 7 - INTERRATER AGREEMENT FOR CATEGORICAL CLASSIFICATION

	Nurse 1			
Nurse 2		Low	Normal	High
	Low	7	7	0
	Normal	0	4	0
	High	4	5	9

	Physician 1			
Physician 2		Low	Normal	High
	Low	0	0	0
	Normal	0	18	17
	High	0	0	1

TABLE 8 - WEIGHTED KAPPA

	Weighted Kappa (95% CI)
Nurses	0.3903 (0.1956 - 0.5850)
Physicians	0.1104 (-0.0934 - 0.3143)

The findings reveal that inter-rater reliability of the numeric scale between the nurses was fair to good (TABLE 6). Conversely, the reliability between the physicians' measures was poor. The point estimate for ICC2 (A,1) was significantly different from 0 for the nurses but not for the physicians. For the collapsed, categorical scale, the nurse weighted kappa was 0.3903 (TABLE 8) which reflects fair to moderate agreement between measures while 0.1104 indicates very poor agreement (Altman, 1991).

CHAPTER 5

DISCUSSION AND CONCLUSION

The overall aim of this study was to conduct a preliminary evaluation of the feasibility and acceptability of using the Mespere Venous 1000 CVP System to measure JVP for the diagnosis and management of HF in primary care and LTC.

5.1 Discussion

The findings indicate that the acceptability, and perceived ease of use of the device were greater among the LTC clinicians than among the primary care clinicians. A number of reasons were identified.

Care processes in primary care appear to be still geared towards more expeditious disposition of patients with suspected HF, especially to the ED even though the transfers are sometimes unnecessary (Grumbach, Keane & Bindman, 1993). In primary care, care processes may be redesigned to facilitate management of complex conditions such as HF, in which case, the device might be seen eventually as more acceptable. In contrast, in LTC, where transfers of residents to the ED are seen less favorably, acceptability of the device is greater. The findings corroborate previous literature which has shown that LTC clinicians prefer to avoid sending residents to the ED (Heckman et. al, 2014). The differing views may be attributed to the awareness among LTC clinicians of the detrimental effects of unnecessary hospitalizations for older adults (Bail et al., 2015). The findings suggest that the Mespere Venous 1000 CVP System is perceived as an additional useful "vital sign" to help guide diagnostic decision-making in LTC.

Physicians in both settings expressed a concern as to whether nurses can use the device to reliably measure JVP. The results of Project ii indicate that the nurses' measurements were more

reliable than that of the physicians using the Lewis method, despite still being modest. Studies investigating inter-rater reliability of the JVP have used categorization of the measure. Findings using two different methods of ultrasonography to identify JVP found kappa values of 1.0 and 0.87 (Socransky et al., 2010), conferring substantially higher reliability than the weighted kappa obtained with the Mespere 1000 CVP System. Dichotomously identifying neck vein distension during physical examination has been shown to confer fair to good reliability at 0.71 (Maestre et al., 2009). Importantly, none of these studies was explicit in how variable categories were determined or measured. The need for clearer descriptions of how the JVP was measured in research studies reporting the variable has been acknowledged (Sankoff & Zidulka, 2008). These studies were conducted in ICU units and EDs on younger patients who were acutely ill. The likelihood of true positive cases of HF is greater in these settings than in the convenience sample of LTC residents who participated in this investigation. Therefore, the measurement of JVP in previous studies may have been easier due to the increased pressure and easily observable vein distension among acutely sick individuals, potentially inflating the reliability reported in those studies.

It has been recommended that for clinical practise, reliability of a measure should approach 0.95 (Streiner & Norman, 2009). This value was chosen arbitrarily and a value of 0.95 indicates that 95% of the variability is due to true variability while 5% is attributed to measurement error. Streiner & Norman specify that due to clinical measures leading to treatment options and diagnoses, a stringent cut-off is needed. However, the recommendation does not invalidate the findings of this investigation. Clinically, assessment of JVP is used in conjunction with other components of physical examination, history and investigative tests to diagnose and manage HF. Thus, the reference by Streiner and Norman may not hold true with regards to the

necessary reliability for the device measure. A convenient sample of residents who were otherwise stable was used for this investigation. In the event of suspected acute HF, it is likely that more residents would have elevated JVPs and thus reliability may be higher. The reliability in a sample of acutely ill residents would need to be demonstrated. The training protocol and practice session necessitate review to further investigate whether reliability can be improved. This was the first study to estimate the reliability of physician raters using numeric values obtained by the Lewis method in an older adult population, thereby, limiting the ability to compare to other reliability coefficients.

