ASSESSMENT OF THE ACCURACY OF THE DIAGNOSIS FOR HEART FAILURE IN A LARGE METROPOLITAN HEALTH CARE SYSTEM

by

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Abstract

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Purpose: There has been no significant improvement in heart failure (HF) readmissions regionally or nationally in the United States over the past decade. Additionally, there is no consensus nationally on defining the complex disease state of HF. This study retrospectively describes the accuracy of HF diagnoses in an adult HF patient population in a large metropolitan hospital setting. It also compares readmission rates between patients who were accurately diagnosed for HF versus those who were inaccurately diagnosed.

Methods: A retrospective record review (N = 712) was performed at a large metropolitan health care center in North Texas from January 2012 to December 2012. Patients with a reported primary diagnosis for HF were reviewed. Key patient variables were collected and analyzed to determine diagnosis accuracy. Thirty-day readmission rates were compared between accurately versus inaccurately diagnosed patients. Additionally, predictors for readmissions for either HF or non-HF–related causes were described.

Results: A total of 133 patients (18.7%) had a low probability of an accurate diagnosis. Additionally, having an inaccurate diagnosis was found to be predictive of being readmitted more frequently for *non-HF* causes ($P = 0.018$), as well as documented

arrhythmias (*P* = 0.0230). Patient age > 60 years was predictive for *non-HF* (*P* = 0.0059) and HF (*P* = 0.0179) readmissions. Documented sleep apnea (*P* = 0.0350), percutaneous coronary intervention (P = 0.0059), non-white race (*P* = 0.0466), and B-type natriuretic peptide > 400 (*P* = 0.0066) were predictive for HF readmissions.

Conclusions: In this cohort, 18.7% of patients admitted with a primary diagnosis of HF were determined to be inaccurately diagnosed. Moreover, an inaccurate diagnosis for HF resulted in patients being 2 times more likely to be readmitted for non-HF–related causes. An inaccurate diagnosis should be considered a determinant for all-cause readmissions in this patient population.

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Chapter 1

Introduction

Background and Significance

Approximately 5.7 million adults are reported to have heart failure (HF) in the United States, and another 25 million persons are reported to have HF worldwide (ACCF/AHA, 2013; Bui, Horwich, & Fonarow, 2011). Approximately 650,000 new cases of HF are diagnosed in the United States each year (ACCF/AHA, 2013). Additionally, an estimated one million hospitalizations occur with the primary diagnosis of HF every year in the United States (Gheorghiade & Pang, 2009). Among acute-care hospital *discharge* diagnoses, the HF diagnosis has tripled over the past decade. Beyond that staggering statistic, during the six months following a HF discharge, there is up to a 50% rate of readmission (Jencks, Williams, & Coleman, 2009).

Having a history of a HF hospitalization is associated with higher mortality due to a HF-related diagnosis. Moreover, frequent HF admissions coupled with shorter times between HF readmissions are also reflective of poor prognosis and increased HF related mortality (Setoguchi & Stevenson, 2009). The literature on HF admissions consistently supports the premise that there has been no significant improvement in HF readmission care either regionally or nationally in the United States over the past decade (Butler, et al., 2012). Contributing to this problem, there is no consensus nationally on how we are defining the complex disease state known as *heart failure* (Butler et al., 2012). Furthermore, inaccurate diagnosis of associated comorbidities mistaken for HF will lead to increased HF-related mortality and morbidity, increased readmissions, and continued increases in health care costs (Butler et al., 2012).

Starting in 2013, the Center for Medicare & Medicaid Services (CMS) altered their payment policies by realigning financial incentives and bundling payments around

HF hospitalizations (Butler et al., 2012). Following an initial HF admission, there will be deductions in reimbursements for all cause readmissions within a 30-day window (Butler et al., 2012). If a hospital's risk-adjusted 30-day readmission rate exceeds the national average, the CMS will penalize the hospital the following year by reducing Medicare payments relative to the cost of the readmissions above the national average (Berenson & Shih, 2012).

Significant disparities exist between evidence based guideline recommendations and treatment regimens for both hospitalized and ambulatory HF patients (ACCF/AHA, 2013). Specifically, provider non-compliance with guideline recommendations and treatments create an environment that may lead to inaccurate diagnosis (ACCF/AHA, 2013). Additionally, diagnostic accuracy will continue to be difficult with the increased prevalence of HF with a normal ejection fraction (EF). Found most frequently in the elderly female, the diagnostic approaches that identify diastolic dysfunction or HF with preserved EF (HFpEF) have a varying degree of reliability (Young, Shoemaker, Kurtz, & Lenihan, 2012). Additionally, *any patient*, but more frequently in the elderly patient with associated comorbidities can often present with HF symptoms yet not have HF (Manzano et. al, 2012). Moreover, underuse of diagnostic testing, i.e., echocardiography, will be encouraged in the setting of decreased reimbursements mandated by the CMS in preparation for the Affordable Care Act law changes (Manzano et. al, 2012).

There are little recent published data regarding the accuracy of the documented diagnosis of HF at hospital discharge (Kumler et. al, 2008). All current data in the United States support the contention that the primary diagnosis that is documented as HF is HF. The primary aim of this study will be to assess the accuracy of diagnosis in patients discharged with a primary diagnosis of HF. Additionally, a secondary aim will be to

compare the readmission rates of patients accurately diagnosed to patients who were not accurately diagnosed.

Theoretical Framework

Heart failure's pathophysiological mechanisms are not completely understood. There are multiple theories that have attempted to explain the condition and its progression. No single theoretical framework exists to explain the pathogenesis of HF. However, the most accepted of those proposed include the following theories: hemodynamics, neurohormonal mechanisms, inflammatory responses, and diastolic dysfunction (MacIver, Dayer, & Harrison, 2012).

Hemodynamic Theory

In the late nineteenth century, Otto Frank found that, immediately before contraction, ventricular contraction strength was increased when the ventricle was stretched in frog hearts (Klabunde, 2007a). In the early twentieth century, Ernest Starling and colleagues discovered that increasing venous return and filling pressures of the left ventricle led to increases in stroke volumes in dogs. These cardiac responses were found to be independent of any neural or humoral influences on the heart. This ability of the heart to increase the force of contraction with subsequent increases in stroke volume in response to venous return is presently known as the Frank-Starling law, Starlings law, or Frank-Starling mechanism (Klabunde, 2007b).

Cardiac output, a function of heart rate and stroke volume, is the volume of blood pumped by the heart per minute (Doohan, 2000). Initial stretching of the cardiac muscle cells (myocytes) is defined as preload, and is related to sarcomere length (Weil et al., 1998). Sarcomeres are repeating micro-anatomical units that provide the ability of the myocyte to contract (Klabunde, 2012a). The relationship of the ability of the heart to respond to enhanced preload, with an increase in cardiac output, is expressed on the

Frank-Starling law. In chronic HF, the Frank-Starling mechanism is exhausted. Elevation of filling pressures cannot maintain stroke volume. Cardiac output along with its regulation is compromised due to the heart's inability to maintain stroke volume without assistance (MacIver & Dayer, 2012).

The hemodynamic hypothesis proposes that HF progresses as a result of the hemodynamic stress triggered by an initial cardiac insult such as a myocardial infarction, resulting in detrimental effects on circulation (MacIver, Dayer & Harrison, 2012). Packer (1992a) states that any loss of healthy myocardium results in increased end-diastolic volume or pressure (preload). This increase then requires the heart to maintain stroke volume (afterload) with a reduced EF, (the amount, or percentage, of blood that is pumped [or ejected] out of the ventricles with each contraction (Heart Failure Society of America [HFSA], 2010). This phenomenon ultimately impacts the integrity of healthy myocardium, both functionally and structurally. Thus, a key assumption in the hemodynamic hypothesis is that the progression of HF is due to prolonged hemodynamic stress resulting in irreversible structural damage to the left ventricle (MacIver et. al., 2012). The left ventricle eventually loses its ability to empty during systole. The ventricle responds by increasing wall tension on healthy myocardium during diastole to enhance the contraction (Packer, 1992a).

In HF, the sympathetic nervous system (SNS) is activated when the ventricles are unable to pump blood into the aortic space. The SNS increases heart rate that initially improves the strength of contraction. Additionally, the sympathetic nervous system reduces venous capacitance and constriction of resistance vessels (Packer, 1992a). SNS stimulation of healthy myocardium results in an increase in the force and frequency of the ventricular contraction (Packer, 1992a). The sympathetic activation increases the delivery of calcium to the myofilaments of the heart muscles, whereas the

dilation of the ventricle increases the sensitivity of the myofilaments of the heart muscle to calcium (Packer, 1992b). These symbiotic compensatory mechanisms are different but work together in what has been termed the intracellular calcium-dependent inotropic pathway.

Neurohormonal Theory

The progression of HF is frequently characterized by the activation of compensatory neurohormonal mechanisms (Triposkiadis, Karayannis, Giamouzis, Skoulargis, & Butler, 2009). These neurohormonal mechanisms include a raised catecholamine level, over activity of the renin-angiotensin-aldosterone system (RAAS), and elevation of natriuretic peptides. Initially, these systems compensate for the depressed myocardial function; however, long-term activation leads to decompensation and subsequent deleterious HF progression (Triposkiadis et al., 2009).

Neurohormonal activation is the result of chronically decreased tissue perfusion (Heras, Castillo Rodriguez, & Navarro Gonzales, 2012). Perfusion to the tissues (e.g., brain and kidneys) in patients with HF is initially decreased only at exertion, eventually progressing to decreased perfusion at rest (MacIver & Dayer, 2012). The neurohormonal theory proposes that over-expression of pressor hormones, such as catecholamines, angiotensin II, and aldosterone, contributes to the progression of the disease. According to this theory, these endogenous neuro-hormonal systems are activated by an initial cardiac insult that, over time, results in detrimental effects on cardiac circulation (Packer, 1992b). A well-known regulator of blood pressure, the RAAS system is the primary neurohormonal system that is activated in HF. This coordinated hormonal cascade controls fluid, electrolyte balance, and arterial pressure. The RAAS also plays a major role in cardiovascular, renal, and adrenal function (Heras et al., 2012).

Along with the activation of the RAAS, the SNS signals the adrenergic system to release catecholamines (Schwinger, 2010). This flight-or-fight stimulation leads to increased myocardial contractility that often results in tachycardia and other arrhythmias. Over-activation of the RAAS ensues to counterbalance this phenomenon. Over-activation of the RAAS results in the retention of salt and water by the kidneys. This results in HF symptoms such as dyspnea and shortness of breath. The use of diuretics that aid to resolve these symptoms perpetuate a vicious circle of prolonged activation requiring more and more diuretics (Schwinger, 2010). The combined effects of the SNS and RAAS activation are therefore thought to worsen the myocardium's performance, causing remodeling of the left ventricle (MacIver et al., 2012). Both of these systems contribute to increased atrial distention, and over time are thought to exacerbate HF progression via secondary baroreceptor dysfunction (Packer, 1992b).

Additionally, in HF progression, endocrine system failures occur. Anabolic impairment, such as the inhibition of growth hormone, insulin resistance, and reduced androgen levels, are speculated to transpire in attempts to compensate for the over-expression of these hormones. The end result of this multi-system failure is apoptosis, or programmed cell death of the myocardium (Pugh et al., 2002). The main assumption of the neurohormonal hypotheses, therefore, is that the prolonged activation of both the SNS and the RAAS will have detrimental effects on the myocardium independent of any adverse hemodynamic actions of these systems (MacIver et al., 2012).

Inflammatory Response Theory

Cytokines are proteins, peptides, or glycoproteins used extensively in cellular communication. These substances are secreted by specific cells of the immune system and carry signals locally between cells, and affect other cells (Pugh et al., 2002). Cytokines are closely involved in mediating immune function. In recent years, it has been

suggested that chronic HF may be an inflammatory response. As inflammatory mediators, cytokines may play a crucial role in pathogenesis and progression of HF (Kosar et al., 2006).

Pugh et al. (2002) suggested that the cytokine hypothesis of HF was a logical progression of the neuro-hormonal model. HF progresses because of the triggering of cytokine cascades following a cardiac insult. T-cells found in HF patients are thought to significantly enhance the gene expression of tumor necrosis factor (TNF) and inflammatory cytokines (Kosar, Aksoy, Ozguntekin, Ozerol, & Varol, 2006).

First described in 1990, elevated circulating levels of TNF were discovered in patients with end-stage HF, specifically those with cachexia (Pugh et al., 2002). Cytokines such as TNF alpha (TNF-α), as well as interleukin (IL)–10 (or human cytokine synthesis inhibitory factor), and IL-6 are increased in patients with chronic HF. IL-10 and IL-6 play a crucial role in regulating immune and inflammatory responses (Yndestad et al., 2002). Associations of clinical severity of HF with circulating levels of TNF and IL-6 have been reported (Pugh et al., 2002). Additionally, higher levels of IL-6 are also thought to be associated with higher pulmonary wedge pressures (volume overload) as well as lower left ventricular EFs (LVEFs; Pugh et al., 2002).

The immune response in HF may be a secondary phenomenon in response to myocyte injury (Yndestad et al., 2002). The myocardium exerts control over myocyte clearance through cell death and removal. In HF, the immune activation occurs as a response to damage or substances that cause the damage, rather than a foreign substance. Over time, these same anti-inflammatory cytokines produce negative inotropic effects on the heart that are thought to result in hemodynamic abnormalities and a poor prognosis (Yndestad et. al., 2007).

Diastolic Dysfunction Theory

Diastolic HF or HFpEF is characterized by having HF symptoms yet having a preserved EF (> 50%). Based on Hope's Theory, diastolic dysfunction is thought to primarily stem from a lack of left ventricular compliance (MacIver & Dayer, 2012). In 1832, James Hope first proposed the Backward Failure Hypothesis. Hope contended that when the left ventricle fails to completely eject blood, blood accumulates in the left ventricle. This results in a backward flow phenomenon (Libby, Bonow, Zipes, & Mann, 2007). The cardiac muscle is flaccid due to an initial insult, and muscle fibers are unable to shorten against the pressure exerted from the residual blood accumulation. This results in increased ventricular end-diastolic volume and pressure. The increased blood volume within the heart and volume-induced pressure ultimately cause pressures to rise in the left atrium behind the failing left ventricle. This triggers another manifestation of the Starling law, the left atrium beating faster to augment normal cardiac output (Libby et al., 2007). The venous and capillary beds upstream also operate against this increased backward flow. This ultimately results in fluid leakage from the capillary beds into the interstitial spaces (pulmonary and/or systemic). Fluid leakage results in shortness of breath and/or peripheral edema in the patient (Libby et al., 2007).

