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Outcomes of heart failure discharge instructions

Gwenneth Anne Jensen
University of Iowa

OUTCOMES OF HEART FAILURE DISCHARGE INSTRUCTIONS

By

Gwenneth Anne Jensen

An Abstract

Of a thesis submitted in partial fulfillment of the requirements for the Doctor of Philosophy degree in Nursing in the Graduate College of The University of Iowa

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Thesis Supervisor: Professor Janet Specht

Acute decompensation of chronic heart failure is common and results in many patients being re-hospitalized every year (Jancin 2008). One of four voluntary core measures deployed by the Joint Commission for evaluation of quality of heart failure care in hospitals is heart failure discharge instructions, also called core measure HF1. Although the core measure is a widely disseminated standardized measure related to discharge education, there is little evidence about its impact on patient or readmission outcomes. The purpose of this study was to determine the relationship between the completion of heart failure discharge instructions as defined by the Joint Commission core measure HF1 in a single site, 500 bed tertiary hospital population in the Upper Midwest and the primary endpoint of subsequent readmission to the hospital 30, 90, 180 and 365 days following an index discharge for primary diagnosis of heart failure. Secondary endpoints included hospital readmission charges and total hospital readmission days per year. Patient characteristics, clinical characteristics, unit factors and index visit utilization variables were controlled. This study also described the relationship between nursing unit factors and completion of HF1.

A retrospective, descriptive design, and analyses using primarily generalized linear models, were used to study the relationship of HF1 to utilization outcomes (readmission, hospital days and cost) and unit context (discharge unit and number of inter-unit transfers). Individual level retrospective demographic, clinical, administrative and performance improvement data were used (n = 1034). Results suggested a weak and non-significant association of completion of the core measure HF1 bundle and readmission within 30 days for all cause readmissions (p = .22; OR 1.32), and no association with HF to HF readmissions at 30 days. There was an inverse association

after 6 months for all cause readmission, and after 90 days for HF to HF readmission. There was a non-significant trend toward a relationship to total hospital days, but no relationship of HF1 to total annual charges. The study did find a significant relationship between type of discharge nursing unit and HF1 completion, and type of discharge unit and readmission. The discharge nursing unit was quite consistently and strongly related to all cause readmissions in binary (p = .029: OR 1.58) and counts analyses (p = .001; OR 1.52), but was not related to the subset of HF to HF readmissions. The study concludes that there is limited relationship between HF1 and 30 day all cause hospital readmission and total readmission days, but a stronger relationship between HF1 and discharge from a cardiology specialty unit. There was also a relationship between cardiology discharge unit and reduction in all cause readmissions.

Abstract Approved: ______________________________
Thesis Supervisor

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Title and Department

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Date

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Iowa City, Iowa

CERTIFICATE OF APPROVAL

PH.D. THESIS

This is to certify that the Ph.D. thesis of

Gwenneth Anne Jensen

has been approved by the Examining Committee for the thesis requirement for the Doctor of Philosophy degree in Nursing at the July 2011 graduation.

Thesis Committee: ___________________________________
Janet Specht, Thesis Supervisor

____
Meridean Maas

____
Timothy Ansley

____
DerFa Lu

____
Lisa Skemp

____
Jennifer Robinson

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CHAPTER I

INTRODUCTION

Nurses contribute to the quality of care and outcomes of patients with heart failure (HF), a prevalent and costly chronic condition. Heart failure, primarily a condition of older adults, has substantial impact on functional ability, quality of life, public health and healthcare expenditures. Acute decompensation of chronic heart failure is common and results in many patients being re-hospitalized every year (Jancin 2008).

Major governmental and regulatory organizations have adopted and reported hospital standards for heart failure care that are consistent with guidelines developed by professional organizations such as the American College of Cardiology and the American Heart Association (Adams and Lindenfeld 2006; American College of Cardiology 2006; Center for Medicare and Medicaid Services 2008; The Joint Commission 2009). Some of these professional organization guidelines, including those related to discharge preparation, have arguably greater support from expert opinion than from high graded evidence and well researched outcomes (Tricoci, Allen et al. 2009; Wingate 2009; Ghali, Massie et al. 2010; Patterson, Hernandez et al. 2010).

One of four voluntary core measures deployed by the Joint Commission for evaluation of quality of heart failure care in hospitals is heart failure discharge instructions, also called core measure HF1. Heart failure discharge instructions (HF1) are to be completed at every discharge for primary diagnosis of HF. It is widely accepted that transition from hospital to home requires discharge preparation and appropriate education and counseling for patients and families (Naylor, Brooten et al. 2004; Adams and Lindenfeld 2006; McCauley, Bixby et al. 2006; Heidenreich and Fonarow 2007; Jessup, Abraham et al. 2009). Compliance with the core measure for heart failure discharge instructions requires that specific written instructions be documented as given to the patient or caregiver at discharge from the hospital after every admission for HF.

Recent publications indicate that the overall quality of discharge instruction and transitional care remains variable among older adults with heart failure (Institute for Clinical Systems Improvement (ICSI) 2006; Fonarow, Abraham et al. 2007; Agency for Healthcare Research and Quality (AHRQ) 2008; Center for Medicare and Medicaid Services (CMS) 2008; The Joint Commission 2009). Outcomes of these hospital heart failure discharge instructions, (Joint Commission core measure HF-1), have received limited study (VanSuch, Naessens et al. 2006) .

Statement of the Problem

Although a chronic condition, heart failure acute exacerbations are common, causing frequent and costly readmissions to the hospital. According to Edwardson (2007), preventing hospital readmission is the most important factor in reducing cost and resource use for care of heart failure patients. Although re-hospitalization rates after a heart failure admission are high, there is considerable variability between States in rates of all-cause, 30 day Medicare readmissions. Jencks et al (2009) indicate that improvements in readmission rates are possible at a national level, suggesting that standardization in discharge interventions should reduce readmissions. Standardization would be of benefit because 20-40% of re-hospitalizations (i.e., readmission to any hospital, not necessarily the same hospital as a prior admission) occur to other hospitals and are essentially lost to follow-up at the local level. Government and third party data are able to capture readmission and re-hospitalization data and could measure the effects of a disseminated standardized practice change.

Although the core measure is a widely disseminated standardized measure related to discharge education, there is little data about its impact on patient or readmission outcomes. Variable, and even poor, process implementation of HF1 has been suggested, i.e. if existing heart failure teaching and discharge planning interventions were instituted "more fully" (p.1371), readmission rates might be reduced (Ross, Mulvey et al. 2008). In fact, there is an overall gap in knowledge about the specific discharge interventions that affect HF readmissions.

Outcomes are needed that assert or deny an association between current discharge instruction and patient self care practices that result in fewer hospitalization events. It is widely reported over the last two decades that better self-care practices can prevent up to two-thirds of HF hospitalizations (Vinson, Rich et al. 1990; Bennett, Huster et al. 1998; Michalson, Konig et al. 1998; Moser and Mann 2002). Certain knowledge and skills are required for adherence to provider recommendations and performance of self care (Evangelista and Dracup 2000; Grady, Dracup et al. 2000; Edwardson 2007). The American College of Cardiology (ACC) and the American Heart Association (AHA) HF management guidelines recommend that upon discharge from the hospital patients receive written education materials relating to activity level, diet, discharge medications, follow-up appointments, weight monitoring, and what to do if symptoms worsen, all of which have been associated with reduced morbidity and improved survival (Krumholz, Amatruda et al. 2002; Bonow, Bennett et al. 2005; Hunt, Abraham et al. 2005; Koelling, Johnson et al. 2005; Jessup, Abraham et al. 2009; Lindenfeld, Albert et al. 2010). The

Joint Commission, responsible for voluntary accreditation of hospitals in the United States, has included the educational topics recommended by the ACC and AHA in its regulatory standard for heart failure discharge instructions, known as core measure HF1 (The Joint Commission 2009).

Process criteria for meeting the standard, however, are non-specific. In order to be considered compliant with the standard core measure HF1, organizations must provide documentation that patients who are being discharged to home, and/or their caregivers, receive "written instructions" in each of six elements. This documentation, however, may be as minimalist as a set of yes/no check boxes with little detail on depth of content or methods of education or plans for follow-up.

A recent large study on hospital readmission related to non-pharmacological interventions for post-discharge care of HF inferred the ubiquitous nature of hospital discharge self care education, stating: "…education on self care management [has] become usual care, rather than a specific intervention of interest" (Agency for Healthcare Research and Quality 2008). However, uniformity and standardization in implementation of HF self-care education is lacking. Patients with heart failure clearly need to be prepared to live with a chronic condition, but how that is best accomplished is multidimensional and poorly described in the existing literature. Although guideline programs such as "Get With The Guidelines" have promoted aggressive education during hospitalization, there is a lack of evidence that in-hospital heart failure education can achieve sustained behavior change or impact outcomes (Agency for Healthcare Research and Quality 2008). There are continued gaps in standard definitions, vital content

(Riegel, Moser et al. 2006), and process implementation (Coster and Norman 2009) of heart failure self care education.

Rather, the literature suggests that written instructions, alone, are unlikely to produce substantive changes in self management of HF which can affect patient outcomes, cost and recidivism (Albert, Fonarow et al. 2007; Davidson, Cockburn et al. 2008). Other studies suggest patient education, particularly using traditional methods, has not resulted in sustained and effective behavior change for self-care and adherence (Jaarsma, Halfens et al. 1999; Ni, Nauman et al. 1999; Carlson, Riegel et al. 2001; Artinian, Magnan et al. 2002; Albert, Fonarow et al. 2007).

Nursing is emerging as a science integral to hospital quality of care and patient safety. The Institute of Medicine (IOM) defines quality of care as “the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge” (Institute of Medicine 1990). The Institute of Medicine’s Committee on the Adequacy of Nurse Staffing in Hospitals and Nursing Homes stated that nursing is a critical factor in determining the quality of care in hospitals and also in the nature of patient outcomes in hospitals (Wunderlich, Sloan et al. 1996). In its report, “Keeping Patients Safe: Transforming the Work Environment for Nurses” (IOM, 2004) the IOM acknowledged the central role of nursing in quality of care in hospitals. The IOM linked the nurses’ skill at surveillance, monitoring and bedside vigilance to improved outcomes and increased defense against errors (Institute of Medicine 2004). Studies imply the central role of nursing in hospital discharge instructions for heart failure patients (Albert, Fonarow et al. 2007), but no studies were found that specifically reported the discipline of the staff, i.e. nursing, pharmacy, nutrition, etc., involved in delivering the recommended heart failure discharge education.

With usual short stay hospitalizations, design opportunities may exist for improved, theory-based, patient-centered heart failure discharge education to be imbedded into continuum of care models. More effective and efficient interdisciplinary strategies may be constructed than handing an older person, or their family member, a set of written instructions. Yet, without baseline data related to the effect on outcomes, the relationship of the standard measure for heart failure discharge instructions, HF1, to hospital readmission and other outcomes, is largely unknown.

Only one previous study was found on the relationship between process compliance with providing patients and/or families with written heart failure discharge instructions (HF1) and endpoints of care such as time to readmission. The study indicated a reduction in readmissions with completion of HF1 (VanSuch, Naessens et al. 2006). However, this single site study did not indicate how HF1 was delivered, nor by what discipline(s), nor the degree of participation by these disciplines in completion of HF1. Neither did the study describe context of care variables such as type of nursing discharge unit, e.g. cardiology nursing specialty unit versus other hospital unit, or number of unit transfers during a hospital stay (VanSuch, Naessens et al. 2006).

Further study is needed to clarify the outcomes of core measure HF1 as it is currently deployed by the Joint Commission. Baseline measures of outcomes related to HF1 are necessary prior to future programs of research that may deploy theory-based and patient-centered nursing interventions related to heart failure discharge education.

Purpose

The specific content and process of HF1 discharge instructions for heart failure lacks detail, resulting in process variation among providers. Variation in process inhibits efforts to evaluate the effect of HF1 on self care preparation prior to hospital discharge (Edwardson 2007). In contrast to evidence or theory-based delivery of heart failure patient education, the current requirement is documentation of receipt of a set of written instructions related to six elements of heart failure self care. The HF1 core measure fosters traditional patient education; it tends to be authoritarian, prescriptive, didactic and information-laden. It may be argued that HF1 is not consistent with the IOM definition of quality of care, i.e. it is not "consistent with current professional knowledge".

The purpose of this study was to determine the relationship between the completion of heart failure discharge instructions as defined by the Joint Commission core measure HF1 in a single site, 500 bed tertiary hospital population and the primary endpoint of subsequent readmission to the hospital 30, 90, 180 and 365 days following an index discharge for primary diagnosis of heart failure. Secondary endpoints included hospital readmission charges and total hospital readmission days per year. Patient characteristics, clinical characteristics, unit factors and index visit utilization variables were controlled. This study also uniquely piloted methods to describe the relationship between nursing unit factors and completion of HF1.

Significance

The estimated cost of care for heart failure in 2009 was USD $37.2 billion, up from USD $32.2 billion in 2007 (American Heart Association 2007; American Heart Association 2009). There are currently about 1.1 million hospital visits and 6.5 million hospital days associated with heart failure every year in the United States, alone (O'Connell 2000; American College of Cardiology 2006). Persons with heart failure account for 37% of all Medicare spending and nearly 50% of all inpatient hospital costs (Jancin 2008). Hospitalizations for heart failure exacerbations are by far the most costly portion of care, accounting for 70% of the total annual cost.

Heart failure is the most common cause of 30 day re-hospitalization in the Medicare population (Jencks, Williams et al. 2009). In addition, 30 day readmission reimbursement for Medicare patients is already lower than for the index admission and is being increasingly scrutinized. Reimbursement is 4% lower than for an index admission and tends to be about 0.6 days longer, making readmission financially detrimental for hospitals with limited bed capacity (Jencks, Williams et al. 2009). In the United States, Congress and the White House are looking at options such as bundling payments and reducing reimbursement for hospitals and physicians with the highest readmission rates (Abelson 2009).

As healthcare costs continue to increase in an unstable global economy, quality of care in hospitals is increasingly scrutinized and linked to financial and patient outcomes. The Institute of Medicine defines quality of care as “the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge” (Institute of Medicine 1990). In spite of intensive efforts in the past 10 years to improve quality related outcomes in hospitalized heart failure patients, quality of care remains inadequate (Fonarow et al 2007).

The National Quality Forum, the Joint Commission, and the Centers for Medicare and Medicaid Services (CMS) all endorse the six elements of hospital discharge instructions as a quality indicator set for heart failure (National Quality Measures Clearinghouse 2009; The Joint Commission 2009). Yet, recent research suggests continued variation in expert opinion about what constitutes requisite heart failure self care and discharge education, and, not surprisingly, what measures should be used to evaluate it (Riegel, Moser et al. 2006; Wingate 2009). The Joint Commission uses core measure HF-1, written instruction given to patients or providers, and reports improvement overall in organizational compliance yet wide variation continues (Fonarow, Yancy et al. 2005; Edwardson 2007; Robert Wood Johnson Foundation 2008) and little has been reported on the relationship of HF-1 to other context of care factors and outcomes.

In addition, broad methodological variation across studies adds to the difficulty in drawing conclusions about best non-pharmacological care for heart failure patients (Agency for Healthcare Research and Quality 2008). There is opportunity for development of valid and replicable nursing research methods from single site pilot studies that may be applied in funded multi-site studies in the future. By applying effectiveness research methods with local databases, nursing has increasing opportunities to develop skills in querying electronic databases within their own organizations, and through multi-site nursing studies, to answer nursing-related quality and safety questions. Hospital quality of care data provide opportunities for large scale analyses of the relationship of completion of HF1 and heart failure inpatient quality of care, and patient and financial outcomes. Yet, analyses to date have not attempted to relate discharge instructions alone with patient outcomes such as readmission and cost, or with hospital contextual issues such as specialty versus generalist nursing unit or number of inpatient unit transfers.

There is a gap in understanding the value of the HF1 intervention as it is currently deployed, i.e. it is unknown whether or not, nor to what degree, HF1 is beneficial to patients, and thus to organizations and the healthcare system. By determining that an intervention is currently not adding value or accomplishing its intent, nurse researchers in partnership with practice, have opportunity for targeted, measureable modifications. Determination of non-value added activities is an area largely unexplored in nursing, including heart failure discharge planning. Based on evidence and theory, nursing's contribution to the intervention HF1 could be strengthened and demonstrate added value while building knowledge and important nursing contributions to better quality and efficiency of hospital care.

Finally, it is of significance to nursing science that this organizational and governmental measurement for quality of heart failure discharge education appears largely unsupported by outcomes or theory (Bandura 1977; Bandura 1982; Institute of Medicine 2001; Naylor, Brooten et al. 2004; Rutherford, Lee et al. 2004; Dickson and McMahon 2008; Riegel and Dickson 2008; Robinson, Callister et al. 2008). This study seeks to inform the question, "Do the regulatory guidelines and the publically reported process data reflect the best application of current knowledge in practice?" Unfortunately, there is a gap in reported outcomes related to HF1 and an un-established baseline against which theory-based nursing interventions can be compared in future studies.

Specific Aims

This program of research will contribute to the base of knowledge related to patient self care of heart failure, and provide the initial study for a program of research examining the effectiveness of nursing and interdisciplinary interventions for older adults hospitalized with heart failure. Such a program of research will contribute by studying the effects of iterative evidence and theory-based changes in heart failure discharge instructions, beginning in the hospital setting.

To establish a descriptive baseline, this single institution study used existing electronic, large database, individual level core measure and medical record data. The study described the relationship between completion of HF1 (heart failure discharge instructions) and hospital readmission at 30, 90, 180 and 365 days, and readmission charges and total hospital readmission days per year, controlling for patient characteristics, clinical characteristics, and nursing unit factors. It also described the relationship of HF1 to hospital nursing unit contextual factors.

These specific aims were applied to subjects age 50 years and older with primary discharge diagnosis of heart failure who are discharged to home with or without services:

1) Describe the relationship between completion of HF1 and hospital readmissions at 30, 90, 180 and 365 days post-discharge, hospital readmission charges at 12 months, and total number of readmission hospital days at 12 months while controlling for patient, clinical, and hospital unit characteristics.

2) Describe the relationship between unit contextual factors including a) discharge unit type, i.e. medical cardiology versus general unit and b) number of inter-unit transfers and all-or-none completion of HF1 at the index hospitalization.

Definitions

Definitions are imbedded in the text of the proposal and a variables table is included. Several definitions will be reiterated in the text:

HF-1 – one of four core performance measurements for hospitals regarding care of heart failure patients and one of the ORYX initiatives from the Joint Commission. HF-1 requires documentation that heart failure patients are discharged home with written instructions or educational materials given to the patient or care giver at discharge or during the hospital stay addressing all of the following: activity level, diet, discharge medications, follow-up appointment, weight monitoring, what to do if symptoms worsen.

Self-care - an active cognitive process that triggers critical behaviors by an individual or care provider to maintain health and manage symptoms of a condition; a naturalistic decision-making process involving the choice of behaviors that maintain physiologic stability (maintenance) and the response to symptoms when they occur (management).

Self-care management – a process initiated by symptom recognition and evaluation that stimulates decision-making, choice of behaviors in response to symptoms, and evaluation of effect of self treatment.

Self-care maintenance – part of a decision-making process involving choice of behaviors related to routine symptom monitoring and treatment adherence that maintain physiologic stability.

Index admission/discharge – the first hospital admission/discharge for primary diagnosis of HF for which HF1 data are available within the study period; the discharge date from this admission marks the beginning of readmission tracking for a 12 month period.

Nursing Units – refers to the number of nursing units upon which a patient resides during a hospital episode of care.

Limitations

Neither electronic nor paper data were available on several important variables related to this study including length of time living with diagnosis of heart failure, patient educational level, and New York Heart Classification. In addition, ejection fraction was not available electronically. Core measures H2 through H4 were not included in the analysis due to the relatively small n available for some of these measures. All of these variables would have added important controls to the analysis. Death data were also not available until the last two years of the study period so that lack of readmission could not be discerned from death.

Data restructuring also required some manual manipulation of identifiers due to a change in the electronic data collection system during the period of the study. Administrative data is known to be subject to inaccuracies, such as miscoded primary discharge diagnoses, missing or inaccurate documentation of medical history or management during hospitalization, and misidentified cases for core measure abstraction. Because 20-30% of re-hospitalizations occur to other hospitals, these cases are lost to local follow up.

CHAPTER II

REVIEW OF THE LITERATURE AND CONCEPTUAL FRAMEWORK

Heart Failure and Readmissions

Despite advances in medical, surgical and pharmacologic treatments, heart failure (HF) is a major cause of death and disability in the United States and in industrialized countries. Heart failure is the final common pathway of cardiovascular disease and continues to increase in incidence and prevalence worldwide (American Heart Association 2009). Primarily a condition of older adults, heart failure affects about 5.7 million Americans, 75% of which are 65 years of age or older (American Heart Association 2009; Jessup, Abraham et al. 2009). In general, following a diagnosis of heart failure, a person experiences a decline in function, reduced quality of life and increased likelihood of death within five to eight years (American Heart Association 2009) .

Heart failure (HF) is a complex clinical syndrome, usually characterized by exercise intolerance and fluid retention (Jessup, Abraham et al. 2009) with related signs and symptoms of weight gain, edema, dyspnea and fatigue, that reduce quality of life and functional ability. It results from any structural or functional cardiac disorder that impairs the ability of the ventricle to fill with or eject blood to meet the metabolic demands of the body (Hunt, Baker et al. 2001). Risk factors include the pre-existence of hypertension, coronary artery disease and/or diabetes mellitus (American Heart Association 2009). After diagnosis, heart failure (HF) generally manifests a negative trajectory of physical functioning and intermittent hemodynamic instability.

Heart failure is a disease of advancing age. HF prevalence increases with population aging and with survival from previously untreatable ischemic cardiovascular disease (Roger, Weston et al. 2004). Longitudinal follow-up over 44 years by the National Heart Lung and Blood Institute indicated that survival from acute myocardial infarction results in one in five men and almost half of women becoming disabled with heart failure within 6 years (Hurst 1998). Mortality within 12 months after an index admission for heart failure is 25-35% (Jessup, Abraham et al. 2009). Of those under age 65 who have heart failure, 80% of men and 70% of women will die within 8 years (American Heart Association 2009). Complicating heart failure for the elderly, DiSalvo and Stevenson (2003) found that more than half of these older adults have at least three comorbid illnesses and take 6 or more prescription medications. Because signs and symptoms of heart failure are often non-specific, they are often mistaken for “aging” by providers and patients alike (Tresch 1997; Tresch 2000). These factors increase the complexity of self management for elders with heart failure and may contribute to acute exacerbations of the condition, delays in seeking treatment, and readmission to the hospital.

One of the most frequent causes of hospitalization in industrialized countries, heart failure admissions have doubled in the last 20 years (Moser and Mann 2002). The over one million hospitalizations per year in the USA account for almost three fourths of annual expenditures related to heart failure, with the estimated cost of care for heart failure increasing to more than USD $37 billion in 2009 (O'Connell 2000; American College of Cardiology 2006; American Heart Association 2009). Cost per case for white men for the year 2005 averaged $26,433 for mild heart failure to $44,433 for severe failure (Phillips, Wright et al. 2004; Jancin 2008).

Preventing hospital readmission is perhaps the most potent factor in reducing cost and resource consumption related to HF (Edwardson 2007). Readmissions are reported as high as 50% within 6 months after an index admission (Jessup, Abraham et al. 2009). Readmission after discharge is a focus of attention for the Institute Of Medicine, the Centers for Medicare and Medicaid Services, and the Medicare Payment Advisory Commission as an indicator of quality and efficiency of care (Ross, Mulvey et al. 2008). In 2004, Medicare reported that it spent an estimated USD $17.4 billion on all unplanned hospital readmissions.

Heart failure is one of the most frequent readmission diagnoses and is particularly cited as preventable with better discharge planning and education (http://www.ipro.org/index/news-app/story.18/title.medicare-spent-an-estimated-17-4-billion-on-unplanned-re-hospitalizations-in-2004; accessed June 04, 2009). In a recent study of almost 12 million Medicare beneficiaries between 2003 and 2004, heart failure was the most common reason for re-hospitalization (26.7%) within 30 days of discharge in medical populations (Jencks, Williams et al. 2009). Of heart failure readmissions, 37% were for recurrent heart failure; 5% for pneumonia and another 4% for renal failure. In addition, Fang et al (2008) indicate that as many as 60-70% of heart failure patients admitted to a hospital are admitted under a non-heart failure primary diagnosis, often missing heart failure treatment, or even “undoing” (pg 42) the work of a specialist to treat the heart failure.

Numerous factors have been associated with hospital readmission for persons with heart failure, including: noncompliance with diet and medication regimens (Ghali, Kadakia et al. 1988; Bennett, Huster et al. 1998), poor follow-up care (Vinson 1990; Happ, Naylor et al. 1997), delays in seeking medical attention (Vinson 1990; Jurgens and Riegel 2007), poor acquisition of knowledge from prior education (Ni, Nauman et al. 1999; Jaarsma, Abu-Saad et al. 2000; Riegel and Carlson 2002), and poor self efficacy (Ghali, Kadakia et al. 1988; Ni, Nauman et al. 1999; Jaarsma, Abu-Saad et al. 2000; Riegel 2002). These studies suggest the need for more comprehensive approaches to HF self care.

Other factors related to readmission include lack of cardiology consultation during hospital admission, living alone, and certain co-morbid conditions such as pulmonary hypertension, renal insufficiency and anemia (Hamner and Ellison 2005). Hallerbach et al (2008), in a study of predictors of early readmission to the hospital in patients with heart failure, found that readmission at 30 days was related to co-morbid chronic renal insufficiency. He also found that approximately half of those readmitted had been incorrectly coded with HF exacerbation by medical coders.

Non-precise assessment and interpretation of patient condition at the time of hospital discharge may also be related to readmission. The traditional dependence on patient physical signs and symptoms may be inadequate to determine readiness for discharge home (Wingate 2009).

Other research related to HF and hospital readmission has demonstrated that comprehensive discharge planning, including arrangements for post discharge support, reduces recidivism and cost of care (Ross, Mulvey et al. 2008). Within the last decade, a plethora of studies related to multidisciplinary disease management programs involving the continuum of care within and outside the hospital setting have reported on the positive collective effects of these programs on cost and readmission rates (Cintron 1983; Naylor, Brooten et al. 1994; Lasater 1996; Rich, Gray et al. 1996; Hanumanthu 1997; Cline, Israelsson et al. 1998; Stewart, Marley et al. 1999; Krumholz, Chen et al. 2000; Moser and Riegel 2001; Krumholz, Amatruda et al. 2002; Stewart and Horowitz 2002; Balinsky and Muennig 2003; Di Salvo and Stevenson 2003; Chriss, Sheposh et al. 2004; Naylor, Brooten et al. 2004; Chaudhry, Phillips et al. 2006). The rapid proliferation of these programs in response to the increase in worldwide prevalence of heart failure resulted in wide variation in approaches, measurements and lack of shared research experience. In a meta-analysis by Phillips et al (2004) to evaluate the effect of heart failure discharge planning and post hospitalization support, eighteen studies were reviewed representing 3304 older adults (≥ 55 years of age). Fewer patients who received the comprehensive discharge planning and follow-up care were readmitted compared with controls [RR 0.75]. Secondary findings included lower all cause mortality during a mean observation period of eight months and similar or lower costs of care (Phillips, Wright et al. 2004). Follow-up care, although a well-recognized deterrent to readmission, is frequently lacking, as documented in a recent Medicare study (n = 12 million) where 52% of those readmitted for heart failure had no recorded bill for an outpatient follow-up visit within the 30 days following hospital discharge (Jencks, Williams et al. 2009).

Although nurses are major contributors to such comprehensive discharge programs (Agency for Healthcare Research and Quality 2008) there continues to be limited information that describes the contribution of nursing, including the details, ingredients, and effects of nursing interventions. This is consistent with a recent Cochrane systematic review in which nurses contributed to a majority of studies (77%) on educational and self management interventions in chronic disease care. However, the details and outcomes of those interventions were poorly described (Coster and Norman 2009). While performance of heart failure self care practices, taught by nurses, are highly regarded as important for successful management and stability of the condition (Adams and Lindenfeld 2006; American College of Cardiology 2006; Jessup, Abraham et al. 2009), focus and funds have been diverted to other post-discharge non-pharmacological care. For instance, in a recent large technology assessment study by the Agency for Healthcare Research and Quality, education on self-care management was considered “usual care”. The study focused little on self care management education, but rather on other interventions for post-discharge HF care. Results were similar to those previously reported, i.e. continuum of care follow-up via several modalities was effective in reducing readmissions (Agency for Healthcare Research and Quality 2008). Follow-up care included interventions such as clinic visits, home care, multi-disciplinary disease management programs, and tele-health. Of note is that these interventions were more effective when initiated during hospitalization, or at hospital discharge, rather than after hospitalization, i.e. in the clinic. Continuity of care that improved readmission outcomes included hospital discharge education, comprehensive planning, and confirmed follow-up after discharge.

Achieving treatment goals and reducing acute exacerbations and readmissions, requires both provider and patient inputs. Successful management of HF, and reduction of readmissions, requires cooperation over time between providers who are knowledgeable about current scientific evidence and patients and families with adequate self care skills. Providers must be aware of and able to apply knowledge about the latest pharmacological and non-pharmacological management strategies, as well as the implications of co-morbid conditions and their concomitant interaction and effects on HF and its treatment.

Generalist physicians, such as internal medicine and family practice physicians, are often primary care providers for patients with heart failure. Between 60-70% of hospitalizations for patients with pre-existing heart failure, list HF as a secondary diagnosis, hampering targeted treatment and potentially “undoing” previous therapies (Fang, Mensah et al. 2008). Based on a representative sample of 1.7 million Medicare beneficiaries during fiscal year 2005 (Jancin 2008), Medicare patients with heart failure visited between 16-23 physician providers annually, with 8.3 – 11.2 physicians ordering some type of care. On the inpatient side, HF patients saw between 5.8 -11 physicians. For outpatients with a diagnosis of heart failure, 80-90% of clinic visits were for other than the heart failure diagnosis; half of these visits were to internal medicine or family practice physician providers. Only 16-20% of outpatient visits were to cardiologists who tended to see the patients with more severe HF (Jancin 2008). Yet, there is evidence that specialty care by a cardiologist produces better outcomes for patients with heart failure (Foody, Rathore et al. 2005; Hallerbach, Francoeur et al. 2008; Jancin 2008). Multiple chronic diseases and multiple medical providers, many of whom are not familiar with current heart failure management guidelines, hamper quality and continuity of care from the hospital into the community, and may contribute to readmissions.

To reduce readmissions, patients and families, themselves, must also be able and willing to adhere to provider recommendations and actively participate in self care at home. Living with heart failure requires careful management of signs and symptoms, and adherence to an often complex care regimen. Much of heart failure care is self-care, or that performed by the individual, alone, or with family or other support (Sorofman, Tripp-Reimer et al. 1990; Jaarsma, Abu-Saad et al. 2000; Carlson, Riegel et al. 2001; Bakas, Pressler et al. 2006). Improved self care contributes to physical stability and reduced admissions.

Heart Failure Self Care

Improved heart failure self care after hospital discharge, along with improved and sustained overall health status, is the intent of core measure HF1. However, as currently deployed, it may allow over-simplification of the current science surrounding heart failure self care. Lack of detail regarding the ingredients and process of the HF1 intervention may reduce it to a set of dichotomous check boxes.