The findings reveal that additional perceived barriers in primary care appear to be related to the availability of equipment. Time constraints can be compounded by the difficulty in accessing mechanical examination tables but this may be specific to the primary care setting used in the study. These barriers were not perceived to be an issue in LTC. The nurses in LTC offered solutions to the patient centric barriers which included added care with the application of patches, and attempting to assess a patient multiple times because of agitation or uncooperative behavior which can sometimes be due to dementia. It should be noted that, although the prevalence of dementia in LTC is approximately 30% (Yu et al., 2012), it remains unclear how many of these residents would have behavioral concerns severe enough to impede the use of the device. To this end, the proposed solutions by the LTC nurses indicate their willingness to adopt the device, therein confirming acceptability.

Cost of the device was a concern for clinicians in primary and LTC settings. Currently, the equipment is priced at $10,000 but as is customary with new technology, it is expected to decrease over time. Considering that CIHI's patient cost calculator estimates that the average cost of a HF hospitalization without a coronary angiogram is $7,411 (CIHI, 2013), it can be

speculated that avoidance of a small number of hospitalizations may offset the cost of the device. However, this would need to be demonstrated in a large scale efficacy study.

The JVP measure was assessed by clinicians using visual observation in both settings with results interpreted categorically, rather than using absolute numbers. The findings showed that some RNs and NPs learnt of the measure during their formal education but in a non-clinical setting. Physicians cited that their experience with the maneuver was limited to internal medicine rotations during their clerkship years. For both settings, it seems as if the teaching provided during formal education may not fully translate to trainees and practice. The underutilization and varied skill to measure JVP potentially results from a theory-to-practice gap which has been a long-standing concern to nursing and medical educators, practitioners, and students (Hewison & Wildman, 1996 ; Bjørk, 1995). Qualified nurses have cited feeling unprepared for practice and often lacked confidence in their clinical abilities. Poor confidence has been linked to inadequate time dedicated to the refinement of clinical skills during training (Monaghan, 2015). Despite the progressively higher levels of formal education among participants, clinical skill and confidence surrounding the JVP did not seem to improve.

There was a difference in the perceptions of the LTC physicians and primary care clinicians towards the role of JVP in HF diagnosis and management. Primary care physicians expressed greater confidence in diagnosis than the LTC physicians and downplayed the importance of the JVP. Primary care physicians were also confident that their chronic HF patients were managed well due in part to a high degree of patient self-care. Previous studies have suggested that physical examination (Cook, 2010; Salcido, 2012) and especially the JVP are devalued (Garg & Garg, 2000) but none have attempted to quantify or describe the value of the JVP in primary care. The low diagnostic confidence of the clinicians in LTC is consistent

with existing literature (Hancock et al., 2014). The high confidence of the primary care physicians in this study may be attributed to their belief of appropriate practice despite relying on the ED. The appropriateness of transfers to and reliance on the ED by primary care clinicians remains unexplored. Nonetheless, a large number of ED cases relating to acute HF have been found to be avoidable as these patients are often not severely ill but instead have congestion due to worsening chronic HF, and require only symptomatic treatment (Collins et al., 2013). HF patients needing hospital based services not available in primary care, such as intravenous inotropic agents, mechanical circulatory support, hemodynamic monitoring, invasive diagnostic testing or intense therapeutic regimens account for a minority of admissions (Abraham et al., 2005; Adams et al., 2005 ; Gheorghiade et al., 2011). Other studies have confirmed that many patients who arrive in the ED were not in need of an acute intervention beyond decongestion (Fonarow et al., 2008 ; Weintraub et al., 2010). Avoidance of the ED is possible with the caveat that patients receive timely and effective care in the community (Collins et al., 2013). Furthermore, any follow-up by the family physician for a patient transferred to the ED would be hinged upon the opinion of another physician, potentially complicating the management of the patient.

Essentially, LTC physicians are also family physicians and would have therefore undergone similar formal training. Despite their lower confidence in diagnosing HF, the LTC physicians in this study were more experienced than the primary care clinicians. The discrepancy in experience suggests that the primary care physicians may be overconfident in their abilities. A study of general practitioners in the UK found that diagnostic overconfidence was independent of diagnostic accuracy and case difficulty, potentially preventing physicians from reconsidering treatment and disposition options for their patients (Meyer, Payne, Meeks, Rao & Singh, 2013).