An extension of this theory proposes that right ventricular failure is frequently a result of left ventricular failure. The prolonged elevation of diastolic dysfunction, left atrial pressures, and pulmonary venous pressures culminate in right ventricular failure. This concept suggests that this backward failure results in higher pressures in the pulmonary artery circulation and eventually plays a role in some forms of pulmonary hypertension (Libby et al., 2007).

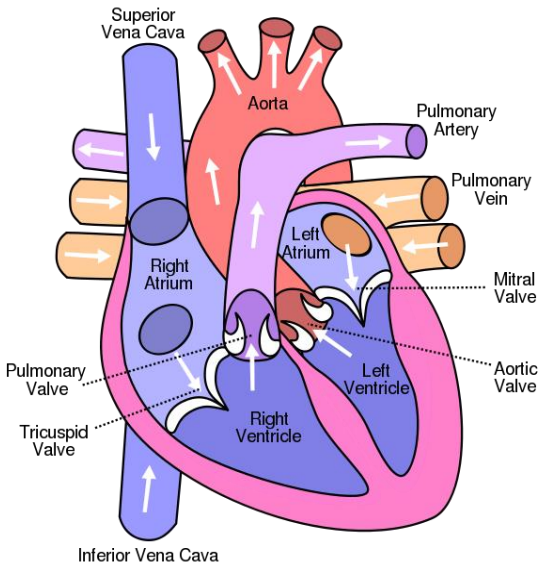


Figure 1-1 Circulation of blood through the heart

Clinical Decision Making

Clinical decision making comprises of primarily diagnosis and treatment plans. In order for the treatment plan to be correct, the diagnosis undoubtedly needs to be accurate. The diagnostic failure rate is estimated to be as high as 15% (Croskerry, 2013). The highest rates are reported among specialties in which the patient's diagnosis has multiple alternative diagnoses as frequently seen in HF (Croskerry, 2013). The principle cause for diagnostic error involves cognitive biases, logical fallacies, and other reasoning failures. Over a 100 biases affecting clinical decision making have been described in the medical disciplines (Croskerry, 2013). The presence of multiple comorbidities also increases the medical providers' uncertainty (Blecker et al., 2013). Uncertainty in diagnosis facilitates inaccurate documentation, which ultimately yields inaccurate accountability of HF admissions (Blecker et al, 2013). Moreover, unclear diagnosis systematically facilitates inappropriate or ineffective treatments of the actual presenting diagnosis, resulting in disparities in health care (Dovidio & Fiske, 2012).

Methods

The study was a retrospective cohort descriptive study. A random sample of 750 records of patients admitted over one calendar year from the Baylor Health Care System (BHCS; N=14 hospitals) in the Dallas/Fort Worth area were analyzed for the study.

Statement of the Purpose

The purpose of this study was to determine if clinical data recorded in the medical record supports the diagnosis of HF. This study also compared readmission rates between patients whose diagnosis was supported versus patients who did not have the documentation to support the diagnosis for HF.

Statement of Essential Assumptions

1. An accurate diagnosis of HF is possible if the clinical assessment, patient history, and diagnostic results (B-type natriuretic peptide [BNP], eechocardiogram) are documented in the patients' chart.

2. The documentation and data extracted from the chart will provide enough information to determine an accurate diagnosis of HF.

3. Supporting documentation will be included in a large percentage of patients' charts to determine the diagnosis of HF at discharge.

4. The providers who assign the medical diagnosis for the patients' discharge will have diverse methods of clinical assessment skills and documentation styles.

Summary of Chapter

Arguably HF is poorly defined as a syndrome and manifests itself differently among patients. Additionally, with the aging population and associated comorbidities, accurate diagnosis remains a challenge. Over the past decade, clinicians who manage HF have garnered access to more tools to facilitate the appropriate diagnosis, yet a plethora of literature on HF admissions consistently supports the premise that there has

been no significant improvement in hospital readmission either regionally or nationally over the past decade. Upon readmission, the etiology may be difficult to pinpoint, as sometimes the diagnosis of the purported *initia*l HF admission is not correct (Butler et. al, 2012). HF patients are more commonly being readmitted for non-HF causes (Butler et al., 2012). There is relatively little or recent published data regarding the accuracy of coding the diagnosis of HF at hospital discharge (Kumler et. al, 2008). All current data in the United States support the contention that the primary diagnosis that is documented as HF is HF. Inaccurate diagnosis of associated comorbidities mistaken for HF will lead to increased mortality and morbidity, increased readmissions, and continued increases in health care costs. Large retrospective health care record reviews such as this one could assist in deciphering inconsistencies and inaccuracies, especially when looking for specific confounders that correlate with increased readmissions in the HF patient.

Chapter 2

Literature Review

Definitions of Heart Failure

Heart failure is the impaired ability of the left ventricle to either fill or eject blood (Hunt et al., 2009). Despite the various origins of HF, left ventricular failure progresses in a similar pattern, a structural and functional disorder that begins with myocyte hypertrophy and fibrosis deposition, which culminates in left ventricular enlargement and remodeling (Hunt et al., 2009). HF is a chronic and progressive disease ultimately resulting in myocardial muscle dysfunction or loss (HFSA, 2010).

The term “heart failure” is the preferred name over the older term “congestive heart failure” (Hunt et al., 2009). The typical symptoms of HF usually include shortness of breath at rest or at exertion, fatigue, extremity edema, and/or abdominal edema (European Society of Cardiology [ESC], 2008). Additionally, the common physical signs of HF usually include tachypnea, pulmonary edema, pleural effusion, elevated jugular venous pressure, peripheral edema, and hepatosplenomegaly (ESC, 2008). Structural or functional evidence of HF can include arrhythmia, cardiac murmurs, third heart sound, abnormal echocardiogram, and elevated BNP concentration (ESC, 2008). Although HF is commonly described as a syndrome recognized by an assemblage of signs and symptoms, to date there is no agreement on one unequivocal definition of HF (Ingelsson, Amlov, Sundstrom, & Lind, 2005). However, a consensus can and should be made based on adequate documentation of clinical symptoms coupled with recommended diagnostic testing and interpretation that support cardiac dysfunction.

Systolic and Diastolic Heart Failure

Heart failure generally manifests itself in one of two types of left ventricular dysfunction, systolic or diastolic HF. Additionally, patients can suffer from both systolic

and diastolic HF simultaneously. HF, regardless of type, is usually associated with a myriad of left ventricular functional abnormalities. This continuum consists of patients with normal left ventricular size and preserved EFs, to patients with severe ventricular dilatation and reduced ejection fractions (EF < 50%; Hunt et al., 2009). Systolic and diastolic dysfunction can exist without clinical signs of HF, symptoms of low cardiac output, or congestion (Chatterjee & Massie, 2007).

Systolic HF (EF < 50%) is "a condition in which the heart fails to discharge its contents adequately" (Chatterjee & Massie, 2007, p. 570). This physiological cascade results in failure of the left ventricle to pump sufficient blood to accommodate the metabolic needs of the body (Chatterjee & Massie, 2007). Diastolic HF (EF > 50%), also referred to as diastolic dysfunction, in contrast, is the inability of the left ventricle to allow sufficient blood into the chamber during the diastolic phase. This prohibits appropriate stroke volume that is caused from ventricular stiffness and/or decreased relaxation (MacIver et al., 2012).

Etiologies of Heart Failure

Heart failure etiology is complex and can be caused by one or more of the myriad of causes. The etiologies are generally categorized into the following: 1) obstructive coronary artery disease (ischemia), 2) valvular heart disease, 3) hypertensive heart disease, and 4) other or unknown (idiopathic) etiologies (Butler et al., 2012; Lee et al., 2009). Many of these etiologies give rise to cardiomyopathies that ultimately trigger the actual HF event (National Heart & Blood Institute [NHLBI], 2011). In the Western world, obstructive coronary artery disease, hypertension, dilated cardiomyopathy, and valvular heart disease are the leading causes of HF (Hunt et al., 2009).

There are two types of cardiomyopathy, ischemic and non-ischemic. Obstructive coronary disease, especially in the setting of myocardial infarction, can lead

to ischemic cardiomyopathy (NHLBI, 2011). Non-ischemic cardiomyopathy is damage to the heart muscle that is *not* associated with interruptions to the heart's blood supply as seen in obstructed coronary disease. One of the most common forms of non-ischemic cardiomyopathy is dilated cardiomyopathy. Dilated cardiomyopathy is frequently the result of uncontrolled hypertensive disease, untreated valvular heart disease, and the other or idiopathic etiologies (NHLBI, 2011). In patients with dilated cardiomyopathy, approximately 10% have myocarditis (Hare, 1999). Viral infections that cause myocarditis often lead to chronic dilated cardiomyopathy. Additionally, 30% of patients with dilated cardiomyopathy may have a genetic etiology (Hunt et al., 2009). Frequently, systemic diseases such as rheumatologic disorders, metabolic disorders, toxic exposures (alcohol, illicit drugs, chemotherapy), and endocrinopathies may also result in a cardiomyopathy (Hare, 1999).

Peripartum cardiomyopathy, a rare form of dilated cardiomyopathy, typically presents in women during their last trimester of pregnancy (Saltzberg, Szymkiewicz, & Bianco, 2012). It has also been seen in women up to 6 months postpartum. The etiology for peripartum cardiomyopathy is still unknown but is thought to involve immune factors and/or inflammatory mediators (Saltzberg et al., 2012). During pregnancy, hormonal and hemodynamic changes facilitate the development of cardiomyopathy. A genetic component is thought to exist in patients having peripartum cardiomyopathy (Saltzberg et al., 2012). Only in a minority of patients is there a specific cause, eg, amyloidosis, hypertrophic cardiomyopathy, or sarcoidosis. Most experts agree, however, that peripartum cardiomyopathy is a form of dilated cardiomyopathy where no other cause of heart dysfunction can be identified (Butler et al., 2012).

Epidemiology of Heart Failure

Incidence and Prevalence

Approximately 5.7 million adults are reported to have HF in the United States, and another 25 million persons are reported to have HF worldwide (American College of Cardiology Foundation/American Heart Association [ACCF/AHA], 2013; Bui, Horwich, & Fonarow, 2011). Additionally, over 650,000 new cases of HF are diagnosed in the United States each year (ACCF/AHA, 2013). This trend has stabilized over the past several decades, but the incidence of HF increases with age, rising from approximately 20 per 1000 individuals in the 65-69-year-old age group to over 80 per 1000 in the over-85-year-old age group (ACCF/AHA, 2013). Over half of the new HF cases are in patients with a preserved LVEF (Bui et al., 2011). Alarmingly, patients aged > 40 years have a 20% lifetime risk of developing HF (ACCF/AHA, 2013).

Heart failure has its highest prevalence among black men, from 3.8% to 4.5%, compared with 1.8% to 2.7% in non-Hispanic white men and women (ACCF/AHA, 2013). The incidence of HF before age 50 in both black men and women is 20 times higher compared with white men and women (Bui et al., 2011). This is believed to be attributed to the higher rates of hypertension, obesity, and chronic kidney disease in the black population (Bui et al., 2011). Additionally, black patients have a greater 5-year case fatality rate than that of white patients, explained again by black patients having increased levels of atherosclerotic risk factors (Bui et al., 2011).

Although men and women are equally affected, HF is different in women. Women present later in life and are more likely to have HF with preserved EFs (ACCF/AHA, 2013). Additionally, women usually survive longer than men, but the exacerbations of HF are generally more severe compared with those of men (ACCF/AHA, 2013).

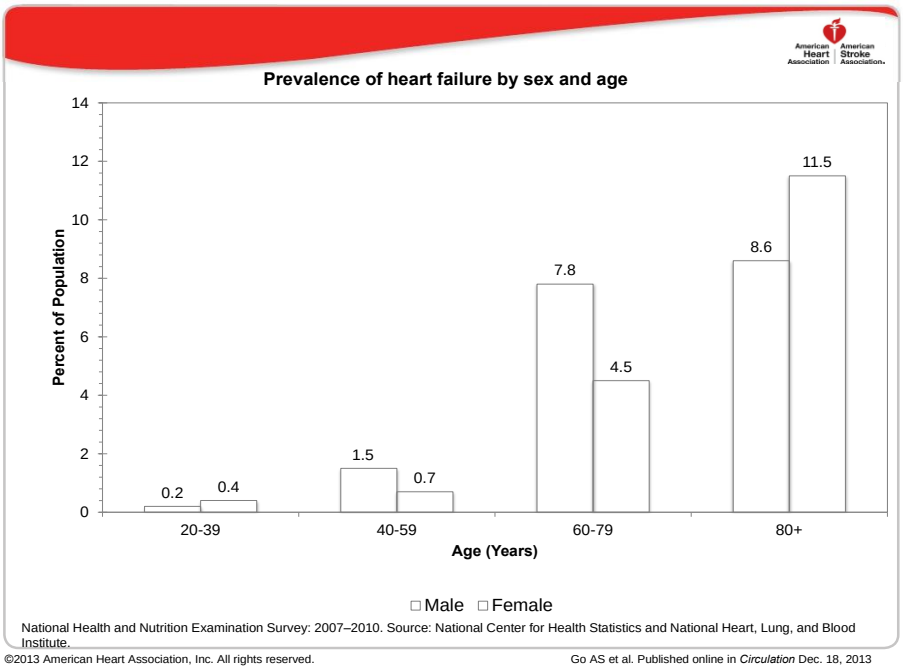


Figure 2-1 Prevalence of heart failure by sex and age

Heart failure is also a growing concern internationally. Researchers in developing nations suggest the etiology is non-ischemic, and patients are generally younger compared with patients in the United States (Stewart et al., 2008). Outcomes for these younger patients are poor, especially in countries where there are limited health care resources. Isolated right HF is more prominent, with suggested causes ranging from tuberculous pericardial disease to lung disease and pollution (Stewart et al., 2008).

This international trend is most likely multi-factorial, including greater awareness and diagnosis of HF, aging populations, increased incidence, and improvements with treatment of coronary artery disease (CAD)(Bui et al., 2011). Data for HF is scarce for most countries; therefore, accurate assessment of the disease burden is difficult. Although not well quantified, the prevalence of HF is expected to increase in developing countries in part from a shift from acute to chronic illness states, aging populations, and

the pervasiveness of HF risk factors such as hypertension, CAD, and obesity (Bui et al., 2011).

Mortality

Heart failure is listed as the primary cause of death for 20% of all deaths in the United States (Bui et al., 2011). The 30-day mortality for HF is estimated at 10%, and 1-year mortality is reported to be estimated 20%-30%. Although survival has improved, the absolute 5-year mortality has remained fairly constant over the past decade, ranging anywhere from 45% to 60%. Frequent hospitalizations are associated with worsening prognosis with subsequent higher mortality. In the ARIC (Arthrosclerosis in Communities) study, the mortality rates reported at 30-days, 1-year, and 5-years for HF after hospitalization were 10.4%, 22%, and 42.3% (ACCF/AHA, 2013).