Lack of specificity and detail regarding chronic disease interventions is not unique to HF1. Defining and describing self care interventions in chronic disease is extremely important to nursing research. This is demonstrated by the findings of a recent systematic review of Cochrane reviews of interventions designed to improve skill and knowledge in patients with chronic illnesses (Coster and Norman 2009). Of the 30 reviews included in the analysis, 77% involved some nursing contribution. Overall, however, studies did not include information on the specifics of the interventions themselves, nor on the discipline of the professional actually delivering the intervention. Of the reviews, 60% were judged to have inadequate evidence of effectiveness of the intervention. The authors concluded that the ingredients of interventions to influence the behavior of those with chronic disease remain largely unknown. Methodological issues and inadequate descriptions in study reports have hampered the progression of this body of research.

Heart failure self care is defined as an active cognitive process that triggers critical behaviors to maintain health and manage symptoms of the condition (Riegel, Carlson et al. 2000). It involves adherence to healthcare provider recommendations from an external source to maintain physiologic homeostasis and prevent acute decompensation. These self-care behaviors reflect the degree to which a patient with HF follows health actions set forth by, and in agreement with, a healthcare provider, e.g. the elements of HF1. Well-educated patients, partnering with providers who are expert in heart failure self management education will: 1) routinely practice good adherence behaviors such as taking prescribed medications, while avoiding others such as select over-the-counter medications; 2) perform heart failure self care activities daily, integrating them into their lifestyle, while learning to monitor their own body responses, including treatment effects or symptoms of exacerbation (Riegel, Carlson et al. 2004; Riegel and Dickson 2008; Lee, Tkacs et al. 2009).

Symptom monitoring, a second essential component in heart failure self care and included in HF1, refers to a concept involving symptom recognition, interpretation as related to heart failure, decision-making and appropriate self directed actions to effectively ameliorate symptoms. It assumes attention to and evaluation of cues, or recognition and interpretation of subtle changes in health status (Rockwell and Riegel 2001; Jurgens 2006; Riegel and Dickson 2008).

The variation in implementation of HF1 may be related to lack of knowledge and/or understanding of current HF self care science. The current science surrounding heart failure self care now includes situation-specific theory that may inform discharge planning and education such as that included in HF1. In a recently published situation-specific theory of heart failure self care, Riegel and Dickson (2008) define self care as a naturalistic decision-making process involving the choice of behaviors that maintain physiologic stability (maintenance) and the response to symptoms when they occur (management). *Self-care maintenance* is further defined to encompass routine symptom monitoring and treatment adherence. *Self-care management* is characterized as a process initiated by symptom recognition and evaluation, which stimulates the use of self-care treatments and treatment evaluation. Confidence in self-care is thought to moderate and/or mediate the effect of self-care on various outcomes. Four propositions were derived from the self-care of heart failure conceptual model: (1) symptom recognition is the key to successful self-care management; (2) self-care is better in patients with more knowledge, skill, experience, and compatible values; (3) confidence moderates the relationship between self-care and outcomes; and (4) confidence mediates the relationship between self-care and outcomes (Riegel and Dickson 2008). The situation-specific theory of heart failure self-care is supported by data and evidence from previous research studies on heart failure self care (Riegel, Carlson et al. 2000; Carlson, Riegel et al. 2001; Riegel and Carlson 2002; Riegel, Carlson et al. 2004; Jurgens 2006).

As one of the six elements of HF1, accurate symptom monitoring leads to appropriate interpretation of signs and symptoms, and appropriate and timely follow-up, reducing hospital admissions. When appropriate self care actions follow, reduction in symptoms is evaluated, and a judgment is made of effectiveness of the self directed intervention. The individual (and/or family) can determine whether further care is required from a professional health care provider, or self – surveillance can safely continue.

Heart failure self care is complex. Many of the physical cues, or symptomatic responses to HF, are often subtle and non-specific, i.e. may occur in other conditions. Such cues may include dyspnea, fatigue, peripheral and central edema, activity intolerance, and intermittent weight gain. There may be associated sleeping difficulties, depression, fluctuating mental acuity, balance problems, falls, lightheadedness, cough, palpitations, and chest pain (Bennett 2000; Riegel, Carlson et al. 2000; Riegel 2002; Munger and Carter 2003). Cues must be recognized, interpreted and evaluated as related to heart failure. Discerning and responding to changes in health status may include a patient's ability related to: detecting the effects of dietary sodium indiscretions and taking diuretics in response to weight gain or dyspnea; evaluating sleep pattern disruptions and the effect of elevation of the head and trunk; noting the effects and potential side effects of prescribed medications, such as angiotensin converting enzyme inhibitors or beta blockers (Bohachick P 1990; Grady KL 1995; Konstam 1996; Lee, Tkacs et al. 2009).

However, studies indicate that symptom recognition and management tends to be poor among patients. They tend to make self-care decisions based on symptom severity versus interpreting earlier, less severe symptoms as being related to HF, thus delaying treatment (Riegel, Carlson et al. 2000; Carlson, Riegel et al. 2001; Francque-Frontiero, Riegel et al. 2002; Riegel 2002; Horowitz, Rein et al. 2004; O'Connell 2004; Jurgens 2006; Jurgens and Riegel 2007). Because of the complexity of symptom recognition and self-directed action, Riegel, Carlson and Glaser (2000) suggest that learning best practices in HF self care involves partnership with experts to validate cues over time. Follow-up after hospital discharge can help patients validate appropriate self-care decision-making and build self-care capacity. Rather than depending on an impersonal set of written instructions, a longer term relationship with expert providers within the continuum of care has been shown to be advantageous for reducing poor outcomes and hospital readmissions (Riegel, Carlson et al. 2000; Edwardson 2007). Follow-up in disease management programs and other multidisciplinary approaches, often led by expert Advanced Practice Registered Nurses, has been successful in reducing readmission, lengthening the time between discharge and readmission, and reducing costs (Stewart, Marley et al. 1999; Naylor, Brooten et al. 2004; Phillips, Wright et al. 2004).

Knowledge of heart failure, and compliance with external recommendations, are positively related to self-care (Riegel, Carlson et al. 2000; Smith, Koehler et al. 2005). Yet, neither knowledge nor compliance is sufficient, alone, to improve self-care. Patient decisions about self-care are also based on past experiences or patterns of experience over time. The decision-making process follows attention to cues, selection of relevant and salient cues, interpretation of their relationship to baseline status, determination of self-care action, and performance of self-care behaviors (Riegel, Carlson et al. 2000). Relevant symptoms lead to further information seeking and extended or more specific goal setting (Bandura 1977; Carlson, Riegel et al. 2001). The experience of symptom relief following a self-care action or behavior reinforces that action or behavior in the future.

This conceptual framework of self care specific to chronic heart failure has culminated in a situation specific nursing theory (Riegel and Dickson 2008). Integrating this theory, current educational theory and discharge instruction and planning may reduce poor outcomes, such as readmissions. But the complexities of self management are unlikely to be accomplished when the minimum requirement for HF discharge education is simplified to a set of written instructions which may never be read or understood or applied.

Heart Failure Self Care and Medical Management

The link between medical management, better self care practices and improved patient clinical, financial, and readmission outcomes is intuitively compelling. However, specific evidence and an explanation of biologic plausibility have been lacking in published works until recently. Lee and colleagues (2009) translated the effects of self care practice into related cardio-protective mechanisms. They linked the complementary nature of effective self care and optimal medical management.

Hormones produced in HF contribute to a cyclical recurrence of congestion and stress on the heart muscle. Stress and stretch on the heart muscle from congestion activate pro-inflammatory cytokines which damage the ventricle, causing myocardial remodeling, fibrosis and apoptosis. In addition, some patients with hibernating myocardium receive particular benefit from beta blocker therapy and careful fluid management. Neurohormonal blockade and diuretic therapy reduce the otherwise recurrent hemodynamic congestion, overloading, stress and stretch of the heart muscle. Medication adherence per provider recommendations includes regular and appropriate dosing of angiotensin converting enzyme inhibitors, beta adrenergic blockers and diuretics, as well as avoidance of contraindicated medication such as over-the-counter non-steroidal anti-inflammatory drugs. Adherence to a medication regimen, avoidance of dietary sodium, monitoring of fluid retention, balancing exercise and rest, attention to bodily cues, and follow-up with healthcare providers are all self maintenance behaviors that, when paired with appropriate provider recommendations, may improve heart failure outcomes of care (American College of Cardiology 2006; Agency for Healthcare Research and Quality 2008; Center for Medicare and Medicaid Services (CMS) 2008; Jessup, Abraham et al. 2009; Lee, Tkacs et al. 2009; The Joint Commission 2009). Adherence to self maintenance practices, along with self management awareness, can delay the progression of myocardial cell death, reduce ventricular dysfunction, reduce acute decompensation, congestive episodes, and resultant poor outcomes, including recurrent hospitalizations.

Early recognition of increasing congestion, including proper and timely interpretation of weight gain, early satiety, fatigue or shortness of breath, followed by self administration of low dose diuretic and limiting fluid and sodium in the diet, may well avert a more serious exacerbation resulting in the need for urgent or emergent care (Riegel, Carlson et al. 2000; Jurgens 2006; Lee, Tkacs et al. 2009). Earlier symptom recognition, followed by relatively nonaggressive actions by the patient at home, may prevent hemodynamic instability and avoid hospitalization. Especially for the elderly, aggressive and complex treatment in the hospital is fraught with potential complications from high dose, potent drugs, and potentially hazardous procedures and treatments used for severe or life-threatening heart failure. Hospitalization, itself, is an independent risk factor for shortened survival in persons with heart failure (Jessup, Abraham et al. 2009; Lee, Tkacs et al. 2009).

Self management awareness, or the ability to detect, interpret and act upon signs and symptoms of heart failure, compliments optimal medical management. The second component of heart failure self care in Riegel and Dickson's situation specific theory, "self management" involves early recognition of signs and symptoms by the individual with HF (or a care provider), proper interpretation of those signs and symptoms, and appropriate actions to limit their negative effects (Riegel, Carlson et al. 2000; Smith, Koehler et al. 2005; Riegel and Dickson 2008) including readmission to the hospital.

Heart Failure Personal Characteristics

Heart failure self care outcomes, including readmission, are influenced by individual characteristics. Advancing age may negatively influence self-care because of its association with multiple co-morbid illnesses, multiple physician providers, and multiple interacting medications. Lower socioeconomic status and lower educational level have been associated with poorer outcomes (Lee, Tkacs et al. 2009). Reduction in cognitive ability and the occurrence of depression are more frequent in those with heart failure and are associated with poorer outcomes, as are negative attitudes toward HF-related impairments (Riegel, Bennett et al. 2002; Clark and McDougall 2006; Morrow, Clark et al. 2006; Turvey, Klein et al. 2006; Mauro, Rosso et al. 2007; Vogels, Scheltens et al. 2007; Albert, Fonarow et al. 2009; Jessup, Abraham et al. 2009; Lee, Tkacs et al. 2009; Woo, Kumar et al. 2009).

Heart Failure and Patient-Centered Care

Patient-Centered Care (PCC) has become the watchword of public and private healthcare advocacy groups, hospital regulators, administrators, nursing leaders and payors. It influences credentialing, licensure, medical education, and quality of care assessment. It is associated with improved communication, increased patient involvement in care decisions, better adherence to provider recommendations, and improved patient satisfaction (Robinson, Callister et al. 2008). In 2001, the Institute of Medicine (IOM) cited patient-centered care as one of six essential aims for the healthcare system (Institute of Medicine 2001). The IOM called for a redesign of health care based on a continuous healing relationship between patients and providers, individualized and customized by the provider according to patient needs, values, beliefs, knowledge and preferences.

The current president of the American College of Cardiology recently endorsed the customized, patient self care approaches described by patient centered care for chronic heart failure patients (Bove 2009). With better knowledge of the patient's perspective, the provider can tailor discharge instructions and care plans based on patient characteristics and, as much as possible, on the patient's ability and willingness to adhere to recommendations. The patient would, in essence, become the source of control in the patient-provider relationship. Patients and providers would share knowledge, decision-making, and develop better self care skills and preventive behaviors using a free flow of information. Patient centered care has demonstrated improved outcomes and provided more equal access to care and quality (Agency for Healthcare Research and Quality (AHRQ) 2008). Improvements in patient self management of chronic conditions have been associated with improved quality of life and health status, and reduced use of resources (Lorig, Sobel et al. 1999; Lorig 2003) .

Hand off communication is vital when patients are transferred within the hospital between specialty units or levels of care to ensure that clinical information is effectively passed between providers. Patient hand offs are communication transition events between providers, or between providers and patients. Inherent in the hand off process is risk of lost or misinterpreted patient information, slowed processes of care and interrupted continuity (Institute of Medicine 2001; Institute of Medicine 2004). Although few studies on the effects of multiple unit transfers are available, Titler et al (2005, 2007) found that multiple unit transfers increased hospital costs for older adults at risk of falling ($n = 11,756$) and for patients hospitalized with heart failure ($n = 1435$ hospitalizations). A study in France by Eveillard et al (2001) found a significant association between unit transfers and nosocomial infection. Finally, Kanak (2008) studied hospital transfers in 7851 hospitalized older adults at risk for falls and found a decreasing per diem use of the nursing treatments ‘patient teaching’ and ‘discharge planning’. Patients received patient teaching 0.97 times per day when they resided on only one unit; this dose of patient teaching dropped to 0.46, or approximately once every other day, when the patient resided on 4-5 different hospital units ($p < .001$). The dose of discharge planning similarly decreased from 0.73 to 0.65 when the patient resided on one versus 4-5 units ($p < .001$). There were associated increases in length of stay ($p < .001$), cost ($p < .001$), and adverse events ($p <.001$) with additional units of residence during hospitalization (Kanak, Titler et al. 2008). These studies suggest that value and effectiveness of care is enhanced when patients experience fewer between unit transitions.

Heart Failure and Patient Education

The paradigm of patient education, particularly for chronic conditions such as heart failure, has shifted to a patient-centered approach, and away from traditional patient education methods which tended to be authoritarian, didactic, prescriptive and information-laden (Evangelista and Dracup 2000; Lorig 2003; Dickson and McMahon 2008; Robinson, Callister et al. 2008). Rather, social learning theory (Bandura 1977), naturalistic decision making theory (Zsambok and Klein 1997) and situation-specific theory related to heart failure self care (Riegel and Dickson 2008) have contributed to modeling new, patient-centered approaches specific to heart failure self care education (Riegel, Dickson et al. 2006; Riegel, Moser et al. 2006). Traditional patient education methods, such as written discharge instructions alone, do not support skill development in heart failure self care (Dickson and Riegel 2008). However, studies suggest these re-conceptualized intervention methods for patient education in heart failure may improve self care outcomes (Riegel, Dickson et al. 2006; Dickson and Riegel 2008).

Patient education, self care counseling, and reduction of lifestyle risk factors are interventions included in what DiSalvo and Stevenson (2003) called the “anchoring role” of the nurse in the management of patients with heart failure (Di Salvo and Stevenson 2003). Whether by nurses or other disciplines, patient education about chronic conditions that results in sustained behavior change is an ongoing multi-faceted process and not a singular task or event that immediately precedes discharge from the hospital (Saarmann, Daugherty et al. 2000; Saarmann, Daugherty et al. 2002; Dickson and McMahon 2008). This conceptualization is important at the patient and episode levels of care in order to reduce waste and inefficiency in quality of care activities at the bedside (James and

Bayley 2006). Patient centered care and reduction of non-valued added activities are consistent with desired elements of heart failure discharge planning and patient education. Patient education must be designed to not only provide information, but to influence patient behavior. Integration of counseling strategies is recommended for heart failure education (Dickson and McMahon 2008). Often, patients with chronic disease are not ready to make the changes necessary to live successfully with their condition; they may underestimate personal risk and believe that control of a health condition can be maintained without lifestyle change or adherence to provider recommendations. Clarification of beliefs about self, about the personal meaning of living with heart failure, about health and health behaviors, all within a context of personal lifestyle, is helpful to better understand the patient's values and likelihood of adherence (Scotto 2005). With this understanding, the RN provider can better facilitate a teaching-learning discussion about the essential elements of heart failure discharge instructions. Such discussions may expose barriers to self care behavior after discharge, and assist with mutual problem-solving and after-care planning with clinic physicians and staff. As previously discussed, the evidence suggests that discharge preparation that begins in the hospital, with immediate follow-up links within the continuum of care, results in better readmission outcomes (Phillips, Wright et al. 2004; Agency for Healthcare Research and Quality 2008).

The goals of patient-centered education are to produce changes in patient knowledge, attitudes and necessary skills to maintain or improve self care (Dickson and McMahon 2008). These concepts complement the situation specific theory of heart failure self care by Riegel and Dickson (2008). The National Quality Forum (2003), the

Agency for Healthcare Research and Quality, the Centers for Medicare and Medicaid Services, the Joint Commission and other health advocacy and regulatory groups have specified that patient education upon hospital discharge must be documented and include written instructions for the patient or caregiver. However, there is disagreement about definitions and distinctive characteristics of patient education and patient self care or self management. Patient education is intended to help patients manage their diseases; self care is intended to give people the skills to live active lives with their health conditions, integrating adherence and self management, or symptom awareness into their daily lives (Lorig 2003; Riegel, Dickson et al. 2006; Dickson and McMahon 2008; Riegel and Dickson 2008). This difference in perspective represents the traditional view of patient education (didactic and directive) versus a patient-centered, self care approach that supports patient autonomy, participation, and control over how treatment recommendations and prescriptions will be implemented into a person's daily life.

Heart failure discharge education is intended to help patients and families understand the prognosis of heart failure, the rationale and regimen of pharmacotherapy, the effects of dietary sodium ingestion, the need for balance between activity and rest, and how to recognize and discriminate heart failure signs and symptoms and act appropriately to self manage or seek provider assistance (Dickson and Riegel 2008; Dickson and McMahon 2008; Jessup, Abraham et al. 2009). However, the hospital regulatory standard core measure (HF1) for hospitals falls short of that intent. According to Edwardson (2007), when evaluating the contribution of nursing services to education and self care of patients with heart failure, "Simply checking a yes or no option about whether or not teaching has occurred is unlikely to accomplish this goal" (pg. 250).

Chung et al (2008) said in a similar statement, "… adherence to careful, unhurried implementation of discharge instructions rather than a cursory, protocol-driven, check-off of performance measures must be employed" (Chung, Guo et al. 2008). Patient education, counseling and follow-up with greater attention to psychosocial dimensions of care are hypothesized to produce significant patient and financial outcome benefits (Koelling, Johnson et al. 2005; Davidson, Cockburn et al. 2008).

The intent of the standard supported by the Joint Commission and other agencies is more evident than its related documented outcomes. Although the process outcome, hospital compliance, has improved in some organizations, translating the provision of written information into therapeutic self care behaviors is challenging and the impact on outcomes of care of heart failure discharge instructions is unclear (Hamner and Ellison 2005; Edwardson 2007). Strengthening and consistency of nursing processes and structures of discharge education are needed (Albert, Fonarow et al. 2007). Examination of the relationship of variables associated with influencing patient self care abilities, i.e. behaviors related to monitoring and responding appropriately to signs and symptoms of HF exacerbation, is lacking.

Guidelines and Regulatory Process Measurement

The Joint Commission's mission is "to continuously improve the safety and quality of care provided to the public through the provision of health care accreditation and related services that support performance improvement in health care organizations" (http://www.jointcommission.org/AboutUs/joint_commission_history.htm). Since 1910, when Ernest Codman, M.D. proposed the "end result system of hospital standardization", there has been a gradual movement to outcomes driven hospital care. Consistent with

Codman's original intent, hospitals then, and now, would track patients' outcomes of care to determine the effectiveness of treatment. The American College of Surgeons adopted the "end results" system in 1913, followed by the American College of Physicians, the American Hospital Association, the American Medical Association, and the Canadian Medical Association to create the Joint Commission on Accreditation of Hospitals which began accrediting hospitals in 1953.

Over time, the voluntary accrediting Commission moved from a unitary approach to a collaborative approach with more national healthcare organizations to enhance healthcare performance measurement. Now called the Joint Commission, it participates in national collaborative activities with large national entities such as CMS, Quality Improvement Organizations, the National Quality Forum, the Agency for Healthcare Research and Quality, and the Institute of Medicine (http://www.jointcommission.org/NR/rdonlyres/333A4688-7E50-41CF-B63D-EE0278DOC653/0/SIWGProloguewebversion.pdf).

The ORYX program was launched by the Joint Commission in 1997 to further integrate the use of outcomes and performance measures in its voluntary accreditation process. The Joint Commission solicited input from multiple stakeholders and convened the Cardiovascular Conditions Clinical Advisory Panel to develop the focus of core measures for hospitals. In 2001, after simultaneous collaboration with the Centers for Medicare and Medicaid Services (CMS), the five core measurement areas for hospitals, including HF, were announced. A common set of measurement specifications documentation was created called the Specifications Manual for National Hospital Quality Measures (Center for Medicare and Medicaid Services 2008; The Joint

Commission 2009). Specifications for the HF core measure is similarly available (Joint Commission on Accreditation of Healthcare Organizations 2006) and can also be found on the web, http://www.jointcommission.org/PerformanceMeasuremetn/PerformanceMeasurement/Heart+Failure+Core+Measure+Set.htm. The Joint Commission's Attributes for Core Measures (available at http://www.jointcommission.org/pms/core+measures/attributes+core+performance+measures.htm) and the National Quality Forum's (NQF) Criteria for the Evaluation and Selection of Measures in the Initial Performance Measure Set (National Quality Forum 2004, 8-9) are notably consistent. While the Joint Commission's attributes are described at a detailed level, they relate to the four NQF criteria: Important, Scientifically Sound, Useable, and Feasible. Alignment with all of these entities (e.g. CMS, NQF and Joint Commission) has required that measure specifications are identical so that data collection efforts by the hospitals can be consolidated, minimized and standardized for national use and comparative analysis.

A database was developed to receive and analyze data from participating health care organizations and to prepare feedback reports. Detailed technical specifications allowed external performance measurement systems (i.e. commercial vendor systems) to receive and aggregate ORYX data. Performance measurement systems were required to pass rigorous evaluation criteria to collect and transmit data to the Joint Commission on behalf of the healthcare organization (Riehle, Hanold et al. 2007).

There are four hospital quality indicators, or core performance measures, for heart failure treatment, including one for discharge instructions. These four initial indicators assess performance of the hospital providers related to: 1) assessment of left ventricular function (LVF) before or during hospitalization or schedule an assessment after discharge; 2) prescriptions of an angiotensin-converting enzyme (ACE) inhibitor, or if the patient is intolerant, an angiotensin receptor blocker (ARB) for patients with left ventricular systolic dysfunction; 3) provision of patient self-management instruction related to weight, diet, medications, activity level, what to do if symptoms recur, and when to contact a provider; and 4) counseling for smoking cessation for smokers (Kfoury, French et al. 2008). Recognizing the benefits of patient education about heart failure self care, the American College of Cardiology, the American Heart Association, and the Heart Failure Society of America collaborated in adopting similar guideline recommendations that patients receive educational materials as part of their hospital discharge instructions (Hunt, Abraham et al. 2005; Adams and Lindenfeld 2006; Jessup, Abraham et al. 2009).

Heart failure discharge instructions (HF1) are to be provided for non-comfort care patients with primary discharge diagnosis of heart failure who are being discharged to home, with or without home care services. Currently, patients or their care providers are to receive written discharge instructions or educational materials on six elements of heart failure care: activity level, diet, discharge medications, follow-up appointment, weight monitoring, and what to do if symptoms worsen (Joint Commission on Accreditation of Healthcare Organizations 2006; The Joint Commission 2009). This information is then abstracted from medical records at the local hospital level according to strict guidelines by trained medical records personnel and transmitted to the Centers for Medicare and Medicaid Services (CMS). Hospital results on core measures are posted on the US

Department of Health & Human Services Hospital Compare website (www.hospitalcompare.hhs.gov). Pilot testing is underway for a Pay for Performance initiative related to this measure in the future (Bufalino, Peterson et al. 2006; Center for Medicare and Medicaid Services (CMS) 2008).

Methods of process measurement and scoring of core measure data affect outcome reports. In early testing of core measures, different scoring approaches were trialed, including: “item by item”, which evaluated each measure and its components for adherence; a second method “eligibility and adherence”, which compared levels of individual adherence within categories of eligibility using a referent of adherent to none; a composite measure provided a ratio of measures adhered to versus all measures for which the patient was eligible, giving partial credit for incomplete compliance; and an all-or-none measure which gave no partial credit across all measures for which the patient is eligible (Nolan and Berwick 2006; O'Brien, DeLong et al. 2007; Reeves, Campbell et al. 2007 ; Chung, Guo et al. 2008).

All–or–none scoring is now used to determine percent compliance for each core measure (Nolan and Berwick 2006). In other words, for an eligible patient record, if five of the six elements are present for HF1, i.e. one or more elements is missing, the bundled set receives no score and the measure, or patient record, is not included in the numerator. The denominator includes all eligible heart failure discharges. Hospitals receive a percent compliance score reflecting provider documentation of all six of the elements of written educational materials included in the bundled discharge instructions. Published reports generally do not include information on each of the elements of HF1; thus, frequency and type of missing educational content delivered at discharge is largely unavailable in the literature for broad comparison. In addition, the specific educational content related to each of the elements, and the process used in educating the patient is not specified. Although process compliance scores for HF1 have improved in recent years, variability is high; no universal process implementation exists; and there is evidence of even poorer delivery compliance to minority groups (Fonarow, Yancy et al. 2005; Ilksoy, Moore et al. 2006; Albert, Fonarow et al. 2007) .

Although not adopted at this time, the Center for Medicare and Medicaid Services (CMS) has recently advocated the "appropriateness of care" measure, or ACM. CMS and the Institute for Healthcare Improvement (IHI) prefer this approach to the item-by-item or composite measure approach (Chung, Guo et al. 2008). The ACM approach is similar to the all-or-none method in that it measures the proportion of patients who actually receive all performance measures for which they are eligible, i.e. all of the core process measures (HF-1 through HF-4) which are completed for the eligible patient.

A single site study (Chung, Guo et al. 2008) using the ACM methodology sought to measure 6 month post discharge outcomes on HF patients with perfect and imperfect ACM scores. A group of HF patients (n=194) with perfect ACM scores on all eligible HF core measures, (HF+ or "perfect care"), was compared to a control group (n=204) with at least one incomplete measure (HF-). The groups had identical median left ventricular ejection fraction and were similar in demographic and clinical characteristics. However, neither the number of comorbid illnesses nor a severity of illness index was reported for the perfect or imperfect groups (Chung, Guo et al. 2008). Three six-month outcomes were measured: time to death or all-cause readmission; time to death; time to all cause readmission. The group data were also analyzed for incremental benefit conferred by compliance to each additional core measure. After hospital discharge, all patients received "usual care" for the intervening 6 months (Chung, Guo et al. 2008). Results indicated significantly more patients in the "perfect care" group received angiotensin converting enzyme inhibitor therapy and higher dose loop diuretics. There were fewer total readmissions at six months in the HF+ perfect care group (p=0.04). Percent of patients in the perfect care versus control group with at least one readmission was 65% versus 73% (NS). The ACM perfect care group showed prolonged time to death and all cause admission. Median days to first readmission were significantly longer in the perfect care group, 138 days versus 87 days (Chung, Guo et al. 2008).

Unfortunately, subgroup analyses of each core measure (HF1 through HF4) were not conducted due to small sample size but were recommended for future studies. Similar to comments previously reported by Edwardson (2007) regarding the core measure HF1, the authors stated: "… in assessing the impact of performance measures, adherence to careful, unhurried implementation of discharge instructions rather than a cursory, protocol-driven, check-off of performance measures must be employed. Therefore, it may be important to also study the methods by which performance measures are applied" (Chung et al, pg.174).

Large scale studies on the relationship of heart failure core measures and patient or financial outcomes have been largely restricted to national registry programs, such as OPTIMIZE-HF (Organized Program To Initiate life-saving treatMent In hospitaliZEd patients with Heart Failure) and ADHERE (Acute Decompensated Heart Failure) (Adams, Fonarow et al. 2005; Fonarow, Yancy et al. 2005; Gheorghiade and Filippatos 2005; Fonarow, Abraham et al. 2007). The Acute Decompensated Heart Failure National

Registry (ADHERE) contained data from 81,142 admissions occurring between July 1, 2002, and December 31, 2003, at 223 academic and nonacademic hospitals in the United States. Median rates of compliance with HF1 from this data were 24%; the authors concluded in the 2005 publication that there was a substantial gap in performance and considerable variability across organizations (Fonarow, Yancy et al. 2005).

OPTIMIZE – HF is a hospital-based quality improvement program and Web-based registry for heart failure. Two hundred fifty-nine (259) US hospitals participating in the Organized Program to Initiate Lifesaving Treatment in Hospitalized Patients With Heart Failure (OPTIMIZE-HF) submitted data on 48,612 patients with HF from March 1, 2003, through December 31, 2004. The OPTIMIZE-HF program provided process-of-care improvement tools to participating hospitals, including evidence-based best-practice algorithms and customizable admission and discharge sets to improved process compliance with HF1. It included an interdisciplinary quality of care intervention program for acceleration of implementation of HF guidelines with the intent of improving clinical outcomes.

It is of interest that hospitals who participated in the OPTIMIZE-HF registry received a process of care improvement program with a toolkit including structured education to inform patients about HF. Such tools included order sets or discharge checklists addressing treatment and patient education, intended to be consistent with recent HF guidelines and performance measures. Interestingly, even in this dedicated program the mean HF1 delivery was 54%, median 57.4%, with a range of 0 – 100%. Reporting on OPTIMIZE-HF outcomes, Albert et al (2007) (n = 33,681) indicated that delivery of the HF1 intervention was more likely in patients receiving some type of performance improvement tool and was associated with use of specialty referral programs after discharge (Albert, Fonarow et al. 2007). Other outcomes related to HF1 were not reported (Fonarow, Abraham et al. 2007).

Although OPTIMIZE-HF and ADHERE were helpful in determining and improving process compliance through the use of quality improvement tools, outcomes of organizational compliance with HF1 are still largely unknown.

Effectiveness Research in Nursing

Outcomes are concerned with bridging the gap between what is done in patient care and what the intervention actually accomplishes (Kane, 1997, p ix). Patient outcomes are the results of healthcare interventions as experienced by the recipient of the intervention (i.e. change in function or physiological parameter) or by some broader measure related to the impact of the intervention, such as readmission to the hospital, length of stay, etc. (Titler, Dochterman et al. 2004). Outcomes and health services research have engaged the patient in objective and subjective measurement of the effects and consequences of health care (Kane 1997). Outcome measures assist in focusing on accountability of providers to produce quality care with less waste and more efficient use of resources.

Effectiveness research studies the effect of provider interventions on patient outcomes that are achieved under ordinary practice circumstances for typical patients (Lohr 1988). Effectiveness research in nursing can enhance clinical decision-making, reinforce patient-centered care, assist in examining nursing resource consumption and waste, and determine the impact of nursing interventions on patient and financial outcomes of care. It is incumbent on nurses to identify the interventions, outcomes, patient and provider characteristics, and contextual factors, as well as appropriate measurements for these variables, in order to evaluate the effectiveness of nursing care. With appropriate baseline description, nurse researchers can apply theory and nursing science to modify interventions, implement best practices, reduce inefficiencies, and improve outcome impact.

As technology and electronic documentation and submission of data becomes commonplace, effectiveness research is now generally linked to the use of large electronic databases. Nursing has the opportunity to contribute to improvement in efficient and effective clinical practices by first examining outcomes using pre-existing clinical and administrative data. Nurses are well positioned at various hospital organizational levels to review and interpret data, and to participate in design decisions to improve care based on outcomes and data trends (Hughes 2008; Hughes 2008). It is incumbent in design and translation methodologies to begin with description, sound measurement and outcomes of currently implemented indicators and interventions. Improvements in nursing indicators, themselves, may be contingent on the addition of nursing science to modify existing indicators through the application of nursing research and theory. This is consistent with the definition of quality previously stated, " the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are *consistent with current professional knowledge"*(Institute of Medicine 2001).