This notion could hold true for the sample of primary care clinicians in this study. Notwithstanding, they dismissed JVP which specialists have stated is useful in diagnosis.

The high diagnostic confidence found in primary care may be biased as the clinic involved in the study had an adjoining HF program. Although the assessment of clinical skill knowledge was not an objective of this study, secondary findings were consistent with a knowledge gap surrounding the clinical significance of the measure.

5.2 Strengths and Limitations

Acceptability, perceived ease of use of the device, and barriers to its implementation were evaluated through the perceptions of clinicians in primary care and LTC. Assessing perceptions from both care settings contributed in validating the findings. The findings provide an opportunity for additional research to be conducted to address potential barriers and/or facilitators for implementing the device in LTC where it was found to be more acceptable. Furthermore, this was the first study to investigate perceptions and reliability of a JVP measuring device in primary care and LTC. The use of qualitative and quantitative data in this study is unique in that it allowed for the interpretation of perceptions towards the device while providing insight into the reliability of the measure.

There were a few limitations to the study. The focus groups in primary care and LTC were conducted at single sites. This could have biased the results and affected the ability to generalize findings to other clinical settings. A kappa statistic was not calculated for the thematic analysis of qualitative results. Due to a restriction on time and resources, a second coder confirmed the initial codes as opposed to independently coding the transcripts. This may bias the themes that emerged and disproportionately influenced the qualitative findings. For Project ii, excluding residents with a CPS score of greater than or equal to 2 introduces selection bias into the sample

and limits the ability to generalize the reliability findings to a broader spectrum of LTC residents. However, ethical obligations were contingent upon a resident having sufficient cognitive ability to provide informed consent in order to participate in the study. Not all residents with a CPS score of greater than 2 would have been unexaminable.

The physicians' measures for the quantitative component were taken within a 48 hour interval. The stability of the JVP measure has not been formally investigated but given its many determinants, the variable could have inherently changed over this time frame. This would have produced unaccounted variation and could have skewed the results. However, despite this interval, most residents were stable and it would have been unusual for a large proportion to have had adjustments to diuretic dosage.

5.3 Recommendations

Based on the findings of this study, four recommendations are suggested. Some stem from an individual project while others are data triangulated and are based on both components of the investigation.

With reference to the JVP measure, the following are suggested:

(i) Provide clinicians with resources to make them aware of the importance of JVP to diagnose and manage HF;

Recommendations relating to the Mespere Venous 1000 CVP System include:

(ii) Determine how to improve device reliability, potentially through a more rigorous training module;

(iii) Conduct a cost-effective analysis for usage of the Mespere CVP 1000 System in primary care and LTC settings; and

(iv) Explore alternate uses of the device, namely as a teaching tool.

5.4 Conclusion

Many clinicians did not appreciate the importance of the JVP and if they did, were not comfortable with its assessment. The most popular method of assessment was visual observation which can lead towards considerable variability and subjectivity surrounding the measure. The Mespere Venous 1000 CVP System was perceived as more acceptable in LTC and provided numerous benefits as recognized by the clinicians. Furthermore, the measures obtained by the device provided a more reliable measure of JVP than the Lewis method in LTC. Thus, the potential of the device to improve diagnostic accuracy and reduce hospitalization through better management warrants further investigation. In primary care settings, enhanced care processes for diagnosis and management of HF may lead to acceptance of the device.