Hospitalizations

An estimated one million hospitalizations with HF as the primary diagnosis occur every year in the United States (Gheorghiade & Pang, 2009). Among discharge diagnoses, the HF diagnosis has tripled over the past decade. From 1979 thru 2003, the number of reported HF discharges rose from 399,000 to 1,093,000, an increase of 174% (Aranda et al., 2009). During the six months following discharge, there is up to a 50% rate of readmission (Jencks, Williams, & Coleman, 2009). Having a history of a HF hospitalization is associated with higher mortality; however, frequent HF admissions and shorter times between HF readmissions are also reflective of poor prognosis and increased mortality (Setoguchi & Stevenson, 2009).

In the Medicare population, HF is the most common diagnosis associated with a 30-day readmission (Hernandez et al., 2010). In fact, one fifth of Medicare beneficiaries are re-hospitalized within 30 days, and over one third within 90 days. Most of these admissions could possibly be prevented, as 90% of these readmissions are unplanned

(Hernandez et al., 2010). There has been little to no improvement in preventing readmissions for HF within the Medicare beneficiary population. As recent as 2010, the national hospital-specific risk-standardized readmission rates were reported to persist at around 25% (Ross et al., 2010).

Economic Burden of Heart Failure

Costs associated with HF in the United States were estimated to be over $40 billion in 2012. This figure includes the cost of medications, healthcare–related services, and lost productivity (ACCF/AHA, 2013). A mean cost of $23,077 per patient was reported for HF hospitalizations in 2012, yet it was even higher in the patient who had HF as the secondary rather than the primary diagnosis (ACC/AHA, 2013). Additionally, HF outpatient visits account for 12-15 million office visits per year (Aranda et al., 2009). Health care provider office visits for HF management were reported to be over $1.8 billion in 2010 (ACCF/AHA, 2013).

The cost of HF makes up 20% of Medicare's hospital payments, or 17 billion dollars per year (Hernandez et al., 2010). Among the Medicare population, 80% of the hospitalizations are in patients who are aged > 65 years, resulting in the heaviest financial burden to Medicare (Bui et al., 2011). In fact, the costs surrounding HF management are unrivaled compared with any other disease process (Bui et al., 2011). Improved survival after myocardial infarction, better prevention of sudden cardiac death, and the aging population will likely increase this fiscal burden in HF patients (Gheorghiade & Pang, 2009).

Hospitals reacted to these economic pressures to contain health care costs by forcing reduction in length of stay (LOS) for HF (Steoguchi & Stevenson, 2009). Unnecessary hospital days have the potential to expose patients to iatrogenic injury such as hospital-acquired infections, as well as increased bed/day costs. However, hospitals

that forced reductions in LOS to five days for HF admissions had the highest all-cause one-space 30-day readmission rates (Steoguchi & Stevenson, 2009). Additionally, performance metrics that in the past looked at endpoints, such as LOS, have not demonstrated any improvement with patient outcomes (Butler et. al, 2012).

Internationally, developed countries expend 1%-2% of all their health care dollars on HF. In the United Kingdom, an estimated $39.2 billion dollars were spent on HF in 2010 (Bui et al., 2011). This estimate was reported to be most likely low as it only addressed HF as the primary diagnosis and ignored any secondary causes or associated comorbidities. Additionally, as in the United States, HF with preserved LVEFs will continue to consume as many health care resources as those with HF and reduced LVEFs (Bui et al., 2011).

Heart Failure Readmissions

To date, a primary diagnosis of HF accounts for over one million hospitalizations annually (ACCF/AHA, 2013). In the United States, over $40 billion is spent on HF management, with 50% of this cost is directed toward HF hospitalizations. The rate of readmissions within 30 days for any cause has consistently been over 25% for the past decade for patients with a HF diagnosis (ACCF/AHA, 2013).

Over the past decade, the decreased length of hospital stay for acute problems has resulted not only in increased readmissions for HF, but also in increased outpatient mortality. Outpatient mortality trends have increased from 4.3% to 6.4% from 1993 to 2005 (ACCF/AHA, 2013). These increases in mortality are attributed to more deaths in the hospital and the aging HF population transitioning from the hospital to skilled nursing facilities or home health (ACCF/AHA, 2013; Steoguchi & Stevenson, 2009). Although many policy makers bemoan the 30-day readmission as a quality measure, it has succeeded in hospitals paying attention to the poor transitional care and provider

fragmentation endured by many patients. Future efforts should incorporate patient-centered care that engages all providers of the care team with a special focus on front-line providers (Williams, 2013).

Hospital Readmissions and the Affordable Care Act

As an example of quality care improvement, the recently updated Hospital Compare (CMS, 2014) web site reveals that the national 30-day readmission HF have had limited, if any, improvement from 2007 through 2010. Therefore, payment incentives to avoid readmissions have been reported in the Department of Health and Human Services' strategic plan for 2010 through 2015 (Kocher & Adashi, 2011). Starting in 2013, the CMS altered their payment policies by realigning financial incentives and bundling payments around HF hospitalizations (Butler et al., 2012). Following an initial HF admission, there will be deductions in reimbursements for all cause readmissions within a 30-day window (Butler et al., 2012). If a hospital's risk-adjusted 30-day readmission rate exceeds the national average, the CMS will penalize the hospital the following year by reducing Medicare payments relative to the cost of the readmissions above the national average (Berenson & Shih, 2012). To date, the Hospital Readmissions Reduction Program has resulted in more than 2000 hospitals losing money in financial penalties for excessive HF readmissions in its first year. The penalties for those hospitals in 2012 are estimated to be over $300 million (Williams, 2013). These penalties are speculated to triple for some hospitals by 2014 under the provisions of the ACA (Williams, 2013).

Comorbidities

Comorbidities are strongly associated with HF readmissions (Shah, Rahim, & Boxer, 2013). Comorbidities influence prognosis, as well as increase the utilization of health care services (Edelmann, et al., 2011). Hypertension, chronic obstructive

pulmonary disease (COPD), atrial fibrillation, diabetes, anemia, ischemic heart disease, and renal disease are seen frequently in HF patients (Table 2-1; Edelmann et al., 2011). These disease states can either increase the risk of a symptomatic HF event, such as atrial fibrillation, or can be associated with an increased lifetime risk of experiencing HF, as in diabetes and ischemic heart disease, resulting in frequent repeat hospitalizations (Edelmann et al., 2011). Additionally, 38% of readmissions for patients with HF are non-cardiac in nature, the most common etiology being pneumonia (Shah, Rahim, & Boxer, 2013).

Chronic obstructive pulmonary disease is consistently one of the most significant independent predictor of a repeated HF admission, predominantly due to the similarities in the clinical presentation of the two disease processes (Hawkins et al., 2008). This frequently challenges the provider to determine if the etiology is a HF exacerbation or COPD exacerbation (Hawkins et al., 2008). Jugular venous distention, ankle edema, hepatomegaly, and signs of right ventricular failure can be misleading in patients with COPD. Hyperinflation of the lung with hepatic displacement mimics right HF and alternatively can obstruct auscultation of crackles or a third heart sound in HF exacerbations, complicating HF diagnoses for admissions and readmissions (Hawkins et al., 2008).

Comorbidities also play a larger role in HF with preserved EF compared with HF with reduced EF, as the proportion of non-cardiovascular readmissions is higher in this patient population (Desai & Stevenson, 2013). In the over-75-year age group, comorbidities frequently contribute to and precipitate the pathophysiology of the sequelae of a HF exacerbation, thereby leading to more hospital admissions (Manzano, Escobar, Cleland, & Flather, 2012). However, what triggers the precipitating event that leads to hospitalization has been ill defined (AHA, 2009).

Table 2-1 Most common co-occurring chronic conditions among Medicare beneficiaries with HF (ACCF/AHA, 2013)

Chronic Condition	Beneficiaries Age > 65 Years, n (%)	Beneficiaries Age < 65 Years, n (%)
Hypertension	3,685,373 (84.2)	461,235 (80.7)
Ischemic Heart Disease	3,145,718 (71.9)	365,889 (64.0)
Hyperlipidemia	2,623,601 (60.0)	325,498 (56.9)
Anemia	2,200,674 (50.3)	284,102 (49.7)
Diabetes	2,027,875 (46.3)	338,687 (59.2)
Arthritis	1,901,447 (43.5)	201,964 (35.3)
Chronic Kidney Disease	1,851,812 (42.3)	257,015 (45.0)
Depression	–	207,082 (36.2)
COPD	1,311,118 (30.0)	191,016 (33.4)
Atrial Fibrillation	1,247,748 (28.5)	–
Asthma	–	88,816 (15.5)
Alzheimer's Disease/Dementia	1,207,704 (27.6)	–

Abbreviations: COPD = chronic obstructive pulmonary disease; HF = heart failure

Patient Adherence

Poor patient adherence has historically been reported as a significant contributor to HF readmissions (ESC, 2008). Patient adherence to treatment regimen is variable, and estimated to be between 10% and 85% over the past decade (Clark et. al, 2012). The reasons for this variability are multifactorial. Historically, patients frequently report either having difficulty understanding or misinterpreting self-care instructions on medications, low-sodium diet, fluid restrictions, or exercise (ESC, 2008). Additional factors such as lower socioeconomic status, minority status, psychosocial variables, and younger age have also been associated with low adherence (Clark et. al, 2012).

Patient adherence in both pharmacological and non-pharmacological regimens is one of the biggest challenges for providers who manage HF. In the hospital setting, documentation of discharge instructions has been mandated and widely assumed to be effective (Hernandez, 2010). This mandate has not proven to be consistent with

improved patient follow-up care, nor has it been correlated with improved readmission rates. Discharge instructions have become a rote process and do little to address patient education, to improve adherence, or to successfully transition the patient into an outpatient management setting (Hernandez et al., 2010). There is also a low rate of early follow-up care across US hospitals.

Early follow-up care needs to be integrated into HF performance measures; however, patients with limited or no insurance scheduled for outpatient follow-up at discharge fail to comply due to out-of-pocket costs (Bradley et al., 2012). These patients, in turn, wait to become symptomatic and present to the emergency room with an acute HF exacerbation. As the disease in these patients progresses, more exacerbations result in more readmissions and subsequent greater lengths of stay (Bradley et. al, 2012). Frequently, the emergency room serves as a source of follow-up care; up to 40% of all post-discharge HF patients present for acute care within 30 days (Williams, 2013). This not only compounds the emergency room crowding but too often results in readmissions that could have been avoided if the patient had followed up in an outpatient clinical setting (Williams, 2013).

Provider Adherence

Provider non-adherence to HF recommended guidelines also contributes to readmissions (Calvin et. al, 2012). Extensive clinical trials have demonstrated adherence to recommended national guidelines for HF management improve outcomes; however, evidence-based medicine historically is adopted slowly (Fonarow et. al, 2010). Additionally, patients are currently seeing more providers, increasing the likelihood of medical errors, duplication of efforts, reduction in quality, all of which result in increased and repeated admissions for chronic disease states such as HF (Williams, 2013).

In Calvin et al.'s (2012) recent study looking at physician adherence (N = 692), only 63% of the physicians prescribed the evidence-based HF medications to their patients ($P < 0.001$). Additionally, four multivariate predictors of physicians' non-adherence to evidence-based recommendations were discussed based on these patient characteristics:

- Mean age, ≥ 62 years (odds ratio [OR], 1.02; 95% [CI], 1.00-1.03; $P < 0.016$)
- Patients were sicker, at least New York Heart Association (NYHA) class III, unable to walk 620 feet on a 6-minute walk test (OR 1.64; 95%[CI] 1.17-2.30; $P < 0.004$);
- Patients had comorbid conditions of asthma and renal disease (OR, 1.11; 95% CI, 1.01-1.22; $P < 0.030$);
- Patients were also more likely to be low-educated ethnic minorities (OR, 1.81; 95% CI, 1.28-2.30; $P < 0.001$).

Sicker patients (patients with comorbidities and NYHA class III) as well as ethnic minority patients were found to have the strongest association for predicting physician non-adherence, followed by comorbid conditions. Detailed data were unfortunately not collected on potential reasons for these associations. The authors suggest physician non-adherence is multifactorial and most likely impacted by scenarios such as patient-provider interaction, individual system access, and insurance status of the patients. Variations in quality health care have been well documented in previous studies, however, suggesting provider prejudice, bias, and stereotypes toward ethnic minorities (Calvin et. al, 2012).

Significant gaps, variations, and disparities exist between evidence-based guideline recommendations and treatment regimens for all HF patients who are either

hospitalized or outpatient (ACCF/AHA, 2013). Providers who care for patients with HF will continue to require more advanced training due to the complexity of this disease state. The aging population, multiple comorbidities, technical advances in HF devices, and growth in transplant cardiology contribute to the complexity. In 2005, however, the HFSA only identified 48 active advanced HF training programs in the United States (ACCF/AHA, 2013). In addition to these challenges, diagnostic accuracy will continue to be difficult with the increased prevalence of HF with a normal EF in the setting of the elderly patient with comorbidities and underuse of diagnostic testing (Manzano et. al, 2012).

Diagnostic Challenges of HF

Diagnosis

The diagnosis of HF is a challenge, especially in the elderly patient. It should not be based on clinical presentation alone, and it requires objective evidence of cardiac dysfunction (Manzano, et. al, 2012). The signs of early HF are also difficult, not only in the elderly patient but also in the obese patient. Therefore, the clinical suspicion of HF must be confirmed by objective diagnostic testing that targets the assessment of cardiac function (ESC, 2008).

The most common symptoms of HF, dyspnea and fatigue, are non-specific (Edelmann et. al, 2011). Other symptoms (eg, orthopnea, paroxysmal nocturnal dyspnea) and signs (e.g., jugular venous distention [JVD] and third heart sound) have only a reported 11%-55% sensitivity for being the cause of HF. Many of the HF comorbidities, such as renal disease, are associated with similar symptoms that cause shortness of breath and limited exercise capacity without the patient having an actual HF exacerbation (Edelmann et al., 2011). Additionally, routine diagnostic testing for HF, such as electrocardiogram (EKG) and chest x-ray, is also insensitive (McMurray, 2010).

Other co-existing diseases and unclear medical histories as found in the elderly frequently confound the clinician's ability to make the diagnosis (Manzano et al. 2012).