In a recent study by Titler et al (2008), types of nursing treatments for heart failure patients were related to cost per hospital visit. This retrospective outcome effectiveness study used three existing hospital operational and clinical databases linked at the individual patient level, n = 1435 hospitalizations for heart failure (Titler, Dochterman et al. 2004). Unique to this study, nursing interventions were documented in the medical record using a standardized language classification system, the Nursing Intervention Classification (NIC) system (McCloskey and Bulechek 2003). Findings of this study associated one co-morbid clinical condition with hospital cost, deficiency anemia, as well as severity of illness using the four level classification APR-DRG (3M Health Information System, 1993). The nursing treatment, discharge planning, was statistically associated with cost per visit ($p = .03$). However, when dose of the intervention was analyzed, cost savings were realized (~ US $400-600) at the highest (1.23 times per day) and lowest utilization, or dose, levels (0.52 times per day), but the mid-level dose (0.91 times per day) increased cost by ~ USD $165.00. However, the definition in this context, " preparation for moving a patient from one level of care to another within or outside of the current health care agency" (Titler et al pg 647) was not specific to patient education, nor to patients discharged to home (Titler, Jensen et al. 2008). Multiple nursing unit transfers during a hospital visit were also related to increased cost. Residing on two units increased median cost by 10% ($p = 0.0015$), while residing on 3-4 units increased median cost by 17% ($p = 0.0001$) in this study. This single site study demonstrates the opportunity and value of using existing data for nursing outcomes effectiveness studies to further describe and explore nursing's effect and contribution to process and financial outcomes of care.

Conceptual Framework

This exploratory study will be guided by an effectiveness model developed by Titler, Dochterman and Reed (2004) that linked patient characteristics, patient conditions and processes of care to outcomes (Titler, Dochterman et al. 2004). This model is also similar to conceptual model by Kane (1997, p. 7), summarized as: Outcomes = f (baseline, patient clinical characteristics, patient demographic/psychosocial characteristics, treatment, setting). Consistent with this framework, Kane states the goal of the model is to isolate the relationship between the outcomes of interest (readmission and cost) and the treatment provided (HF1) by controlling for the effects of other relevant variables; he refers to this as “risk adjustment”. For this study, independent variables in the framework reflect concepts related to patient characteristics, patient clinical characteristics, nursing unit contextual factors, and the treatment, HF1. The primary endpoint, dependent variable, is hospital readmission. A secondary endpoint is annual cost of hospitalization.

Patient characteristics related to HF include modest gender effects, i.e. a greater incidence and prevalence in men than women, and poorer survival after onset in men than women (American Heart Association 2009). Both Black men and women have higher incidence of HF than whites or Hispanics. Social support and socioeconomic advantage are associated with improved outcomes and less hospital recidivism in some studies. Cardiologist primary providers have also been positively associated with reduced recidivism. Finally, heart failure is age-related, with 80% of those hospitalized and 75% of the heart failure population being 65 years of age and older.

Heart failure and older age are associated with clinical characteristics, risk factors, of patients. Consistent with older age, multiple co-morbid conditions, multiple medications, and multiple providers, all complicate care and self management. Particular high risk co-morbid conditions associated with readmission and adverse events in some studies (not associated in others) include renal insufficiency, chronic pulmonary disease, deficiency anemia (Titler, Jensen et al. 2008), and diabetes. Seventy-five percent of those with HF have antecedent hypertension; diabetes is an independent risk factor for death (American Heart Association 2009). All Patient Refined Diagnosis Related Groups (APRDRG; 3M Health Information Systems; Wallingford CT) is a risk adjuster for use in determining severity of illness and resource use (Iezzoni 2003).

Little information is available regarding the effects of hospital contextual variables on HF1 outcomes. Studies by Titler et al (2005, 2007), Kanak (2007) and Eveillard (2001) indicate a relationship between unit transfers and adverse hospital outcomes and increased hospital cost (Eveillard, Quenon et al. 2001). The study by Kanak (2007) also indicated a reduction in the dose of nursing interventions related to discharge planning and patient education. No publications were discovered relating contextual variables such as a specialty cardiology unit versus a general unit to HF1 outcomes.

Finally, HF1, as currently deployed, serves as a proxy for self care education, yet is inconsistent with current knowledge and theory. Although the six elements are based on expert consensus, the content surrounding the elements is unspecified and the method of educating patients and caregivers undefined. Using these concepts and variables, this study will pilot a strategy to establish a baseline of effectiveness of the current HF-1 core measure by evaluating its relationship to readmission and cost of care. Future studies with imbedded nursing science and theory-based modifications to the intervention for heart failure self management can then be evaluated.

CHAPTER III

METHODOLOGY

This study described the relationship between the completion of heart failure discharge instructions (HF1) and the primary endpoint of subsequent readmission to the same hospital following an index discharge for primary diagnosis of heart failure. Secondary endpoints included the relationship of HF1 to hospital cost for readmissions and total hospital readmission days per year. Included in this chapter are descriptions of the design, setting, data sources, sample, variables and measures, and procedures for this study.

Study Design

Because little is known about outcomes specific to core measure HF1 (heart failure discharge instructions as defined by the Joint Commission), a retrospective, descriptive design was used to study the relationship of HF1 to utilization outcomes (readmission, hospital days and cost) and institution contextual outcomes (discharge unit and number of inter-unit transfers) as defined in aims 1 and 2.

Setting and Data Sources

The setting was a 500 bed tertiary medical center within a metropolitan service area in the upper Midwest. Data for the period of interest were abstracted from records between July 2002 and December 2009.

Individual level retrospective demographic, clinical, administrative and performance improvement data were used. Data sources were two: hospital medical record data and hospital performance improvement data related to core measures. Permission was obtained to use demographic, administrative and clinical data abstracted by the organization's Decision Support department from the medical records of patients with primary discharge diagnosis of heart failure for the period specified. Performance improvement data specific to completion of HF-1 were obtained from two vendors. Patient level HF-1 data from 2002 through 2007 were generated by a commercial regulatory reporting system, CareDiscovery ™ Quality Measures, a core measures product from vendor company Thomson Healthcare (www.thomsonhealthcare.com). The second HF-1 data source for data from January 2008 through December 2009 was a second vendor, MIDAS DataVision™ Comparative Performance Measurement System (www.midasplus.com/DV.asp). Both vendors met The Joint Commission (TJC) requirements for data submission for hospital accreditation. HF-1 data used in this study were similar to that submitted to and accepted by the Joint Commission and the Centers for Medicare and Medicaid Services during the period of study. HF-1 data was collected and submitted after every discharge for primary diagnosis of HF. Only the HF-1 data from the index admission was used in this study.

Sample

The convenience sample was obtained from patient records that met the eligibility requirements for core measure HF-1 data abstraction as prescribed by the Joint Commission (Joint Commission on Accreditation of Healthcare Organizations 2006; Center for Medicare and Medicaid Services (CMS) 2008) (http://www.jointcommission.org/PerformanceMeasurement/PerformanceMeasurement/Heart+Failure+Core+Measure+Set.htm). For this study, eligible patients were at least 50 years of age or older, hospitalized for non-comfort care, had a primary discharge diagnosis of heart failure (International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), Principal Diagnosis Code for heart failure), and were discharged to home, with or without home care services. Excluded were records of patients who: were less than 50 years of age; were without a discharge destination described as home or home with home health; had a length of stay greater than 120 days; were enrolled in clinical trials; and/or were designated as comfort care only in the medical record. Eligible records were included regardless of patient gender, ethnicity or national origin.

The initial hospital medical record sample with primary discharge diagnosis of heart failure included 1546 records from July 2002 through December 2009, 1473 (95.3%) of which were 50 years of age and older. Performance improvement data for core measure HF1 were then merged with these records based on medical record and hospital encounter numbers. The HF1 data included discharge destination of assisted living and several other non-home or home with home health discharge designations during the study period for a total initial n of 1579. After merging and limiting cases to those discharged to home or home with home health, 1312 cases remained that were HF discharges and had documentation of HF1 completion. The final step toward an index case database was to sort by date of admission, retaining only first-occurring, or index cases (n = 1034).

All cause readmissions for the same individuals in the index sample were tracked by medical record and hospital encounter number identifiers. There were 1126 all-cause readmissions within the year following the index case discharge date. All-cause readmissions included HF readmissions as well as other admission diagnoses. Of these, 278 (24.7%) were HF readmissions and 848 (75.3%) were for non-HF causes. There was a mean of 1.09 total readmissions per index admission, and a mean of 0.27 HF readmissions per index admission within the follow-up year.

Variables and Measures

Independent variables abstracted from the hospital medical record included HF1 core measure completion and variables related to patient characteristics, clinical characteristics, unit contextual characteristics, and length of stay and cost variables. All variables were abstracted for the index hospitalization and a subset of variables for the readmission hospitalizations. All data was abstracted at the individual patient level. See Variable Table below for definitions and data sources.

Independent Variables

There were 17 independent variables, 12 categorical and 5 continuous. The primary variable of interest was completion of the bundle of discharge instructions, HF1. Patient demographic variables included gender, age, ethnicity, and marital status. Clinical characteristics included the severity of illness index (APRDRG), and the presence or absence of seven (7) comorbid conditions: anemia, chronic obstructive pulmonary disease, pneumonia, coronary artery disease, hypertension, diabetes mellitus and renal insufficiency. Hospital contextual variables included the number of units where the patient resided, and the unit from which the patient was discharged. Administrative variables included length of stay and direct cost.

HF1

The primary variable of interest for this study was heart failure core measure HF1, which includes written instructions or educational materials given to the patient or care giver at discharge or during the hospital stay addressing all of the following: activity level, diet, discharge medications, follow-up appointment, weight monitoring, and what to do if symptoms worsen. The indicator was scored as a bundle and coded dichotomously as either met (0) or not met (1). To be considered "met", all six HF1 elements had to be documented as given to the patient or family. If one or more elements were missing, HF1 was scored as "not met". For the index discharges, HF1 was met in n = 884 (85.5%) of index cases and not met in n = 150 (14.5%) of index cases.

Patient Characteristics

Patient characteristics of interest included one continuous variable, age at the time of the index hospitalization, and three categorical variables, gender, marital status, and ethnicity. The rationale for choosing these variables is based on the literature and the potential relationship of these variables to the diagnosis and outcomes related to HF. The ethnicity variable was recoded for the analysis from six categories to two (White; Other) due to very low numbers of non-White individuals in the dataset (i.e., all other ethnic groups accounted for only about 5% of the sample). The demographic characteristics during the entire period under study are not available. However, inpatient race data from CY2010 (Decision Support Data Source) for the study hospital indicate about 91% White, 5.35% Native American, and all others between 0.4 and 1.4%.

Clinical Characteristics

Multiple co-morbid conditions are common among the elderly. Those selected for this study have been related to HF outcomes in older adults. For this study, seven (7) clinical conditions were targeted as dichotomous categorical control variables related to HF outcomes. These included hypertension, coronary artery disease, diabetes mellitus, renal insufficiency, chronic obstructive pulmonary disease, anemia and pneumonia.

These diagnoses were abstracted by ICD-9 codes from patient records and included in Decision Support data transfer.

In addition, All Patient Refined Diagnosis Related Groups (APRDRG; 3M Health Information Systems; Wallingford CT) served as a risk adjuster for use in determining severity of illness (SOI) and resource use (Iezzoni 2003). Severity of illness was defined as the extent of physiologic decompensation or organ system loss of function (http://www.qualityindicators.ahrq.gov/APR-DRG.pdf). The underlying clinical principles of APRDRGS are that higher severity of illness (SOI) scores are dependent on multiple co-morbid conditions as they relate to, or interact with, one another and the base condition, i.e., HF. The four SOI subclasses are numbered sequentially from 1 to 4 indicating minor, moderate, major, and extreme severity of illness, respectively. Higher SOI levels represent difficult-to-treat patients who tend to have poorer outcomes. The mean SOI score for the index cases was 2.48 (SD 0.70; range 1 – 4).

Hospital Context

Two predictor variables were related to hospital context. Discharge nursing unit represents the type of clinical focus of the unit from which the patient was discharged. Seven units were included from the index discharge database: cardiology; mixed surgical-renal; general and cardiovascular surgical; mixed medical and oncology; pulmonary; mixed orthopedics and neurology; and intensive care. Because approximately 88% of index discharges were from the cardiology unit, and no other unit had more than 4.5% of discharges (range 0.3% to 4.5%) this variable was collapsed into cardiology and other. The second contextual variable was the number of units upon which the patient resided during the index hospital stay. Multiple unit transfers have been shown in prior studies to affect quality of care and outcomes. The maximum number or units within this study was 4, with a mean of 1.18 (SD 0.44).

Administrative

Direct costs and length of stay (LOS) were abstracted for each index admission. Mean direct cost was 5852.00 (SD 6849) and median 3418.50; (95% CI 5433.25 – 6270.74; range 13.00 – 41,902). Mean LOS was 4.13 days (SD 2.77) and median 3.0 (95% CI 3.96 – 4.30; range 1 – 18 days).

Dependent Variables

Readmissions

Readmission was defined as an admission to the study hospital within 365 days of the index discharge date. There were 1126 readmissions by 543 individuals. The relationship between HF1 and readmission to the hospital within the year following the index discharge was the primary endpoint for this study.

Readmissions were analyzed as all cause; then the subset of readmissions that were for HF only, was re-analyzed. Data were analyzed at each readmission interval: 30 days, 90 days, 180 days and 365 day intervals. Within the respective intervals, they were analyzed as occurring, or not occurring (yes/no), and by count of readmissions within an interval (e.g., sum at 90 days).

Total Readmission Charges and Total Hospital Readmission Days

The relationship of HF1 to all cause readmission charges and to all cause readmission days for the year following the index admission were secondary endpoints.

Table 1. Variable Table

	Variable Category	Name	Definition	Type and Code	Data Source
	Primary Predictor				
1	Independent	Core Measure HF-1	Heart failure patients discharged home with written instructions or educational materials given to the patient or care giver at discharge or during the hospital stay addressing all of the following: activity level, diet, discharge medications, follow-up appointment, weight monitoring, what to do if symptoms worsen. Specifications manual for national hospital inpatient quality measures, version 2.5b.	Categorical Bundle of six (6) elements Dichotomous: Bundle met = 0 Bundle not met = 1	CareDiscovery ™ Quality Measures, Thomson Healthcare; MIDAS DataVision™ Comparative Performance Measurement System
	Patient Characteristics	**Name**	**Definition**	**Type and Code**	**Data Source**
2	Independent	Gender	Male or Female	Categorical Female = 0 Male = 1	Decision Support
3	Independent	Marital Status	Married; divorced/separated; single; widowed	Categorical Married = 0 Divorced/separated = 1 Widowed = 2 Single = 3	Decision Support
4	Independent	Age	Age in years on day admitted to the hospital for index admission	Continuous	Decision Support

Table 1 continued

	Variable Category	Name	Definition	Type and Code	Data Source
	Primary Predictor				
5	Independent	Ethnicity	White; Black; Hispanic; American Indian; Asian; Other	Categorical White = 0 Other = 1	Decision Support
	Clinical Characteristics	**Name**	**Definition**	**Type and Code**	**Data Source**
6 - 12	Independent	Specific Co-morbids	Documentation in the medical record: anemia, chronic obstructive pulmonary disease; pneumonia, diabetes mellitus, hypertension, coronary artery disease, renal insufficiency	Categorical Condition not present = 0 Condition present = 1	Decision Support
13	Independent	Severity of Illness	The extent of physiological decompensation or organ system loss of function as assigned by the APR-DRG system (3M Health Information Systems 1993): 1 = minor, 2 = moderate, 3 = major, 4 = severe.	Continuous Minimum = 1 Maximum = 4	Decision Support
	Hospital Unit Context				
14	Independent	Discharge Unit	Type unit from which the patient was discharged after index hospitalization	Categorical Cardiology = 0 Other = 1 (Pulmonary, Medical Oncology,Surgical, Critical Care,Surgical Renal, Ortho/Neuro)	Decision Support

Table 1 continued

	Hospital Unit Context				
15	Independent	Number of Unit Transfers	Number of units upon which patient resided during the index hospitalization	Continuous	Decision Support
	Administrative/Utilization				
16	Independent	Days	Length of stay of the index admission	Continuous	Decision Support
17	I	Direct cost	Direct Cost of the index admission	Continuous	Decision Support
	Outcome/Dependent	**Name**	**Definition**	**Type and Code**	**Data Source**
1	Dependent	All Cause Readmissions	Number of readmissions for any cause to the index hospital within 30, 90, 180 and 365 days after the index hospitalization	1) Binary = Yes/No for each interval 2) Sum/Count = Number of admissions within each interval	Decision Support
2	Dependent	HF Readmissions	Number of readmissions for HF to the index hospital within 30, 90, 180 and 365 days after the index hospitalization	1) Binary = Yes/No for each interval 2) Sum/Count = Number of admissions within each interval	Decision Support
3	Dependent	All Cause Readmission Charges	All cause readmission charges per year from the study hospital during the 12 months following the index discharge	Continuous	Decision Support
4	Dependent	All Cause Readmission Days	Total hospital readmission days within 12 months of an index admission; does not include the index admission	Continuous	Decision Support

Procedures

The study was approved by the organization's Institutional Review Board and the University of Iowa Institutional Review Board prior to data collection. See Appendix B & C.

Both the hospital medical record data and the performance improvement data were transferred electronically from the host organization's databases to the investigator's password protected computer in Microsoft Excel format using a secure system. Core measure data from the different source files were reformatted and merged into one Excel file. All data were transferred to SPSS version 18.0 for further formatting, cleaning, merging and analysis. Variables, such as dates, were transformed to SPSS formatting as appropriate. Hospital medical record data for index admissions contained complete demographic information in addition to medical record and hospital encounter identifiers; performance improvement data contained only the medical record number (MRN) and the hospital encounter identifiers, along with dates of admission and discharge. Medical record data were limited by age and merged with core measure data based on MRN (individual) and then hospital encounter number (i.e., identifies the specific hospitalization).

Prior to de-identifying the final dataset, multiple problems were encountered in working with the data and cleaning was extensive. Individuals with more than one medical record number were discovered, usually due to slight variation in the recording of the person's name. The problem was compounded in this dataset because the organization's electronic medical record (EMR) vendor changed in 2006 and some medical record numbers (MRN) were altered for hospital encounters occurring after that time.

For obtaining medical records for index cases and readmissions, the MRN was the unique identifier for each person and was the key to matching recurring admissions for one individual over time. To ensure a unique MRN per individual, the data sort included patient name; multiple entries of one name were reviewed to ensure one MRN was used for eligible episodes of care throughout the database. Date of birth, gender and address were used for further confirmation of identity when it appeared that one person had multiple hospital encounters and more than one unique MRN. For instance, there were occurrences (n = 34) of the same individual being entered under more than one MRN due to differences in use of middle name or initial, differences in the case of letters, nickname versus full name, etc. These records and identifiers were matched with hospital encounter numbers, sorted and ultimately matched under one MRN. When a definite match was uncertain (which was rare) the record was excluded. All database merges were done electronically to reduce manual errors, but manual cleaning and validation were conducted for quality control of the final database.

Encounter numbers from the medical record, which identified a hospitalization episode, were matched with the core measure (HF1) encounter numbers. Dates of admission and discharge for each hospital encounter also had to match between the core measure record and medical record. There were, inexplicably, core measure encounter numbers without corresponding hospital medical record encounters. There were also hospital medical record encounter numbers for primary diagnosis of HF which did not have corresponding core measure data available. To be included in the study dataset, index medical records had to match on name, age, dates of admission and discharge, medical record number, and encounter number. Core measure charts had to match with index records on MRN, encounter number and dates of admission and discharge. Readmission records had to match on medical record and encounter numbers and fall within 365 days of the index discharge date.

The index case was the first primary discharge diagnosis of heart failure that also had core measure HF-1 documentation within the study time period. Select data from individual level readmissions following the index admission were obtained for a follow-up period of 12 months. Index cases (n = 1034) and readmissions (n = 1126) were merged into one database for data recoding and variable creation. For instance, a time to readmission variable was created in SPSS using index discharge dates and readmission dates, resulting in days between discharge and readmission. Then, to distinguish the index admission from readmissions and to analyze readmissions by intervals, dummy variables were created for readmissions at each of the four intervals, 30, 90, 180 and 365 days. Similarly, total readmission days for each individual were computed from all readmission days and total readmission charges were computed from individual readmission charge data.

The index case file was eventually re-aggregated with all recoded and transformed variables for final analyses. Readmissions were ultimately analyzed as either 1) all-cause, or 2) heart failure and by intervals of 30, 90, 180 or 365 days following the index discharge.

When the index and readmission data sets were clean and finalized, unique identifiers were re-coded for privacy and confidentiality of personal health information.

The original identifiers were stored on a password protected computer and were inaccessible except to the primary investigator.

Analysis

Steps in the analysis were conducted by the investigator under the guidance of a former University of Iowa and current health services research statistician. The database was downloaded and constructed as previously described. Primary endpoints were readmissions categorized as all cause or heart failure. Secondary endpoints were total hospital days and total charges during the year following the index admission. Contextual variables were included in the models to determine nursing unit effects.

Some predictor variables were centered or standardized for use in analysis. Age and days (length of stay during the index admission) were standardized, i.e., the mean subtracted from the individual score and divided by the standard deviation (SD), creating new variables with a mean of 0 and a standard deviation of 1 (e.g., ZAge, ZDays). When used in regression, the parameter represents the amount of change associated with a 1 SD change in the predictor, while the intercept is the value of the outcome measure for an individual with the average score on that predictor. For the continuous predictor variable direct cost, the metric was kept in dollars divided by 1000 and then centered on the mean. This was done by standardizing the variable and then multiplying by the SD. For both of the continuous variables, number or nursing units upon which the patient resided (nursunits) and APRDRG severity of illness, with small ranges starting at one (1), one (1) was subtracted from the score to make zero equal to 1, or meaning no transfers or lowest severity. Zero then became a meaningful value on the scale. No other adjustment was then necessary for these variables.

After merging index and readmission databases, variables were created to differentiate index admission data versus readmissions. Index cases with core measure information were then re-aggregated after data transformation and variable creation to allow for binary and count analyses of readmissions per interval, i.e., readmission yes/no versus readmission sum within the period of interest. Readmission cases only were used to address the research questions related to readmission charges and total readmission days per year.

Exploratory descriptive statistics were run on study variables. They are displayed along with the results of contingency tables that also demonstrate differences between HF1 “met” and “not met” groups, using chi square tests for each categorical variable and t tests for continuous variables. See Chapter Four for tables and results. Initially, general estimating equations (GEE) were used for the primary analysis. This method was chosen for two reasons: because of repeated visits by the same patient; and because of the high likelihood of non-independent, correlated variables due to nesting of hospitalizations within units. However, the issue of repeated visits was nullified by taking a single index admission and using the other visits only to calculate outcomes measures in relation to that single admission. Each record in the index database represents a single individual and there are not clusters of visits within an individual.

The second issue of nesting within units was also found to be weak. When the index database was constructed, it was found that about 88% of HF discharges were from one medical cardiology unit. Due to the small number of discharges from the other 6 units from which HF patients were discharged during the study period, the variable was collapsed into a dichotomous categorical variable, cardiology and other, and used as a predictor variable.

Another problem in the early trial analyses was related to the lack of availability of zero-inflated Poisson regression in SPSS 18.0. Data was run using GLM GEE Poisson loglinear. Without the zero-inflated Poisson regression option, a simultaneous comparison of logistic regression runs on an outcome of ‘zero versus other’ and counts of ‘1 or more’, was not possible. Such a zero-inflated method would likely have stabilized the models used for counts or sums.

For these reasons, a decision was made to move away from GEE to another of the generalized linear model (GLM) family of models for the primary analysis (Nelder and Wedderburn (1972) (p625 Applied Linear Regression). GLM includes normal error linear regression models and the nonlinear exponential, logistic and Poisson regression models, as well as others, such as log-linear models for categorical data. The class of generalized linear models can be described as:

- Response variables follow a probability distribution belonging to the exponential family of probability distributions, with the expected value $E = \mu_{i.}$
- A linear predictor based on the predictor variables $X_{i1,\ldots,}\ X_{i,p-1}$ is used, denoted by $X'_i\beta$, where $X'_i\beta = \beta_0 + \beta_1 X_{i1} + \ldots + \beta_{p-1} X_{i,p-1}$
- A link function g relates the linear predictor to the mean response: $X'_i\beta = g(\mu_i)$.

GLM binary logistic regression was used to analyze the relationship of any readmission occurrence (all cause readmission yes/no) and HF1 during each of the 30, 90, 180 and 365 day intervals. Steps included bivariate analysis of each of the independent variables related to patient and clinical characteristics, hospital context and administrative variables to each of the four (4) response intervals. Variables with significance $p \leq 0.20$ were retained for further analysis. The threshold significance of $p \leq 0.20$ was chosen to ensure that no variable was prematurely excluded from the final model. Variables retained after the bivariate analysis then underwent backward stepwise elimination, one variable at a time, until all remaining variables had a value of $p \leq .05$ for each interval model. These analyses steps were then repeated for the subset of HF to HF readmissions.

As indicated previously, the initial analysis of counts, or sum of readmissions per interval, trialed the use of the Poisson distribution. However, this distribution produced excessive chi squares and less satisfactory model fit compared to the negative binomial model with maximum likelihood estimation of the dispersion parameter. The negative binomial model uses a log link, like the Poisson model, but allows for greater dispersion (higher variance) than the Poisson model allows (Lloyd-Smith 2007). Therefore the negative binomial model was finally used to analyze counts of all cause, and HF, readmissions within each response interval, as well as with the count of total readmission days per year. Again, bivariate analysis with exclusion of variables at threshold of $p \leq 0.20$ was conducted for each independent variable and response variable. Remaining variables underwent backward stepwise elimination at threshold of $p \leq 0.05$ to determine final models for each interval (Mantel 1970; Harrell 2001).

The relationship of HF1 to total all cause readmission charges was analyzed using GLM custom model with normal distribution and identity link. The response variable was transformed to log base 10 to account for its lack of normal distribution. Only readmission cases were used in this analysis. The same overall steps were used in the analysis of this variable, including bivariate analysis to trim variables and backward stepwise elimination.

The literature indicates that statistical models for the study of factors related to hospital readmissions for heart failure have been varied. Models attempting to predict risk of readmission have also varied in methods and results. According to Ross, et al (2008), in a systematic review (n = 117 studies) to describe models designed to compare hospital rates of readmission related to heart failure, or to predict patients' risk of readmission, a validated model is unavailable. Studies have been heterogeneous in methods, data sources, study outcomes, and periods of time of follow-up (i.e. 14 days to 4 years) (Ross, Mulvey et al. 2008). No studies compared hospital rates of readmission for HF and the authors concluded that no hospital level measure exists to do so. Only 5 studies (4.3%) were designed to predict patient risk of readmission. The other 95.7% of studies examined patient characteristics associated with readmission without the emergence of consistent predictors. Most studies used between 11 – 25 candidate variables and Cox proportional hazards regression, multivariate logistic regression and χ^2 for analysis.

Overall, studies in the systematic review did not derive a statistical model to predict patient readmission risk. The authors suggested that, opposed to a critical patient risk characteristic being omitted, a possible explanation is that other non-patient factors have a larger role in HF readmissions, i.e. patient characteristics may represent less of the variance associated with readmission. Readmission may be more responsive to discharge planning, post-discharge follow-up and acute care system characteristics. (No studies included discharge preparation as an independent variable.) They also suggested that patient risk of readmission models use patient characteristics on discharge, such as co-morbid conditions and complications that would be included in risk adjustments. Finally, they suggested that clustering of patients within hospitals and the non-independence of readmissions be considered in future statistical modeling (Ross, Mulvey et al. 2008).

CHAPTER IV

DATA ANALYSIS AND FINDINGS

The purpose of this study was to describe outcomes of hospital discharge instructions. This chapter presents findings of the relationship between the completion of the heart failure discharge instructions bundle (HF1) and the primary endpoint of subsequent readmission to the hospital following an index discharge for primary diagnosis of heart failure. Secondary endpoints include findings of the relationship of total readmission hospital charges and total readmission hospital days per year to HF1. This study also describes the relationship between nursing unit factors and completion of HF1. The first section of this chapter provides descriptive characteristics of the heart failure index population and the hospital unit context.

Patient Characteristics

The first section of this chapter describes demographic characteristics of the heart failure index population. The index sample population (n = 1034) includes patients between the ages of 50 and 98 years, mean 74.3 (10.75), who were discharged with a primary diagnosis of heart failure and who had documented evidence of the core measure HF1 bundle. Those 65 and over accounted for 79.5% of the sample, quite consistent with the national average of 78% of hospitalized HF patients (Rosamond, Flegal et al. 2008). More than half of the sample were men (58.1%) and the vast majority (95%) were White, with the second highest ethnic group being Native American (4.4%). The percent of White patients in the sample is somewhat higher than that of overall inpatients for calendar year 2010 at the study hospital (90.5%); ethnicity data for the entire period of the study were not available. During the same calendar year, Native Americans accounted for 5.35% of inpatients. Consistent with the higher number of older men in the sample, 59.5% of the total sample were married and 10.5% were single. Another 13.5% and 16.5% were divorced or widowed, respectively.

Patient characteristics were also compared by HF1 bundle completed or not completed. There was no significant difference in the completion of the HF1 discharge instruction bundle by gender (χ^2 .11; p = .75) or by marital status (χ^2 1.14; p = .77). Ethnicity approached significance (χ^2 3.24; p = .07). There was, however, a significant difference by mean age. Those patients in the not completed (not met) category were significantly *younger* (mean age 72.39; SD 8.49) than those in the completed (met) category (mean age 74.63; SD 10.76; t = 2.365; p = .018).

Table 2. Patient Demographic Characteristics by HF1 Bundle Completion

Variables	**Index Cases N=1034**	**HF1 Met N=884 (85.5%)**	**HF1 Not Met N=150 (14.5%)**	**Pearson χ^2**
Gender				
Male	601 (58.1%)	512 (85.2%)	89 (14.8%)	Value .105
Female	433 (41.9%)	372 (85.9%)	61 (14.1%)	Sig .75
Ethnicity				
White	982 (95%)	844 (85.9%)	138 (14.1%)	Value 3.243
Native American	46 (4.4%)	35 (76.1%)	11 (23.9%)	Sig .07
Other	6 (0.6%)	5 (83%)	1 (17%)	
Marital Status				
Married	618 (59.5%)	526 (85.1%)	92 (14.9%)	Value 1.144
Single	111 (10.5%)	93 (83.8%)	18 (16.2%)	Sig .77
Divorced	139 (13.5%)	119 (85.6%)	20 (14.4%)	
Widowed	166 (16.5%)	146 (88%)	20 (12%)	
		Mean (SD)	**Mean (SD)**	**Sig**
Age		74.63 (10.76)	72.39 (8.49)	.018

*Column two equals 100% summed vertically

+ Column three and four equal 100% summed horizontally

Clinical Characteristics

Clinical characteristics of the sample include the presence or absence of seven (7) co-morbid conditions related to heart failure: anemia; chronic obstructive pulmonary disease (COPD); pneumonia; diabetes mellitus (DM); hypertension (HTN); coronary artery disease (CAD); and renal insufficiency (RI). In addition, patient severity of illness for the index admission is also described.

Overall APRDRG severity of illness (SI) for the sample was 2.48 on a four point scale, 1 being least severely ill and 4 being most severely ill (Iezzoni 2003). Upon testing, there was no statistically significant difference in SI between the HF1 completed (met) group ($\bar{x}$ = 2.48; SD .70) and the not completed (not met) group ($\bar{x}$ = 2.53; SD .70; $t = -.817$; $p = .41$).