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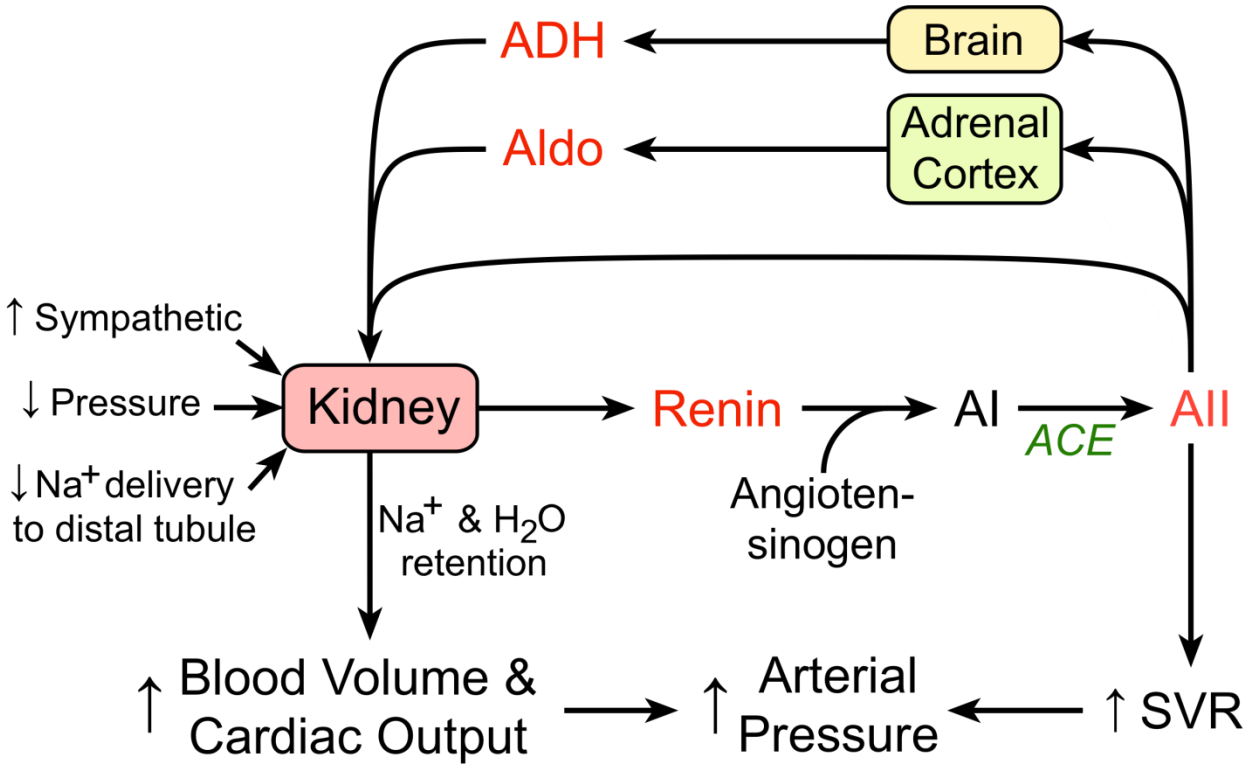
APPENDICES

APPENDIX i

Renin-Angiotensin-Aldosterone Activation



APPENDIX ii

Minnesota Living with Heart Failure Questionnaire
Did your heart failure prevent you from living as you wanted during the last month by: 1. causing swelling in your ankles, legs, etc.? 2. making you sit or lie down to rest during the day? 3. making your walking about or climbing stairs difficult? 4. making your working around the house or yard difficult? 5. making your going places away from home difficult? 6. making your sleep at night difficult? 7. making your relating to or doing things with your friends and family difficult? 8. making your working to earn a living difficult? 9. making your recreational pastimes, sports, or hobbies difficult? 10. making your sexual activities difficult? 11. making you eat less of the foods you like? 12. making you short of breath? 13. making you tired, fatigued, or low on energy? 14. making you stay in a hospital? 15. costing you money for medical care? 16. giving you side effects from medicine? 17. making you feel you are a burden to your family or friends? 18. making you feel a loss of self-control in your life? 19. making you worry? 20. making it difficult for you to concentrate or remember things? 21. making you feel depressed?

Source: (Rector and Cohn, 1992)