The best diagnostic test for evaluating a patient with, or at risk for, HF is a comprehensive 2-dimensional EKG that includes Doppler flow studies. Not only does use of EKGs provide disease identification, it is also essential for appropriate medical management (ACCF/AHA, 2013). Patients who do undergo evaluation for ventricular dysfunction fall into three subtypes: patients at risk for HF, suspected HF patients having signs and symptoms, or known HF patients that are symptomatic. Unfortunately, in all subtypes, ventricular assessment is nationally not consistently performed upon patients assigned with the HF diagnosis presenting in the emergency room (HFSA, 2010).

Beyond that conundrum, HFpEF is inherently difficult to define due to the challenges of measuring diastolic function (MacIver & Dayer, 2012). The distinction between systolic and diastolic continues to be arbitrary, and many patients with diastolic HF frequently also have some level of systolic dysfunction (ESC, 2008). Furthermore, there is no consensus surrounding the cut-off EF % for HFpEF. The symptoms associated with either type of HF are also subjective; thus, absolutely ruling in or out the diagnosis of HF is difficult (MacIver & Dayer, 2012).

Brain Natriuretic Peptides

Over the past decade, clinicians that manage HF have garnered access to more tools to facilitate the appropriate diagnosis. B-type natriuretic and NT pro-BNPs (NT BNPs) have been established as the best predictor for (BNP < 100 pg/mL, NT BNP < 300 pg/mL) *not* having a HF diagnosis. A negative BNP result has proven to be more sensitive than the traditional physical exam, history, or chest X-ray for establishing that the patient does not have the diagnosis of HF (Chang, Maisel, & Hollander, 2009).

Synthesized in the myocytes, BNP is a 134-amino-acid peptide that is cleaved to the prohormone BNP of 108 amino acids (Braunwald, 2008). The prohormone is released during hemodynamic stress, i.e., when the ventricles are dilated or hypertrophic, or when the ventricles are subjected to increased wall tension. Assessing BNP levels is recommended in patients suspected of having HF, especially if the diagnosis is uncertain (HFSA, 2010).

Natriuretic peptide values are not, however, sensitive in multiple patient populations. Levels of NPs tend to be higher in women and older patients with or without cardiac dysfunction (Krupicka et al., 2009). Hormone replacement therapy is associated with higher BNP levels, revealing a potential association with estrogen and BNP concentrations (Krupicka et al., 2009). In the elderly, myocardial fibrosis and renal dysfunction is common; therefore, a moderate increase in circulating BNP will also be seen outside of HF (Braunwald, 2008). Conversely, diastolic HF and pulmonary hypertension are more common in the elderly; however, BNP levels are frequently not as high as with those seen with systolic HF (Krupicka et al., 2009). This variance in sensitivities has led to confusion in the hospital setting and to the potential of over-diagnosis for clinicians who are not trained in the nuances of the values (ESC, 2008, Figure 2-2).

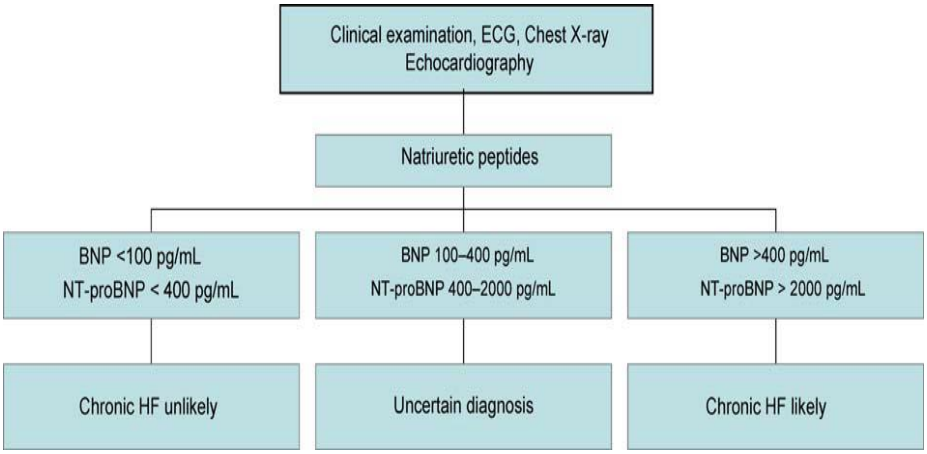


Figure 2-2 Chronic HF diagnosis algorithm utilizing BNP

Abbreviations: BNP = B-type natriuretic peptide; ECG = electrocardiogram; HF = heart failure

Clinical Decision Making

The literature has supported that most physicians generally make two to three diagnoses during the initial visit with a patient (Groopman, 2007). The seasoned and skilled providers may be able to juggle four or five diagnoses in their consciousness to develop their decisions, medical hypothesis from incomplete information. This process has been described as shortcuts known as heuristics (Groopman, 2007). The heuristic method of learning results in experiential thinking and the development of "rules learned on the job" or "rules of thumb"; when successful, it is hailed as economical, resourceful, and effective. When this method fails, it is referred to as cognitive bias (Groopman, 2007). Cognitive biases or mental shortcuts are commonly used in decision making that can result in faulty reasoning or conclusions (Gigerenzer & Gaissmaier, 2011). The medical community historically accepts that physicians use heuristics and bias for diagnosing patients, as heuristics have been deemed more accurate than more complex strategies even though it results in processing less information (less is more effect),

(Gigerenzer & Gaissmaier, 2011). Unfortunately, heuristics methodology is flawed when attempting to accurately diagnose a complex disease state.

Social psychology has shed light on how unexamined biases can influence medical decisions, despite the providers' good intentions (Dovidio & Fiske, 2012). The decision-making processes are affected by a variety of factors as clinical treatment decisions are often made in the setting of incomplete or conflicting evidence. Additionally, the presence of multiple chronic conditions, as stated previously, is associated with worse outcomes and higher readmissions in HF patients. According to Blecker et al. (2013), the presence of multiple comorbidities increases physician uncertainty. Uncertainty in diagnosis facilitates inaccurate documentation, which ultimately yields inaccurate accountability of HF admissions (Blecker et al., 2013). Moreover, unclear diagnosis systematically facilitates inappropriate or ineffective treatments of the actual presenting diagnosis resulting in disparities in health care (Dovidio & Fiske, 2012).

HF Provider Variances

A HF diagnosis is more likely to be accurate and treatment more effective if a cardiologist is involved in the care of the patient versus a primary care provider alone. In their hallmark study, Ansari, Alexander, Tutar, Bello, and Massie (2003) investigated HF outcomes in patients managed by both cardiologists and primary care providers versus primary care providers alone (N = 403). The primary endpoint was a cardiovascular-related admission or all-cause death. The patients who were managed with the assistance of a cardiologist had consistent measurements of LVEF as well as assessments for myocardial ischemia. Additionally, a higher proportion of the patient cohort was treated appropriately with angiotensin-converting enzyme inhibitors, especially in the setting of a documented low EF. Recommended therapies for

associated conditions were also more likely to be initiated by the assisted cardiology managed group, such as lipid-modifying agents for cardiovascular disease as well as warfarin for atrial fibrillation.

Overall, the researchers found a significant reduction ($P = 0.03$) in mortality, morbidity, and cardiovascular hospitalization in HF patients who were managed in part by a cardiologist (Ansari et al., 2003). The majority of HF patients, however, are managed by primary care providers (Desai & Stevenson, 2012). Although this clinical practice is not optimal, management by a cardiologist comes at a higher cost. Cardiologists frequently order more procedures and diagnostic testing compared with primary care providers. To contain these types of additional health care costs, managed care organizations have limited the utilization of cardiologists as well as limiting diagnostic testing (Desai & Stevenson, 2012).

Coding and Accountability of the Heart Failure Diagnosis

The International Classification of Diseases (ICD) defines HF on the basis of diagnostic coding (Goff, Pandey, Chan, Ortiz, & Nichaman, 2000). The ICD code 428 is the assigned code for HF; however, older, limited data suggest that there is only a 62.8% sensitivity value for the accurate accountability of HF hospitalizations (Goff et al., 2000). In European studies, discharge coding registries have been reported to accurately identify patients with clinical HF. Discharge coding, however, was not found to be accurate with regard to estimating prevalence and incidence for the HF population. In fact, the codes were found to severely underreport the amount of patients diagnosed with HF (Kumler et al., 2008).

In a recent US study, Blecker et al. (2013) aimed to describe HF hospitalizations as either having a primary or secondary diagnosis for HF. Using the Nationwide Inpatient Sample (NIS) and ICD-9-CM codes, the researchers analyzed whether the HF

hospitalization was due to a primary or secondary HF diagnosis code. The researchers determined that the actual number of primary HF hospitalizations for the years 2001-2009 decreased from 1,137,944 in 2001 to 1,086,685 in 2009. In contrast, hospitalizations for HF coded as a secondary diagnosis of HF increased from 2,753,793 in 2001 to 3,158,179 in 2009. Interestingly, the common primary diagnoses for these admissions were pulmonary and renal disease, as well as infections. These diseases that were coded out as the primary diagnosis, not surprisingly, are well documented to be known risk factors or comorbidities for HF.

Summary

ICD-9 discharge codes have historically been considered an easy and accessible source of information on disease burden (Blecker et. al, 2013). Interrogation of large databases containing ICD codes has frequently been used to determine readmission rates as well as incidence and prevalence of HF. The coding system has also provided a means to analyze the economic burden of HF and has served as a means to help determine appropriate patient management as well as allocation of health care resources (Blecker, et. al, 2013).

There is relatively little or recent published data regarding the accuracy of diagnosis using the coded discharge diagnosis of HF (Kumler et. al, 2008). All current data in the United States support the contention that the primary discharge diagnosis that is documented as HF is HF. Upon readmission, the etiology may be difficult to pinpoint, as sometimes the diagnosis of the purported *initia*l HF admission is not correct (Butler et al., 2012). More research is urgently needed to evaluate the accuracy of the current reporting system. Furthermore, research to evaluate the congruence of HF diagnosis especially in the setting of ACA, where hospitals will be penalized for excessive documented HF readmissions.

The plethora of literature on HF admissions consistently supports the premise that there has been no significant improvement in hospital re-admission care either regionally or nationally over the past decade (Butler et al., 2012). Additionally, there is no consensus nationally on how we are defining an ill-defined complex disease state (Butler et al., 2012). More importantly, inaccurate diagnosis of associated comorbidities mistaken for HF will lead to increased mortality and morbidity, increased readmissions, and continued increases in health care costs.

Research Question

What is the accuracy in the diagnosis of HF in patients who were discharged with the primary diagnosis of HF? Additionally, are there differences in readmission rates in patients who are accurately diagnosed for HF compared with patients who are inaccurately diagnosed? A retrospective multi-hospital record review will be attempted at a large metropolitan health care system. The medical review will be utilizing the hospital system's electronic medical record (EMR) system and the reported discharge ICD-9 codes for these patients with a primary diagnosis of HF.

Key patient variables were collected that have been documented to be either a risk factor or comorbidity that leads to a HF diagnosis and input. These data points were then placed into an ACCESS data base created for this study. These variables included demographics (age, sex, race, weight, and body surface area), cardiac risk factors (diabetes, renal failure, creatinine level, chronic lung disease, obstructive sleep apnea [OSA], hypertension, peripheral vascular disease, cerebrovascular disease, smoking status), previous cardiac interventions (percutaneous coronary intervention [PCI], coronary artery bypass graft surgery [CABG]), and cardiac status (previous or current myocardial infarction, angina, atrial fibrillation, valve disease).

The primary aim of this study was to assess the accuracy of diagnosis in patients discharged with a primary diagnosis of HF. Additionally, a secondary aim was to compare the readmission rates of patients accurately diagnosed with those of patients who were not accurately diagnosed. Large retrospective health care record reviews such as this one could assist in deciphering inconsistencies and inaccuracies, especially when looking for specific confounders that correlate with increased readmissions in the HF patient.

Chapter 3

Methods and Procedures

Introduction

This study retrospectively describes the accuracy of HF diagnoses in an adult HF patient population in a large metropolitan hospital setting. It also compared readmission rates between patients who were accurately diagnosed for HF versus those who were inaccurately diagnosed.

Research Design

The proposed study was a retrospective cohort descriptive design.

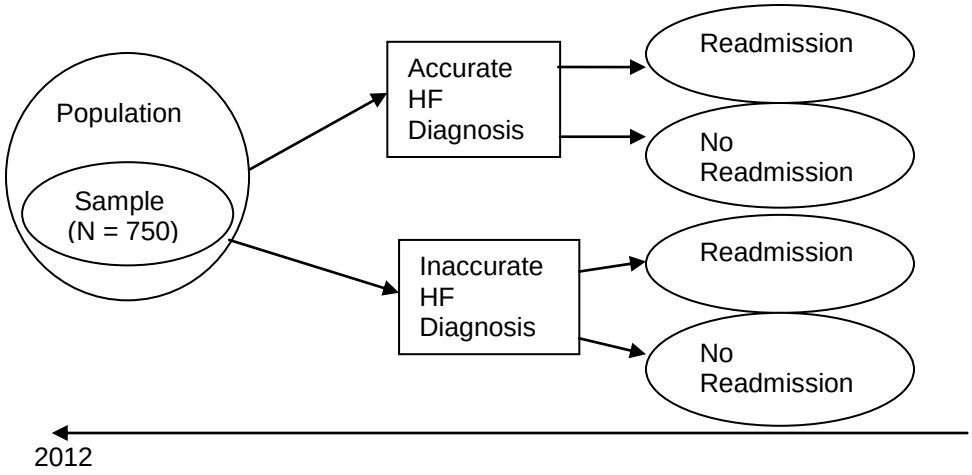


Figure 3-1 Retrospective observational model

Abbreviation: HF = heart failure

Sample

A random sample of 750 records of patients admitted over one calendar year from the Baylor Health Care System (BHCS; N =14 hospitals) in the Dallas/Fort Worth area were analyzed for the study. The sample was composed of patients aged > 18 years, discharged from any of the 14 BHCS hospitals with a primary diagnosis code for

HF between January1, 2012, and December 31, 2012. The sample was stratified by hospital and by sex. The number of charts retrieved from each hospital was based on its proportion (relative to the whole BHCS admissions) of HF admissions by sex.

BHCS's Institutional Review Board (IRB) was the primary IRB, with the University of Texas at Arlington's (UTA) IRB being secondary. A unique study identifier was assigned to each patient. The unique study identifier did not contain any patient personal identifiers. Only the principle investigator had access to the key; subsequently, no patient identifiers were collected. With an alpha level set at 0.05, a sample of 750 patients was estimated to provide 80% power to detect 5% absolute difference in a misdiagnosis of HF using SAS (version 9.3). The estimate assumed a 5% absolute misdiagnosis rate in the study cohort. The power and the sample size associated where then estimated (Figure 3-2).