Of the sample population, almost three-fourths had a pre-existing diagnosis of hypertension (74.5%) and more than half had pre-existing CAD (61.4%). Diabetes mellitus was present in 40.6%. Almost one-third had a diagnosis of COPD (28.8%) and/or anemia (28.3%). Yet, less than one in five (19.8%) had a secondary diagnosis of renal insufficiency and only 6.2% had co-morbid pneumonia at the index admission. Of the sample, 96% had at least one of these seven diagnoses and 80% had two or more; the mean number of co-morbids from this grouping was 2.6. Interestingly, of the 44 index cases with none of these co-morbid conditions, almost one case in five did not have the HF1 bundle completed (18.2%). This was higher than any single co-morbid condition. When analyzed in a 2 X 2 contingency table, none of the co-morbid conditions was statistically significantly related to meeting HF1 bundle completion.

Table 3. Patient Clinical Characteristics by HF1 Bundle Completion

Variables	**Index Cases N=1034**	**HF1 Met N=884 (85.5%)**	**HF1 Not Met N=150 (14.5%)**	**Pearson χ^2 dfl**
Anemia				
No	741 (71.7%)*	635 (85.7%)+	106 (14.3%)	Value .086
Yes	293 (28.3%)	249 (85%)	44 (15%)	Sig .77
COPD				
No	736 (71.2%)	629 (85.5%)	107 (14.5%)	Value .002
Yes	298 (28.8%)	255 (85.6%)	43 (14.4%)	Sig .96
Pneumonia				
No	970 (93.8%)	828 (85.4%)	142 (14.6%)	Value .222
Yes	64 (6.2%)	56 (87.5%)	8 (12.5%)	Sig .64
Diabetes				
No	614 (59.4%)	528 (86%)	86 (14%)	Value .305
Yes	420 (40.6%)	356 (84.8%)	64 (15.2%)	Sig .58
Hypertension				
No	264 (25.5%)	218 (82.6%)	46 (17.4%)	Value 2.433
Yes	770 (74.5%)	666 (86.5%)	104 (13.5%)	Sig .119
Coronary Artery Disease				
No	399 (38.6%)	333 (83.5%)	66 (16.5%)	Value 2.169
Yes	635 (61.4%)	551 (86.8%)	84 (13.2%)	Sig .141
Renal Insufficiency				
No	829 (80.2%)	701 (84.6%)	128 (15.4%)	Value 2.938
Yes	205 (19.8%)	183 (89.3%)	22 (10.7%)	Sig .087
	Mean (SD)	**Mean (SD)**	**Mean (SD)**	**Sig**
Severity of Illness	2.48 (.699)	2.48 (.698)	2.53 (.70)2	.414

*Column two equals 100% summed vertically

+Column three and four equal 100% summed horizontally

Hospital Unit Context

Hospital context variables included the number of units on which the individual resided during the index admission and the unit of discharge after the index admission. There were a total of seven (7) nursing units from which the index sample was discharged with primary diagnosis of heart failure. Of the 1034 cases in the sample, 906 or 87.7% were discharged from the medical cardiology unit. The next highest discharge number was 47, or 4.5% of cases, discharged from the surgical-renal nursing unit; 39 cases (3.8%) were discharged from the pulmonary step down unit; and 26 cases (2.5%) from the medical-oncology unit. Less than 1% were discharged from the cardiovascular surgery unit, critical care and orthopedics/neurology during the study period.

Because the vast majority of discharges were from the cardiology unit, the variable was converted to a dichotomous categorical predictor variable, cardiology or other. Of the 906 cases in the data set discharged from this unit, 805 (89%) had a completed HF1 discharge instruction set. The 127 cases (12.3%) discharged from other units during the study period included 79 (62.2%) completed HF1 bundles and 48 (37.8%) incomplete HF1 bundles. On cross tabulation, the discharge department was strongly statistically significantly associated with completion of HF1 (Pearson χ^2 63.31; p = .000).

The number of nursing unit transfers was the other variable of interest related to hospital unit context. In other studies, the number of unit transfers has been significantly related to adverse outcomes (Kanak, Titler et al. 2008). However, in this study, only 16.3% of all cases in the sample had any transfer at all during the index hospitalization. The mean transfers for all index cases was 1.15. There was no statistically significant relationship with HF1 completion (mean difference .041; Levene test positive-df = 239; t = 1.256; p = .21).

Table 4. Unit Contextual Variables by HF1 Bundle Completion

Variables	**Index Cases N=1034**	**HF1 Met N=884 (85.5%)**	**HF1 Not Met N=150 (14.5%)**	**Pearson χ^2 df l**
Unit of Discharge				
Cardiology	907 (87.7%)	805 (88.8%)	102 (11.2%)	Value 63.31
Other	127 (12.3%)	79 (62.2%)	48 (37.8%)	Sig .000
	Mean (SD)	**Mean (SD)**	**Mean (SD)**	**Sig**
Number of Nursing Units	1.18 (.440)	1.19 (.453)	1.15 (.335)	.210

*Column two equals 100% summed vertically

+ Column three and four equal 100% summed horizontally

Note: Levene Test F= 5.04; Sig= .025

Administrative Variables

The last category of variables is the administrative, or utilization category including direct cost and length of stay of the index admission.

The mean length of stay for heart failure during the study period was 4.13 days, SD 2.77 with a range of one to 18 days. Median length of stay was 3.00 days for the HF1 Not Met group (Mean 4.01; SD 3.10) and 4.00 days for the HF1 Met group (Mean 4.15; SD 2.71). There was no statistically significant difference between means of HF1 groups and length of stay (t = .574; df 1032 p =.57).

The mean direct cost associated with the index admission was $5852 (SD 6849). Mean direct cost of the HF1 Met group (x = 5803; SD 6874) was somewhat lower than the HF1 Not Met group (x = 6145; SD 6714) but not statistically significantly different (t = -562; df 1028 p = .57).

Table 5. Administrative Variables by HF1 Bundle Completion

Variable	**Index Case**	**HF1 Met**	**HF1 Not Met**	**p**
	Mean (SD)	**Mean (SD)**	**Mean (SD)**	**Sig**
Length of Stay	4.13 (2.77)	4.15 (2.71)	4.01 (3.10)	.566
Direct Cost	5852 (6849)	5803 (6874)	6145 (6714)	.573

The second section of this chapter describes findings related specifically to research aim number 1:

> Describe the relationship between completion of HF1 and hospital readmissions at 30, 90, 180 and 365 days after an index discharge, hospital readmission charges at 12 months, and total number of readmission hospital days at 12 months while controlling for patient, clinical, and hospital unit characteristics.

The analysis used the Generalized Linear Model (GLM) family, with distributions and links appropriate to the part of the research question under analysis.

The first stage in the analysis of readmissions focused on binary analysis of readmission within each interval, i.e., 30, 90, 180 and 365 days after the index discharge. The GLM binomial distribution and logit link were used. The type of model for the "readmission yes/no" run was binary logistic.

The second stage in the analysis of readmissions focused on the sum, or count of admissions, within each interval. Initially, GLM Poisson log link was used but large chi squares suggested instability of the model and less effective model fit. Poisson was replaced with negative binomial (MLE) log link for all counts of readmissions within an interval. In addition, this model type was also used for the count of all cause readmission hospital days, later in this section.

In general, there were two steps to each readmission interval analysis process. The first step in the analysis of the relationship between any readmission interval and HF1 bundle completion was bivariate. Each independent variable (df1) was run with the outcome/response variable, i.e., readmission within nth days of index discharge. Those with a significance level of $p \leq .20$ were retained, followed by backward elimination of single variables from highest to lowest significance $\geq .05$. Those with $p \leq .05$ are retained in the final model for each outcome/response interval. Because HF1 was the primary independent predictor, it remained in all models regardless of the final level of significance.

In the findings to follow, the first stage (GLM binary logistic model) describes readmission as occurring, or not occurring (readmission yes/no), within an interval. Then, the *count* of readmissions within the same interval will be described using the GLM negative binomial (MLE) log link model. This process is then repeated for the HF to HF readmission subset for each interval.

30 Day Readmission and HF1

The 30 day all cause readmission (yes/no) rate was 18.2%; 188 individuals were readmitted at least once in the period. Bivariate analysis left 5 independent variables, plus HF1, in the model at a threshold of $p \leq .20$: ethnicity, discharge department, anemia, diabetes and length of stay (Days) of the index admission. See Table 6 & 7. After backward elimination, length of stay (Days) dropped out of the final model. HF1 was not related to readmission ($p = 0.22$; OR 1.32). Ethnicity, non-white ($p = .02$; OR 0.32), was negatively associated with readmission, i.e., the odds of readmission for non-white ethnic groups were lower than for whites. The discharge nursing unit was positively associated with readmission, i.e., probability of readmission was more likely if the individual was discharged from a non-medical cardiology unit (p = .025; OR 1.67). Secondary diagnoses of anemia (p = .052; OR 1.41) or diabetes mellitus (p = 0.016; OR 1.49) was also associated with increased odds of readmission by as much as 49%.

The 30 day all cause count of readmissions was 214, mean 0.21 per individual with a range of 0 – 3 admissions. There were 8 variables with a threshold $p \leq .20$, including HF1, after bivariate analysis of the 30 day sum response variable: ethnicity, discharge department, anemia, diabetes mellitus, severity of illness, length of stay (Days) and age. See Table 8. After backward elimination, only four variables remained, three of which were significant at $p \leq .05$: discharge department not cardiology (p =.019; OR 1.55); diabetes mellitus (p = .016; OR 1.40); and ethnicity non-white (p = .025; OR .35). See Table 9. HF1 was not significantly related to 30 day readmission in the counts analysis (p = .131; OR 1.32), as well as the binary analysis previously reported. Discharge department, diabetes mellitus and ethnicity were significantly related in both binary and count analyses.

A subset of HF to HF 30 day readmissions was analyzed separately. The binary readmission rate (yes/no) was 5.3%, n = 55. Only three variables met the threshold $p \leq .20$ on bivariate analysis: HF1, coronary artery disease (CAD) and length of stay (Days). See Table 10. In the final model, after backward elimination using the same methodology used in the all cause binary analysis (readmission yes/no), only Days (p = .009 OR 1.35) was significant. See Table 11. The primary independent variable, HF1 (p

= .438; OR .71), was not significant in binary analysis.

The HF to HF 30 day readmission count outcome was analyzed in a similar manner. Four variables met the $p \leq .20$ threshold in the bivariate analysis: hypertension, CAD, diabetes mellitus, and length of stay (Days). HF1 did not meet threshold but was included in final analysis as the primary variable of interest. As in the binary analysis, the only variable significant at the $p \leq .05$ was Days ($p = .007$; OR 1.34). HF1 discharge instructions were again not significantly related to readmission ($p =.397$; OR .69). See Tables 12 – 13.

Table 6. Bivariate Analysis Summary: 30 Day All Cause Readmission Binary Analysis (yes/no)

Variable	B	Std Error	95% Wald Confidence Interval		Hypothesis Test			Exp(B)
			Lower	Upper	Wald Chi-Square	df	Sig.	
HF1 Not Met*	**0.374**	**0.2125**	**-0.042**	**0.791**	**3.103**	**1**	**0.078**	**1.454**
Gender=Male	-0.034	0.1632	-0.354	0.286	0.043	1	0.835	0.967
Ethnicity=Non-White	**-0.767**	**0.4775**	**-1.703**	**0.169**	**2.579**	**1**	**0.108**	**0.464**
Marital Status=Single	0.313	0.2471	-0.172	0.797	1.601	1	0.206	1.367
Marital Status=Widowed	-0.056	0.2294	-0.505	0.394	0.059	1	0.809	0.946
Marital Status=Divorced	-0.286	0.2631	-0.802	0.229	1.183	1	0.277	0.751
DC Dept=Not Cardiology	**0.581**	**0.2191**	**0.152**	**1.01**	**7.032**	**1**	**0.008**	**1.788**
Anemia=Yes	**0.359**	**0.1718**	**0.023**	**0.696**	**4.374**	**1**	**0.036**	**1.432**
COPD=Yes	-0.07	0.1798	-0.422	0.283	0.151	1	0.698	0.933
Pneumonia=Yes	-0.467	0.3869	-1.225	0.291	1.456	1	0.228	0.627
Diabetes=Yes	**0.362**	**0.1621**	**0.044**	**0.68**	**4.982**	**1**	**0.026**	**1.436**
HTN=Yes	-0.034	0.184	-0.395	0.327	0.034	1	0.853	0.967
CAD=Yes	-0.04	0.1652	-0.364	0.284	0.058	1	0.810	0.961
Renal Insufficiency=Yes	-0.138	0.2079	-0.545	0.27	0.438	1	0.508	0.871
Nursing Units	0.06	0.1795	-0.292	0.412	0.111	1	0.739	1.062
APR Severity	0.149	0.1167	-0.079	0.378	1.637	1	0.201	1.161
Direct Cost	0.005	0.0114	-0.017	0.028	0.227	1	0.634	1.005
Days	**0.184**	**0.0755**	**0.036**	**0.332**	**5.944**	**1**	**0.015**	**1.202**
Age	-0.083	0.08	-0.24	0.074	1.065	1	0.302	0.921

*Bold = within p≤0.20 trim threshold in bivariate analysis

Table 7. Final Binary Model: 30 Day All Cause Readmissions

Variable	B	Std Error	95% Wald Confidence Interval		Hypothesis Test			Exp(B)
			Lower	Upper	Wald Chi-Square	df	Sig.	
HF1 Not Met	0.276	0.2234	-0.162	0.714	1.529	1	0.216	1.318
Ethnicity=Non-White	-1.14	0.4906	-2.101	-0.178	5.396	1	0.020	0.32
DC Dept=Not Cardiology	0.516	0.2303	0.064	0.967	5.014	1	0.025	1.675
Anemia=Yes	0.34	0.1751	-0.003	0.683	3.766	1	0.052	1.405
Diabetes=Yes	0.399	0.1662	0.074	0.725	5.775	1	0.016	1.491

Note: Readmission Yes=n=188; 18.2%

Table 8. Bivariate Analysis Summary: 30 Day All Cause Readmissions Sum

Variable	B	Std Error	95% Wald Confidence Interval		Hypothesis Test			Exp(B)
			Lower	Upper	Wald Chi-Square	df	Sig.	
HF1 Not Met*	**0.364**	**0.178**	**0.014**	**0.714**	**4.161**	**1**	**0.041**	**1.439**
Gender=Male	-0.027	0.143	-0.306	0.253	0.035	1	0.852	0.974
Ethnicity=Non-White	**-0.795**	**0.459**	**-1.694**	**0.105**	**2.996**	**1**	**0.083**	**0.452**
Marital Status=Single	0.209	0.213	-0.208	0.626	0.967	1	0.325	1.233
Marital Status=Widowed	-0.095	0.203	-0.492	0.302	0.219	1	0.64	0.909
Marital Status=Divorced	-0.292	0.236	-0.755	0.17	1.534	1	0.216	0.747
DC Dept=Not Cardiology	**0.496**	**0.182**	**0.139**	**0.852**	**7.421**	**1**	**0.006**	**1.642**
Anemia=Yes	**0.29**	**0.148**	**-0.001**	**0.581**	**3.825**	**1**	**0.05**	**1.337**
COPD=Yes	-0.133	0.160	-0.447	0.181	0.691	1	0.406	0.875
Pneumonia=Yes	-0.407	0.348	-1.089	0.274	1.371	1	0.242	0.665
Diabetes=Yes	**0.286**	**0.141**	**0.01**	**0.563**	**4.121**	**1**	**0.042**	**1.331**
HTN=Yes	-0.033	0.161	-0.348	0.281	0.043	1	0.836	0.967
CAD=Yes	0.031	0.145	-0.254	0.316	0.046	1	0.83	1.032
Renal Insufficiency=Yes	-0.168	0.186	-0.532	0.196	0.817	1	0.366	0.845
Nursing Units	0.072	0.155	-0.231	0.375	0.217	1	0.641	1.075
APR Severity	**0.142**	**0.103**	**-0.059**	**0.344**	**1.922**	**1**	**0.166**	**1.153**
Direct Cost	0.01	0.010	-0.009	0.028	1.074	1	0.3	1.01
Days	**0.148**	**0.063**	**0.024**	**0.272**	**5.5**	**1**	**0.019**	**1.16**
Age	**-0.108**	**0.070**	**-0.244**	**0.029**	**2.392**	**1**	**0.122**	**0.898**

*Bold = within p≤0.20 trim threshold in bivariate analysis

Table 9. Final Count Model: 30 Day All Cause Readmissions

Variable	B	Std Error	95% Wald Confidence Interval		Hypothesis Test			Exp(B)
			Lower	Upper	Wald Chi-Square	df	Sig.	
HF1 Not Met	0.278	0.184	-0.083	0.639	2.281	1	0.131	1.320
Ethnicity=Non-White	-1.038	0.463	-1.944	-0.131	5.035	1	0.025	0.354
DC Dept=Not Cardiology	0.441	0.188	0.073	0.810	5.501	1	0.019	1.554
Diabetes=Yes	0.399	0.141	0.063	0.616	5.777	1	0.016	1.404

Note: Mean 0.21; n=214; Range 0-3

Negative Binomial Log Link MLE

Table 10. Bivariate Analysis Summary: 30 Day HF to HF Readmission Binary Analysis

Variable	B	Std Error	95% Wald Confidence Interval		Hypothesis Test			Exp(B)
			Lower	Upper	Wald Chi-Square	df	Sig.	
HF1 Not Met	**-0.342**	**0.442**	**-1.208**	**0.524**	**0.601**	**1**	**0.438**	**0.710**
Gender=Male	-0.076	0.2795	-0.624	0.472	0.074	1	0.786	0.927
Ethnicity=Non-White	-1.088	1.0194	-3.086	0.91	1.139	1	0.286	0.337
Marital Status=Single	-0.019	0.4553	-0.911	0.874	0.002	1	0.967	0.982
Marital Status=Widowed	-0.279	0.4246	-1.112	0.553	0.433	1	0.51	0.756
Marital Status=Divorced	0.048	0.4047	-0.745	0.841	0.014	1	0.906	1.049
DC Dept=Not Cardiology	0.207	0.3948	-0.567	0.981	0.275	1	0.6	1.23
Anemia=Yes	0.219	0.296	-0.361	0.8	0.55	1	0.458	1.245
COPD=Yes	0.281	0.2923	-0.292	0.854	0.923	1	0.337	1.324
Pneumonia=Yes	-0.583	0.7322	-2.018	0.852	0.634	1	0.426	0.558
Diabetes=Yes	0.286	0.2778	-0.258	0.831	1.06	1	0.303	1.331
HTN=Yes	-0.282	0.3009	-0.872	0.308	0.878	1	0.349	0.754
CAD=Yes	**-0.453**	**0.2776**	**-0.997**	**0.091**	**2.665**	**1**	**0.103**	**0.636**
Renal Insufficiency=Yes	0.238	0.3274	-0.404	0.88	0.528	1	0.467	1.269
Nursing Units	0.095	0.3	-0.493	0.683	0.099	1	0.753	1.099
APR Severity	0.016	0.1987	-0.373	0.405	0.006	1	0.936	1.016
Direct Cost	-0.013	0.0225	-0.057	0.031	0.318	1	0.573	0.987
Days	**0.305**	**0.1161**	**0.077**	**0.532**	**6.894**	**1**	**0.009**	**1.356**
Age	-0.084	0.137	-0.353	0.185	0.376	1	0.54	0.919

*Bold = within p≤0.20 trim threshold in bivariate analysis; HF1 always included

Table 11. Final Binary Model: 30 Day HF to HF Readmissions

			95% Wald Confidence Interval		Hypothesis Test			
Variable	**B**	**Std Error**	**Lower**	**Upper**	**Wald Chi-Square**	**df**	**Sig.**	**Exp(B)**
HF1 Not Met	-0.344	0.444	-1.213	0.525	0.601	1	0.438	0.709
Days	0.306	0.117	0.078	0.535	6.895	1	0.009	1.358

Note: Readmission Yes=n=55

Table 12. Bivariate Analysis Summary: 30 Day HF to HF Readmission Sum

Variable	B	Std Error	95% Wald Confidence Interval		Hypothesis Test			Exp(B)
			Lower	Upper	Wald Chi-Square	df	Sig.	
HF1 Not Met	**-0.366**	**0.434**	**-1.217**	**0.484**	**0.712**	**1**	**0.399**	**0.693**
Gender=Male	-0.081	0.269	-0.608	0.446	0.091	1	0.763	0.922
Ethnicity=Non-White	-1.087	1.012	-3.069	0.895	1.155	1	0.283	0.337
Marital Status=Single	-0.075	0.444	-0.945	0.796	0.028	1	0.866	0.928
Marital Status=Widowed	-0.323	0.416	-1.138	0.491	0.604	1	0.437	0.724
Marital Status=Divorced	-0.012	0.394	-0.784	0.760	0.001	1	0.976	0.988
DC Dept=Not Cardiology	0.154	0.385	-0.600	0.907	0.159	1	0.690	1.166
Anemia=Yes	0.235	0.283	-0.320	0.790	0.686	1	0.407	1.265
COPD=Yes	0.289	0.280	-0.259	0.837	1.067	1	0.302	1.335
Pneumonia=Yes	-0.596	0.723	-2.013	0.821	0.679	1	0.410	0.551
Diabetes=Yes	**0.345**	**0.267**	**-0.178**	**0.868**	**1.669**	**1**	**0.196**	**1.411**
HTN=Yes	**-0.377**	**0.283**	**-0.932**	**0.178**	**1.775**	**1**	**0.183**	**0.686**
CAD=Yes	**-0.430**	**0.267**	**-0.952**	**0.093**	**2.595**	**1**	**0.107**	**0.651**
Renal Insufficiency=Yes	0.178	0.138	-0.446	0.802	0.313	1	0.576	1.195
Nursing Units	0.056	0.294	-0.521	0.633	0.036	1	0.849	1.058
APR Severity	0.052	0.192	-0.325	0.429	0.073	1	0.786	1.504
Direct Cost	-0.012	0.022	-0.054	0.031	0.286	1	0.593	0.988
Days	**0.289**	**0.107**	**0.078**	**0.499**	**7.241**	**1**	**0.007**	**1.335**
Age	-0.100	0.132	-0.358	0.158	0.578	1	0.447	0.905

*Bold = within p≤0.20 trim threshold in bivariate analysis; HF1 always included

Note: Mean 0.055; n = 57; range 0-2

Table 13. Final Count Model: 30 Day HF to HF Readmission Sum

			95% Wald Confidence Interval		Hypothesis Test			
Variable	**B**	**Std Error**	**Lower**	**Upper**	**Wald Chi-Square**	**df**	**Sig.**	**Exp(B)**
HF1 Not Met	-0.366	0.432	-1.213	0.481	0.718	1	0.397	0.693
Days	0.291	0.108	0.079	0.502	7.258	1	0.007	1.337

90 Day Readmission and HF1

The 90 day all cause binary readmission rate (readmission yes/no) was 33.2%; 343 individuals were readmitted at least once in the first three months after the index discharge. Bivariate analysis of each independent variable with the response variable left 5 independent variables, plus HF1, for final model analysis at a threshold of $p \leq .20$: discharge department, anemia, COPD, diabetes and length of stay (Days) of the index admission. See Table 14. After backward stepwise elimination, length of stay (Days) was the only variable to remain significantly associated with 90 day readmission ($p = .008$; OR 1.18). HF1 was again not related to readmission in binary analysis ($p =0.54$; OR 0.88). See Table 15.

The 90 day all cause count of readmissions was 483, mean 0.47 per individual with a range of 0 – 6 readmissions. There were six (6) variables with a threshold $p \leq .20$, including HF1, after bivariate analysis using the 90 day readmission count response variable: discharge department, anemia, COPD, diabetes mellitus, and length of stay (Days). See Table 16. After the process of backward stepwise elimination, three variables remained, including the primary independent, which was again statistically insignificant, HF1 ($p =.27$; OR .84). The other two variables remaining in the model at $p \leq .05$, were discharge department (not cardiology) ($p = .002$; OR 1.58) and diabetes mellitus ($p = .044$; OR 1.24). See Table 17.The odds of readmission if an individual discharged from a non-cardiology unit was 58% greater; if the individual had a secondary diagnosis of diabetes mellitus, the odds were 24% greater.

A subset of HF to HF 90 day readmissions was analyzed and the binary readmission rate (yes/no) was 10.7%, n = 111. Five (5) variables, including HF1, met the threshold $p \leq .20$ on bivariate analysis: CAD; severity of illness; direct cost of the index admission, and number of nursing units upon which the patient resided. See Table 18. After backward elimination, severity of illness dropped out and four variables remained: HF1 (p = .013; OR .367); CAD (p = .028; OR .636); direct cost of the index admission (p = .051; OR .961); and number of nursing units (p = .034; OR 1.56). See Table 19. Only the number of nursing units in this analysis increased the odds of readmission. The other significant variables had an inverse relationship, or were related to reduced odds of readmission.

The count analysis of all variables in HF to HF 90 day readmissions (n = 124) reduced to 5 variables left after Bivariate analysis: HF1; pneumonia; CAD; severity of illness; and direct cost of the index admission. After backward stepwise elimination, the final model contained HF1 (p =.007; OR .344); and CAD (p = .039; OR .677). Heart failure discharge instructions were negatively related to readmissions, i.e., the HF bundle not met, or incomplete, was related to reduced odds of readmission after six months. Similarly, presence of CAD as a secondary diagnosis was also inversely related to readmission. See Tables 20 -21.

Table 14. Bivariate Analysis Summary: 90 Day All Cause Readmission Binary Analysis (yes/no)

Variable	B	Std Error	95% Wald Confidence Interval		Hypothesis Test			Exp(B)
			Lower	Upper	Wald Chi-Square	df	Sig.	
HF1 Not Met	**-0.134**	**0.1909**	**-0.509**	**0.24**	**0.496**	**1**	**0.481**	**0.874**
Gender=Male	0.119	0.1344	-0.144	0.383	0.789	1	0.374	1.127
Ethnicity=Non-White	-0.023	0.3033	-0.617	0.572	0.006	1	0.940	0.977
Marital Status=Single	0.317	0.2114	-0.097	0.732	2.256	1	0.133	1.374
Marital Status=Widowed	-0.029	0.1864	-0.394	0.336	0.024	1	0.876	0.971
Marital Status=Divorced	-0.241	0.2072	-0.647	0.165	1.355	1	0.244	0.786
DC Dept=Not Cardiology	**0.384**	**0.194**	**0.004**	**0.764**	**3.913**	**1**	**0.048**	**1.468**
Anemia=Yes	**0.291**	**0.1441**	**0.009**	**0.574**	**4.082**	**1**	**0.043**	**1.338**
COPD=Yes	**0.254**	**0.1437**	**-0.027**	**0.536**	**3.131**	**1**	**0.077**	**1.29**
Pneumonia=Yes	-0.253	0.2862	-0.814	0.308	0.78	1	0.377	0.777
Diabetes=Yes	**0.282**	**0.1338**	**0.02**	**0.544**	**4.435**	**1**	**0.035**	**1.325**
HTN=Yes	0.013	0.1516	-0.284	0.31	0.008	1	0.931	1.013
CAD=Yes	0.025	0.1358	-0.241	0.291	0.034	1	0.854	1.025
Renal Insufficiency=Yes	-0.139	0.1638	-0.469	0.19	0.686	1	0.407	0.87
Nursing Units	0.146	0.1468	-0.142	0.434	0.99	1	0.32	1.157
APR Severity	-0.043	0.0945	-0.229	0.142	0.211	1	0.646	0.957
Direct Cost	-0.004	0.0098	-0.024	0.015	0.207	1	0.649	0.996
Days	**0.173**	**0.0647**	**0.046**	**0.3**	**7.125**	**1**	**0.008**	**1.189**
Age	-0.005	0.0661	-0.134	0.125	0.006	1	0.94	0.995

*Bold = within p≤0.20 trim threshold in bivariate analysis; HF1 always included

Table 15. Final Binary Model: 90 Day All Cause Readmission

Variable	**B**	**Std Error**	**95% Wald Confidence Interval**		**Hypothesis Test**			**Exp(B)**
			Lower	**Upper**	**Wald Chi-Square**	**df**	**Sig.**	
HF1 Not Met	-0.128	0.192	-0.504	0.248	0.447	1	0.504	0.880
Days	0.172	0.065	0.045	0.299	7.076	1	0.008	1.188

Note: Readmission n=343; 33.2%

Table 16. Bivariate Analysis Summary: 90 Day All Cause Readmission Sum

			95% Wald Confidence Interval		Hypothesis Test			
Variable	**B**	**Std Error**	**Lower**	**Upper**	**Wald Chi-Square**	**df**	**Sig.**	**Exp(B)**
HF1 Not Met	**-0.052**	**0.151**	**-0.348**	**0.244**	**0.119**	**1**	**0.73**	**0.949**
Gender=Male	-0.074	0.106	-0.281	0.134	0.487	1	0.485	0.929
Ethnicity=Non-White	-0.104	0.249	-0.592	0.384	0.175	1	0.676	0.901
Marital Status=Single	0.158	0.165	-0.166	0.481	0.916	1	0.339	1.171
Marital Status=Widowed	-0.051	0.149	-0.344	0.241	0.118	1	0.731	0.95
Marital Status=Divorced	-0.117	0.164	-0.438	0.204	0.514	1	0.473	0.889
DC Dept=Not Cardiology	**0.422**	**0.142**	**0.143**	**0.701**	**8.797**	**1**	**0.003**	**1.525**
Anemia=Yes	**0.216**	**0.113**	**-0.005**	**0.436**	**3.686**	**1**	**0.055**	**1.241**
COPD=Yes	**0.23**	**0.112**	**0.01**	**0.449**	**4.217**	**1**	**0.04**	**1.258**
Pneumonia=Yes	-0.108	0.226	-0.551	0.334	0.23	1	0.632	0.897
Diabetes=Yes	**0.218**	**0.105**	**0.012**	**0.424**	**4.282**	**1**	**0.039**	**1.243**
HTN=Yes	0.081	0.122	-0.158	0.321	0.443	1	0.506	1.085
CAD=Yes	0.074	0.109	-0.139	0.286	0.464	1	0.469	1.077
Renal Insufficiency=Yes	-0.104	0.135	-0.369	0.16	0.599	1	0.439	0.901
Nursing Units	0.073	0.115	-0.152	0.299	0.404	1	0.525	1.076
APR Severity	0.006	0.077	-0.144	0.157	0.007	1	0.934	1.006
Direct Cost	-0.005	0.008	-0.021	0.01	0.406	1	0.524	0.995
Days	**0.097**	**0.050**	**-0.001**	**0.195**	**3.756**	**1**	**0.053**	**1.102**
Age	-0.024	0.053	-0.127	0.079	0.203	1	0.652	0.977

*Bold = within $p \leq 0.20$ trim threshold in bivariate analysis; HF1 always included

Note: Mean=0.47; n=483; Negative Binomial MLE Log Link

Table 17. Final Count Model: 90 Day All Cause Readmission Sum

			95% Wald Confidence Interval		**Hypothesis Test**			
Variable	**B**	**Std Error**	**Lower**	**Upper**	**Wald Chi-Square**	**df**	**Sig.**	**Exp(B)**
HF1 Not Met	-0.173	0.156	-0.478	0.132	1.233	1	0.267	0.841
DC Dept Not Cardiology	0.457	0.147	0.169	0.745	9.673	1	0.002	1.579
Diabetes=Yes	0.211	0.105	0.005	0.416	4.048	1	0.044	1.235