APPENDIX iii

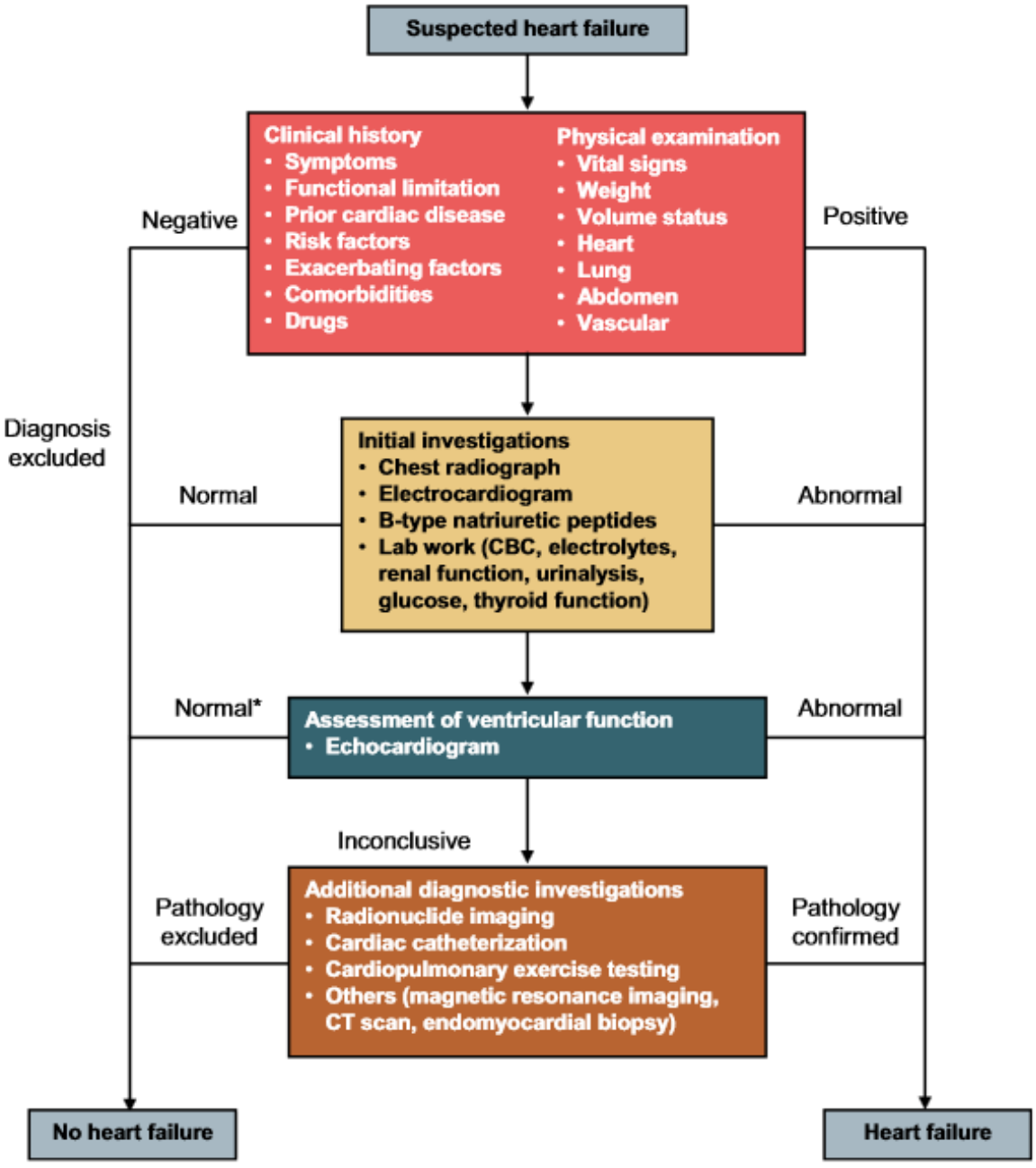
PRIDE clinical scoring system for Acute Heart Failure

Predictor	Odds Ratio	Score
Age (>75 years old)	2.7 (95% CI 1.4 - 5.2)	1
Lack of cough	2.3 (95% CI 1.2 – 4.3)	1
Current loop diuretic (before presentation)	3.4 (95% CI 1.8 – 6.4)	1
Rales on lung exam	2.4 (95% CI 1.2 – 4.7)	1
Orthopnea present	9.6 (95% CI 4.0 – 23.0)	2
Lack of fever	6.0 (95% CI 2.0 - 18.0)	2
Interstitial edema on chest x-ray	11 (95% CI 4.5 – 26.0)	2
Elevated NT-proBNP (≥ 450 pg/mL if age ≤ 50 years and ≥ 900 pg/mL if age ≤ 50 years)	44 (95% CI 21.0 - 91.0)	4

Source: (Baggish et al., 2006)

APPENDIX iv

CCS Algorithm for diagnosis of Chronic Heart Failure



Source: (McKelvie et al., 2012)

APPENDIX v

Device Protocol

STEP 1:
Find the right external jugular vein (EJV)

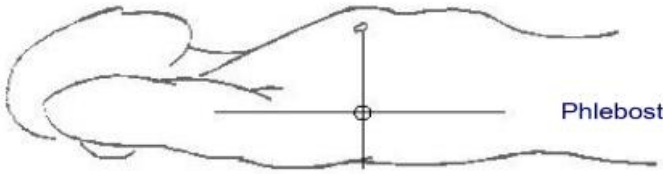
- On the patient, identify the right-side external jugular vein by pressing down on the vein just above the clavicle.