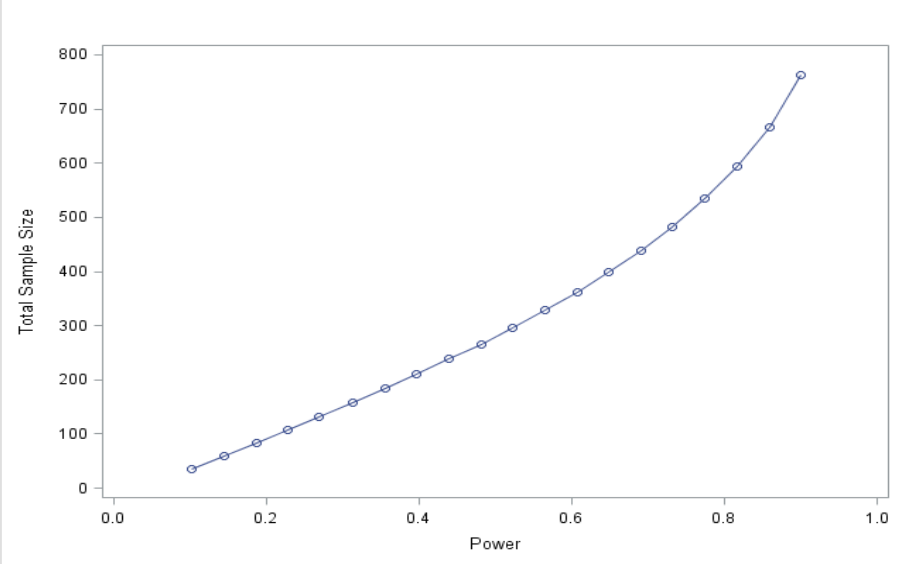


Figure 3-2 Power analysis

Inclusion/Exclusion Criteria

Inclusion criteria consisted of any adult >18 years of age discharged with primary ICD code for diagnosis of HF. Additional inclusion criteria were as follows:

1. All patients required a documented echocardiogram within 6 months of admission.
2. All patients required a documented BNP level during the time of admission.
3. All patients required ≥ 2 of the following admitting criteria documented to be considered an accurate diagnosis for HF: dyspnea, edema, volume overload, cough, jugular venous distention, S_3 gallop, arrhythmia, heart rate (HR) > 100, generalized fatigue. To confirm diagnosis, ≥ 1 criterion on chest x-ray: pulmonary edema, pulmonary congestion, cardiomegaly, pleural effusion, and/or the term "suggestive for heart failure" needed to be documented in the medical record.

Exclusion criteria consisted of no documented 2-D echocardiogram within the 6 months prior to admission or not having a documented BNP level during the admission.

Patients were identified for inclusion using administrative data, while clinical data were abstracted from patients' medical charts.

Data Collection

Hospitals utilizing an electronic medical record (EMR) system were queried using ICD-9 codes extracted from Medical Information Data Analysis System (MIDAS) and Enterprise Data Warehouse (EDW). Records from facilities not utilizing an EMR were manually abstracted. Specific variables have been associated with increased risk for a HF diagnosis (EHJ, 2008). The key variables that have been documented in the literature were abstracted and entered into the study database (Table 3-1).

Table 3-1 Abstraction data

Demographics/ Clinical History	Cardiac Risk Factors	Previous Cardiac Interventions and status	Admission/ Coding Data	Diagnostic Testing
Age, sex, race, weight, and body mass index, presenting clinical exam, medical and social history	Diabetes, renal failure, creatinine level, chronic lung disease, obstructive sleep apnea, hypertension, peripheral vascular disease, cerebrovascular disease, smoking status	Previous or current: myocardial infarction, angina, atrial fibrillation, valve disease, percutaneous coronary intervention, coronary artery bypass graft	Initial admission date, readmission dates, primary ICD-9 coding and diagnosis	Heart catheterization, echocardiography, radiographic and laboratory testing

The primary investigator (PI) was a nurse practitioner with more than 15 years of experience managing patients with HF in multiple settings. For the purposes of this study, the PI established a diagnostic schema based on peer-reviewed literature to determine if the data documented in the medical records met the criteria to support the diagnosis of HF (Table 3-2). Additionally, a blinded team of 3 clinical experts was used for arbitration for a proportion of the study sample. This team consisted of 3 cardiologists with expertise in clinical HF as well as echocardiography to assess the criterion used to quantify accurate or inaccurate diagnosis in the study sample.

Table 3-2 Criteria for HF diagnosis

Low Probability of HF			
Normal Echo: LVEF > 50%, normal chamber sizes, right ventricular systolic pressure < 35, no evidence or documentation of diastolic HF	Any normal BNP level: < 100	No clinical signs or symptoms of HF	Normal chest x-ray
Intermediate Probability of HF			
Major Criteria on Exam (Documentation of ≥ 1 Major Criteria**)	Major Criteria on Chest X-ray Documentation of ≥ 1 Criteria	Major Criteria on Echo	Major Criteria for Laboratory Testing
**Pt described as volume overload (admitting diagnosis before surgery) **Jugular venous distention **Dyspnea on exertion, paroxysmal nocturnal, at rest, orthopnea **Edema: peripheral, ankle, alveolar, pulmonary, interstitial, ascites, abdominal **Lungs: rales, rhonchi, diminished, crackles S_3 gallop (third heart sound) cough Generalized fatigue Wheezing Arrhythmia > 100	Radiography Cardiomegaly Pleural effusion Pulmonary edema Pulmonary or central vascular congestion, pericarditis Documented term: "Suggestive for HF"	Documented systolic dysfunction: left ventricular ejection fraction of > 50% and/or no documentation of diastolic dysfunction	BNP > 100, but < 400 documented at any time during the admission in the setting of meeting the other major criteria *In the absence of renal disease Cr > 2.0

Table 3-2—*Continued*

High Probability of HF			
Major Criteria on Exam (Documentation of ≥ 2 Major Criteria**)	Major Criteria on Chest X-ray Documentation of ≥ 1 Criteria	Major Criteria on Echo	Major Criteria for Laboratory Testing
**Pt described as volume overload (admitting diagnosis before surgery) **Jugular venous distention **Dyspnea on exertion, paroxysmal nocturnal, at rest, orthopnea **Edema: peripheral, ankle, alveolar, pulmonary, interstitial, ascites, abdominal **Lungs: rales, rhonchi, diminished, crackles S_3 gallop (third heart sound) cough Generalized fatigue Wheezing Arrhythmia any type Heart rate > 100	Radiography Cardiomegaly Pleural effusion Pulmonary edema Pulmonary or central vascular congestion, pericarditis Documented term: "Suggestive for HF"	Documented systolic dysfunction: left ventricular ejection fraction of < 50 % and/or documentation of diastolic dysfunction	BNP > 400 documented at any time during the admission in the setting of meeting the other major criteria

Data Analysis

Aim 1: To Determine the Accuracy of Diagnosis in Patients Discharged in 2012 Assigned With a Primary Diagnosis of HF

Subjective assessments from the arbitration committee were analyzed using the inter-rater agreement Fleiss' kappa. Subjects with a high and low probability of HF were

assumed to be more likely to be correctly diagnosed. To assure adequate representation of the subjects, the study population was stratified into low, medium, and high probability of HF. Fifty percent of the overall sample, or 34 subjects, were obtained from the high- and low-probability groups; the remaining 34 subjects were from the medium probability group.

A sample size of 68 was estimated to detect a statistically significant 3-rater kappa coefficient of 0.80 (95% CI, 0.60-0.90), assuming that the anticipated proportion of subjects with correct diagnosis of HF would be 0.75. The R package "kappaSize" (R Core Team, Michael A. Rotondi, 2013) was used to calculate the sample size.

Subjects deemed misdiagnosed by the PI were classified as misdiagnosed. Additionally, diagnostic characteristics of subjects in the high, medium, and low probability of HF groups were summarized and compared (Table 3.1).

Continuous variables were summarized for each group by the mean and standard deviation or median and interquartile (IQR) range, as appropriate. Categorical variables were expressed as percentages of groups. Group differences were also compared using Wilcoxon rank-sum test for continuous data and Fisher's exact test for 2×2 tables, or likelihood ratio χ^2 test for larger tables. A *P* value < 0.05 was considered statistically significant.

Aim 2: To Compare the 2012 Re-Admission Rates of Patients With HF Accurately Diagnosed to Patients Who Were Found To Be Inaccurately Diagnosed

Demographics, clinical history, diagnostic testing, misdiagnosis of HF, and other important patient characteristics of subjects readmitted and not readmitted within 30 days were summarized and compared (Table 3.1). Readmission in the first 30 days of discharge was modeled as a binary outcome. The effect of each potential risk factor,

including the misdiagnosis of HF, hypothesized to be associated with the outcome (Table 3.1) was analyzed with univariate logistic regression models.

The univariate logistic regression results were used as a screening tool to identify a subset of potential predictors to be used in subsequent analyses. Stepwise multivariable models were built using factors from the univariate analysis that had a *P* value < 0.2. The variable entry criteria was set to 0.1, and the variable retention criteria was set to 0.05. All the factors in the final stepwise model were statistically significant with $P < 0.05$. The misdiagnosis of HF was forced in a final multivariate logistic regression model regardless of its significance. This allowed assessment of the impact of misdiagnosis on readmissions while controlling for other significant factors. All analyses were performed using SAS 9.3 and the statistical software R 3.0.2.

Data Management

Data were managed in compliance with HIPPA regulations and were stored on an encrypted BHCS computer.

Chapter 4

Results

Sample Demographics

A total of 750 patient charts were initially queried using ICD-9 codes extracted from the hospital systems Medical Information Data Analysis System (MIDAS) and Enterprise Data Warehouse (EDW). Records from facilities that did not have an electronic medical record (EMR) in place were manually abstracted. A total of 38 charts did not meet the inclusion criteria and were therefore excluded. This resulted in a final sample size of 712. Table 4.1 describes overall demographic characteristics of the remaining sample. The study was initially powered to detect a 5% difference; however, because *over* an 18% (n = 133) difference was detected, the remaining sample size was determined to be adequately powered with the final sample size.

Table 4-1 Demographic characteristics of the sample

Variable, %	Sample (N = 712)
Mean Age, Years ± SD	68.2 ± 15.4
Age ≥ 60 Years	69.4
Male Sex	52.7
Hispanic	8.8
Race	
White	64.2
Black	29.8
Other	4.5
Asian	1.5

Abbreviation: SD = standard deviation

Research Question #1: Diagnostic Accuracy

18.7% of the remaining cohort was determined to have a low probability or inaccurately diagnosed. Using the diagnostic criteria described in Table 3-2, the remaining study sample was divided into the following groups: low probability of HF (inaccurate diagnosis), medium probability of HF (indeterminate diagnosis), and high

probability of HF (accurate diagnosis). Demographic characteristics including age, sex, race, ethnicity, and body mass index (BMI) are described in Table 4-2. Only patients identifying themselves as Hispanics were observed to be significantly different among the groups (*P* = 0.039; Table 4-2). Hispanic's were found more frequently in the medium and high probability diagnosis groups.

In Figure 4-1, the butterfly grouped bar displays the age and sex distribution of the study sample compared with the distribution of low, medium, and high groups. Of note, the study cohort overall had a high BMI that was nearly equivalent across the 3 groups. The low-probability group had a mean BMI of 31.7 versus 31.9 in the medium group and 30.1 in the high group (Table 4-2).

Table 4-2 Baseline demographics characteristics in patients with low, medium, and high probability of correct diagnosis of HF

Variable, %	Low (n = 133)	Medium (n = 235)	High (n = 344)	*P* Value
Mean Age, Years ± SD	68.1 ± 15.4	69.0 ± 15.1	67.7 ± 15.7	0.584
Age ≥ 60 Years	67.7	71.1	68.9	0.765
Male Sex	46.6	51.9	55.5	0.209
Hispanic	3.8	10.6	9.6	0.039
Race				0.315
White	69.9	63.0	62.8	–
Black	24.8	28.5	32.6	–
Other	3.8	6.8	3.2	–
Asian	1.5	1.7	1.5	–
Mean Body Mass Index, kg/m^2, ± SD	31.7 ± 10.6	31.9 ± 10.6	30.1 ± 8.6	0.365

Abbreviations: HF = heart failure; SD = standard deviation

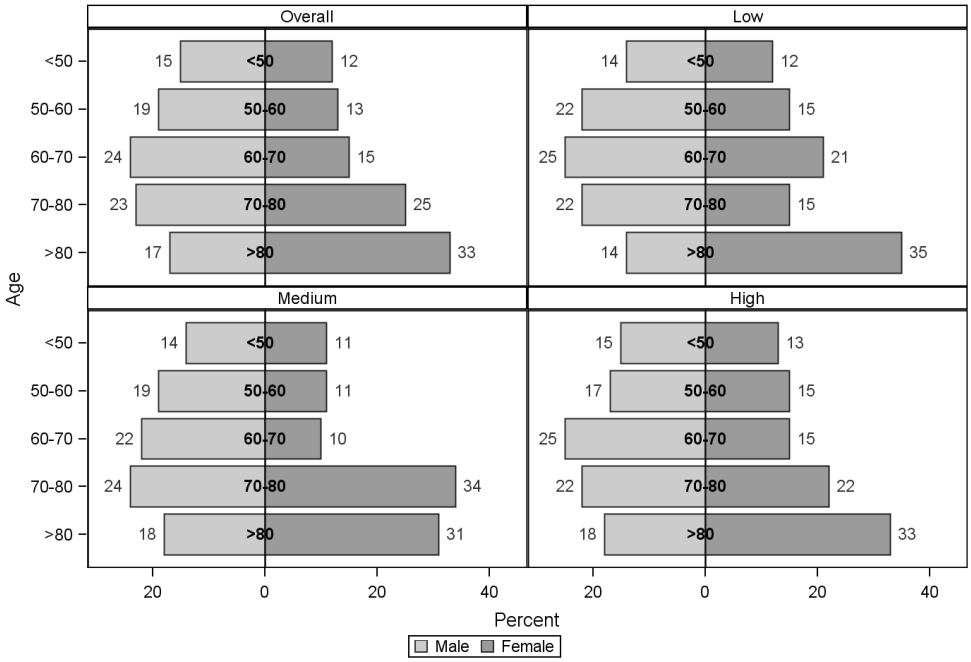


Figure 4-1 Percentage frequency distribution by age and sex

Group Differences by Accurate Diagnosis of HF

Of the comorbidities listed, diabetes ($P = 0.003$) and renal disease ($P = 0.005$) were the only variables that were found to be significantly associated with an accurate HF diagnosis. Presenting complaints including dyspnea ($P \leq 0.0001$), edema ($P = 0.0001$), or gastrointestinal symptoms ($P = 0.012$) were found to be significantly associated with the probability of an accurate HF diagnosis. Additionally, exam findings of jugular venous distention (JVD; $P \leq 0.0001$) and rales ($P \leq 0.0001$) were significantly associated with the probability of an accurate HF diagnosis. Diagnostically, abnormal echo findings ($P \leq 0.024$), LVEF < 50% ($P \leq 0.0001$), and positive chest x-ray findings ($P = 0.0103$) were significantly associated with the probability of an accurate HF diagnosis. Documented mitral valve regurgitation/insufficiency ($P = 0.003$) were significantly associated with the low probability for HF group, and documented diastolic dysfunction ($P \leq 0.0001$) were

significantly associated in the low and medium probability of an accurate HF diagnosis groups.