Note: Mean 0.47; n=483; range 0-6

Table 18. Bivariate Analysis Summary: 90 Day HF to HF Readmission Binary Analysis

Variable	**B**	**Std Error**	**95% Wald Confidence Interval**		**Hypothesis Test**			**Exp(B)**
			Lower	**Upper**	**Wald Chi-Square**	**df**	**Sig.**	
HF1 Not Met	**-1.002**	**0.4009**	**-1.788**	**-0.216**	**6.246**	**1**	**0.012**	**0.367**
Gender=Male	0.104	0.2052	-0.298	0.506	0.255	1	0.613	1.109
Ethnicity=Non-White	-0.384	0.5304	-1.423	0.656	0.523	1	0.47	0.681
Marital Status=Single	-0.1	0.343	-0.773	0.572	0.085	1	0.77	0.905
Marital Status=Widowed	0	0.2812	-0.551	0.551	0	1	0.999	1
Marital Status=Divorced	-0.005	0.3024	-0.598	0.588	0	1	0.986	0.995
DC Dept=Not Cardiology	-0.161	0.3215	-0.791	0.47	0.249	1	0.617	0.852
Anemia=Yes	0.218	0.2156	-0.204	0.641	1.024	1	0.312	1.244
COPD=Yes	0.191	0.2155	-0.231	0.614	0.789	1	0.374	1.211
Pneumonia=Yes	-0.62	0.5265	-1.652	0.411	1.389	1	0.239	0.538
Diabetes=Yes	0.203	0.2022	-0.193	0.599	1.007	1	0.316	1.225
HTN=Yes	-0.087	0.2267	-0.531	0.358	0.146	1	0.702	0.917
CAD=Yes	**-0.421**	**0.2018**	**-0.817**	**-0.026**	**4.357**	**1**	**0.037**	**0.656**
Renal Insufficiency=Yes	0.182	0.2419	-0.292	0.656	0.568	1	0.451	1.2
Nursing Units	**0.31**	**0.2002**	**-0.083**	**0.702**	**2.393**	**1**	**0.122**	**1.363**
APR Severity	**-0.239**	**0.1424**	**-0.518**	**0.04**	**2.811**	**1**	**0.094**	**0.788**
Direct Cost	**-0.033**	**0.019**	**-0.07**	**0.004**	**3.018**	**1**	**0.082**	**0.968**
Days	0.116	0.0946	-0.069	0.302	1.514	1	0.218	1.123
Age	0.039	0.1011	-0.159	0.238	0.151	1	0.697	1.04

*Bold = within p≤0.20 trim threshold in bivariate analysis

Table 19. Final Binary Model: 90 Day HF to HF Readmissions

Variable	B	Std Error	95% Wald Confidence Interval		Hypothesis Test			Exp(B)
			Lower	Upper	Wald Chi-Square	df	Sig.	
HF1 Not Met	-1.002	0.403	-1.792	-0.212	6.180	1	0.013	0.367
CAD=Yes	-0.453	0.205	-0.856	-0.050	4.856	1	0.028	0.636
Direct Cost	-0.040	0.020	-0.079	0.000	3.801	1	0.051	0.961
Nursing Units	0.444	0.210	0.033	0.854	4.476	1	0.034	1.558

Note: n = 111; 10.7%

Table 20. Bivariate Analysis Summary: 90 Day HF to HF Readmission Sum

			95% Wald Confidence Interval		Hypothesis Test			
Variable	**B**	**Std Error**	**Lower**	**Upper**	**Wald Chi-Square**	**df**	**Sig.**	**Exp(B)**
HF1 Not Met*	**-1.042**	**0.397**	**-1.821**	**-0.264**	**6.890**	**1**	**0.009**	**0.353**
Gender=Male	-0.134	0.190	-0.507	0.239	0.494	1	0.482	0.875
Ethnicity=Non-White	-0.463	0.526	-1.494	0.568	0.774	1	0.379	0.629
Marital Status=Single	-0.176	0.338	-0.838	0.487	0.27	1	0.604	0.839
Marital Status=Widowed	0.115	0.257	-0.389	0.619	0.2	1	0.655	1.122
Marital Status=Divorced	0.092	0.278	-0.453	0.637	0.109	1	0.741	1.096
DC Dept=Not Cardiology	-0.268	0.317	-0.889	0.354	0.713	1	0.398	0.765
Anemia=Yes	0.223	0.202	-0.173	0.618	1.215	1	0.27	1.249
COPD=Yes	0.235	0.201	-0.158	0.628	1.372	1	0.241	1.265
Pneumonia=Yes	**-0.683**	**0.523**	**-1.707**	**0.342**	**1.706**	**1**	**0.192**	**0.505**
Diabetes=Yes	0.218	0.190	-0.154	0.59	1.318	1	0.251	1.244
HTN=Yes	-0.014	0.216	-0.439	0.41	0.004	1	0.947	0.986
CAD=Yes	**-0.368**	**0.189**	**-0.739**	**0.003**	**3.772**	**1**	**0.052**	**0.692**
Renal Insufficiency=Yes	0.07	0.233	-0.386	0.527	0.091	1	0.763	1.073
Nursing Units	0.206	0.196	-0.178	0.589	1.104	1	0.293	1.228
APR Severity	**-0.182**	**0.135**	**-0.448**	**0.083**	**1.818**	**1**	**0.178**	**0.833**
Direct Cost	**-0.035**	**0.019**	**-0.072**	**0.001**	**3.609**	**1**	**0.057**	**0.965**
Days	0.09	0.089	-0.084	0.264	1.03	1	0.31	1.094
Age	0.06	0.095	-0.127	0.246	0.395	1	0.529	1.062

*Bold = within p≤0.20 trim threshold in bivariate analysis

Table 21. Final Count Model: 90 Day HF to HF Readmission Sum

Variable	B	Std Error	95% Wald Confidence Interval		Hypothesis Test			Exp(B)
			Lower	Upper	Wald Chi-Square	df	Sig.	
HF1 Not Met	-1.066	0.397	-1.844	-0.288	7.214	1	0.007	0.344
CAD=Yes	-0.390	0.189	-0.760	-0.021	4.280	1	0.039	0.677

Note: Mean 0.12; n=124; range 0-3

180 Day Readmission and HF1

The 180 day all cause readmission rate was 43.6%; 451 individuals had at least one readmission within the first 6 months after the admission discharge. There were six (6) variables, plus the HF1 variable, that met the $p \leq .20$ threshold: gender, discharge department, COPD, diabetes mellitus, length of stay, days, and number of nursing transfer units. See Table 22. The final model was again constructed after backward stepwise elimination of the remaining variables, dropping gender and nursing transfer units, leaving five (5) significant findings. At six months, the HF1 discharge instruction variable was, for the first time, significantly related to readmission, but in the unexpected direction (p = .026; OR .65). HF1 "not met" was associated with reduced odds of being readmitted to the hospital. Presence of secondary diagnosis pneumonia (p = .038: OR .56) was also associated with reduced likelihood of readmission. Discharge from a non-cardiology specialty unit was again associated with increased likelihood of admission at 6 months (p = .03; OR 1.56), as was the secondary diagnosis of diabetes mellitus (p = .000; OR 1.59). Finally, once again at 180 days, the length of stay of the index admission was associated with increased likelihood of readmission (p = .009; OR 1.19). See Table 23.

Findings of the 180 day readmission count analysis indicated a mean readmission rate of 0.74 with range of 0 – 6 readmissions for a total of 764 all cause readmissions. There were six (6) variables in the bivariate analysis that met the criteria for $p \leq .20$: HF1, ethnicity, discharge department (not cardiology), COPD, diabetes mellitus and length of stay of the index admission (Days). See Table 24. After the backward elimination, the final model included: HF1 (p = .04; OR.75), non-white ethnicity (p = .025; OR .59); non-cardiology discharge nursing unit (p = .002; OR 1.50); COPD (p =

.008; OR 1.29) and diabetes mellitus (p = .000; OR 1.41). See Table 25.

The subset analysis of HF to HF readmission at 180 days included a 14% readmission rate, n =145 HF to HF readmissions. Bivariate analysis at threshold p ≤ .20 included the following seven (7) variables: HF1, pneumonia, diabetes mellitus, renal insufficiency, direct cost of the index admission, days and nursing units. See Table 26. The final model, after backward elimination, included: HF1 (p = .002; OR .31); direct cost (p = .032; OR .96); pneumonia (p = .040; OR .34); and length of stay (Days) (p = .009; OR 1.29). See Table 27. HF1 was again inversely related to 6 month readmission indicating about a 69% less probability of readmission. Direct cost was statistically significantly related to readmission but at an odds ratio close to one, indicating only a modest 4% difference in direct cost. Pneumonia was inversely related to readmission (70%). And length of stay in days of the index admission was again related to readmission with a 29% increased probability of readmission versus no readmission.

In the count analysis of HF to HF readmissions, there were 188 total readmissions, range 0 -5 and mean 0.18. Bivariate analysis of six (6) months sum of readmissions yielded the following none (9) variables eligible for the final model: HF1; non-White ethnicity; anemia; COPD, pneumonia; diabetes mellitus; renal insufficiency; direct cost of the index admission and number of nursing units upon which the subject resided. See Table 28. In the final model for HF to HF readmissions for this interval, the primary independent variable, HF1 (p = .172; OR .831), was not statistically significantly related to readmission. Non-white ethnicity was associated with lower odds of readmission (p = .023; OR .583). Three of the comorbid conditions were associated with

HF to HF readmission: anemia (p = .051; OR 1.21), COPD (p = .003; OR 1.34) and diabetes mellitus (p = .000; OR 1.40). See Table 29.

Table 22. Bivariate Analysis Summary: 180 Day All Cause Readmission Binary Analysis (yes/no)

Variable	B	Std Error	95% Wald Confidence Interval		Hypothesis Test			Exp(B)
			Lower	Upper	Wald Chi-Square	df	Sig.	
HF1 Not Met	**-0.304**	**0.182**	**-0.661**	**0.052**	**2.803**	**1**	**0.094**	**0.738**
Gender=Male	**0.192**	**0.1275**	**-0.058**	**0.442**	**2.271**	**1**	**0.132**	**1.212**
Ethnicity=Non-White	-0.224	0.2922	-0.797	0.348	0.59	1	0.443	0.799
Marital Status=Single	0.403	0.207	-0.003	0.809	3.794	1	0.051	1.497
Marital Status=Widowed	-0.2	0.1785	-0.55	0.15	1.257	1	0.262	0.819
Marital Status=Divorced	-0.213	0.192	-0.589	0.163	1.232	1	0.267	0.808
DC Dept=Not Cardiology	**0.383**	**0.1899**	**0.011**	**0.755**	**4.072**	**1**	**0.044**	**1.467**
Anemia=Yes	0.178	0.1387	-0.094	0.449	1.638	1	0.201	1.194
COPD=Yes	**0.248**	**0.1379**	**-0.022**	**0.519**	**3.244**	**1**	**0.072**	**1.282**
Pneumonia=Yes	-0.342	0.2684	-0.868	0.184	1.623	1	0.203	0.71
Diabetes=Yes	**0.502**	**0.1281**	**0.251**	**0.753**	**15.384**	**1**	**0.000**	**1.652**
HTN=Yes	0.086	0.1443	-0.197	0.369	0.356	1	0.551	1.09
CAD=Yes	0.134	0.1292	-0.12	0.387	1.07	1	0.301	1.143
Renal Insufficiency=Yes	-0.11	0.1581	-0.42	0.2	0.482	1	0.488	0.896
Nursing Units	**0.202**	**0.1421**	**-0.077**	**0.48**	**2.02**	**1**	**0.155**	**1.224**
APR Severity	-0.009	0.0898	-0.185	0.167	0.009	1	0.922	0.991
Direct Cost	-0.005	0.0092	-0.023	0.013	0.249	1	0.618	0.995
Days	**0.195**	**0.0633**	**0.071**	**0.319**	**9.464**	**1**	**0.002**	**1.215**
Age	-0.047	0.0627	-0.17	0.076	0.564	1	0.453	0.954

*Bold = within p≤0.20 trim threshold in bivariate analysis

Table 23. Final Binary Model: 180 Day All Cause Readmission

Variable	B	Std Error	95% Wald Confidence Interval		Hypothesis Test			Exp(B)
			Lower	Upper	Wald Chi-Square	df	Sig.	
HF1 Not Met	-0.430	0.1930	-0.809	-0.052	4.973	1	0.026	0.650
DC Dept Not Cardiology	0.446	0.2053	0.044	0.849	4.728	1	0.030	1.563
Pneumonia=Yes	-0.583	0.2818	-1.136	-0.031	4.287	1	0.038	0.558
Diabetes=Yes	0.465	0.1298	0.210	0.719	12.812	1	0.000	1.592
Days	0.174	0.0666	0.044	0.305	6.843	1	0.009	1.190

Note: readmission Yes=n=451; 43.6%

Table 24. Bivariate Analysis Summary: 180 Day All Cause Readmission Sum

Variable	B	Std Error	95% Wald Confidence Interval		Hypothesis Test			Exp(B)
			Lower	Upper	Wald Chi-Square	df	Sig.	
HF1 Not Met	**-0.178**	**0.137**	**-0.447**	**0.091**	**1.689**	**1**	**0.194**	**0.837**
Gender=Male	-0.054	0.094	-0.238	0.13	0.33	1	0.565	0.948
Ethnicity=Non-White	**-0.368**	**0.236**	**-0.832**	**0.095**	**2.428**	**1**	**0.119**	**0.692**
Marital Status=Single	0.254	0.145	-0.031	0.538	3.049	1	0.081	1.289
Marital Status=Widowed	-0.056	0.133	-0.317	0.204	0.179	1	0.673	0.945
Marital Status=Divorced	0.029	0.140	-0.245	0.303	0.042	1	0.837	1.029
DC Dept=Not Cardiology	**0.381**	**0.130**	**0.127**	**0.636**	**8.643**	**1**	**0.003**	**1.464**
Anemia=Yes	0.207	0.100	0.011	0.403	4.274	1	0.039	1.230
COPD=Yes	**0.289**	**0.099**	**0.095**	**0.482**	**8.561**	**1**	**0.003**	**1.334**
Pneumonia=Yes	-0.26	0.207	-0.665	0.146	1.573	1	0.21	0.771
Diabetes=Yes	**0.317**	**0.093**	**0.135**	**0.498**	**11.698**	**1**	**0.001**	**1.373**
HTN=Yes	0.042	0.107	-0.168	0.252	0.155	1	0.694	1.043
CAD=Yes	0.055	0.096	-0.133	0.242	0.325	1	0.569	1.056
Renal Insufficiency=Yes	-0.012	0.117	-0.241	0.216	0.011	1	0.917	0.988
Nursing Units	0.080	0.100	-0.116	0.277	0.647	1	0.421	1.084
APR Severity	0.01	0.069	-0.125	0.145	0.022	1	0.882	1.01
Direct Cost	-0.009	0.007	-0.022	0.005	1.444	1	0.23	0.992
Days	**0.096**	**0.046**	**0.007**	**0.186**	**4.493**	**1**	**0.034**	**1.101**
Age	-0.023	0.047	-0.114	0.068	0.245	1	0.621	0.977

*Bold = within p≤0.20 trim threshold in bivariate analysis

Mean 0.74; n=764; Range 0-6

Table 25. Final Count Model: 180 Day All Cause Readmission Sum

Variable	B	Std Error	95% Wald Confidence Interval		Hypothesis Test			Exp(B)
			Lower	Upper	Wald Chi-Square	df	Sig.	
HF1 Not Met	-0.288	0.140	-0.563	-0.013	4.221	1	0.040	0.75
Ethnicity=Non-White	-0.529	0.236	-0.992	-0.067	5.027	1	0.025	0.589
DC Dept Not Cardiology	0.407	0.133	0.145	0.668	9.311	1	0.002	1.502
COPD=Yes	0.258	0.098	0.066	0.45	6.937	1	0.008	1.294
Diabetes=Yes	0.341	0.093	0.159	0.522	13.553	1	0.000	1.406

Note: Mean 0.74; n=764; range 0-6

Table 26. Bivariate Analysis Summary: 180 Day HF to HF Readmission Binary Analysis

Variable	B	Std Error	95% Wald Confidence Interval		Hypothesis Test			Exp(B)
			Lower	Upper	Wald Chi-Square	df	Sig.	
HF1 Not Met	**-1.18**	**0.3751**	**-1.915**	**-0.445**	**9.903**	**1**	**0.002**	**0.307**
Gender=Male	0.157	0.1836	-0.203	0.517	0.733	1	0.392	1.17
Ethnicity=Non-White	-0.447	0.4792	-1.386	0.493	0.869	1	0.351	0.64
Marital Status=Single	0.348	0.2737	-0.188	0.885	1.62	1	0.203	1.417
Marital Status=Widowed	0.036	0.2537	-0.461	0.533	0.02	1	0.887	1.037
Marital Status=Divorced	0.02	0.2736	-0.516	0.557	0.006	1	0.941	1.021
DC Dept=Not Cardiology	-0.061	0.2775	-0.605	0.483	0.049	1	0.825	0.941
Anemia=Yes	0.151	0.1945	-0.23	0.532	0.604	1	0.437	1.163
COPD=Yes	0.161	0.1933	-0.218	0.54	0.692	1	0.405	1.175
Pneumonia=Yes	**-0.937**	**0.5244**	**-1.964**	**0.091**	**3.19**	**1**	**0.074**	**0.392**
Diabetes=Yes	**0.33**	**0.1799**	**-0.022**	**0.683**	**3.375**	**1**	**0.066**	**1.392**
HTN=Yes	-0.041	0.2039	-0.441	0.359	0.04	1	0.841	0.96
CAD=Yes	-0.169	0.1819	-0.525	0.188	0.861	1	0.353	0.845
Renal Insufficiency=Yes	**0.342**	**0.2104**	**-0.071**	**0.754**	**2.635**	**1**	**0.105**	**1.407**
Nursing Units	**0.348**	**0.1791**	**-0.003**	**0.699**	**3.778**	**1**	**0.052**	**1.416**
APR Severity	-0.149	0.1274	-0.399	0.101	1.365	1	0.243	0.862
Direct Cost	**-0.029**	**0.0162**	**-0.061**	**0.002**	**3.274**	**1**	**0.07**	**0.971**
Days	**0.135**	**0.0842**	**-0.03**	**0.3**	**2.568**	**1**	**0.109**	**1.145**
Age	0.06	0.095	-0.127	0.246	0.395	1	0.529	1.062

*Bold = within p≤0.20 trim threshold in bivariate analysis

Note: 14%; n=145

Table 27. Final Binary Model: 180 Day HF to HF Readmissions

Variable	B	Std Error	95% Wald Confidence Interval		Hypothesis Test			Exp(B)
			Lower	Upper	Wald Chi-Square	df	Sig.	
HF1 Not Met	-1.159	0.376	-1.897	-0.422	9.490	1	0.002	0.314
Direct Cost	-0.040	0.019	-0.078	-0.003	4.573	1	0.032	0.960
Pneumonia=Yes	-1.090	0.532	-2.133	-0.048	4.204	1	0.040	0.336
Days	0.255	0.098	0.063	0.448	6.785	1	0.009	1.291

Note: Readmission Yes=n=145; 14%

Table 28. Bivariate Analysis Summary: 180 Day HF to HF Readmission Sum

Variable	B	Std Error	95% Wald Confidence Interval		Hypothesis Test			Exp(B)
			Lower	Upper	Wald Chi-Square	df	Sig.	
HF1 Not Met	**-1.340**	**0.384**	**-2.093**	**-0.587**	**12.155**	**1**	**0.000**	**0.262**
Gender=Male	-0.114	0.177	-0.461	0.232	0.418	1	0.518	0.892
Ethnicity=Non-White	**-0.662**	**0.504**	**-1.650**	**0.327**	**1.722**	**1**	**0.189**	**0.516**
Marital Status=Single	0.164	0.284	-0.393	0.721	0.331	1	0.565	1.178
Marital Status=Widowed	0.104	0.246	-0.377	0.586	0.180	1	0.672	1.110
Marital Status=Divorced	0.282	0.251	-0.211	0.774	1.255	1	0.263	1.325
DC Dept=Not Cardiology	-0.220	0.284	-0.775	0.336	0.599	1	0.439	0.803
Anemia=Yes	**0.243**	**0.188**	**-0.126**	**0.611**	**1.665**	**1**	**0.197**	**1.275**
COPD=Yes	**0.313**	**0.186**	**-0.051**	**0.677**	**2.845**	**1**	**0.092**	**1.368**
Pneumonia=Yes	**-1.110**	**0.543**	**-2.174**	**-0.046**	**4.182**	**1**	**0.041**	**0.329**
Diabetes=Yes	**0.380**	**0.175**	**0.036**	**0.723**	**4.697**	**1**	**0.030**	**1.462**
HTN=Yes	-0.028	0.200	-0.420	0.364	0.019	1	0.890	0.973
CAD=Yes	-0.121	0.179	-0.471	0.229	0.459	1	0.498	0.886
Renal Insufficiency=Yes	**0.270**	**0.209**	**-0.139**	**0.679**	**1.678**	**1**	**0.195**	**1.310**
Nursing Units	**0.274**	**0.179**	**-0.077**	**0.626**	**2.344**	**1**	**0.126**	**1.316**
APR Severity	-0.067	0.128	-0.318	0.184	0.276	1	0.600	0.935
Direct Cost	**-0.027**	**0.016**	**-0.057**	**0.004**	**3.001**	**1**	**0.083**	**0.974**
Days	0.088	0.085	-0.079	0.255	1.056	1	0.304	1.092
Age	0.074	0.089	-0.099	0.248	0.708	1	0.400	1.077

*Bold = within p≤0.20 trim threshold in bivariate analysis

Table 29. Final Count Model: 180 Day HF to HF Readmission Sum

Variable	B	Std Error	95% Wald Confidence Interval		Hypothesis Test			Exp(B)
			Lower	Upper	Wald Chi-Square	df	Sig.	
HF1 Not Met	-0.185	0.135	-0.450	0.080	1.865	1	0.172	0.831
Ethnicity=Non-White	-0.539	0.237	-1.003	-0.075	5.177	1	0.023	0.583
Anemia=Yes	0.194	0.099	-0.001	0.389	3.815	1	0.051	1.214
COPD=Yes	0.292	0.098	0.101	0.483	8.974	1	0.003	1.339
Diabetes=Yes	0.335	0.093	0.152	0.517	12.949	1	0.000	1.398

Note: Mean 0.18; n=188; range 0-5

365 Day Readmission and HF1

At the end of one year following the index HF discharge, the all cause readmission rate (yes/no) was 52.2%, and 543 individuals were readmitted for any cause at least once, with a range of readmissions 1 – 11. Eight variables, including the HF1 variable, were significant in bivariate analysis at the threshold of p = .20: HF1, ethnicity, discharge department, anemia, COPD, pneumonia, diabetes mellitus, and length of stay (Days). See Table 30. After backward elimination, the final model contained six (6) of the eight (8) variables: HF1 (p = .02; OR .65), non-white ethnicity (p = .017; OR .49), discharge department (p = .029; OR 1.58), pneumonia (p = .017; OR .52), diabetes mellitus (p = .000; OR 1.65) and length of stay (Days) (p = .001; OR 1.26). See Table 31. The inverse relationship between HF1 and readmission continues in this model, as does the inverse relationship with non-white ethnicity and pneumonia. The non-cardiology discharge department is associated with a 58% increased odds of all cause readmission; diabetes mellitus is associated with a 65% increased odds of readmission within a year; and length of stay of the index admission is also associated with 26% increased odds of readmission.

In the count analysis of all cause readmissions at one year, there were a total of 1126 readmissions, mean of 1.09 and a range of 0 – 11. In bivariate analysis using the cut-off threshold $p \leq .20$, there were nine (9) variables that met the criteria: HF1, discharge department, anemia, COPD, pneumonia, diabetes mellitus, CAD, direct cost and length of stay (Days). See Table 32. Afterward backward elimination, the final model was trimmed to HF1 (p = .002; OR .66); discharge department not cardiology (p = .001; OR 1.52); COPD (p = .013; OR 1.32); pneumonia (p = .013; OR .62) and diabetes mellitus (p = .000; OR 1.40). See Table 33. The primary independent variable, HF1, was again inversely related to readmission at one year; a discharge department other than the cardiology unit increased the odds of readmission by about 50%; presence of pneumonia as a secondary diagnosis reduced the likelihood of readmission; and diabetes mellitus once again was associated with a 40% increased odds of readmission at one year.

The final subset analysis of HF to HF readmissions (yes/no) included 199 individuals (19.2%) readmitted at least once in the year following the index admission. Bivariate analysis trimmed the potential model variables to nine (9): HF1, gender, pneumonia, diabetes mellitus, renal insufficiency, direct cost, days, age and nursing units. See Table 34. The backward elimination resulted in a final model with six (6) variables: HF1 ($p = .000$; OR .26); gender ($p = .047$; OR 1.40); direct cost of the index admission ($p = .005$; OR .95; pneumonia ($p = .011$; OR .30); diabetes mellitus ($p = .030$; OR 1.425) and length of stay (Days) of the index admission ($p = .004$; OR 1.29). See Table 35. The inverse relationship between completion of HF1 and readmission continued in this interval analysis. Direct cost and pneumonia were also inversely related to readmission, although the odds ratio for direct cost was very close to 1.0. Diabetes and length of stay of the index admission were both related to greater odds of readmission at +42.5% and +29%, respectively.

In the total count analysis of HF to HF readmissions at one year, there were 278 HF to HF readmissions, mean .27 and range 0 – 5. In bivariate analysis, seven (7) variables were trimmed at threshold $p \leq .20$: HF1 not met; COPD, pneumonia, diabetes mellitus, renal insufficiency, direct cost and number of nursing units. See Table 36. After backward stepwise elimination, five (5) variables remained, including HF1 ($p = .000$; OR .23), which continued to be inversely related to readmission at one year. Additionally, pneumonia (p = .008; OR .28) and direct cost (p = .006; OR .96) were also inversely related to readmission, although again the OR of direct cost was close to one. Diabetes mellitus (p = .010; OR 1.47) was again related to 50% increased odds of readmission at one year. The number of nursing units (p = .008; OR 1.48), at one year, was also associated with 48% increased odds of readmission. See Table 37.

Table 30. Bivariate Analysis Summary: 365 Day All Cause Readmission Binary Analysis (yes/no)

Variable	B	Std Error	95% Wald Confidence Interval		Hypothesis Test			Exp(B)
			Lower	Upper	Wald Chi-Square	df	Sig.	
HF1 Not Met	**-0.337**	**0.177**	**-0.684**	**0.011**	**3.607**	**1**	**0.058**	**0.714**
Gender=Male	0.134	0.1262	-0.114	0.381	1.211	1	0.29	1.413
Ethnicity=Non-White	**-0.433**	**0.2879**	**-0.997**	**0.132**	**2.257**	**1**	**0.133**	**0.649**
Marital Status=Single	0.304	0.2101	-0.108	0.716	2.092	1	0.148	1.355
Marital Status=Widowed	-0.117	0.1749	-0.459	0.226	0.445	1	0.505	0.89
Marital Status=Divorced	-0.217	0.188	-0.586	0.151	1.338	1	0.247	0.805
DC Dept=Not Cardiology	**0.337**	**0.1934**	**-0.002**	**0.756**	**3.793**	**1**	**0.051**	**1.457**
Anemia=Yes	**0.252**	**0.139**	**-0.02**	**0.524**	**3.287**	**1**	**0.07**	**1.287**
COPD=Yes	**0.237**	**0.1382**	**-0.033**	**0.508**	**2.952**	**1**	**0.086**	**1.268**
Pneumonia=Yes	**-0.375**	**0.2601**	**-0.885**	**0.135**	**2.081**	**1**	**0.149**	**0.687**
Diabetes=Yes	**0.477**	**0.1281**	**0.226**	**0.728**	**13.861**	**1**	**0.000**	**1.611**
HTN=Yes	-0.007	0.1428	-0.287	0.273	0.003	1	0.959	0.993
CAD=Yes	0.074	0.1279	-0.177	0.325	0.336	1	0.562	1.077
Renal Insufficiency=Yes	0.057	0.1564	-0.249	0.364	0.134	1	0.714	1.059
Nursing Units	0.066	0.1421	-0.213	0.344	0.215	1	0.643	1.068
APR Severity	-0.02	0.0892	-0.195	0.154	0.053	1	0.819	0.98
Direct Cost	-0.007	0.0091	-0.025	0.011	0.613	1	0.434	0.993
Days	**0.246**	**0.0653**	**0.118**	**0.374**	**14.165**	**1**	**0.000**	**1.279**
Age	0.05	0.0623	-0.072	0.172	0.646	1	0.421	1.051

*Bold = within p≤0.20 trim threshold in bivariate analysis

Table 31. Final Binary Model: 365 Day All Cause Readmission

Parameter	B	Std Error	95% Wald Confidence Interval		Hypothesis Test			Exp(B)
			Lower	Upper	Wald Chi-Square	df	Sig.	
HF1 Not Met	-0.438	0.1889	-0.808	-0.068	5.378	1	0.020	0.645
Ethnicity=Non-White	-0.720	0.3015	-1.311	-0.129	5.695	1	0.017	0.487
DC Dept Not Cardiology	0.459	0.2104	0.047	0.872	4.767	1	0.029	1.583
Pneumonia=Yes	-0.658	0.2751	-1.197	-0.119	5.722	1	0.017	0.518
Diabetes=Yes	0.501	0.1341	0.238	0.764	13.972	1	0.000	1.651
Days	0.233	0.0688	0.098	0.368	11.459	1	0.001	1.262

Note: 52.2%; readmission Yes=n=543

Table 32. Bivariate Analysis Summary: 365 Day All Cause Readmission Sum

Variable	**B**	**Std Error**	**95% Wald Confidence Interval**		**Hypothesis Test**			**Exp(B)**
			Lower	**Upper**	**Wald Chi-Square**	**df**	**Sig.**	
HF1 Not Met	**-0.28**	**0.128**	**-0.531**	**-0.029**	**4.783**	**1**	**0.029**	**0.756**
Gender=Male	0.068	0.0871	-0.103	0.239	0.609	1	0.435	1.07
Ethnicity=Non-White	0.152	0.203	-0.55	0.246	0.559	1	0.455	0.859
Marital Status=Single	0.215	0.1371	-0.054	0.484	2.463	1	0.117	1.24
Marital Status=Widowed	0.023	0.1207	-0.213	0.26	0.037	1	0.846	1.024
Marital Status=Divorced	0.031	0.1294	-0.223	0.284	0.057	1	0.812	1.031
DC Dept=Not Cardiology	**0.339**	**0.1229**	**0.099**	**0.58**	**7.63**	**1**	**0.006**	**1.404**
Anemia=Yes	**0.173**	**0.0934**	**-0.01**	**0.356**	**3.423**	**1**	**0.064**	**1.189**
COPD=Yes	**0.304**	**0.0915**	**0.125**	**0.484**	**11.052**	**1**	**0.001**	**1.356**
Pneumonia=Yes	**-0.33**	**0.1918**	**-0.706**	**0.046**	**2.958**	**1**	**0.085**	**0.719**
Diabetes=Yes	**0.362**	**0.0854**	**0.195**	**0.529**	**17.949**	**1**	**0.000**	**1.436**
HTN=Yes	0.04	0.0988	-0.154	0.234	0.164	1	0.685	1.041
CAD=Yes	**0.116**	**0.0886**	**-0.058**	**0.29**	**1.712**	**1**	**0.191**	**1.123**
Renal Insufficiency=Yes	0.086	0.1062	-0.122	0.294	0.653	1	0.419	1.09
Nursing Units	0.099	0.092	-0.082	0.279	1.151	1	0.238	1.104
APR Severity	0.013	0.064	-0.113	0.138	0.041	1	0.84	1.013
Direct Cost	**0.009**	**0.0066**	**-0.022**	**0.004**	**1.83**	**1**	**0.176**	**0.991**
Days	**0.104**	**0.0431**	**0.02**	**0.189**	**5.842**	**1**	**0.016**	**1.11**
Age	0.074	0.043	-0.085	0.084	0	1	0.988	0.999