STEP 2:
Neck Patch Placement

- Have the patient position their head such that they are looking straight and do **not** have their neck tilted or twisted. Make sure that the neck is relaxed and it is not strained or tense.
- Position and adhere the Neck Patch to the patient's skin such that it is aligned with the patient's EJV and the orientation arrow is pointing towards the head.

STEP 3:
Reference Patch Placement

- Carefully place the Reference Patch on the patient at the phlebostatic axis (4th intercostal space & midaxillary line)

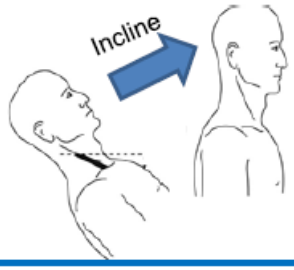


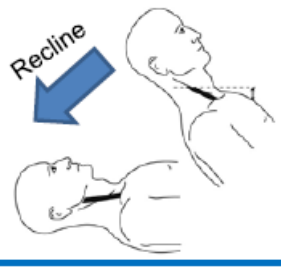
STEP 4:
CVP Measurement

- Start the patient at a 30-45 degree angle.
- Press the Start button located on the right-hand side of the Handheld.
- A CVP number and waveform should display shortly.

STEP 4A:
CVP Measurement – Incline or Recline Patient Angle

- If prompted by the Handheld:
  - **incline** the patient by increasing their angle towards a sitting up position,
  - **recline** the patient by decreasing/lowering their angle towards a lying down (supine) position.
- Wait 10 seconds after each angle adjustment to obtain a CVP number and waveform





APPENDIX vi

Consent Form

By signing this consent form, you are not waiving your legal rights or releasing the investigator(s) or involved institution(s) from their legal and professional responsibilities.

I have read the information presented in the information letter about the session being facilitated by *Vishaka Chetram* for Dr. George Heckman, Associate Professor, School of Public Health and Health Systems and Dr. Veronique Boscart, Adjunct Professor. I have had the opportunity to ask the facilitator any questions related to this session, to receive satisfactory answers to my questions, and any additional details I wanted. I am aware that I may withdraw from the session without penalty at any time by advising the facilitator of this decision. In appreciation of my time given to this session I am aware that I will receive a $5 gift certificate.

This project has been reviewed by, and received ethics clearance through a University of Waterloo Research Ethics Committee. I understand that if I have any comments or concerns resulting from my participation in this study, I may contact the Director, Dr. Maureen Nummelin in the Office of Research Ethics at 1-519-888-4567, Ext. 36005 or maureen.nummelin@uwaterloo.ca

This study has also been reviewed and received ethics clearance through the Conestoga College (CCITAL) Research Ethics Board.

If you have questions regarding your rights as a research participant, contact:

Research Ethics Coordinator
Conestoga College Institute of Technology and Advanced Learning
299 Doon Valley Drive, Kitchener, ON, N2G 4M4
rebcoordinator@conestogac.on.ca

With full knowledge of all foregoing, I agree, of my own free will, to participate in this session and to keep in confidence information that could identify specific participants and/or the information they provided.

_____

Print Name

_____

Signature

Recruitment Letter

Note: this letter will be distributed by administrators to recruit potential participants on behalf of the researchers

Hello staff members/students,

The following letter is being distributed on behalf of the researchers at the University of Waterloo.

My name is Vishaka Chetram and I am a graduate student in the School of Public Health and Health Systems at the University of Waterloo. I am currently conducting a research project for my Master's thesis under the supervision of Dr. George Heckman. Dr. Veronique Boscart is a co-investigator for the project and is a Schlegel Research chair at the University of Waterloo and a faculty member with Conestoga College.