Admitting (or first), and discharge (or last), documented laboratory results were compared among groups. All BNP values *anytime* during the admission were collected for each patient. Significant laboratory results associated with the probability of an accurate HF diagnosis included the first result of creatinine ($P = 0.033$) as well as BNP > 400 at any time during the admission ($P \leq 0.0001$). Finally, patients who were documented as having a pacemaker/implantable cardiac defibrillator (ICD) were also significantly associated with the probability of an accurate HF diagnosis (Table 4-3).

Table 4-3 Comorbidities and diagnostic characteristics in patients with low, medium, and high probability of correct diagnosis of HF

Variable, %	Low (n = 133)	Medium (n = 235)	High (n = 344)	*P* Value
Comorbidity				
Arrhythmia	35.3	47.2	42.4	0.083
CVD	44.4	53.2	51.2	0.253
Lung	30.8	32.8	28.2	0.494
Anemia	30.1	32.3	29.4	0.743
Diabetes	38.3	55.3	44.2	0.003
Hyperthyroidism	0.8	2.1	2.3	0.455
Renal Disease	45.1	60.9	50.0	0.005
Sleep Apnea	12.0	15.3	13.4	0.651
Hypertension	83.5	84.3	85.2	0.888
Cardiomyopathy	27.8	36.6	38.7	0.078
Presenting Complaint				
Angina	5.3	6.8	5.8	0.813
Dyspnea	77.4	91.5	94.8	< 0.0001
Edema	57.1	67.7	76.7	0.0001
Gastrointestinal Symptoms	11.3	17.9	22.7	0.012
General Fatigue	20.3	27.2	23.3	0.294
Exam findings				
JVD	13.5	12.8	31.1	< 0.0001
Lung Rales	33.8	37.9	54.9	< 0.0001
Volume Overload	14.3	14.9	14.5	0.986
Wheezing	6.0	13.2	12.8	0.0543
Echo findings				
Echo Performed	85.7	88.1	86.0	0.727
Abnormal Echo Findings	55.6	54.0	44.5	0.024
Aortic Stenosis	11.3	14.9	12.5	0.562
Mitral Stenosis	2.3	3.8	2.9	0.677
Aortic/Regurgitation/Insufficiency	91.0	82.1	84.9	0.058
Mitral/Regurgitation/Insufficiency	63.9	47.2	48.0	0.003
LVEF < 50	25.5	57.2	72.8	< 0.0001
Diastolic Dysfunction	41.4	43.4	25.6	< 0.0001
Positive Chest X-Ray Findings	85.7	91.5	94.5	0.0103

Table 4-3—*Continued*

Variable, %	Low (n = 133)	Medium (n = 235)	High (n = 344)	*P* Value
Lab Results				
BUN (md/dL) ≥ 18 at admission	62.6	74.4	68.7	0.059
GLU (md/dL) ≥ 100 at admission	75.6	73.4	78.5	0.362
Creat (md/dL) ≥ 1.5 at admission	63.4	49.4	55.7	0.033
BUN (md/dL) ≥ 18 at discharge	80.3	83.6	79.5	0.464
GLU (md/dL) ≥ 100 at discharge	62.9	63.6	57.4	0.281
BNP	39.8	61.3	85.8	< 0.0001
Intervention				
PCI	21.8	20.0	16.9	0.397
Pacemaker ICD	24.1	32.3	38.1	0.011

Abbreviations: BUN = Blood Urea Nitrogen; BNP = Brain Natriuretic Peptide; Creat = creatinine; CVD = cardiovascular disease; GLU =glucose; HF = heart failure; ICD = implantable cardiac defibrillator; JVD = jugular venous distention; LVEF = left ventricular ejection fraction; PCI = percutaneous coronary intervention.

Research Question #2: Readmissions

Predictors for Readmission

Readmissions were analyzed in two ways:

1. Readmission for non-HF within 30 days versus no readmissions.
2. Readmission for HF within 30 days versus no readmissions.

The overall readmission rate for this cohort was 17.6%. In order to answer aim 2, the three diagnostic groups were reduced to two levels, accurate (medium and high) and inaccurate (low) diagnosis for HF. Additionally, merging the medium and high groups assured the most likely patients fell into the accurate diagnosis group.

For each comparison, the two outcomes were first compared with the individual patient criterion characteristics used to determine the three diagnostic groups. Next, selected patient characteristics and accuracy of the HF diagnosis were individually used to predict the outcome using univariate logistic regression analysis. A subset of those

variables with a *P* value of < 0.20 was included in a stepwise multivariate logistic regression analysis.

In the total study cohort (N = 712), 47 patients were readmitted for HF versus 78 patients who were admitted for non-HF within 30 days from the initial admission. The readmission LOS was not found to be statistically different among the 3 diagnostic groups (Table 4-4). The low-probability group had the highest proportion of readmissions in 30 days (19.5%), when compared to the high-probability group (19.2%) and the medium-probability group (14.0%), respectively. The high-probability group had the largest proportion of *HF*-related readmissions (7.8%) when compared to the medium-probability group (6.8%) and the low-probability group (3.0%), respectively. The low-probability group additionally had the highest proportion of the *non-HF* readmissions (16.5%) when compared to the high-probability group (11.3%) and the medium-probability group (7.2%), respectively (Table 4-4).

Comparisons of the non-readmitted and the *non-HF*–related readmissions groups were performed. White patients (*P* = 0.006) appeared to be readmitted more frequently between the 2 groups (Table 4-5). Specifically, comorbidities were of interest for this analysis. However, comorbidities as well as diagnostic measures were not individually associated with readmission for non-HF causes (Table 4.6).

Comparisons of the non-readmitted and the *HF-related* readmissions group were also performed. Black patients (*P* = 0.014) and patients aged < 60 years *(P* = 0.025) appeared to be readmitted more frequently and white patients less frequently (Table 4.7). Comorbidities in this group were also of interest for this analysis. Among the presenting symptoms, dyspnea (*P* = 0.075) and edema (*P* = 0.048) were observed more frequently in patients who were readmitted for HF (Table 4.8). Among the diagnostic testing, glucose (*P* = 0.050) and BNP > 400 mm/dL (*P* = 0.0016) were documented more

frequently in the patients who were readmitted for HF. PCI (*P* = 0.054) was also reported more frequently in patients who were readmitted for HF.

Table 4-4 Readmission summary statistics in patients with low, medium, and high probability of correct diagnosis of HF

Variable	Low (n = 133)	Medium (n = 235)	High (n = 344)	*P* Value
Readmission Statistics				
Median LOS, days (25%-75% IQR)	4.0 (2.0-7.0)	4.0 (3.0-6.0)	4.0 (2.5-7.0)	0.568
Readmission				0.021
Readmitted in 30 days, n (%)	26 (19.5)	33 (14.0)	66 (19.2)	0.223
Readmissions for HF, n (%)	4 (3.0)	16 (6.8)	27 (7.8)	0.156
Readmission for non-HF, n (%)	22 (16.5)	17 (7.2)	39 (11.3)	0.021

Abbreviations: HF = heart failure; IQR = interquartile range; LOS = length of stay

Table 4-5 Baseline demographics and characteristics in patients readmitted and not readmitted for non-HF

Characteristic, %	Not Readmitted (n = 634)	Readmitted (n = 78)	*P* Value
Mean Age, Years ± SD	69.5 ± 13.8	68.06 ± 15.6	0.520
Age ≥ 60 Years	68.6	75.6	0.242
Male Sex	47.2	48.7	0.811
Hispanic	91.0	92.2	0.835
Race			0.004
White	62.3	79.5	-
Black	31.7	14.1	-
Other	4.6	308	–
Asian	1.4	2.6	–
Mean Body Mass Index, kg/m^2 ± SD	31.1 ± 9.7	29.9 ± 9.3	0.271

Abbreviations: HF = heart failure; SD = standard deviation

Table 4-6 Comorbidities and diagnostic characteristics in patients readmitted and not readmitted for non-HF

Variable, %	Not Readmitted (n = 634)	Readmitted (n = 78)	*P* Value
Comorbidity			
Arrhythmia	41.5	52.6	0.129
CVD	49.7	57.7	0.189
Lung	30.8	25.6	0.433
Anemia	30.3	32.1	0.794
Diabetes	47.2	43.6	0.631
Hyperthyroidism	1.9	2.6	0.659
Renal Disease	53.0	50.0	0.634
Sleep Apnea	13.7	14.1	0.863
Hypertension	85.2	79.5	0.187
Cardiomyopathy	36.3	33.3	0.708
Angina	6.2	5.1	1.000
Dyspnea	90.7	88.5	0.539
Edema	69.9	71.8	0.794
Gastrointestinal Symptoms	19.2	16.7	0.648
General Fatigue	25.1	14.4	0.067
Exam Findings			
JVD	21.3	25.6	0.384
Lung Rales	45.3	46.2	0.904
Volume Overload	14.0	19.2	0.234
Wheezing	12.1	7.7	0.348
Echo Findings			
Echo Performed	87.2	82.1	0.216
Abnormal Echo Findings	50.0	47.4	0.719
Aortic Stenosis	12.6	16.7	0.372
Mitral Stenosis	2.8	5.1	0.288
Aortic Regurgitation/Insufficiency	85.2	84.6	0.867
Mitral Regurgitation/Insufficiency	50.3	53.8	0.631
LVEF < 50	60.3	50.8	0.169
Diastolic Dysfunction	35.8	23.1	0.031
Positive Chest X-Ray Findings	92.0	91.0	0.825

Table 4-6—*Continued*

Variable, %	Not Readmitted (n = 634)	Readmitted (n = 78)	*P* Value
Lab Results			
BUN (md/dL) ≥ 18 First Set	69.2	71.1	0.793
GLU (md/dL) ≥ 100 First Set	76.2	76.9	1.000
Creat (md/dL) ≥ 1.5 First Set	55.8	48.7	0.278
BUN (md/dL) ≥ 18 Second Set	81.1	80.0	0.876
GLU (md/dL) ≥ 100 Second Set	60.9	56.6	0.534
BNP > 400 (pg/dL)	68.9	70.5	0.897
Intervention			
PCI	18.1	24.4	0.218
Pacemaker ICD	33.6	33.3	1.000

Abbreviations: BUN = blood urea nitrogen; BNP = brain natriuretic peptide; Creat = creatinine; CVD = cardiovascular disease; GLU = glucose; HF = heart failure; ICD = implantable cardiac defibrillator; JVD = jugular venous distention; LVEF = left ventricular ejection fraction; PCI = percutaneous coronary intervention

4-7 Baseline demographics and characteristics in patients readmitted and not readmitted for HF

Characteristic, %	Not Readmitted (n = 665)	Readmitted (n = 47)	*P* Value
Mean Age, Years ± SD	68.6 ± 15.2	63.10 ± 16.4	0.025
Age ≥ 60 Years	70.7	51.1	0.008
Male Sex	53.2	44.7	0.291
Hispanic	9.3	2.1	0.111
Race			0.014
White	65.6	44.7	–
Black	28.3	51.1	–
Other	4.7	2.1	–
Asian	1.5	2.1	–
Mean Body Mass Index, kg/m^2 ± SD	31.0 ± 9.7	29.5 ± 8.35	–

Abbreviations: HF = heart failure; SD = standard deviation

4-8 Comorbidities and diagnostic characteristics in patients readmitted and not readmitted for HF

Variable, %	Not Readmitted (n = 665)	Readmitted (n = 47)	*P* Value
Comorbidities			
Arrhythmia	43.5	31.9	0.129
CVD	50.5	51.1	1.000
Lung	30.2	29.8	1.000
Anemia	29.9	38.3	0.252
Diabetes	46.3	53.2	0.369
Hyperthyroidism	2.1	0.00	0.616
Renal Disease	52.3	57.4	0.547
Sleep Apnea	13.2	21.3	0.126
Hypertension	84.5	85.1	1.000
Cardiomyopathy	35.8	38.3	0.754
Angina	5.9	8.5	0.517
Dyspnea	89.9	97.9	0.075
Edema	69.2	83.0	0.048
Gastrointestinal Symptoms	19.2	14.9	0.566
General Fatigue	23.9	25.5	0.860
Exam Findings			
JVD	21.5	25.5	0.583
Lung Rales	45.4	44.7	1.000
Volume Overload	14.6	14.9	1.000
Wheezing	11.9	8.5	0.640
Echo Findings			
Echo Performed	86.6	87.2	1.000
Abnormal Echo Findings	49.0	59.6	0.176
Aortic Stenosis	13.2	10.6	0.823
Mitral Stenosis	2.9	6.4	0.172
Aortic Regurgitation/Insufficiency	85.0	87.2	0.833
Mitral Regurgitation/Insufficiency	50.8	48.9	0.880
LVEF < 50	58.7	68.3	0.252
Diastolic Dysfunction	34.3	36.2	0.874
Positive Chest X-Ray Findings	91.4	97.9	0.166

Table 4-8—*Continued*

Variable, %	Not Readmitted (n = 665)	Readmitted (n = 47)	*P* Value
Lab Results			
BUN (md/dL) ≥ 18 First Set	69.4	70.2	1.000
GLU (md/dL) ≥ 100 First Set	77.2	63.8	0.050
Creat (md/dL) ≥ 1.5 First Set	44.7	48.9	0.649
BUN (md/dL) ≥ 18 Second Set	19.1	17.4	1.000
GLU (md/dL) ≥ 100 Second Set	60.3	62.2	0.875
Creat (md/dL) ≥ 1.5 Second Set	44.9	52.2	0.361
BNP(md/dL) >400	67.7	89.4	0.0016
Intervention			
PCI	18.0	29.8	0.054
Pacemaker ICD	66.8	61.7	0.523

Abbreviations: BUN = blood urea nitrogen; BNP = brain natriuretic peptide; Creat = creatinine; CVD = cardiovascular disease; GLU = glucose; HF = heart failure; ICD = implantable cardiac defibrillator; JVD = jugular venous distention; LVEF = left ventricular ejection fraction; PCI = percutaneous coronary intervention

Readmission for HF or non-HF in the first 30 days of discharge was modeled as a binary outcome. The effect of each potential risk factor, including the misdiagnosis of HF, hypothesized to be associated with any non-HF–related readmission was analyzed with univariate logistic regression models (Table 4-9). The unadjusted odds ratios (ORs) and their 95% confidence intervals (CIs) are also shown here. Inaccurately diagnosed patients (OR, 1.93; 95% CI, 1.08-3.44), patients aged > 60 years (OR, 2.67; 95% CI, 1.31-5.44), and patients having a documented arrhythmias (OR, 2.11; 95% CI, 1.24-3.57) were determined to be a risk factor for non-HF readmissions.