*Bold = within p≤0.20 trim threshold in bivariate analysis

Note: Mean=1.09; n=1126; range 0-11

Table 33. Final Count Model: 365 Day All Cause Readmission Sum

Variable	B	Std Error	95% Wald Confidence Interval		Hypothesis Test			Exp(B)
			Lower	Upper	Wald Chi-Square	df	Sig.	
HF1 Not Met	-0.409	0.131	-0.666	-0.152	9.731	1	0.002	0.664
DC Dept Not Cardiology	0.417	0.128	0.167	0.667	10.673	1	0.001	1.517
COPD=Yes	0.280	0.090	0.102	0.457	9.558	1	0.002	1.323
Pneumonia=Yes	-0.477	0.192	-0.853	-0.101	6.173	1	0.013	0.621
Diabetes=Yes	0.338	0.084	0.173	0.503	16.059	1	0.000	1.402

Note: Mean=1.09; n=1126; range 0-11

Table 34. Bivariate Analysis Summary: 365 Day HF to HF Readmission Binary Analysis

Variable	B	Std Error	95% Wald Confidence Interval		Hypothesis Test			Exp(B)
			Lower	Upper	Wald Chi-Square	df	Sig.	
HF1 Not Met	**-1.337**	**0.338**	**-1.998**	**-0.676**	**15.695**	**1**	**0.000**	**0.263**
Gender=Male	**0.295**	**0.163**	**-0.025**	**0.615**	**3.271**	**1**	**0.071**	**1.343**
Ethnicity=Non-White	-0.001	0.361	-0.709	0.707	0	1	0.998	0.999
Marital Status=Single	**0.33**	**0.244**	**-0.148**	**0.808**	**1.829**	**1**	**0.176**	**1.391**
Marital Status=Widowed	-0.046	0.227	-0.49	0.397	0.042	1	0.838	0.955
Marital Status=Divorced	-0.004	0.241	-0.476	0.467	0	1	0.986	0.996
DC Dept=Not Cardiology	0.143	0.233	-0.313	0.599	0.377	1	0.539	1.154
Anemia=Yes	0.139	0.172	-0.198	0.476	0.651	1	0.42	1.149
COPD=Yes	0.109	0.172	-0.228	0.446	0.403	1	0.525	1.115
Pneumonia=Yes	**-1.082**	**0.473**	**-2.008**	**-0.155**	**5.239**	**1**	**0.022**	**0.339**
Diabetes=Yes	**0.41**	**0.159**	**0.1**	**0.721**	**6.694**	**1**	**0.01**	**1.507**
HTN=Yes	-0.071	0.179	-0.442	0.28	0.157	1	0.692	0.931
CAD=Yes	0.047	0.163	-0.272	0.366	0.084	1	0.772	1.048
Renal Insufficiency=Yes	**0.245**	**0.190**	**-0.127**	**0.618**	**1.672**	**1**	**0.196**	**1.278**
Nursing Units	**0.314**	**0.163**	**-0.006**	**0.634**	**3.704**	**1**	**0.054**	**1.369**
APR Severity	-0.079	0.113	-0.3	0.141	0.495	1	0.482	0.924
Direct Cost	**-0.033**	**0.014**	**-0.062**	**-0.005**	**5.396**	**1**	**0.02**	**0.967**
Days	**0.136**	**0.075**	**-0.011**	**0.283**	**3.287**	**1**	**0.07**	**1.146**
Age	**0.116**	**0.080**	**-0.041**	**0.273**	**2.092**	**1**	**0.148**	**1.123**

*Bold = within p≤0.20 trim threshold in bivariate analysis

Note: 19.2%; n=199

Table 35. Final Binary Model: 365 Day HF to HF Readmissions

			95% Wald Confidence Interval		Hypothesis Test			
Parameter	**B**	**Std Error**	**Lower**	**Upper**	**Wald Chi-Square**	**df**	**Sig.**	**Exp(B)**
HF1 Not Met	-1.343	0.340	-2.009	-0.677	15.626	1	0.000	0.261
Direct Cost	-0.048	0.017	-0.082	-0.015	8.036	1	0.005	0.953
Pneumonia=Yes	-1.217	0.481	-2.159	-0.274	6.396	1	0.011	0.296
Days	0.255	0.089	0.080	0.430	8.181	1	0.004	1.291
Diabetes=Yes	0.354	0.163	0.034	0.675	4.704	1	0.030	1.425
Gender=Male	0.334	0.168	0.004	0.663	3.944	1	0.047	1.396

Note: 19.2%; readmission Yes=n=199

Table 36. Bivariate Analysis Summary: 365 Day HF to HF Readmission Sum

			95% Wald Confidence Interval		**Hypothesis Test**			
Variable	**B**	**Std Error**	**Lower**	**Upper**	**Wald Chi-Square**	**df**	**Sig.**	**Exp(B)**
HF1 Not Met	**1.515**	**0.344**	**-2.189**	**-0.840**	**19.355**	**1**	**0.000**	**0.220**
Gender=Male	0.051	0.153	-0.250	0.351	0.109	1	0.741	1.052
Ethnicity=Non-White	0.076	0.353	-0.768	0.615	0.047	1	0.828	0.926
Marital Status=Single	0.170	0.244	-0.308	0.648	0.486	1	0.486	1.185
Marital Status=Widowed	0.183	0.207	-0.223	0.589	0.783	1	0.376	1.201
Marital Status=Divorced	0.137	0.224	-0.302	0.577	0.375	1	0.540	1.147
DC Dept=Not Cardiology	0.074	0.234	-0.532	0.385	0.099	1	0.753	0.929
Anemia=Yes	0.175	0.164	-0.146	0.495	1.142	1	0.285	1.191
COPD=Yes	**0.312**	**0.160**	**-0.002**	**0.626**	**3.796**	**1**	**0.051**	**1.366**
Pneumonia=Yes	**1.282**	**0.488**	**-2.238**	**-0.325**	**6.900**	**1**	**0.009**	**0.278**
Diabetes=Yes	**0.409**	**0.151**	**0.114**	**0.704**	**7.367**	**1**	**0.007**	**1.505**
HTN=Yes	0.129	0.170	-0.461	0.204	0.577	1	0.448	0.879
CAD=Yes	0.081	0.156	-0.225	0.386	0.269	1	0.604	1.084
Renal Insufficiency=Yes	**0.289**	**0.179**	**-0.063**	**0.641**	**2.594**	**1**	**0.107**	**1.335**
Nursing Units	**0.299**	**0.147**	**0.012**	**0.587**	**4.161**	**1**	**0.041**	**1.349**
APR Severity	0.080	0.110	-0.296	0.136	0.529	1	0.467	0.923
Direct Cost	**0.035**	**0.014**	**-0.063**	**-0.008**	**6.403**	**1**	**0.011**	**0.965**
Days	0.079	0.075	-0.069	0.227	1.088	1	0.297	1.082
Age	0.085	0.076	-0.064	0.235	1.251	1	0.263	1.089

*Bold = within p≤0.20 trim threshold in bivariate analysis

Note: Mean=0.27; n=279; Range 0-5

Table 37. Final Count Model: 365 Day HF to HF Readmission Sum

Variable	B	Std Error	95% Wald Confidence Interval		Hypothesis Test			Exp(B)
			Lower	Upper	Wald Chi-Square	df	Sig.	
HF1 Not Met	-1.488	0.343	-2.160	-0.816	18.843	1	0.000	0.226
Pneumonia=Yes	-1.287	0.486	-2.239	-0.334	7.011	1	0.008	0.276
Diabetes=Yes	0.384	0.148	0.094	0.675	6.716	1	0.010	1.469
Direct Cost	-0.040	0.014	-0.069	0.012	7.705	1	0.006	0.961
Nursing Units	0.393	0.149	0.101	0.685	6.952	1	0.008	1.481

Note: Mean=0.269; n=278; range 0-5

All Cause Charges Per Year and HF1

There were 543 individuals (52.5%) who were readmitted and 491 (47.5%) not readmitted within a year of the index discharge. The range for readmissions was 1 – 11. Of those readmitted, 12.5% did not meet HF1 bundle completion, versus 14.5% for the sample and 16.7% for those not readmitted.

Mean length of stay was 4.13 (SD 2.77) days; 4.15 (SD 2.71) for HF met and 4.01 (SD 3.10) for HF1 not met. The range of charges for an individual readmission was $1509 – 123,315, mean $21,271(SD 20264.80). The sum of all readmission charges for the year following the index admission was ~$11,600,000.00.

Bivariate analysis of the response variable and each independent variable were again run for this outcome. However, in this GLM analysis, normal distribution was used with log link and the response variable was transformed to log base 10. There were seven (7) variables that met the threshold of $p \leq .20$ and were retained: gender, widowed marital status, anemia, COPD, diabetes mellitus, APR severity of illness and age. HF1 as the primary independent variable of interest was also retained. See Table 38. Backward elimination was conducted and the final model contained HF1 ($p = .982$; OR .999) which was not significant; male gender ($p = .023$; OR 1.10) which was associated with charges at a 10% higher level; marital status (widow) ($p = .008$; OR .85) which was associated with odds of less charges; anemia ($p = .007$; OR 1.12) which was significantly associated with charges; and age ($p = .003$; OR .94) where slightly younger age was associated with greater charges. See Table 39.

Table 38. Bivariate Analysis Summary: All Cause Readmissions Charges

Parameter	B	Std Error	95% Wald Confidence Interval		Hypothesis Test			Exp(B)
			Lower	Upper	Wald Chi-Square	df	Sig.	
HF1 Not Met	**0.004**	**0.0595**	**-0.112**	**0.121**	**0.005**	**1**	**0.943**	**1.004**
Gender=Male	**0.127**	**0.0397**	**0.049**	**0.204**	**10.142**	**1**	**0.001**	**1.135**
Ethnicity=Non-White	0.071	0.0978	-0.121	0.262	0.523	1	0.469	1.073
Marital Status=Single	0.001	0.06	-0.117	0.118	0.000	1	0.991	1.001
Marital Status=Widowed	**-0.242**	**0.0553**	**-0.351**	**-0.134**	**19.143**	**1**	**0.000**	**0.785**
Marital Status=Divorced	0.035	0.0607	-0.084	0.154	0.337	1	0.562	1.036
DC Dept=Not Cardiology	0.048	0.0561	-0.062	0.158	0.743	1	0.389	1.05
Anemia=Yes	**0.087**	**0.0425**	**0.004**	**0.170**	**4.172**	**1**	**0.041**	**1.091**
COPD=Yes	**0.064**	**0.0424**	**-0.019**	**0.147**	**2.287**	**1**	**0.13**	**1.066**
Pneumonia=Yes	-0.084	0.089	-0.259	0.09	0.899	1	0.343	0.919
Diabetes=Yes	**0.062**	**0.0394**	**-0.015**	**0.139**	**2.48**	**1**	**0.115**	**1.064**
HTN=Yes	0.011	0.0451	-0.077	0.1	0.062	1	0.803	1.011
CAD=Yes	0.037	0.0405	-0.043	0.116	0.814	1	0.367	1.037
Renal Insufficiency=Yes	-0.003	0.049	-0.099	0.093	0.003	1	0.958	0.997
Nursing Units	0.017	0.0435	-0.069	0.102	0.146	1	0.703	1.017
APR Severity	**0.089**	**0.0299**	**0.03**	**0.147**	**8.783**	**1**	**0.003**	**1.093**
Direct Cost	-0.002	0.003	-0.008	0.004	0.614	1	0.433	0.998
Days	0.01	0.0188	-0.027	0.046	0.267	1	0.605	1.01
Age	**-0.069**	**0.0198**	**-0.108**	**-0.031**	**12.3**	**1**	**0.000**	**0.933**

*Bold = within p≤0.20 trim threshold in bivariate analysis; HF1 always included

Note: Mean 2.07; n=543 Individuals; 1126 Readmissions; GLM Normal Distribution Identity Link

Table 39. Final Model: All Cause Readmission Charges Sum

Variable	B	Std Error	95% Wald Confidence Interval		Hypothesis Test			Exp(B)
			Lower	Upper	Wald Chi-Square	df	Sig.	
HF1 Not Met	-0.001	0.0576	-0.114	0.112	0.000	1	0.982	0.999
Gender=Male	0.097	0.0428	0.013	0.181	5.132	1	0.023	1.102
Marital Status=Widowed	-0.159	0.0598	-0.276	-0.042	7.088	1	0.008	0.853
Anemia=Yes	0.112	0.0417	0.030	0.193	7.181	1	0.007	1.118
Age	-0.062	0.0207	-0.102	-0.021	8.858	1	0.003	0.94

Note: n=1126; Normal Distribution Identity Link

All Cause Readmission Days

Similarly, the variable total readmission days was examined for its relationship to HF1 bundle completion. For the 1126 readmissions (543 individuals), there were 5916 hospital days, ranging from 1 to 118 days for the year following the index admission. Mean readmission days per individual were 10.9 (SD 12.67), median 6.0. Bivariate analysis using GLM and distribution negative binomial MLE with log link at the $p \leq .20$ threshold resulted in the following variables remaining for final model analysis: discharge department (not cardiology); anemia, COPD, pneumonia, diabetes mellitus, severity of illness and length of stay of the index admission (Days). See Table 40. After backward elimination, six (6) variables remaining in the final model included: HF1 not met ($p = .085$; OR .723) which was not statistically related to total days per year; discharge department other than cardiology ($p = .021$; OR 1.60); COPD ($p = .031$; OR 1.35); pneumonia ($p = .002$; OR .43); diabetes mellitus ($p = .017$; OR 1.36); and length of stay of the index admission ($p = .009$; OR 1.197). See Table 41. Discharge department other than the cardiology nursing unit was associated with increased odds of more total days per year. COPD and diabetes mellitus were also both associated with about 35% increased odds of more total days, and pneumonia was associated with fewer days per year. Finally, length of stay of the index admission was also associated with total days per year.

Table 40. Bivariate Analysis Summary: All Cause Readmission Days

Variable	B	Std Error	95% Wald Confidence Interval		Hypothesis Test			Exp(B)
			Lower	Upper	Wald Chi-Square	df	Sig.	
HF1 Not Met	**-0.217**	**0.183**	**-0.576**	**0.141**	**1.411**	**1**	**0.235**	**0.805**
Gender=Male	0.063	0.130	-0.192	0.319	0.236	1	0.627	1.065
Ethnicity=Non-White	-0.171	0.295	-0.749	0.408	0.334	1	0.564	0.843
Marital Status=Single	0.301	0.212	-0.115	0.716	2.014	1	0.156	1.351
Marital Status=Widowed	-0.005	0.181	-0.349	0.359	0.001	1	0.978	1.005
Marital Status=Divorced	0.07	0.195	-0.31	0.45	0.13	1	0.719	1.072
DC Dept=Not Cardiology	**0.513**	**0.195**	**0.134**	**0.893**	**7.021**	**1**	**0.008**	**1.67**
Anemia=Yes	**0.292**	**0.142**	**0.014**	**0.57**	**4.228**	**1**	**0.04**	**1.339**
COPD=Yes	**0.391**	**0.141**	**0.115**	**0.667**	**7.726**	**1**	**0.005**	**1.479**
Pneumonia=Yes	**-0.589**	**0.270**	**-1.118**	**-0.06**	**4.764**	**1**	**0.029**	**0.555**
Diabetes=Yes	**0.384**	**0.13**	**0.129**	**0.639**	**8.726**	**1**	**0.003**	**1.468**
HTN=Yes	0.002	0.148	-0.287	0.291	0	1	0.989	1.002
CAD=Yes	0.065	0.132	-0.194	0.324	0.245	1	0.621	1.068
Renal Insufficiency=Yes	0.131	0.161	-0.184	0.447	0.666	1	0.414	1.14
Nursing Units	0.093	0.141	-0.182	0.368	0.439	1	0.508	1.098
APR Severity	**0.177**	**0.098**	**-0.016**	**0.37**	**3.229**	**1**	**0.072**	**1.193**
Direct Cost	-0.009	0.010	-0.03	0.011	0.837	1	0.36	0.991
Days	**0.214**	**0.068**	**0.081**	**0.347**	**9.9**	**1**	**0.002**	**1.239**
Age	-0.047	0.063	-0.171	0.078	0.544	1	0.461	0.954

*Bold = within p≤0.20 trim threshold in bivariate analysis; HF1 always included

Note: Mean 2.07; n=543 Individuals; 1126 Readmissions; GLM Normal Distribution Identity Link

Table 41. Final Model: All Cause Total Readmission Days

Parameter	B	Std Error	95% Wald Confidence Interval		Hypothesis Test			Exp(B)
			Lower	Upper	Wald Chi-Square	df	Sig.	
HF1 Not Met	-0.324	0.188	-0.692	0.045	2.967	1	0.085	0.723
DC Dept Not Cardiology	0.468	0.203	0.071	0.865	5.332	1	0.021	1.597
COPD=Yes	0.302	0.140	0.028	0.577	4.653	1	0.031	1.353
Pneumonia=Yes	-0.85	0.272	-1.383	-0.318	9.8	1	0.002	0.427
Diabetes=Yes	0.307	0.129	0.055	0.559	5.689	1	0.017	1.359
Days	0.18	0.069	0.045	0.315	6.855	1	0.009	1.197

Note: n=543 Individuals; 1126 Readmissions

CHAPTER V

DISCUSSION

This chapter contains a summary of findings, discussion and limitations of the study. Implications of the results for practice, education and research are discussed.

Summary of Findings and Discussion

Introduction

The purpose of this study was to describe the relationship between the completion of heart failure discharge instructions as defined by the Joint Commission core measure HF1 and the primary endpoint of subsequent readmission to the hospital at 30, 90, 180 and 365 days following an index discharge for primary diagnosis of heart failure. Secondary endpoints were to describe the relationship of HF1 to hospital charges and total hospital days per year. Patient characteristics, clinical characteristics and unit factors were controlled. The study also described the relationship between nursing unit factors and completion of HF1.

Specific aims of the study were to:

1) Describe the relationship between completion of HF1 and hospital readmissions at 30, 90, 180 and 365 days post-discharge, hospital readmission charges at 12 months, and total number of readmission hospital days at 12 months while controlling for patient, clinical, and hospital unit characteristics.
2) Describe the relationship between unit contextual factors including a) discharge unit type, i.e. medical cardiology versus general unit and b) number of inter-unit transfers and all-or-none completion of HF1 at the index hospitalization.

The study was intended as a preliminary step in a program of research to contribute to the base of knowledge related to patient self care of heart failure. It was intended to examine an aspect of effectiveness of nursing and interdisciplinary interventions for older adults hospitalized with heart failure, presumably reflected by completion of the HF1 discharge instruction bundle at an index admission. Findings of this study may help establish a baseline of outcomes related to HF1, as currently deployed, that may contribute to future research. There is a gap in understanding the needs of patients with heart failure transitioning from hospital to home, including optimal discharge interventions and patient instructions. Future research using theory-based approaches to heart failure discharge instructions and transitional care, beginning in the hospital setting, may be informed by these results.

Findings Related to HF1

The next portion of this chapter will discuss the findings related to each research question, beginning with the relationship of HF1 to readmissions. Studies have reported on varying intervals for readmission, but the preponderance of interest, study and controversy recently has been on 30 day readmission. This focused scrutiny is due not only to data demonstrating a rise in HF readmission rates (Jancin 2008; Bueno, Ross et al. 2010), but to recent public health policy changes that will financially penalize hospitals with high readmission rates which may be seen as indicators of poor quality and failure to coordinate care (Ross, Chen et al. 2010; Joynt and Jha 2011). Unadjusted 30-day all-cause readmission rates were 22.9% in 2006 (Ross, Chen et al. 2010).

The Centers for Medicare and Medicaid Services (CMS) is now publicly reporting hospital risk-standardized readmission rates for HF (Bernheim, Grady et al. 2010). In addition, public reporting is available on performance measures (Maeda 2010) such as core measure HF1, and CMS financial reimbursement will soon be based on performance measure completion, or “pay for performance” (Lindenauer, Remus et al.

2007). Yet, controversy remains regarding these performance measures as valid indicators of quality of care and as links to reimbursement (Patterson, Hernandez et al. 2010). Therefore, this study contributes to the knowledge base of indicator HF1 and its relationship to the outcomes of readmission, hospital charges and total hospital days.

The primary independent variable, HF1, heart failure discharge instructions [not met], approached a statistically significant relationship with 30 day all cause readmission in bivariate analysis (p = .08; OR 1.45), and in the final binary multivariate model (p = .22; OR 1.32). In the counts analysis, HF1 is significant in bivariate analysis (p = .041; OR 1.44) but not in the final counts model controlling for patient, clinical, contextual and administrative independent variables (p = .13; OR 1.32). Although not meeting the alpha level set at p = .05, the odds for readmission when HF1 was "not met" were 1.32 in both final models. In both multivariate models, diabetes (p = .016; OR 1.44), discharge department (p =.025; 1.68) and non-White ethnicity (p = .02; OR 0.32) are significant in all cause models.

In the HF to HF 30 day subset analysis, there is no relationship between HF1 and readmission in bivariate or final multivariate models in either the binary or counts response analyses. In the multivariate analyses, length of stay of the index admission is the only variable significantly associated with readmission in both final models of the HF to HF subset (p = .009; OR 1.36; p = .007; OR 1.34).

At 90 days, no relationship exists between HF1 and all cause readmission in bivariate or final multivariate models of binary and counts analyses. However, there is a statistically significant relationship between HF1 and HF to HF readmissions. HF1 is significant in bivariate HF to HF binary analysis (p = .012; OR .37) and bivariate HF to

HF counts analysis (p = .009: OR .35). In the final multivariate models for binary and counts, it is again related (p = .013; OR .37; and p = .007; OR .34, respectively). Of particular interest is the direction of the relationship. There is an inverse relationship between HF1 completion and HF to HF readmissions, i.e., when the HF1 bundle is “not met”, there is a significantly lower odds of readmission.

At 90 days, length of stay of the index admission (p = .008; OR 1.18) is the sole significant variable in binary analysis; discharge department (p = .002; OR 1.58 and diabetes (p = .044; OR 1.24) are again significantly associated with increased odds of all cause readmissions in the counts analysis. Coronary artery disease (CAD) is associated with reduced odds of readmission in the HF to HF subset, while the number of nursing unit transfers is significantly associated with increased odds of readmission within 3 months of the index discharge. This finding is compatible with a clinical scenario including an admission for a chest pain trigger, treatment in the intensive care unit (ICU) with intravenous nitroglycerin, followed by transfer out to the cardiology unit. It is plausible that the CAD trigger may have been resolved, or the seriousness of the condition resulted in death, either way reducing readmissions. Other severe decompensation related to HF may have resulted in intensive care unit stays preceded or followed by transfer to a medical unit. Further drill down within the data would be necessary to discern the actual patterns related to unit transfers. Understanding precipitants of ICU stays related to HF may be helpful in preventing severe decompensation and reducing costs in the future.

Interestingly, at 6 months, neither of the HF1 bivariate analyses (i.e., all cause or HF to HF) is significant at p = .05, but an incomplete HF1 bundle is significantly related to all cause readmission in both of the final binary (readmission yes/no) multivariate models (p =.026; OR .65; and p = .040; OR .75, respectively) when controlling for covariates. Again, the direction of the relationship is inverse, i.e., the incomplete HF1 bundle is associated with reduced odds of all cause readmission. In the final binary model, diabetes (p = .000; OR 1.59), discharge department (p = .03; 1.56) and length of stay of the index admission (p = .009; OR 1.19) are again significantly associated with increased odds of readmission, while pneumonia is again associated with reduced odds of readmission (p = .038; .56). The counts model repeats the significant association of diabetes and discharge department to increased odds of readmission, adding COPD (p = .008; OR 1.29) and the negative association of ethnicity (p =.025; .59). Patients discharged from other than a cardiology unit are more likely to have incomplete HF1 bundle instructions in this study, perhaps related to differences in staff awareness and education and perhaps aspects of the care delivery between a specialty and non-specialty unit. Diabetes and COPD may again be associated with multi-system complications related to other end organs and return to the hospital for respiratory or fluid balance issues.

Similarly, in HF to HF readmission at 6 months, bivariate and final multivariate models indicate HF1 is significantly related to readmission in the inverse direction, except in the final model of the counts analysis, where results approach, but do not achieve significance. The two final models for HF to HF are starkly different, however, in remaining variables. Variables in the binary (yes/no) model include: HF1 (p = .002; OR .31), direct cost (p =.032; OR .96), pneumonia (p =.040; OR .34) and length of stay of the index admission (Days) (p = .009; OR 1.29). Direct cost is positively correlated with length of stay in this study, as expected, but at a low to moderate magnitude (Pearson correlation .211, p = .01). Length of stay in the hospital may be affected by multidimensional factors such as delayed response to treatment, multisystem complications, psychosocial discharge issues, intensity of treatment and physician practice patterns. Pneumonia, when significant as a secondary infectious disease diagnosis, is always inversely related to readmission. Further study may suggest whether these reduced odds of readmission are related to death, cure or interaction of diagnoses. Length of stay (LOS) at the index admission, on the other hand, is always positively related to readmission within the HF to HF subset, consistent with other studies (Krumholz, Parent et al. 1997; Tsuchihashi, Tsutsui et al. 2001)

In contrast to the 6 month binary multivariate model, three of five variables in the final *counts* model for HF to HF readmissions are co-morbid conditions: anemia (p =.05: OR 1.21), COPD (p =.003: OR 1.34) and diabetes (p =.000; OR 1.40), all of which were associated with increased odds of readmission of ~20 – 40%. These co-morbid conditions may complicate and exacerbate HF symptoms, such as fatigue and respiratory distress, leading to readmission for HF. HF1 is not significant when controlling for these co-morbid conditions. Non-white ethnicity (p = .023; OR .58) once again reduces the odds of readmission and would also be of interest in future studies. Non-white ethnicity tends to associate inversely with readmission, particularly in African Americans (Roger, Go et al. 2011), who are under-represented in this study.

Finally, at one year after the index admission for HF, HF1 continues to trend toward, or is statistically significantly related to readmission, but in the inverse direction for all multivariate analyses. HF to HF subset analyses demonstrate the greatest magnitude of the inverse relationship. See Tables 45-47.

In all cause binary analysis at one year following the index discharge, discharge department (p =.029; OR 1.58), diabetes (p = .000; OR 1.65) and length of stay of the index admission continue to be positively related to increased odds of readmission. Non-white ethnicity (p = .017; OR .487) and pneumonia (p = .017; OR .518) continue to be associated with reduced odds of readmission. In counts analysis, length of stay and ethnicity drop out of the model, and COPD (p = .002; OR 1.32) enters.

In HF to HF binary analysis at one year, HF1, pneumonia and direct cost are associated with reduced odds for readmission (p = .000; OR .26, p = .011; OR .30, p = .005; OR .95, respectively). Length of stay on the index visit (p = .004; 1.29), secondary diagnosis of diabetes (p = .030; OR 1.43) and male gender (p =.047; OR 1.40) are all associated with increased odds of readmission. In the counts HF to HF analysis, variables that reduced odds of readmission are the same as binary analysis, with similar magnitude. Diabetes is similarly associated with increased odds of readmission as in previous intervals. Nursing transfer units reoccur (see 90 Day HF to HF Table 19) in this final model with strong association with readmission at one year (p = .008; OR 1.48).

Overall, the effects of HF1 trend from a modest and non-significant association with readmission at 30 days to an opposite and significant inverse association at one year. The magnitude of the inverse relationship is greatest for HF to HF at one year. The HF1 results are summarized in the following tables which display bivariate association of HF1 and all cause readmissions at each interval (30, 90, 180 and 365 days) followed by summary tables of HF1 with binary and, then, counts results. A second set of tables similarly display bivariate and then multivariate results of HF1 and the subset of HF to HF readmissions. These summary tables directly demonstrate the association of the primary independent variable, HF1, and readmission:

- 30 days:
    - All cause - results approach a positive, but non-statistically significant association
    - HF to HF - there is no statistical relationship
- 90 days:
    - All cause - there is no statistical relationship
    - HF to HF - there is an inverse relationship (OR ~ 0.36)
- 180 days:
    - All cause and HF to HF - there is an inverse relationship; OR~0.85 and OR~0.32 (binary only), respectively.
- 365 days:
    - All cause and HF to HF - there is an inverse relationship; OR~0.65 and OR~0.24, respectively.

Table 42. Summary of HF1 [Not Met] All Cause Readmission ~ Bivariate Analyses Across Intervals

			95% Wald Confidence Interval		Hypothesis Test			
Interval	**B**	**Std Error**	**Lower**	**Upper**	**Wald Chi-Square**	**df**	**Sig.**	**Exp(B)**
30 Day Binary	0.374	0.2125	-0.042	0.791	3.103	1	0.078	1.454
30 Day Count	0.364	0.178	0.014	0.714	4.161	1	0.041	1.439
90 Day Binary	-0.134	0.1909	-0.509	0.24	0.496	1	0.481	0.874
90 Day Count	-0.052	0.151	-0.348	0.244	0.119	1	0.73	0.949
180 Day Binary	-0.304	0.182	-0.661	0.052	2.803	1	0.094	0.738
180 Day Count	-0.178	0.137	-0.447	0.091	1.689	1	0.194	0.837
365 Day Binary	-0.337	0.177	-0.684	0.011	3.607	1	0.058	0.714
365 Day Count	-0.28	0.128	-0.531	-0.029	4.783	1	0.029	0.756

Table 43. Summary of HF1 [Not Met] All Cause Readmission ~ Binary Multivariate Analyses Across Intervals

Interval	B	Std Error	95% Wald Confidence Interval		Hypothesis Test			Exp(B)
			Lower	Upper	Wald Chi-Square	df	Sig.	
30 Day n=188	0.276	0.2234	-0.162	0.714	1.529	1	0.216	1.318
90 Day n=343	-0.128	0.192	-0.504	0.248	0.447	1	0.504	0.880
180 Day n=451	-0.430	0.1930	-0.809	-0.052	4.973	1	0.026	0.650
365 Day n=543	-0.438	0.1889	-0.808	-0.068	5.378	1	0.020	0.645

Table 44. Summary of HF1 [Not Met] All Cause Readmissions ~ Counts Multivariate Analyses Across Intervals

Interval	B	Std Error	95% Wald Confidence Interval		Hypothesis Test			Exp(B)
			Lower	Upper	Wald Chi-Square	df	Sig.	
30 Day n=214	0.278	0.184	-0.083	0.639	2.281	1	0.131	1.320
90 Day n=483	-0.173	0.156	-0.478	0.132	1.233	1	0.267	0.841
180 Day n=764	-0.288	0.140	-0.563	-0.013	4.221	1	0.040	0.75
365 Day n=1126	-0.409	0.131	-0.666	-0.152	9.731	1	0.002	0.664

Table 45. Summary of HF1 [Not Met] HF to HF Readmissions ~ Bivariate Analyses Across Intervals

Interval	B	Std Error	95% Wald Confidence Interval		Hypothesis Test			Exp(B)
			Lower	Upper	Wald Chi-Square	df	Sig.	
30 Day Binary	-0.342	0.442	-1.208	0.524	0.601	1	0.438	0.710
30 Day Count	-0.366	0.434	-1.217	0.484	0.712	1	0.399	0.693
90 Day Binary	-1.002	0.4009	-1.788	-0.216	6.246	1	0.012	0.367
90 Day Count	-1.042	0.397	-1.821	-0.264	6.890	1	0.009	0.353
180 Day Binary	-1.18	0.3751	-1.915	-0.445	9.903	1	0.002	0.307
180 Day Count	-1.340	0.384	-2.093	-0.587	12.155	1	0.000	0.262
365 Day Binary	-1.337	0.338	-1.998	-0.676	15.695	1	0.000	0.263
365 Day Count	1.515	0.344	-2.189	-0.840	19.355	1	0.000	0.220

Table 46. Summary of HF1 [Not Met] HF to HF Readmission ~ Binary Multivariate Analyses Across Intervals

			95% Wald Confidence Interval		Hypothesis Test			
Interval	**B**	**Std Error**	**Lower**	**Upper**	**Wald Chi-Square**	**df**	**Sig.**	**Exp(B)**
30 Day n=55	-0.344	0.444	-1.213	0.525	0.601	1	0.438	0.709
90 Day n=111	-1.002	0.403	-1.792	-0.212	6.180	1	0.013	0.367
180 Day n=145	-1.159	0.376	-1.897	-0.422	9.490	1	0.002	0.314
365 Day n=199	-1.343	0.340	-2.009	-0.677	15.626	1	0.000	0.261

Table 47. Summary of HF1 [Not Met] HF to HF Readmissions ~ Counts Multivariate Analyses Across Intervals

			95% Wald Confidence Interval		Hypothesis Test			
Interval	**B**	**Std Error**	**Lower**	**Upper**	**Wald Chi-Square**	**df**	**Sig.**	**Exp(B)**
30 Day n=57	-0.366	0.432	-1.213	0.481	0.718	1	0.397	0.693
90 Day n=124	-1.066	0.397	-1.844	-0.288	7.214	1	0.007	0.344
180 Day n=188	-0.185	0.135	-0.450	0.080	1.865	1	0.172	0.831
365 Day n=279	-1.488	0.343	-2.160	-0.816	18.843	1	0.000	0.226

Discussion Related to HF1

This exploratory study is guided by two similar conceptual frameworks: an effectiveness model developed by Titler, Dochterman and Reed (2004) that links patient characteristics, patient conditions and processes of care to outcomes (Titler, Dochterman et al. 2004); and a conceptual model by Kane (1997). The overall goal is to isolate the relationship between the outcomes of interest (e.g. readmission) and the treatment (or processes of care) provided (HF1), while controlling for the effects of other relevant variables, or adjusting for risk (Donabedian 1988; Kane 1997; Titler, Dochterman et al. 2004). Under this type of structure, process, outcome framework for quality of healthcare assessment, performance measures should be linked to specific outcomes to infer that processes of care impact outcomes and improve persons' health (Donabedian 1988; Maeda 2010). Yet the end results of inpatient care are difficult to determine because of the many antecedents that influence outcomes. Process outcomes, such as compliance with core measures like HF1, have become surrogates for quality outcomes because they are observable and measureable, assumed to improve patients' health, and have been endorsed by the American College of Cardiology and the American Heart Association (Maeda 2010).