I am seeking nurses/physicians/trainees to conduct a usability analysis on a point of care device to measure jugular venous pressure and its' utility in diagnosing Heart Failure in your care setting. You will be asked to observe a demonstration of the device, have a brief trial period and then participate in a guided focus group designed to assess usability, perceived barriers and feasibility. The session will take approximately 2 hours. For your participation in the study, lunch will be provided and you will receive a $5 Tim Horton's gift card. I want to reassure you that this study has been reviewed by and received ethic clearance through a University of Waterloo Research Ethics Committee and the Conestoga College Research Ethics Board.

If you are interested in participating, please contact me at vkchetram@uwaterloo.ca with your expressed interest. I will provide you with further information about the study and let you know the location and time of the focus group. I am open to answering any questions you may have. Please note that your choice to participate is entirely voluntary and I understand if you are not interested or your schedule does not fit these sessions.

Thank you.

Vishaka Chetram
School of Public Health and Health Systems | University of Waterloo

APPENDIX vii
Focus Group Guide

Completed by RA: _____
Other:_____
Date:_____
Faculty – LTC Staff - Group #_____
Focus groups (n=2 staff groups and n=2 faculty groups)
Week 1

Introduction
Thank you for participating in the study. We appreciate your comments and thoughts in relation to the study.

1. Start with overview of study and objectives of focus groups
2. Explain consent and audio tape procedures
3. Start audio tape (state date and focus group number)

Focus Group Questions
Measuring the height of the jugular vein is a useful way to determine whether a person might have heart failure. If the jugular vein is elevated, this suggests that the resident has an elevated central venous pressure and might be retaining fluid, as might occur in heart failure. If it is low, this suggests that the resident might be dehydrated. Mespere Life Sciences has developed a portable device that helps measure central venous pressure in the external jugular vein. This device could be useful to assess patients with suspected heart failure in primary care and LTC settings by nurses in these settings.

I would like to discuss some of your beliefs and perspectives to better understand your view on the device. In this focus group, we will discuss your thoughts on the use of a device as an assessment tool to assess residents/patients for possible heart failure.

Note: There may be variations and omissions in the questions depending on the progress of the study and the responses from the participants.

Perceptions of Device

1. What problems have you encountered that you feel are barriers for assessing suspected heart failure in long term care/primary care?

2. What role do nurses play in assessing long term care/primary care residents/patients with suspected HF?

    a. How comfortable are you in your ability to assess a resident/patient with suspected heart failure?
        i. How well do you understand jugular venous pressure measurement?
        ii. Do you assess the jugular vein on a regular basis? What challenges do you face in doing so?

b. How comfortable are you informing a colleague or a physician about a resident/patient you suspect might have heart failure?

3. Do you think that the Venus 1000 might have a role in assessing LTC residents/ primary care patients with suspected HF?
    a. How comfortable do you feel in using the device?
    b. If the device were to be adopted for use in the LTC/primary care setting for this purpose, what barriers might be encountered? When? Where? How? How often? With whom?
    c. How would the information obtained from the device be used in care planning?
    d. What processes could be put in place to guide and support this process?
    e. How long do you think new implementation of this device in your care setting would take?

4. Do you foresee any positive or negative outcomes of this device on resident/patient outcomes? Staff or facility/practice outcomes? Do you foresee these outcomes/consequences as long-term or short term?

5. In what other ways might this device help nurses improve care to older adults?

6. Do the benefits of the device outweigh the costs (about $8000.00) associated with it?

Closing Focus Group

I would like to thank you for your input and perspectives. Are there any other comments you would like to make or stories you would like to share?

Thank you.

APPENDIX viii

Feedback Letter

Hello,

Thank you for participating in our study. Your insight has been incredibly valuable and very much appreciated by our research team. The purpose of our study is to conduct an acceptability, perceived barriers and usability assessment of the Venus 1000 CVP System for two applications:

1..Use of the device as an assessment tool to measure the JVP of patients in primary care and LTC settings by registered nursing staff in these settings;

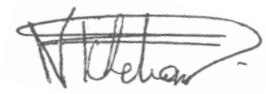
2..Use of the device as a teaching tool to detect and measure the JVP to help train nursing students and family medicine residents.

As a reminder, all information collected during this study, will be kept confidential and will not be shared with anyone outside the study unless required by law. You will not be named in any reports, publications or presentations that may come from this study. We will not make public anything that might identify you or your family, unless legally required to do so. Your name will be removed and replaced with a coded number to protect your identity. Only the research staff at the University of Waterloo will have access focus group transcripts and data. A summary of the results of the study will be provided to the sponsor, Mespere Life Sciences.