Factors from the univariate analysis that had a *P* value < 0.2 were indicated and then were used in a stepwise multivariate logistic regression analysis. The variable entry was set at 0.1, and the variable retention criteria were set at 0.05. After adjusting for the effect of the other factors in the model, the inaccurate diagnosis or low-probability group

(OR, 2.26; 95% CI, 1.15-4.44), and the age > 60 years (OR, 2.37; 95% CI, 1.03-5.50) had over twice the likelihood of being readmitted for a non-HF–related reason within 30 days compared with patients who were accurately diagnosed and patients aged ≤ 60 years. Additionally, the patients documented to have an arrhythmia (OR 1.98, 95% CI 1.07-3.66) had nearly twice the likelihood of being readmitted within 30 days (Table 4-9). The C-statistic was acceptable at 0.69.

Table 4-9 Univariate and stepwise multivariate logistic regression for readmission for non-HF

Variable		Univariate Analysis			Multivariable Analysis		
		Odds Ratio	95% CI	*P* Value	Odds Ratio	95% CI	*P* Value
Diagnosis of HF	Accurate	1.00					
	Inaccurate	1.93	1.08-3.44	0.021	2.26	1.15-4.44	0.018
Age	≤ 60 Years	1.00					
	> 60 Years	2.67	1.31-5.44	0.007	2.37	1.03-5.50	0.044
CABG	No	1.00					
	Yes	1.68	0.96-2.93	0.071	–	–	–
Gastrointestinal Symptoms	No	1.00					
	Yes	0.55	0.24-1.21	0.137	–	–	–
MI	No	1.00					
	Yes	1.47	0.8-2.7	0.217	–	–	–
PCI	No	1.00					
	Yes	1.59	0.88-2.9	0.1260	–	–	–
Volume Overload	No	1.00					
	Yes	1.67	0.88-3.17	0.119	–	–	–
Arrhythmia	No	1.00					
	Yes	2.11	1.24-3.57	0.006	1.98	1.07-3.66	0.0230
CVD	No	1.00					
	Yes	1.49	0.88-2.52	0.139	–	–	–
Aortic Stenosis	No	1.00					
	Yes	1.93	1.01-3.70	0.046	–	–	–

Abbreviations: CABG = coronary artery bypass graft; CI = confidence interval; CVD = cardiovascular disease; HF = heart failure; PCI = percutaneous coronary intervention

Readmission for HF in the first 30 days of discharge was also modeled as a binary outcome; individual comorbidities and diagnostic characteristics were compared with HF readmissions and were summarized. The effect of each potential risk factor, including the misdiagnosis of HF, hypothesized to be associated with any HF readmission, was additionally analyzed using a univariate logistic regression model (Table 4-10).

The unadjusted ORs and their 95% CIs are shown in Table 4-9. Patients aged > 60 years (OR, 2.31; 95% CI, 1.28-4.17), non-white race (OR, 2.34; 95% CI, 1.30.-4.24), serum glucose ≥ 100 mm/dL (OR, 1.93; 95% CI, 1.04-3.58), PCI (OR, 1.96; 95% CI, 1.02-3.75) had about twice the odds of being readmitted for HF within 30 days. Patients with high BNP pg/mL (BNP > 400) had almost 4 times the odds of being readmitted for HF within 30 days.

Factors from the univariate analysis that had a $P < 0.2$ were used in a stepwise multivariate logistic regression analysis. The variable entry criteria were set at 0.1 and the variable retention criteria was set at 0.05. The misdiagnosis of HF was forced in a final multivariate logistic regression model regardless of its significance. The final model resulted in a good discriminating ability (C-statistic = 0.738; Table 4-10).

After adjusting for the effect of the other factors, patients aged >60 years (OR, 2.18; 95% CI, 1.14-4.17), non-white race (OR, 1.91; 95% CI, 1.00-3.60), PCI (OR, 2.61; 95% CI, 1.32-5.16), and sleep apnea (OR, 2.24; 95% CI, 1.06-4.75) had nearly twice the odds of being readmitted for HF within 30 days. High BNP (BNP > 400) had nearly 4 times the odds of being readmitted for HF within 30 days (OR, 3.62; 95% CI, 1.43-9.16; Table 4-10).

Table 4-10 Univariate and stepwise multivariate logistic regression for readmission for HF

Variable		Univariate Analysis			Multivariable Analysis		
		Odds Ratio	95% CI	*P* Value	Odds Ratio	95% CI	*P* Value
Diagnosis of HF	Accurate	1.00					
	Inaccurate	0.43	0.16-1.16	0.0944	1.56	0.56-4.34	0.3919
Age	≤ 60 Years	1.00					
	>60 Years	2.31	1.28-4.17	0.0055	2.18	1.14-4.17	0.0179
Race	White	1.00					
	Non-White	2.34	1.3-4.24	0.0048	1.91	1.00-3.60	0.0466
BNP	≤ 400	1.00					
	> 400	3.70	1.50-9.14	0.0046	3.62	1.43-9.16	0.0066
GLU	< 100	1.00					
	≥ 100	1.93	1.04-3.58	0.0361	–	–	–
Anemia	No	1.00					
	Yes	1.47	0.80-2.69	0.2150	–	–	–
Dyspnea	No	1.00					
	Yes	3.5.	0.67-18.4	0.1382	–	–	–
Edema	No	1.00					
	Yes	2.07	0.97-4.44	0.0602	–	–	–
PCI	No	1.00					
	Yes	1.96	1.02-3.75	0.0422	2.61	1.32-5.16	0.0059
Sleep Apnea	No	1.00					
	Yes	1.83	0.89-3.76	0.1012	2.24	1.06-4.75	0.0350
Arrhythmia	No	1.00					
	Yes	0.62	0.33-1.16	0.1252	–	–	–
Chest X-Ray	Negative	1.00					
	Positive	2.92	0.56-15.2	0.2035	–	–	–

Abbreviations: BNP = brain natriuretic peptide; CI = confidence interval; GLU = glucose; HF = heart failure; PCI = percutaneous coronary intervention

Arbitration Committee Results

The arbitration committee consisted of 3 board certified cardiologists. Additionally, rater 1 is board certified in HF and cardiac transplantation. Rater 2 is considered a national expert echo sonographer and chairs a cardiology research and medical education board. Finally, rater 3 is board certified in interventional cardiology. The physicians comprising this committee individually had > 20 years of clinical experience in cardiology at the time of this exercise.

All the raters were given 68 identical medical records to review. The raters performed the review independently and were blinded to the other members' results. Table 4-11 shows the number of agreements, percentage of agreement, and the Kappa statistic with 95% CIs.

Additionally shown Table 4-10 is a 1-tailed *P* value was used to test the hypothesis that the agreement between raters was higher than expected by chance. The Kappa agreement for the diagnosis of HF between rater 1 and rater 2 was 0.50 (95% CI, 0.29-0.72) and rater 1 and 3 was .35 (95% CI, 0.11-0.58). As shown in the table, the Kappa between 2 raters ranged between 0.21 (raters 2 and 3) and 0.50 (raters 1 and 2), with an overall Kappa agreement among raters 1, 2, and 3 of 0.35 (95% CI, 0.11-0.58).

In accordance with Landis and Koch (1977), clinicians 1 and 2 had a moderate agreement, while the pairs of raters 1 and 3 and 2 and 3 had a fair agreement. Overall, the raters had a fair agreement when determining a diagnosis of HF in this study sample.

Table 4-11 Inter-clinician agreement in the diagnosis of HF

Clinician 2								
		No-HF	HF	Total	% Agreement	Kappa Statistics	95% CI	*P* Value
Clinician 1	No-HF	15 (22%)	6 (9%)	21 (31%)				
	HF	9 (13%)	38 (56%)	47 47(%)	78%	0.50	0.29-0.72	< 0.001
	Total	24 (35%)	44 (65%)	68 (100%)				
Clinician 3								
		No-HF	HF	Total	% Agreement	Kappa Statistics	95% CI	*P* Value
Clinician 1	No-HF	7 (10%)	14 (21%)	21 (32%)				
	HF	2 (3%)	45 (66%)	47 (69%)	76%	0.35	0.11-0.58	0.001 1
	Total	9 (13%)	59 (66%)	68 (100%)				
Clinician 3								
		No-HF	HF	Total	% Agreement	Kappa Statistics	95% CI	*P* Value
Clinician 2	No-HF	6 (9%)	18 (26%)	24 (35%)				
	HF	3 (4%)	41 (60%)	44 (65%)	69%	0.21	-0.003-0.43	0.017 2
	Total	9 (13%)	59 (87%)	68 (100%)				

Abbreviations: CI = confidence intervals; HF = heart failure

Chapter 5

Discussion, Conclusions, and Recommendations

Discussion

Of the patients in the study cohort, 18.7% were determined to have a low probability of an accurate diagnosis for HF when adjudicated against the diagnostic criteria. Diagnostic failure rates in previous studies have been estimated to be as high as 15% (Croskerry, 2013). This rate has been reported the highest among specialties where the diagnosis is undifferentiated, such as emergency and internal medicine (Croskerry, 2013). However, to date, no studies have reported a diagnostic failure rate specifically for HF. As a reminder, the diagnostic criterion was formulated directly from the most recent HFSA (2010) and ESC (2008) guidelines. Additionally, an inaccurate diagnosis for HF in this study was not found to be a predictor for a HF readmission; however, it was found to be a significant predictor for a *non-HF* readmission ($P = 0.018$)

Diagnostic Accuracy

Defining a HF diagnosis has historically challenged health care providers. The diagnosis is often described as a syndrome rather than an actual diagnosis (Chang, Maisel,& Hollander, 2009). This study analyzed specific presenting patient complaints, examination findings, and diagnostic results that have historically been considered when determining a HF diagnosis. The data, however, did not support that many of these accepted variables determined an accurate diagnosis. In fact, the majority of the variables analyzed did not reach statistical significance as a correlate for making an accurate HF diagnosis. Additionally, and as a confounder, over 30% (n = 235) of this study sample was determined to have a medium likelihood or indeterminate HF

diagnosis. Therefore, in this group, no clinical decision could be made to determine a probability of either an accurate or inaccurate diagnosis for HF.

Of the variables that were found to be statistically highly associated with a probability for and accurate diagnosis, dyspnea ($P = 0.0001$), edema ($P = 0.0001$), JVD ($P \leq 0.0001$), and rales ($P \leq 0.0001$) are all consistent with accepted clinical signs and symptoms of HF. In this sample, gastrointestinal complaints ($P = 0.012$) were also found to be associated with a probability of an accurate HF diagnosis, yet this has not been historically characterized as a routine finding in a patients admitted with a primary diagnosis of HF.

Conversely, volume overload, a clinical descriptor for a HF exacerbation, was not found in this study sample to be associated with a probability of an accurate HF diagnosis. Arrhythmias and hypertension have been historically reported, and strongly associated with HF (Dumitru & Baker, 2012). In addition, arrhythmias and hypertension are common etiologies of dilated cardiomyopathy, yet none of these variables reached statistical significance for being associated with a probability of an accurate HF diagnosis in this sample group. Other diagnostic results found statistically significant for a high probability of an accurate HF diagnosis (abnormal echo [$P = 0.024$], LVEF < 50% [$P = 0.0001$], and positive chest x-ray [$P = 0.0103$]) were expected as echocardiography and chest radiography are considered the gold standards for making an accurate HF diagnosis (ACC/AHA, 2013). Documented diastolic dysfunction ($P < 0.001$) was found to be statistically more associated in the low *and* medium probability for HF diagnosis groups. This finding warrants a secondary review of the patients in these groupings to validate if this finding was just described in the clinical notes or clearly defined with an echocardiogram.

Reviewing the comorbidity data, diabetes (P = 0.003) and renal disease (P = 0.005) reached statistical significance for having a medium/high probability of an accurate HF diagnosis. These particular disease processes among others have been previously described in the literature as independent correlates of HF (Table 2-1; Edelmann et al., 2011); however, no other comorbidities in this sample study reached statistical significance.

The arbitration committee was carefully selected to provide additional credible clinical expertise when reviewing the data from this cohort. Additionally, determining the inter-rater reliability for the criterion used to determine how to categorize the accuracy of a HF diagnosis was critical. The raters overall had fair agreement, with two of the raters achieving moderate agreement. The raters were all cardiologists; however, rater 1 and rater 2 had arguably more clinical expertise in making a determination for an accurate diagnosis of HF. Rater 1 is a credentialed HF and cardiac transplant physician, and rater 2 is a world-renowned echo sonographer. Rater 3 is a seasoned interventionist and although clearly qualified to determine a diagnosis of HF, when compared with the other two raters, perhaps not as qualified of the three.

One could also hypothesize that the level of independence displayed among the raters could be translated to higher levels of independence or diagnostic inaccuracy in the non-HF–expert provider. Theorizing further, non-HF–expert providers are generally the front-line clinicians for the acutely ill patient in the hospital setting and most likely the providers making the initial diagnosis. Furthermore, a non-HF-expert provider will most likely be creating the clinical problem list that follows the patient through his or her hospital course and beyond in potential readmissions. If the initial HF diagnosis was made in error and added to the problem list, the possibility of repeat errors exists.

Predictors of Readmission

To date, there are few studies that have been able to establish predictors for a HF readmission. Moreover, no studies have attempted to determine if an inaccurate HF diagnosis would predict readmission. Our secondary aim of this study was to determine if an inaccurate diagnosis would result in more readmissions compared with an accurate HF diagnosis. Although not found to be a significant predictor for a HF readmission, it was found to be a significant predictor for a non-HF–related readmission ($P = 0.018$).

This is a very provocative finding, especially when considering that from the 125 readmissions, only 41 were determined to be for a HF-related cause. This finding supports more recent studies suggesting that patients with HF are frequently being readmitted for non-HF–related causes due to the associated comorbidities in the patient population (Blecker et al., 2013). This is a critical finding in the current setting of the Affordable Health Care Act. Hospitals are currently penalized for excessive *all-cause* readmissions within a 30-day period from the initial admission.