Efficacy studies support the supposition of improved outcomes (Bonow, Bennett et al. 2005), but effectiveness in 'real world' practice remains less clear. The real world includes more heterogeneous populations, patients with multiple and variable co-morbid conditions, as well as complex psychological and socioeconomic circumstances that are difficult to measure, let alone include in prediction models. The relationship between conformance with HF performance measures and patient outcomes is not clear and implementation of standardized processes of care varies widely (Fonarow, Abraham et al. 2007). Patterson and colleagues (2010) recently demonstrated this wide variation in hospital conformity to HF core measures. They also found that CMS process measures were not independently associated with patient outcomes within one year of discharge. Conclusions from that study questioned whether current CMS metrics are able to accurately differentiate hospital quality of care for heart failure patients (Patterson, Hernandez et al. 2010).

In a systematic review of heart failure performance measures, Maeda (2011) identified 352 studies in the literature, but only 11 original articles and one literature review met inclusion criteria. Most studies were observational and did not include a control group. Of these 11 studies there were 6 different research designs. Overall, mortality and readmission benefit were reported for ACEI/ARB at discharge, and beta blocker at discharge (not a core measure), but evidence was weaker for discharge instructions, and lacking for smoking cessation. Pooled risk for readmission and mortality could not be calculated because of the heterogeneous nature of study designs, performance measures, unit of analysis, sample populations, statistical methods and length of follow up. However, the systematic review concluded a decreased risk for near term readmissions within a “narrower timeframe” (pg. 416) associated with discharge instructions.

In the current study, there are a number of factors that may influence the results related to HF1. First and importantly, the lack of available death data in this dataset is recognized as unfortunate and likely confounding, i.e., reduced readmission for some individuals was doubtless related to death, which was a variable only accessible for a small subset of the sample in this data set (n = 218). In that pilot analysis, 57 of 218 individuals (26.1%) died within one year; 43% of these were readmitted only once. Approximately one in five people who have HF die within one year of diagnosis (Lloyd-Jones, Adams et al. 2010). Death rates are directly proportionate to age, with more than 90% of deaths occurring in those aged 65 or greater (Haldeman, Rashidee et al. 1998). End stage HF patients without documentation of "comfort care" may have been less likely to receive full HF1 instructions from providers and may have later expired outside the hospital.

Other factors influencing the results of this study are likely similar to those known to influence HF readmission, overall. The literature has suggested that written instructions, alone, are unlikely to produce substantive changes in self management of HF which may impact patient outcomes, cost and recidivism (Albert, Fonarow et al. 2007; Davidson, Cockburn et al. 2008). Studies suggest that patient education, particularly using traditional methods, does not result in sustained behavior change for self-care and adherence (Jaarsma, Halfens et al. 1999; Ni, Nauman et al. 1999; Carlson, Riegel et al. 2001; Artinian, Magnan et al. 2002; Albert, Fonarow et al. 2007), and that the effects of HF instructions, given at the index visit, may weaken over time (Jaarsma, Halfens et al. 1999; Butler, Arbogast et al. 2004). The data in this study support a weak but short term effect of HF1 for all cause readmission, but no effect on HF to HF readmission.

Other interventions may have a more potent influence on readmission outcomes than HF1. Studies suggest that comprehensive discharge and transitional planning, early follow up phone calls, and a face to face visit with a clinical provider within 7 days reduce early readmission (Phillips, Wright et al. 2004; Hernandez, Greiner et al. 2010).

Maintaining an ongoing relationship with a clinical provider(s) specializing in HF management has also been shown to reduce readmissions over the longer term (Riegel, Carlson et al. 2000; Velez, Westerfeldt et al. 2008; Daley 2010). Nurse-led clinics and disease management programs have demonstrated reduced readmission outcomes (Naylor, Brooten et al. 2004; Phillips, Wright et al. 2004; Davidson, Cockburn et al. 2008).

Strength of association of HF instructions to outcomes may be related to the level of intensity of the intervention, i.e., the duration, magnitude, provider education and skill, and resource access (Albert, Fonarow et al. 2007; Agency for Healthcare Research and Quality 2008; Dickson and Riegel 2008; Dickson and McMahon 2008). All of the intervention modalities mentioned in the preceding paragraph include a greater level of intensity of application of self care management education, more specificity in HF content and individual lifestyle application, and ongoing counseling to sustain self management practices. In a study by Koelling and colleagues (2005), HF patients received an in-depth, 1 hour, 1:1 education and counseling intervention conducted by an RN educator versus the control group who received usual discharge instructions (Koelling, Johnson et al. 2005). Results included in shorter length of stay, reduced readmissions and reduced total inpatient days per year for the intervention group versus controls.

HF instructions at hospital discharge may begin important patient self management education and counseling, but be insufficient to produce substantive or sustained outcomes. Core measure HF1, as currently deployed, may be insufficient to provide effective instructions. In some instances, particularly with reimbursement increasingly linked to core measure performance, compliance with core measure threshold for payment may trump best practices for patients. Maeda (2011) mentions the often unspoken practice of “gaming” to elevate core measure scores by documenting measures that may have been marginally completed or completed by the “letter” but not the “intent” of the standard or core measure. An example is a loosely constructed yes/no checklist of compliance for written discharge instructions for each of the six elements of HF1. Although the relevance of the elements to better HF self management and improved patient outcomes is clear, the relevance of completion of HF1 may be less clinically meaningful. Receiving written discharge instructions does not necessarily equate with the instructions being read and understood by patients, or with any intention to adhere to these practices. Health literacy, motivation for lifestyle integration, and self efficacy are important to success in HF self management.

Only one prior study was found that specifically examined HF1 bundle completion and its relationship to readmission (VanSuch, Naessens et al. 2006). Similar to the current study, 18% of patients (age $\geq$ 18 versus age $\geq$ 50 in the current study) were readmitted at 30 days, although a lower percentage had a complete HF1 bundle, 68% versus 85.5% in the current study. VanSuch and colleagues study did show a statistically significant relationship of HF1 to all cause readmissions ($p = .003$) and to HF-related readmissions ($p = .035$). However, when adjusted for covariates such as demographics, severity of illness and co-morbid conditions, the p values fell to .01 and .09, respectively. HF1 completion was greater (76%; $p = .109$) in those receiving ACEI/ARB treatment and was lower (60%; $p < .001$) in patients who did not have left ventricular dysfunction. Those providing HF1 instructions may not have been as aware of HF with preserved ejection fraction or may not have perceived the same need for HF1 due to lack of information specific to treatment and interventions for diastolic dysfunction.

Chung and colleagues (2008) reported that all cause hospitalizations and combined time until death or readmission was shorter for patients who received all four of the HF performance measures: discharge instructions, use of angiotensin converting enzyme inhibitor, measurement of left ventricular dysfunction, and smoking cessation (Chung, Guo et al. 2008). However, other studies found no difference in mortality, or combined mortality and readmission rates, related to discharge instructions (VanSuch, Naessens et al. 2006; Fonarow, Abraham et al. 2007).

Multiple antecedents are simultaneously interacting in the hospital setting to impact patient outcomes. Independent control variables in this study were chosen based on the literature and on accessibility of variables within existing electronic systems at the host organization.

Findings Related to Covariates

Patient Characteristics

Gender and age for the sample are consistent with reports of hospitalized patients with HF (Rosamond, Flegal et al. 2008; Roger, Go et al. 2011). The index sample (n = 1034) is 58% male with an average age of 74.3 years (SD 10.75; range 50 – 98). Almost 80% of the sample is 65 years of age or older. Almost 60% of the sample is married and 95% are of white ethnicity, consistent with the host organization ethnic demographic.

Of the demographic characteristics, only age is significantly related to the completion of HF1. Those with HF1 “not met” are of mean age 72.3 years, 2 years younger than the overall mean. There are no reports of the relationship of patient age and

HF1 completion found in the literature. Although 75% of patients hospitalized for HF are not those with a first diagnosis (Fonarow, Heywood et al. 2007), younger age may be more consistent with first diagnosis. Younger persons may be more likely to be in the workforce, may have more time constraints with the discharge process, and may be assumed to seek out more information on their own via online resources. It may be of interest in future studies to evaluate the relationship of non-white ethnicity and age.

Risk of readmission has been related to various patient characteristics. Increasing age, especially age greater than 80, has been associated with increased risk of readmission (Kossovsky, Sarasin et al. 2000), as has living alone (Tsuchihashi, Tsutsui et al. 2001). Age is not associated with readmission or total annual readmission days in this study, and reduced odds associated with readmission charges is modest ($p = .003$; OR .94). Higher readmission rates have been reported for men in some studies, and for women in others (Giamouzis, Kalogeropoulos et al. 2011). Inconsistent with the results of this study, non-white ethnicity is often associated with higher readmission rates, especially in African Americans and Hispanics; no published data were found on Native Americans (Philbin and DiSalvo 1998; Lee, Chan et al. 2009; Roger, Go et al. 2011). The proportion of African Americans and Hispanics in the current study is minimal, consistent with the local demographics.

Clinical Characteristics

Heart failure is commonly associated with a history of hypertension. Consistent with prior studies (Roger, Go et al. 2011), the prevalence of HTN in the sample is 74.5%. Those without HTN trended more toward HF1 not met, though the relationship is not significant. Although a very common secondary diagnosis related to heart failure, HTN is not associated with any of the readmission intervals, nor with total charges or total days per year.

Similarly, coronary artery disease (CAD) is commonly related to HF and is a secondary diagnosis in more than 61% of cases. Again, the relationship of an incomplete HF1 bundle trended somewhat higher in those with CAD but is not statistically significant in bivariate analysis. Not completing the HF1 bundle in some cases could be related to an undisclosed diagnosis of HF prior to discharge coding, a process which is often adjudicated by an administrative coder versus a medical provider (Giamouzis, Kalogeropoulos et al. 2011).

Ischemic disease and depressed ejection fraction have been associated with readmission (Kossovsky, Sarasin et al. 2000; Perna, Macin et al. 2005). However, in the present study, in bivariate analysis, CAD trends toward a relationship with 30 day and 90 day HF to HF readmission ($p = .10$; OR .65; $p = .037$; OR .66) but in a direction away from readmission. CAD appears in the final binary model ($p = .034$; OR .64) and the counts model ($p =.039$; OR .68) at 90 days. However, at 6 months and one year CAD is no longer significant in any all cause or HF to HF models. Neither is it associated with total charges or total days per year. Clinically, the admitting trigger in those with prominent CAD may be acute chest pain precipitating a stay in the intensive care unit for monitoring and intravenous infusions. Together with procedures to remediate ischemic coronary artery disease, the relationship of CAD to reduced readmissions is plausible, i.e., the patient recovers, at least for a time.. In the 90 days after discharge, the early association with reduced odds of readmission may also be related to death, which was not controlled in this study.

Diabetes mellitus (DM) has been found to be independently associated with HF in recent studies (Murarka and Movahed 2011). In the current study, 41% of individuals have a secondary diagnosis of DM, which has been associated with diastolic dysfunction and preserved left ventricular ejection fraction, as well as systolic dysfunction and low ejection fraction (Greenberg, Abraham et al. 2007). Not unexpectedly, there is no bivariate association with completion of discharge HF1 and diabetes. But, consistent with prior research, this study demonstrates that secondary diagnosis of DM is associated with increased readmission after discharge for HF (Giamouzis, Kalogeropoulos et al. 2011). It is associated with all cause readmission at 30, 90, 180 and 365 days. However, this association is not seen until 6 months after the index discharge in HF to HF readmission. At six (6) months and one year, diabetes is strongly associated with binary and counts analyses for HF to HF readmissions. (See Tables 31 – 38).

Others of the seven (7) co-morbid conditions are less prevalent in the study sample. About 30% of index cases have COPD identified as a co-morbid condition. COPD has been associated with over-ratings on functional class (i.e., New York Heart Association classifications) due to the primary symptom of shortness of breath in both conditions. It has also been associated with mortality in HF patients (De Blois, Simard et al. 2010). There is no bivariate relationship between COPD and HF1 in this study and no prior studies identified. COPD is not associated with all cause or HF to HF readmission at 30 or 90 days. At 6 months, it is related to increased odds of readmission in counts analysis ($p = .008$; OR 1.29) for both all cause and HF to HF readmissions ($p = .003$: OR 1.34). This positive relationship to hospital readmission is consistent with other reports

(Braunstein, Anderson et al. 2003; Howie-Esquivel and Dracup 2007; De Blois, Simard et al. 2010).

Similarly, anemia is present in 28.3% of the sample and has been associated with readmission in other studies (Giamouzis, Kalogeropoulos et al. 2011). It is significantly related to odds of readmission in binary all cause analysis at 30 days ($p = .052$; OR 1.41) and in HF to HF counts at 6 months ($p = .05$; OR 1.21) (See Table 30). At one year, anemia is significant in bivariate all cause analysis, but is not included in final models with HF1. Anemia is significantly related to increased total charges per year in the final model, similar to findings in other studies (Komajda 2004; Titler, Jensen et al. 2008). It is related to increased odds of total hospital days in bivariate analysis only.

Renal insufficiency (RI) is present in just under 20% of the sample and its relationship to HF1 trended toward significance at $p = .087$. Those with a secondary diagnosis of RI are less likely to have incomplete HF1 teaching (10.7% vs 14.5% for the sample). This may relate to the increased caregiver awareness of fluid overload in these patients and potential for recurrent admission for either RI or HF. There is a trend toward HF to HF readmission in bivariate analysis after 6 months, but there is no statistically significant findings in any analysis for readmission, total charges or total days per year.

Finally, pneumonia is seen in only 6.2% of individuals as a secondary diagnosis and is not related to completion of HF1. There is no relationship between pneumonia in the readmission models until 6 months after discharge. It is included in the all cause binary final model at 6 months and one year ($p = .038$; OR .558) ($p =.017$; OR .51, respectively), the counts model at one year ($p = .013$; OR .62) and the HF to HF binary final model at six months ($p = .04$; OR .336), and in both binary and counts HF to HF models at one year (p =.013; OR.621 and p =.011; OR.269). Secondary diagnosis of pneumonia on the index admission was consistently related to reduced odds of readmission in all analyses where there was an association identified. The reduction in readmission odds after 6 six months may be related to successful treatment of infectious disease, or to death. Further research and/or secondary analysis of the existing data set is needed to look at the relationship of pneumonia to death, and the potential interaction of pneumonia and COPD.

The final variable related to patient characteristics is severity of illness which averaged 2.48 out of maximum four (4) point scale using the APRDRG scale. This mean score indicates a severity between moderate and major. Severity of illness on this scale is unrelated to completion of HF1 (p = .414). Severity of illness is not related to readmission at any interval. It is, however, related to total annual charges in bivariate binary analysis (p = .003; OR 1.09) but not in the final model with HF1. Severity trends toward bivariate significance, only, for total days per year (p = .07; OR 1.19).

Hospital Context/Nursing Unit

An outcome of interest in descriptive bivariate analysis is the discharge department, or unit from which the individual was discharged. In the index database in the current study, 88% of all discharges for HF are from the medical cardiology unit and completion of HF1 is 89% versus 62% on other HF discharge units. Discharge unit is strongly associated with completion of the HF1 discharge instruction bundle (p = .000; χ^2 63.31).

Similar to the bivariate chi square analysis discussed above, discharge department, or nursing unit [not medical cardiology], is strongly associated with odds of all cause 30 day readmission in binary and counts multivariate analysis (p = .025; OR 1.67; p = .019; OR 1.55).

The relationship between discharge department and readmissions recurs in other intervals: binary bivariate analysis at 90 days, all cause counts analysis at 90 days (p = .002; OR 1.57); 180 day binary (p = .030; OR 1.56) and counts (p =.002; OR 1.50) analyses; and again at the end of one year in all cause readmission binary (p = .029: OR 1.58) and counts analysis (p = .001; OR 1.52). The discharge department, or discharge nursing unit, does appear to be strongly and consistently related to increased odds of heart failure all cause readmissions.

No studies were found that specifically examined the effects of a cardiac specialty unit in the hospital versus a general medical or medical-surgical unit. However, a recent study by Joynt and colleagues (2011) refers to the effect of volume of cases on outcomes (Joynt, Orav et al. 2011). They looked at risk adjusted readmission rates and costs from Medicare claims data for HF from 2006-2007. They found a positive relationship between HF case volume and performance scores, and an inverse relationship between case volume and 30 day readmission (Joynt, Orav et al. 2011). In their conclusions, Joynt and colleagues suggested that increased case volume may assume more experience, and perhaps knowledge and skill, in caring for patients with HF, which may translate into improved patient outcomes.

If the argument for experience, skill and knowledge is true, however, one would expect similar results in HF to HF readmissions. Instead, only length of stay on the index admission is significantly related to HF to HF readmission at 30 days. The lack of relationship to HF to HF readmissions continues through each of the successive intervals.

Without further analysis, it is difficult to interpret this finding. It may be that HF patients not discharged from a cardiology unit may be less likely to be readmitted with HF at all, but rather with a non-HF disorder, i.e., these patients may have other co-morbid conditions for which they are more likely to be readmitted such as COPD, renal problems, oncology conditions or cardiovascular conditions other than HF (Braunstein, Anderson et al. 2003).

Further research is needed to describe and measure the effects of specialty nursing unit care for inpatients with HF. Limited studies have looked at relationships between nursing unit volume and outcomes (Rimar and Diers 2006). Studies have described the effects of specialty and advanced practice staff, such as advanced practice registered nurses, cardiologists and other disciplines with specialty expertise in cardiovascular care (Foody, Rathore et al. 2005; Avery and Schnell 2010; Ghali, Massie et al. 2010), but not of the characteristics of specialty units themselves. Clinicians, especially advanced practice nurses (Kleinpell and Gawlinski 2005; Throndson and Sawatsky 2009) often participate in unit-based staff education, implementation of evidence-informed tools and instruments (e.g. clinical pathways, protocols or standardized order sets), or in direct consultation and care of patients and families. Localized on nursing units, the effects of these clinicians may be assumed to impact patient outcomes attributed to a specialty care unit (Grady, Dracup et al. 2000). Other strategies such as the "clinical development unit" have been implemented at the unit level to improve patient outcomes through staff development based on research evidence and translation of evidence into practice (Boyde, Henderson et al. 2005).

In a study on hospital costs related to older adults with HF, Titler and colleagues (2008) reported a relationship between RN staffing (below the average) and number of unit transfers, and increased cost. This study also described specific nursing interventions related to decreased costs of heart failure hospitalizations (Titler, Jensen et al. 2008). However, specific studies on attributes of a cardiovascular or HF specialty unit have not been described.

The number of nursing unit transfers is less interesting in this study with only 16.3% of individuals experiencing a transfer (mean = 1.18). With so few transfers overall, there is no association with completion of HF1 and only a .04 difference in mean number of units where the patients resided. See Table 4. There is no association with 30 day all cause or HF to HF readmissions. There is significant association with 90 day binary HF to HF readmissions and number of nursing units ($p = .034$; OR 1.55). There is also a trend toward bivariate association of all cause and HF to HF readmissions at 6 months, but neither carried through to the final HF1 models. However, at one year, the number of nursing units is significantly related to readmissions in the final HF to HF count model ($p = .008$; OR 1.48). It is of interest that transferring to more than one unit during the index admission is associated with increased odds of HF to HF readmissions at 3 months and one year. These transfers likely occur between the intensive care unit and the cardiology nursing unit for severe acute decompensation related to HF or a chest pain trigger.

Table 48. All Cause Binary Multivariate Analysis

Indicator	30 Day		90 Day		180 Day		365 Day	
	sig	**OR**	**sig**	**OR**	**sig**	**OR**	**sig**	**OR**
HF1	.216	1.32	.504	.88	.026	.65	.020	.65
Gender								
Ethnicity	.020	.32					.017	.487
Marital Status								
DC Department	.025	1.68			.030	1.56	.029	1.58
Anemia	.052	1.41						
COPD								
Pneumonia					.038	.59	.017	.52
Diabetes	.016	1.49			.000	1.59	.000	1.65
Hypertension								
Coronary Artery Disease								
Renal Insufficiency								
Nursing Units								
APR Severity								
Direct Cost								
Days			.008	1.19	.009	1.19	.001	1.26
Age								

Table 49. All Cause Counts Multivariate Analysis

Indicator	30 Day		90 Day		180 Day		365 Day	
	sig	**OR**	**sig**	**OR**	**sig**	**OR**	**sig**	**OR**
HF1	.131	1.32	.267	.841	.040	.75	.002	.66
Gender								
Ethnicity	.025	.354			.025	.59		
Marital Status								
DC Department	.019	1.55	.002	1.58	.002	1.50	.001	1.52
Anemia								
COPD					.008	1.29	.002	1.32
Pneumonia							.013	.62
Diabetes	.016	1.40	.044	1.24	.000	1.41	.000	1.40
Hypertension								
Coronary Artery Disease								
Renal Insufficiency								
Nursing Units								
APR Severity								
Direct Cost								
Days								
Age								

Table 50. HF to HF Binary Multivariate Analysis

Indicator	30 Day		90 Day		180 Day		365 Day	
	sig	**OR**	**sig**	**OR**	**sig**	**OR**	**sig**	**OR**
HF1	.438	.71	.013	.37	.002	.31	.000	.26
Gender (Male)							.047	1.40
Ethnicity								
Marital Status								
DC Department								
Anemia								
COPD								
Pneumonia					.040	.34	.011	.30
Diabetes							.030	1.43
Hypertension								
Direct Cost			.051	.961	.032	.96	.005	.95
Coronary Artery Disease			.028	.636				
Renal Insufficiency								
Nursing Units			.034	1.56				
APR Severity								
Days	.009	1.36			.009	1.29	.004	1.29
Age								

Table 51. HF to HF Counts Multivariate Analysis

Indicator	30 Day		90 Day		180 Day		365 Day	
	sig	OR	sig	OR	sig	OR	sig	OR
HF1	.397	.69	.007	.344	.172	.83	.000	.23
Gender (Male)					.023	.58		
Ethnicity								
Marital Status								
DC Department								
Anemia					.051	1.21		
COPD					.003	1.34		
Pneumonia							.008	.28
Diabetes					.000	1.40	.010	1.47
Hypertension								
Coronary Artery Disease			.039	.677				
Direct Cost							.006	.96
Renal Insufficiency								
Nursing Units							.008	1.48
APR Severity								
Days	.007	1.34						
Age								

Administrative

There are two administrative, or utilization, variables among the independent variables in the analysis: length of stay of the index hospitalization and direct cost of the index visit. From 1993 until 2006, mean hospital length of stay (LOS) for HF decreased from 8.81 to 6.33 days (Bueno, Ross et al. 2010). Mean LOS in days for the index admission in the current study from 2002 through 2009 is 4.13 (SD 2.77) days. Length of stay of the index admission has been associated with readmissions in prior studies

(Krumholz, Parent et al. 1997); length of stay greater than 14 days increases the risk of readmission three-fold (Giamouzis, Kalogeropoulos et al. 2011).

In this study, length of stay (Days) is also related to readmission in each of the intervals. In bivariate analysis related to both binary and counts, length of stay of the index admission (Days) is associated with increased odds of all cause readmission at 30 days. Days are related to the binary final model for HF to HF 30 day readmissions (p = .009; OR 1.36) and in the HF to HF count final model (p = .007; OR 1.34). At 90 days, Days are significant in the final binary all cause model (p = .008; OR 1.19), but not significant in either of the analyses of HF to HF. At six (6) months, Days is again associated with increased odds of readmission in binary all cause and HF to HF readmission (p = .009; OR 1.19 and p = .009; OR 1.29, respectively). At the end of one year after the index discharge, Days is again strongly associated with readmission in binary all cause and HF to HF readmission analyses (p = .001; OR 1.26 and p = .004; OR 1.29, respectively).

Length of stay of the index admission is not associated with total all cause readmission charges per year, but is related to increased odds of greater total readmission days per year (p =.009; OR 1.20).

Mean direct cost of the index admission in this study is $5852 (SD 6849), with no relationship to completion of HF1. Even though Days is often associated with readmission at all intervals, direct cost is only related to HF to HF binary and count readmission at one year (p = .005; OR .95 and p = .006; OR .96, respectively). The odds ratios are near one reflecting marginal effect on readmission. There is no relationship between HF1 and total annual charges or total hospital days in one year.

Table 52. HF1 and Total Readmission Charges (ln) Per Year

Indicator	sig	OR
HF1	.982	.999
Gender (Male)	.023	1.10
Ethnicity		
Marital Status		
DC Department		
Anemia	.007	1.12
COPD		
Pneumonia		
Diabetes		
Hypertension		
Coronary Artery Disease		
Direct Cost		
Renal Insufficiency		
Nursing Units		
APR Severity		
Days		
Age	.003	.94

Note: n = 1126; Normal distribution Identity link

Table 53. HF1 and Total Readmission Days Per Year

Indicators	sig	OR
HF1	.085	.723
Gender (Male)		
Ethnicity		
Marital Status		
DC Department	.021	1.60
Anemia		
COPD	.031	1.35
Pneumonia	.002	.427
Diabetes	.017	1.36
Hypertension		
Coronary Artery Disease		
Direct Cost		
Renal Insufficiency		
Nursing Units		
APR Severity		
Days	.009	1.20
Age		

Note: n = 543 individuals, 1126 readmissions, Negative binomial log link MLE

Conclusions, Implications and Future Direction

Heart failure affects more than 5 million persons in the United States with 570,000 new cases diagnosed each year. It accounts for about one million hospitalizations per year as primary diagnosis, and approximately 2.6 million as a secondary diagnosis (Fang, Mensah et al. 2008; Roger, Go et al. 2011). Hospitalization, itself, is an independent predictor of re-hospitalization and may mark a shift in the natural history of the condition (Giamouzis, Kalogeropoulos et al. 2011). About half of patients hospitalized for HF are re-hospitalized within 6 months (44% in the current study) and

~35 - 70% of these readmissions have been reported as HF, or related to heart failure (Roger, Go et al. 2011). About half of all patients diagnosed die within 5 years, with greater likelihood among those with diastolic dysfunction.

Because of the heart failure epidemic, hospitals are scrambling for valid readmission risk profiles to help in predicting and preventing readmissions. Hospital readmission, as well as core performance measures, are increasingly interpreted as markers of quality of care and care coordination. By 2012, readmission and other performance indicators will be linked to reimbursement by CMS. It is incumbent upon policy makers, health care providers and researchers to ensure that these measures accurately reflect quality of care and health outcomes of patients.

Nurses are integrally involved in quality of care in hospital settings and perform much of discharge education and care coordination within systems of care. Staff salaries are one of the largest expense categories in hospital budgets and nurses can be considered an expensive and scarce resource. Their time should be utilized with evidence-informed and efficient best practices that produce optimum outcomes for patients in their care. Time spent in activities directed at reimbursement linked process compliance only loosely related to patient outcomes may be considered unnecessary and costly waste.

Core measure HF1 drives discharge education for patients with heart failure as organizations strive to reach performance compliance thresholds that will be linked to reimbursement in the future. Given this current reality, research is needed to confirm the link between HF1 and patient outcomes, particularly the effect of discharge education on readmission (Patterson, Hernandez et al. 2010). Only one prior study examined the relationship of the six (6) element HF1 bundle and patient readmission (VanSuch, Naessens et al. 2006) and one experimental study used an intensive educational intervention based on the elements of HF1 (Koelling, Johnson et al. 2005). Both results indicated a positive relationship between discharge education and reduced readmissions. However, other studies, though few, have evaluated HF1 and have found no, or only weak, relationships to readmission (Fonarow, Abraham et al. 2007; Maeda 2010; Patterson, Hernandez et al. 2010).

The current study is unique in that it evaluated four (4) readmission intervals and the relationship of an index admission HF1 episode and readmission for either all cause or HF to HF readmission. Overall findings indicate a possible weak but non-significant short term effect of HF1 on all cause readmission, but no effect at 30 days on HF to HF readmission. The short term effect would suggest that not meeting the entire set of bundle elements within HF1 may be weakly related to increased odds of readmission. At 90 days, however, there was no effect on all cause readmissions and an inverse effect on the odds of HF to HF readmission. The inverse relationship to odds of readmission is then consistent throughout the last two periods of the index year of follow-up for both all cause and HF to HF readmissions, and the magnitude of the odds ratio is even less in HF to HF than all cause readmissions. This drift in association has been discussed previously, i.e., the potential effects of death missing in the analysis; the overall drift related to temporal factors; co-morbid factors; and the potential for more influential interventions that may better defer readmission, which were not included in, nor the focus of, this study.

The multivariate models demonstrate the strength of association of covariates to readmission. Diabetes, with overall adult population prevalence of 8%, is a secondary diagnosis in 40% of this sample and is consistently associated with all cause readmission and HF to HF readmission after 6 months. Anemia is associated with all cause readmission but only at 30 days. COPD is related to increased odds of readmission in the latter half of the index year, while pneumonia is inversely related, raising questions related to overlapping symptom presentation, successful treatment of pneumonia, or death. Length of stay of the index admission seems to trend across intervals and is supported in the literature. Non-white ethnicity is related to reduced odds of readmission, a finding contrary to the literature and in need of further analysis in this single site study where Native Americans are the next largest ethnic group, albeit less than 5% of the sample.