If you have any questions, concerns or would like to speak to the study team for any reason, please contact Vishaka Chetram, BSc, Research Assistant at (519) 781-7864 and/or vkchetram@uwaterloo.ca . The anticipated completion date of the research report is October 31st, 2014 and you may request a copy by contacting Vishaka Chetram.

If you have any questions about your rights as a research participant or have concerns about this study, you may, as always, contact Dr. Maureen Nummelin, the Director, Office of Research Ethics, at 1-519-888-4567, Ext. 36005 or maureen.nummelin@uwaterloo.ca or the Research Ethics Coordinator at Conestoga College Institute of Technology and Advanced Learning,(CCITAL) by email at rebcoordinator@conestogac.on.ca. This project was reviewed by, and received ethics clearance through a University of Waterloo Research Ethics Committee and the Conestoga College Research Ethics Board.

Thank you.



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APPENDIX ix

ICC Macro

```
%macro intracc(data=_LAST_,target=TARGET???,rater=RATER???,
            depvar=DEPVAR???,nrater=0,out=_DATA_,print=1);

title2 'Intraclass Correlations for Inter-Rater Reliability';
proc glm data=&data outstat=_stats_
  %if &print<3 %then noprint; ;
  * use glm to get sums of squares for use in reliability calculation;
  class &target &rater;
  model &depvar = &target &rater ;
  run;

proc sort data=_stats_;
  by _name_ _SOURCE_;
  run;

%if &print>=2 %then %do;
proc print data=_stats_;
  title3 'Statistics from 2-way ANOVA w/o Interaction';
  run;
%end;

data &out;
  title3 'Calculate all reliabilities in one fell swoop';
  retain msw msb wms ems edf bms bdf jms jdf k;
  set _stats_;
  by _name_;
  if upcase(_type_)='SS1' then delete;
  if upcase(_source_)='ERROR' then do;
     ems=ss/df;
     edf=df;
  end;
  if upcase(_source_)="%upcase(&target)" then do;
     bms=ss/df;
     msb=bms;
     bdf=df;
  end;
  if upcase(_source_)="%upcase(&rater)" then do;
     jms=ss/df;
     jdf=df;
     k=df+1;
  end;
  if last._name_ then do;
```

```
   msw=((ems*edf)+(jms*jdf))/(edf+jdf);
   wms=msw;
   n=bdf+1;
   theta=(msb-msw)/(k*msw);              * used in Winer formulae;
   wsingle=theta/(1+theta);             * Winer ICC(1,1);
   wk=(k*theta)/(1+k*theta);             * Winer ICC(1,k);
   %if &nrater %then %do;
   wnrater=(&nrater*theta)/(1+&nrater*theta); * Winer reliability
                                  if mean of nraters;
   %end;
   sfsingle=(bms-wms)/(bms+(k-1)*wms);      * ICC(1,1);
   sfrandom=(bms-ems)/
      ((bms)+((k-1)*ems)+((k*(jms-ems))/n)); * ICC(2,1);
   sffixed=(bms-ems)/(bms+((k-1)*ems));     * ICC(3,1);
   sfk=(bms-wms)/bms;                    * ICC(1,k);
   sfrandk=(bms-ems)/(bms+((jms-ems)/n));    * ICC(2,k);
   sffixedk=(bms-ems)/bms;               * ICC(3,k) with no
                                  interaction assumption;
   output;
  end;
  label wsingle="Winer reliability: single score"
       wk="Winer reliability: mean of k scores"
       %if &nrater %then %do;
       wnrater="Winer reliability: mean of &nrater scores"
       %end;
       sfsingle="Shrout-Fleiss reliability: single score"
       sfrandom="Shrout-Fleiss reliability: random set"
       sffixed="Shrout-Fleiss reliability: fixed set"
       sfk="Shrout-Fleiss reliability: mean k scores"
       sfrandk="Shrout-Fleiss rel: rand set mean k scrs"
       sffixedk="Shrout-Fleiss rel: fxd set mean k scrs";
run;

%if &print %then %do;
proc print label;
  id _name_;
  var msw msb wms ems edf bms bdf jms jdf k theta
     wsingle wk %if &nrater %then wnrater;
     sfsingle sfrandom sffixed sfk sfrandk sffixedk;
run;
%end;

%mend intracc;
```