Patient age > 60 years ($P = 0.0179$) and presence of arrhythmias ($P = 0.0230$) also reached statistical significance for a non-HF–related readmission. Advanced age is well known to be predictive for repeat admissions, so this finding was expected by the investigator (CMS.org, 2014b). More data analysis is needed, however, to make inferences about why, in this study sample, a documented arrhythmia was predictive for a non-HF–related readmission.

The statistical model also yielded other predictors for both HF and non-HF readmissions. An elevated BNP was found to be very predictive of a HF readmission ($P = 0.0066$). Previous studies have supported the hypothesis that high BNPs at discharge increase the likelihood of a readmission (Hernandez et al., 2013). However a BNP > 400 during the admission could also be argued as an insensitive tool that is now relied upon

too heavily to make a diagnosis. In the elderly, myocardial fibrosis and renal dysfunction is common; therefore, a moderate increase in circulating BNP will also be observed outside of HF (Braunwald, 2008). The average age of this study population was > 60 years, and 14% (n = 98) were aged > 70 years. Renal disease was additionally found to be independently associated when making an accurate HF diagnosis in our cohort.

Non-white race (P = 0.0048) and age > 60 years (P = 0.044) were also found to be significant predictors for a HF readmission. It has been well described that racial/ethnic minorities do not receive equitable health care in the United States when compared to white patients (Dovidio & Fiske, 2012). Although not analyzed in this study, explanations for this finding could be differences in socioeconomic status and limited access to this health care system. Additionally, bias in health care providers should be explored as this has been reported as an independent factor contributing to health care disparity in non-white patients (Dovidio & Fiske, 2012).

Patients with a diagnosis of sleep apnea (P = 0.0350) and patients undergoing a PCI (P = 0.0059), however, were predictors of a HF readmission. These were unique and unexpected findings, as to date there are few, if any studies linking either to a HF readmission. Theorizing, patients with HF who undergo PCI are most likely sicker than are patients who do not, thus the increased likelihood of a HF readmission.

Shifting focus to the sleep apnea finding, we observed that the cohort's BMI average was > 30 kg/m^2, which is categorized as obese, and obesity is one of the biggest risk factors for obstructive sleep apnea (Wachter et al., 2012). Additionally, diastolic dysfunction, previously mentioned, was determined to be a very significant correlate ($P \leq$ 0.0001) for a medium likelihood of HF diagnosis. Diastolic dysfunction has been reported in the literature as being independently associated with moderate to severe sleep apnea (Wachter et al., 2012).

Limitations

This study is limited by what is inherent to a retrospective chart review. The investigator had no control regarding the accuracy of the documentation that was abstracted from the EMR system or the data collected from paper medical records. A retrospective review of medical records also most likely has missing data. Missing and erroneous data could potentially have resulted in a change in the final analysis in the variables of interest.

Additionally, our all-cause readmission rate in this cohort was consistent with national averages (17.5%); however, our high probability for HF readmission grouping rate was small (6%). Therefore, any inferences made on this particular outcome should only be considered evocative.

Disputably, the investigator also attempted to categorize subjective findings into an objective format. However, based on established diagnostic criterion, one could also argue that the rater-to-rater agreement reflects only a fair sensitivity when assigning the sample into the three diagnostic groupings and that reaching a diagnosis is always a subjective exercise. Finally, the findings in this study are limited to similar populations with a similar health care system and should not be generalized to other populations across the country or internationally.

Conclusions

The diagnosis of HF is undoubtedly one of the most complex disease processes. The health care community is aware of its complexities, but the subjectivity among providers when determining this diagnosis has yet to be fully explored.

In this cohort, we have identified that 18% of the sample displayed a low likelihood that the admitting primary diagnosis of HF was actually HF. Moreover, patients who had an inaccurate diagnosis in this study sample had over 2 times the likelihood of

being readmitted for non-HF–related issues compared with patients who were accurately diagnosed.

Additionally, this data set provided significant predictors for readmissions for both HF and non-HF causes. Patients aged > 60 years had nearly 2 times the likelihood of being readmitted for both HF and non-HF–related causes than did their younger counterparts aged < 60 years. Non-white patients had nearly 2 times the likelihood of being readmitted for a HF diagnosis compared with the white patients in this sample. Moreover, a patient having a BNP > 400 at any time during an admission had nearly 4 times the likelihood of being readmitted for HF than did those patients who did not have a BNP > 400 during their admission.

Sleep apnea and PCI were unique findings as predictors for a HF readmission. In fact, a patient in this study sample undergoing a PCI, or having sleep apnea, was nearly 2 times more likely to be readmitted for HF compared with patients who did not have a PCI or sleep apnea. Finally, patients with a documented arrhythmia were nearly 2 times more likely to be readmitted for non-HF–related causes.

Recommendations

Larger prospective trials evaluating the accuracy of the supporting clinical documentation for a HF diagnosis is indicated. Specifically with this sample, a secondary analysis of the intermediate likelihood for a HF diagnostic group is warranted, as the number of patients in this group comprised 30% of the total sample size.

It would be interesting to explore and better define why it was so difficult to assign a definitive diagnosis to this particular sample patient grouping. Additionally, could some aspect of this difficulty be explained in part by socioeconomic endpoints? This study's aim was to look only at one potential contributor to the persistent readmissions for HF. However, older patients were observed to be predictors for HF *and*

non-HF readmissions. Additionally, black patients were noted to be more likely to be readmitted for HF. Racial and ethnic disparities have been well reported in the national and international literature as significant risks for readmission for HF, especially in patients aged > 65 years (Damiani et al., 2014).

Currently hospitals are documenting more measures in electronic medical records in the vein of social disadvantages. These include language proficiency, health literacy, and social support. Stronger prospective trials looking at these indices are now possible allowing a more sophisticated way to measure, identify, and manage high-risk patients who would be readmitted for *any* chronic illness for non-clinical and vulnerable factors (Calvillo-King et al., 2012).

Of the clinical predictors that were determined for HF readmission, sleep apnea was the most novel in this study sample. There are limited studies looking at sleep apnea and its relationship in HF. Additionally, examination of sleep apnea and its correlation with diastolic dysfunction is warranted, as it is not fully understood. There are significant gaps in the literature on how to diagnose, define, and successfully treat these two conditions.

The rater-to-rater agreement of the arbitration committee results was especially intriguing to this investigator. This committee consisted of experienced clinicians considered experts in their fields. Therefore, it would be interesting to re-analyze this patient sample looking for confounders in these patients that the committee members mutually agreed or disagreed upon when assigning them to a diagnostic group. To date, no qualitative studies have been performed evaluating cognitive bias in providers who care for the acutely or chronically ill. These types of studies are needed, however, and may provide some insight in developing a better schema for determining diagnosis. If the experts cannot agree, this will certainly be even more critical for the next generation of

novice health care providers, which includes a growing number of advanced practice nurses managing this patient population.

The challenges that face today's growing population of advanced practice nurses are immense. Reductions in time spent on individual patients, the growing number of patients expected to be seen per work day, financial limitations for diagnostic testing, and increased complex illnesses in the growing elderly patient population are daunting. Additionally, the hospital system under study utilized hospitalists in part to ease these burdens. Hospitalists in this study setting functioned as the primary care provider and/or gatekeeper for the hospitalized patient. The hospitalists were generally not only held responsible for assigning the discharge diagnosis, but were also held accountable for improving patient outcomes and reducing length of stay and readmissions by adhering to evidence-based guidelines. This study's purpose was not to delve into the experience or training backgrounds of these providers; however, it would be worthy to look at these factors for future studies.

Nationally, hospitalist providers also have the critical role of implementing recommended strategies to support effective transitions to home with the goal again being to improve outcomes and reduce readmissions. Recent studies, however, have evaluated and compared hospital systems with and without hospitalists. For hospitals that used hospitalists, there was no significant change in any of the outcome measures, with an increasing percentage of patients admitted by hospitalists (Goodrich et al., 2012).

Furthermore, as of 2011, health care systems that had participated in prominent quality initiatives—STAAR (State Action on Avoidable Rehospitalization) and H2H (Hospital-to-Home Campaign)—reported that frequently hospitalists were not implementing the recommended strategies in reducing readmissions (Bradley et al., 2013). More studies are clearly needed to evaluate this phenomenon so that

improvements are made for the successful utilization of these types of providers. Hospitalists and advanced practice nurses who care for hospitalized patients will continue to play a critical role in incentivizing adherence to hospital-based initiatives as well as driving transitional care programs that have had reported success in reducing costs and readmissions for *all* chronic illnesses.

Finally, from an economic standpoint, a large amount of diagnostic data was abstracted to complete this study. A sub-analysis is warranted looking at the frequency and costs of the diagnostic testing per patient, per admission, and per primary admitting diagnosis, to evaluate opportunities for improvement. Health care spending in 2012 was estimated at $2.8 trillion or $8915 per person (CMS.gov, 2014b). Clearly, more research is needed to impart fiscal soundness and economic sustainability for our future generations' health care needs.

Appendix A

Baylor Research Institute IRB Approval Letter

BAYLOR
Research Institute
Affiliated with Baylor Health Care System

IRB Approval – Expedited Review of Continuing Review

To: Sandra Carey, NP

Copy to: Sandra Carey, NP

Date: August 05, 2014

Re: 012-176
"Assessment of the aCCURAcy of the diagnosis of CHF in a large metropolitan healTh carE system"
Reference Number: 077285

Your request for continuing review was reviewed by a designated member of Baylor IRB Red via expedited review.

This study was determined to be eligible for expedited review as it involves no greater than minimal risk to the subjects and fits into the following category(ies) from the 1998 approved list:
Category 5: Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis)

This review included the following components:

Study Application	
Form Name	**Outcome**
Study Application - Review by BRI IRB	Approved as Presented

Study Document			
Title	**Version Number**	**Version Date**	**Outcome**
CHF Form 15	Version 1.1	08/03/2012	Approved
CHF_DataCollection Form_IRB	Version 1.1	08/03/2012	Approved
Protocol Amendment	Version 1.0	06/09/2014	Approved

Your submission has been approved. The approval period begins on 08/05/2014 and expires on 07/30/2015. Your next continuing review is scheduled for 06/15/2015.

This study is approved to be conducted at the following locations:
Baylor Regional Medical Center at Grapevine, Main
Baylor Jack and Jane Hamilton Heart & Vascular Hospital, Main
Other Baylor Facility - IHCRI- 8080 N Central Expwy

The following individuals are approved as key study personnel (research team members & administrative support):
Carey, Sandra, NP; East, Cara A., MD; Grayburn, Paul A., MD; Hall, Shelley A., MD; Jennings, Linda, PhD; Moshayedi, Poupak, RC; Saracino, Giovanna, MS

Based on the information provided in your submission, the IRB has determined that this study qualifies for a waiver of informed consent in accordance with 45 CFR 46.116 (d) and a waiver of HIPAA Authorization 45 CFR 160 and 164.

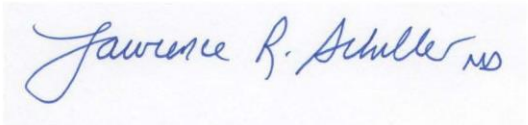
All events that occur on this study including protocol deviations, serious adverse events, unanticipated problems involving risks to subjects/others, subject complaints or other similar events must be reported to the IRB in accordance with the respective policies.

Remember that this study is approved to be conducted as presented. Any revisions to this proposal and/or any of the referenced documents must be approved by the IRB prior to being implemented. Additionally, if you wish to begin using any new documents, these must receive IRB approval prior to implementation of them in the study.

IRB approval may not be the final approval needed to begin the study. All contractual, financial or other administrative issues must be resolved through Baylor Research Institute prior to beginning your study.

If you need additional assistance, please contact the IRB Specialist at 214-820-9989.

Sincerely,



Signature applied by Lawrence R. Schiller on 08/06/2014 12:53:00 AM CDT

Appendix B

UTA IRB Approval Letter

UNIVERSITY OF TEXAS ARLINGTON | OFFICE OF RESEARCH ADMINISTRATION
REGULATORY SERVICES

Institutional Review Board
Acknowledgment of Approved Research Activity

July 9, 2014

Sandra Carey
Dr. Donelle Barnes
College of Nursing
The University of Texas at Arlington
Box 19407

UTA Protocol No.: 2014-0676
Protocol Title: *ASSESSMENT OF THE ACCURACY OF THE DIAGNOSIS FOR HEART FAILURE IN A LARGE METROPOLITAN HEALTH CARE SYSTEM*

The UT Arlington Office of Research Administration - Regulatory Services and Institutional Review Board (IRB) are pleased to acknowledge your engagement in this research protocol involving human subjects which has been approved by the IRB at Baylor. The Baylor IRB is noted as the "IRB of record" for this protocol. An IRB of record assumes IRB responsibilities for another institution as specified in each institution's Federalwide Assurance (FWA), and has an agreement of reliability on file. Having met the conditions for approval set forth by the IRB at Baylor, and in compliance with applicable regulations, acknowledgment of such approval has been granted by the UTA IRB or designee.
Baylor IRB No: 012-176
Review Level: Expedited
Approval Date: July 8, 2014

Please note that you are responsible for providing UT Arlington's IRB with a copies of official notifications or approvals from the IRB of record, including but not limited to: approval letters for continuing reviews, approval letters for protocol modifications, incident or adverse event reports, audit or monitoring reports, or study closures.

The UT Arlington IRB and the Office of Research Administration - Regulatory Services appreciate your continuing commitment to the protection of human subjects engaged in research and wish you all the best in your research endeavors. Should you require further assistance, please contact Robin Dickey at robind@uta.edu or you may contact the office of Regulatory Services at regulatoryservices@uta.edu or 817-272-3723.

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Biographical Information

Sandra A. Carey has served in health care for over 20 years. She began her health education as a military medic in the United States Air Force (USAF) at the age of 18, just after graduating from high school. While serving as a medic, she began taking prerequisite courses and eventually received a scholarship from the military to attend nursing school. In 1995, she graduated from Southwestern Oklahoma State University with a Bachelor of Science in Nursing. She was subsequently commissioned as an officer in the USAF. She then continued with her military service as a cardiology critical care nurse. Always involved in military research, in 2001 she graduated with a Master of Public Health from University of Texas Health Science Center, at Houston. Also in 2001, she was accepted into a military-sponsored nurse practitioner program. She graduated with a Master of Science from Ball State University in 2005 and then began her career as a cardiology adult nurse practitioner, retiring from the USAF after 20 years of service. In the following 4 years in civilian practice, she once again returned to school to complete a lifelong goal of obtaining a Ph.D. at the University of Texas at Arlington.