This study and others are gradually mounting evidence for use in risk profiles for hospitals, which are eager to employ risk stratification schemas. Valid risk prediction must next be linked to feasible and efficient intervention strategies to reduce readmission. Further research is necessary to answer questions about temporal associations of risk factors, i.e., are 30 day readmission risks different, or of different risk magnitude, than 6 month or one year risks. Do certain combinations of, or interactions between, risk factors better predict readmission at specific intervals?

Another consistent association demonstrated by this study is the increased odds of readmission related to discharge of a heart failure patient from a non-cardiology unit. Completion of the HF1 bundle is significantly less on non-cardiology units. Further research is needed related to the potential contextual effects of a specialty unit for care of heart failure patients, such as evidence-informed instruments, credentialing of RN's, and specialty focused interdisciplinary care delivery. Although the effects of intensive patient education efforts involving discharge education have been reported (Koelling, Johnson et al. 2005; Kutzleb and Reiner 2005), as have the effects of advanced practice nurse led clinics and evidence-informed programs (Boyde, Henderson et al. 2005; Albert and Zeller 2007; Albert, Fonarow et al. 2010; Avery and Schnell 2010) specific nursing unit factors have not been well-described. While it is plausible that an HF discharge from a non-cardiology unit may result in a non-HF readmission, further analysis is needed to interpret the finding of no association between discharge nursing unit and HF to HF readmissions.

Finally, HF1, as currently deployed, serves as a proxy for self care education, yet is inconsistent with current knowledge and theory. As described in the review of the literature in chapter two (2), best knowledge and theory of patient-centered HF education, and HF self management, could be more clearly represented in performance measurements. The elements of patient discharge instruction in HF1 are actually quite generalist in nature, i.e., generic hospital discharge instruction forms usually contain information on recommended diet, activity, medications, follow-up appointments, and when to call the doctor after hospitalization. The only really unique element in HF1 differentiating it from general discharge instructions is the recommendation about daily weights.

Nursing knowledge and theory may contribute importantly to revisions to the content and the implementation of the HF1 core measurement intervention. If reconstructed based on best theory and knowledge of HF, the measure, which even now shows some, albeit weak, outcome benefits, may actually be strengthened and the effects compounded. Research is needed on performance measure reconstruction that:

elucidates specific aspects of HF education related to the existing HF1 elements; includes lifestyle counseling on living with heart failure; integrates the need for patient engagement over time; provides for access to follow-up and transitional programs into the community; and bridges the gap with primary care clinics by standardizing processes of care over the continuum. Application of best evidence, theory and research to accomplish such core measure amendment requires the commitment and cooperation of policy makers, interdisciplinary expert clinicians and researchers. Nursing contributions to simple changes to core measure HF1 in the short term are conceivable and desirable. Nursing's voice should be audible in the emerging controversy over performance and outcome based reimbursement in an environment of shrinking resources.

Limitations

As descriptive effectiveness research, this study examines routine processes of care in daily practice settings with less rigor and protocol standardization, loosened inclusion criteria, and more variation in compliance (Shadish, Cook et al. 2002; Iezzoni 2003). The primary outcome of interest is evaluated using data derived from patient hospital visits during which less-than-ideal conditions exist in a real world setting. Threats to validity, or reasons why inferences about associations between independent and dependent variables may be inaccurate, are evident in this and other effectiveness studies related to HF. The degree of validity of the observed co-variation between the independent variable of interest and the presumed outcome was limited by a number of factors.

One the greatest threats to validity was the lack of available mortality data at the host organization. As previously described, this data was not available until late in the study period, i.e., after 2006. A trial of available cases for which alive/not alive status was known produced an n of 218. Although an extensive analysis was conducted on this subset, the models were considered unstable related to the small n and were not reported.

Risk adjustment is of particular importance to this type of research and outcomes are a function of intrinsic patient-related risk factors, the effects of the intervention of interest, quality of care and random chance (Iezzoni 2003). Internal validity may have been threatened by the lack of a more comprehensive risk adjustment. Risk adjustment focused on patient attributes, patient clinical co-morbid conditions, length of stay and cost, and effects of the setting. Seventeen independent candidate variables were chosen based on the conceptual framework and evidence from the literature about their relationship to HF and HF outcomes. Although most studies have used between 11-25 candidate variables, no consistent predictors have emerged in previous research (Ross, Mulvey et al. 2008). Statistical and prediction models for risk of HF readmission have varied in methods and results, and no validated model is available. Studies related to HF readmissions have been heterogeneous in design, methods, data sources, study outcomes, and periods of time of follow-up (i.e. 14 days to 4 years) (Ross, Mulvey et al. 2008; Maeda 2010).

In this study, the co-morbid conditions chosen are based on their documented relationship to HF, but the seven (7) conditions did not comprehensively address the scope of co-morbid illness impact. Another measure such as Elixhauser (Elixhauser, Steiner et al. 1998) or the Charlson Co-mordibity Index (Charlson, Pompei et al. 1987) may add greater validity to control for co-morbid illnesses. Clearly, other psychosocial conditions have been associated with readmission and with HF self management, e.g.

depression, cognition (Clark and McDougall 2006), living alone, lower socioeconomic status and health literacy.

Inclusion of additional risk indicators may strengthen the study. Heart failure functional status is not included as this measurement data is not collected at the host organization. Functional status is an important risk descriptor, often determined by the New York Heart Association Classification (NYHA), a well-recognized measure related to heart failure. Similarly, this study did not include two clinical variables related to HF severity, B-type natriuretic peptide (BNP) lab results (Maisel, Hollander et al. 2004; Ancheta 2006) , and left ventricular ejection fraction, both of which would have required manual data abstraction at the study inception.

Threats of history and maturation of this sample of chronically ill older adults may include not only health status, but also effects of time and intervening life events. The effects of index education may weaken over time; changes in health status may occur over the study period; changes in lifestyle or occurrence of life events (e.g. change of residence, loss of spouse, retirement, etc.) may also impact overall health and need for hospitalization.

External validity, or generalizability, is limited by the single site study. The upper Midwest locale limits the sample to an almost all white ethnic group with the general diet, activity, health-seeking behaviors and general cultural predilections thereof. In addition, readmission to the single host hospital likely eliminates an important proportion of re-hospitalized HF patients admitted during the subsequent year but to another hospital (Jencks, Williams et al. 2009; Nasir, Lin et al. 2010).

Because of the heterogeneity of other studies and the lack of a valid model, generalizability is also threatened by the design, variables, time interval, sample, methods and statistical analysis applied. Interaction between the independent variable of interest and the setting, new technology, the individual educator's motivation and characteristics, and the intensity of the educational intervention also limit the generalizability of the study results.

Research Considerations and Future Steps

After review of the conduct and outcomes of this dissertation research, several considerations would prompt alterations in approach. Given an adequate funding source, death data from a national database would have been extremely helpful and would almost certainly have altered the magnitude, if not the direction in some intervals, of the odds ratios for readmission. In additions, inclusion of a valid comorbidity risk adjustment instrument, such as that by Elixhauser, would likely strengthen that component of the study versus using the seven comorbid conditions selected.

Future steps for this research, from an effectiveness perspective, might include further secondary analysis of the existing dataset. It would be of interest to describe HF in the Native American population, an area of apparently limited study to date. In the present study, outcomes related to readmission of Native Americans were unexpected and contradictory to that suggested in other non-White ethnic groups. Secondly, it would be of interest to examine those readmissions that were initially discharged from non-cardiology units and determine the relationship to the primary readmission diagnosis, i.e., are there patterns of other, chronic, non-HF conditions such as respiratory or oncology conditions.

Future research may also focus on an intervention related to: 1) enhancements to the HF1 core measure that are guided by nursing situational theory of HF, patient-centered HF educational approaches, and features of transitional care into the community, and 2) intensiveness of the HF instruction intervention. Such a study might also consider risk adjustments not immediately available from administrative data, such as a depression screen, literacy screen, and evaluation of social supports.

Effectiveness Epilogue

This study demonstrates the need for increased involvement of nurses in effectiveness research. With increasing access to data that assists in describing and articulating nursing practice and patient outcomes, nurses are accountable to link that data in meaningful ways to inform practice, to differentiate levels of effectiveness of practice on health outcomes, and to disseminate best practices and eliminate waste. It is incumbent upon the discipline to participate in the development and evaluation of performance measures based on current best nursing theory and science. Enhancements to performance measures that are justifiably within the domain of nursing disciplinary perspective are imperative to better and more efficient health outcomes.

APPENDIX A

HEART FAILURE CODES

Version 2.1a Specifications Manual for National Hospital Inpatient Quality Measures	
Code	ICD-9-CM Description
402.01	Hypertensive heart disease, malignant, with heart failure
402.11	Hypertensive heart disease, benign, with heart failure
402.91	Hypertensive heart disease, unspecified, with heart failure
404.01	Hypertensive heart and chronic kidney disease, malignant, with heart failure and with chronic kidney stage V or end stage renal disease
404.03	Hypertensive heart and chronic kidney disease, malignant, with heart failure and with chronic kidney stage V or end stage kidney disease
404.11	Hypertensive heart and chronic kidney disease, benign, with heart failure and with chronic kidney stage I through IV, or unspecified
404.13	Hypertensive heart and chronic kidney disease, benign, with heart failure and with chronic kidney stage V or end stage renal disease
404.91	Hypertensive heart and chronic kidney disease, unspecified, with heart failure and with chronic kidney stage I through IV, or unspecified.
404.93	Hypertensive heart and chronic kidney disease, unspecified, with heart failure and chronic kidney stage V or end stage renal disease
428.0	Congestive heart failure, unspecified
428.1	Left heart failure
428.20	Unspecified systolic failure
428.21	Acute systolic heart failure
428.22	Chronic systolic heart failure
428.23	Acute or chronic systolic heart failure

Appendix A1 Heart Failure Codes continued

428.30	Unspecified diastolic heart failure
428.31	Acute diastolic heart failure
428.32	Chronic diastolic heart failure
428.33	Acute or chronic diastolic heart failure
428.40	Unspecified combined systolic and diastolic heart failure
428.41	Acute combined systolic and diastolic heart failure
428.42	Chronic combined systolic and diastolic heart failure
428.43	Acute or chronic combined systolic and diastolic heart failure
428.9	Heart failure, unspecified

APPENDIX B

UNIVERSITY OF IOWA IRB APPROVAL

THE UNIVERSITY OF IOWA

Human Subjects Office
340 Medicine Administration Building
Iowa City, Iowa 52242-1101
319-335-6564 *Fax* 319-335-7310
irb@uiowa.edu
http://research.uiowa.edu/hso

IRB ID #: 200912753

To: Gwenneth Jensen

From: IRB-01 DHHS Registration # IRB00000099,
Univ of Iowa, DHHS Federalwide Assurance # FWA00003007

Re: Outcomes of Heart Failure Discharge Instructions

Protocol Number:
Protocol Version:
Protocol Date:
Amendment Number/Date(s):

Approval Date: 12/29/09

Next IRB Approval Due Before: 12/29/10

Type of Application:	**Type of Application Review:**	**Approved for Populations:**
☒ New Project	☐ Full Board:	☐ Children
☐ Continuing Review	Meeting Date:	☐ Prisoners
☐ Modification	☒ Expedited	☐ Pregnant Women, Fetuses, Neonates
	☐ Exempt	

Source of Support:

Investigational New Drug/Biologic Name:
Investigational New Drug/Biologic Number:
Name of Sponsor who holds IND:

Investigational Device Name:
Investigational Device Number:
Sponsor who holds IDE:

This approval has been electronically signed by IRB Chair:
Catherine Woodman, MD
12/29/09 0955

OFFICE OF THE VICE PRESIDENT FOR RESEARCH

IRB Approval: IRB approval indicates that this project meets the regulatory requirements for the protection of human subjects. IRB approval does not absolve the principal investigator from complying with other institutional, collegiate, or departmental policies or procedures.

Agency Notification: If this is a New Project or Continuing Review application and the project is funded by an external government or non-profit agency, the original HHS 310 form, "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption," has been forwarded to the UI Division of Sponsored Programs, 100 Gilmore Hall, for appropriate action. You will receive a signed copy from Sponsored Programs.

Recruitment/Consent: Your IRB application has been approved for recruitment of subjects not to exceed the number indicated on your application form. If you are using written informed consent, the IRB-approved and stamped Informed Consent Document(s) are attached. Please make copies from the attached "masters" for subjects to sign when agreeing to participate. The original signed Informed Consent Document should be placed in your research files. A copy of the Informed Consent Document should be given to the subject. (A copy of the *signed* Informed Consent Document should be given to the subject if your Consent contains a HIPAA authorization section.) If hospital/clinic patients are being enrolled, a copy of the signed Informed Consent Document should be placed in the subject's chart, unless a Record of Consent form was approved by the IRB.

Continuing Review: Federal regulations require that the IRB re-approve research projects at intervals appropriate to the degree of risk, but no less than once per year. This process is called "continuing review." Continuing review for non-exempt research is required to occur as long as the research remains active for long-term follow-up of research subjects, even when the research is permanently closed to enrollment of new subjects and all subjects have completed all research-related interventions and to occur when the remaining research activities are limited to collection of private identifiable information. Your project "expires" at 12:01 AM on the date indicated on the preceding page ("Next IRB Approval Due on or Before"). You must obtain your next IRB approval of this project on or before that expiration date. You are responsible for submitting a Continuing Review application in sufficient time for approval before the expiration date, however the HSO will send a reminder notice approximately 60 and 30 days prior to the expiration date.

Modifications: Any change in this research project or materials must be submitted on a Modification application to the IRB for prior review and approval, except when a change is necessary to eliminate apparent immediate hazards to subjects. The investigator is required to promptly notify the IRB of any changes made without IRB approval to eliminate apparent immediate hazards to subjects using the Modification/Update Form. Modifications requiring the prior review and approval of the IRB include but are not limited to: changing the protocol or study procedures, changing investigators or funding sources, changing the Informed Consent Document, increasing the anticipated total number of subjects from what was originally approved, or adding any new materials (e.g., letters to subjects, ads, questionnaires).

Unanticipated Problems Involving Risks: You must promptly report to the IRB any serious and/or unexpected adverse experience, as defined in the UI Investigator's Guide, and any other unanticipated problems involving risks to subjects or others. The Reportable Events Form (REF) should be used for reporting to the IRB.

Audits/Record-Keeping: Your research records may be audited at any time during or after the implementation of your project. Federal and University policies require that all research records be maintained for a period of three (3) years following the close of the research project. For research that involves drugs or devices seeking FDA approval, the research records must be kept for a period of three years after the FDA has taken final action on the marketing application.

Additional Information: Complete information regarding research involving human subjects at The University of Iowa is available in the "Investigator's Guide to Human Subjects Research." Research investigators are expected to comply with these policies and procedures, and to be familiar with the University's Federalwide Assurance, the Belmont Report, 45CFR46, and other applicable regulations prior to conducting the research. These documents and IRB application and related forms are available on the Human Subjects Office website or are available by calling 335-6564.

APPENDIX C

SANFORD USD MEDICAL CENTER APPROVALS

Sanford
IRB

Sanford Human Research Protection Program
1018 W. 18th Street
Sioux Falls, SD 57104
605-328-1372

January 18, 2010

Gwen Jensen, RN, MN, PhDc
Sanford Medical Center
1305 W. 18th Street
Sioux Falls, SD 57117-5039

Dear Gwen:

I have reviewed and approved the protocol dated 12/29/09, the Consent Waiver application dated 1/12/10 and the HIPAA Form – Full Waiver Authorization dated 1/12/10 for the protocol entitled "Outcomes of Heart Failure Discharge Instructions," as this meets the criteria for expedited approval under 45 CFR 46.110(b)(1) category 5 for population 1 and 45 CFR 46.110(b)(1) category 7 for population 2.

In one year or less you will be asked to send in an updated report on the above named project, which will be reviewed by the Sanford Health Institutional Review Board #1. Approval is granted until 1/17/11.

Sincerely,

Michael G. Duncan, Pharm.D., R.Ph.
IRB Manager
Sanford Health IRB #1

rjs

Consent Waiver Application

Consent Waiver Application
Sanford Human Research Protection Program
1018 W. 18th Street • Sioux Falls SD 57104
Fax: 605-328-0357

RECEIVED
JAN 13 2010
SH IRB

☒**Sanford Health Institutional Review Board #1 (605-328-0354)**
☐**Sanford Health Institutional Review Board #2 (605-328-0353)**

If you have questions regarding which IRB to submit your project/study to, please call the IRB Director at 605-328-0356.

Submit (1) copy with new study application

Project Title: Outcomes of Heart Failure Discharge Instructions

Principal Investigator: Gwenneth A. Jensen

The IRB may approve a consent procedure that does not include, or which alters, some or all of the elements of informed consent or may waive the requirement to obtain informed consent if the IRB finds that the research meets specific criteria. Note: Exempt projects do not require a waiver.

Please check all that apply below:

- ☐ The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
- ☐ Public benefit or service programs.
- ☐ Procedures for obtaining benefits or services under those programs.
- ☐ Possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs.
- ☐ The research could not practicably be carried out without the waiver or alteration, as in prospective emergency research conducted under 21 CFR 50.24, when time may not permit informed consent.
- ☐ The research is not FDA-regulated.

Or that:

- ☒ The research involves no more than minimal risk to the subjects.
- ☒ The waiver or alteration will not adversely affect the rights and welfare of the subjects.
- ☒ The research could not practicably be carried out without the waiver or alteration.
- ☒ Whenever appropriate, the subjects will be provided with additional pertinent information after participation and
- ☒ The research is not FDA-regulated.

Consent Waiver Application

When Obtaining Informed Consent from a Parent is Not Reasonable

If the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or legally authorized representative permission is not a reasonable requirement to protect the subject (e.g. abused or neglected children), it may waive the consent requirements provided that:

Please check all that apply below:

- ☐ The research was designed for conditions or for a participant population for which parental or guardian permission was not a reasonable requirement to protect participants.
- ☐ An appropriate mechanism for protecting the children who would participate as participants in the research was substituted; and
- ☐ The research was not FDA-regulated.

The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

The IRB may waive parental permission by determining that:

Please check all that apply below:

- ☐ The research involves no more than minimal risk to the subjects.
- ☐ The waiver or alteration will not adversely affect the rights and welfare of the subjects.
- ☐ The research could not practicably be carried out without the waiver or alteration.
- ☐ Whenever appropriate, the subjects will be provided with additional pertinent information after participation; and
- ☐ The research is not FDA-regulated.

Please provide documentation for any items checked above.

Gwenneth A Jensen 01-12-10
Signature of Investigator Date

MP 1/19/2010

☒ Approved: 45 CFR 46.110(b)(1) Category 5 for population 1 ~~and 45 CFR 46.110(b)(1) Category 7 for population 2~~
Citation

☐ Disapproved: ____________________
Reason

[signature] Ph.D. 1/19/2010
Signature of IRB Chair or Designate Date

Consent Waiver Application

Consent Waiver Application
Sanford Human Research Protection Program
1018 W. 18th Street • Sioux Falls SD 57104
Fax: 605-328-0357

☒**Sanford Health Institutional Review Board #1 (605-328-0354)**
☐**Sanford Health Institutional Review Board #2 (605-328-0353)**

If you have questions regarding which IRB to submit your project/study to, please call the IRB Director at 605-328-0356.

Submit (1) copy with new study application

Project Title: Outcomes of Heart Failure Discharge Instructions

Principal Investigator: Gwenneth A. Jensen

The IRB may approve a consent procedure that does not include, or which alters, some or all of the elements of informed consent or may waive the requirement to obtain informed consent if the IRB finds that the research meets specific criteria. Note: Exempt projects do not require a waiver.

Please check all that apply below:

☐ The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
☐ Public benefit or service programs.
☐ Procedures for obtaining benefits or services under those programs.
☐ Possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs.
☐ The research could not practicably be carried out without the waiver or alteration, as in prospective emergency research conducted under 21 CFR 50.24, when time may not permit informed consent.
☐ The research is not FDA-regulated.

Or that:
☒ The research involves no more than minimal risk to the subjects.
☒ The waiver or alteration will not adversely affect the rights and welfare of the subjects.
☐ The research could not practicably be carried out without the waiver or alteration.
☒ Whenever appropriate, the subjects will be provided with additional pertinent information after participation and
☒ The research is not FDA-regulated.

Consent Waiver Application

When Obtaining Informed Consent from a Parent is Not Reasonable

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Please check all that apply below:

- ☐ The research was designed for conditions or for a participant population for which parental or guardian permission was not a reasonable requirement to protect participants.
- ☐ An appropriate mechanism for protecting the children who would participate as participants in the research was substituted; and
- ☐ The research was not FDA-regulated.

The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

The IRB may waive parental permission by determining that:

Please check all that apply below:

- ☐ The research involves no more than minimal risk to the subjects.
- ☐ The waiver or alteration will not adversely affect the rights and welfare of the subjects.
- ☐ The research could not practicably be carried out without the waiver or alteration.
- ☐ Whenever appropriate, the subjects will be provided with additional pertinent information after participation; and
- ☐ The research is not FDA-regulated.

Please provide documentation for any items checked above.

Gwenneth A. Jensen 01-12-10

Signature of Investigator Date

☒ Approved: 45 CFR 46.110(b)(1) CATEGORY 7 (POPULATION 2)

Citation

☐ Disapproved: ______

Reason

[signature] 1/18/2010

Signature of IRB Chair or Designate Date

HIPAA FORM – Full Waiver Authorization

APPLICATION for WAIVER of AUTHORIZATION (HIPAA)

For Research within the Covered Entity (Biomedical Research)

RECEIVED
JAN 13 2010
SH IRB

Protocol Title: Outcomes of Heart Failure Discharge Instructions		
Principal Investigator: Gwenneth A. Jensen	Email: jenseng@sanfordhealth.org	Phone: 605-328-4223
Contact Person: (If different than PI)	Email:	Phone:
Address: 1305 W. 18th Street Sioux Falls SD 57117	Dept: Nursing/Ctr of Care Management	

All of the following must be completed:	
1.	Explain why the *PHI* to be used or disclosed is the minimum necessary to accomplish the research objectives: The variables related to PHI that are involved in the research questions are the minimum necessary to answer the research questions using statisticala analysis.
2.	Explain why the research could not practicably be conducted without the waiver or alteration: It is not feasible or practical to obtain retrospective consent from up to 2000 subjects whose records were created over more than 7 years, some of whom have expired since the medical record data was recorded.
3.	Explain why the research could not practicably be conducted without access to and use of the *PHI*: In order to answer the research questions about heart failure discharge instructions and determine the relationship to patient outcomes, while controlling for intervening and mediating variables, PHI is necessary and core to the study aims. It is not possible to conduct this research without this information
4.	Explain why the research and privacy risks of the research are no more than minimal[1, 2]: 1) Retrospective subject medical record data will not be identifiable and confidentiality of data and protected information will be maintained by deidentifying data. No names or unique identifiers will be used. 2) No individual's data will be reported. Only aggregate data will be used in any publications or reports
4.a.	Describe your plan to protect the identifiers from improper use and disclosure, and indicate where the *PHI* will be stored and who will have access: Original identifiers will be stored in a secured file on a separate computer in a locked office accessible only to the PI. No names will be used. Addresses will be recoded to urban or rural only. Medical record numbers(MRN) and hospital encounter numbers will be recoded unrelated to the original numbers, linked by an alpha tag, i.e., 1a first encounter, 1b second, etc. Birthdates will be recoded to age in years. Original database will be secured in a separate computer in a locked location, accessible only to PI. There will be no links to individual records in reports or publications.
4.b.	The identifiers must be destroyed at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law. Describe how and when you will destroy the identifiers, or justify their retention: Subject identifiers will be destroyed within 3 months of the close of the research project.

[1] *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. 45 CFR 46.102(i)
[2] For HIPAA only, the requirement is: Explain why the use or disclosure of the PHI involves no more than minimal risk to the privacy of the individuals.

rev 7/8/09

HIPAA FORM – Full Waiver Authorization

4.c.	Describe the measures you will take to ensure the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research approved by the IRB: Subject privacy and confidentiality will be maintained by scrupulous data handling.Information will be grouped for reporting; no individual subject data will be reported or identifiable. Subjects rights to confidentiality and privacy will be protected by maintaining the data in a secure unidentifiable structure within the software; files will be inaccessible, locked and/or password protected. Individual subject rights and welfare will not be jeopardized in any foreseeable manner.
5. Principal Investigator's Signature Gwenneth A. Jensen Date: 01-12-10	

HIPAA FORM – Full Waiver Authorization

For IRB/ Privacy Board Use Only
This research preparation application has been reviewed and approved: Date Approved: 1/18/2010
[signature] IRB Chair Signature — Date: 1/18/2010

SANFORD HEALTH

January 13, 2011

PI: Gwenneth A Jensen, RN MN
Project: Outcomes of Heart Failure Discharge Instructions
Project Review Level: Expedited
Project Risk: No More than Minimal
Continuation approved via Expedited Review: Expedited 5 and 7 on 01/13/2011
Project Approval Period: 01/13/2011 – 01/12/2012

Your request for continuation of the above referenced project has been approved by the Sanford Health Institutional Review Board (IRB).

This project has been approved through the expiration date listed above.

Your study has been granted a Waiver of the Process of Informed consent.

Your project has been granted a Full Waiver of HIPAA Authorization:

- The use of disclosure of protected health information involves no more than minimal risk to the individuals;
- The waiver will not adversely affect the privacy rights and welfare of the individuals;
- The research could not be practicably conducted without the waiver;
- The research could not be practicably conducted without access to the use of the protected health information;
- The privacy risks to individuals whose protected health information is to be used or disclosed are reasonable in relation to the anticipated benefits if any to the individuals, and the importance of the knowledge that may reasonably be expected to result from the research;
- There is an adequate plan to protect the identifiers from improper use and disclosure;
- There is an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers, or such retention is otherwise required by law; and
- There is adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted.

No alteration to the procedures described in the Application for Waiver of HIPAA authorization as reviewed may be instituted unless this IRB has reviewed and approved the alteration.

When this study is completed please submit a closure form to the IRB. If the study is to continue for more than one year, a continuation form is to be submitted to the IRB prior to the submission deadline in order to assure adequate time for IRB review. You must obtain PRIOR approval for any significant changes in your research project.

The forms to assist you in filing your: project closure, continuation, adverse/unanticipated event, project updates /amendments, etc. can be accessed online at SanfordConnect.

Sincerely,

Deb Langstraat, CIP
Sanford Health
Director-Human Research Protection Program

Sanford

1305 W 18TH ST
PO BOX 5039
SIOUX FALLS SD 57117-5039
Phone: (605) 333-1000
www.sanfordhealth.org

Date 12/21/09

To The University of Iowa IRB-01:

This is to confirm that we are willing to collaborate with University of Iowa researchers on a research project entitled Outcomes of Heart Failure Discharge Instructions, conducted by UI principal investigator Gwenneth A. Jensen.

We are aware that the procedures used in this project involve the use and/or disclosure of protected health information (PHI) for *research* purposes *without* authorization from the patients at this institution.

We have policies and procedures in place to document our Privacy Officer's approval of a waiver of authorization per 45 CFR 164.512, *Uses and disclosures for which an authorization or opportunity to agree or object is not required*, specifically 45 CFR 164.512(i), *Uses and disclosures for research purposes*.

We are also aware of that we must provide to our patients, upon request, an accounting of disclosures of their PHI under a waiver of authorization per 45 CFR 164.528, *Accounting of disclosures of protected health information*.

This letter confirms that a waiver of authorization will be approved by our Privacy Officer for the project named above.

Sincerely,

Ruth Krueger MS, RHT, CHC
Ruth Krueger
Sanford Medical Center Privacy Officer

Sanford

1305 W 18TH ST
PO BOX 5039
SIOUX FALLS SD 57117-5039
Phone: (605) 333-1000
sanfordhealth.org

December 21, 2009

To the University of Iowa IRB 01:

This is to confirm that we agree to collaborate with the University of Iowa researcher on a research project entitled Outcomes of Heart Failure Discharge Instructions, conducted by University of Iowa graduate student Gwenneth A. Jensen. We agree to supply data sources for this project.

We are aware that the procedures used in this project involve the review of data from medical records for research purposes from patients at this institution. We are also aware that data will be abstracted from existing databases containing core measure information on heart failure. We know that the minimum of information necessary to the research will be collected from existing medical record and performance improvement databases at Sanford Medical Center from 2002 through 2009.

We understand that protected health information will be de-identified and that confidentiality and privacy of patient records will be maintained appropriately. Appropriate authorizations are in place according to HIPAA guidelines.

This letter confirms that we agree to provide agreed upon data sources to the researcher for the project entitled Outcomes of Heart Failure Discharge Instructions.

Sincerely,

Diana L Berkland

Diana Berkland RN, MS
Chief Nurse Executive/ VP of Patient Services

Sanford
1305 W 18TH ST
PO BOX 5039
SIOUX FALLS SD 57117-5039
Phone: (605) 333-1000
www.sanfordhealth.org

December 21, 2009

To the University of Iowa IRB 01:

This is to confirm that we agree to collaborate with the University of Iowa researcher on a research project entitled Outcomes of Heart Failure Discharge Instructions, conducted by University of Iowa graduate student Gwenneth A. Jensen.

We are aware that the procedures used in this project involve the review of medical records of adult patients for research purposes without authorization from patients at this institution. We know that the minimum of information necessary to the research will be collected from medical record and performance improvement databases, and that precautions are in place so that information will not be identifiable. The study is about select outcomes of heart failure discharge teaching.

We understand that any protected health information, such as names, addresses, social security numbers, medical record numbers, account numbers, birthdates, admission and discharge dates, that is abstracted from medical records for research purposes will be de-identified by recoding by the principal investigator and then deleted from the working database. Original identifiers will be secured on a separate file in a separate computer in a locked area on the Sanford Medical Center Campus, accessible only to the principal investigator. There will be no data transfer. Analysis will be done on inaccessible, password protected computers, and original identifiers will be deleted by the PI within 3 months after completion of the study.

Policies and procedures are in place to document our Privacy Officer's approval of a waiver of authorization per 45 CFR 164.512, *Uses and disclosures for which an authorization or opportunity to agree or object is not required*, specifically 45 CFR 164.512(i), *Uses and disclosures for research purposes*.

We are also aware of that we must provide to our patients, upon request, an accounting of disclosures of their PHI under a waiver of authorization per 45 CFR 164.528, *Accounting of disclosures of protected health information*.

This letter confirms that we agree to collaborate with the researcher and the project entitled Outcomes of Heart Failure Discharge Instructions.

Sincerely,

Diana L Berkland — Ruth Krueger MS, RRT, CHC

Diana Berkland RN, MS
Chief Nurse Executive/ VP of Patient Services

Ruth Krueger ~~MS~~, RRT, CHC
SMC Director of Compliance / Privacy Officer

APPENDIX D

ASSURANCE DOCUMENTATION

Gwenneth Jensen, BSN, MSN, RN
Outcomes of Heart Failure Discharge Instructions

Assurances

Principal Investigator (PI) - *As PI, I assure that:*

- I am ultimately responsible for the conduct of the study.
- I agree to comply with all applicable UI policies and procedures, and applicable federal, state and local laws.
- The application is consistent with proposal(s) submitted to external funding agencies.
- The research will only be performed by qualified personnel.
- All persons assisting with the research are adequately informed about the protocol and their research-related duties and functions.
- I will not implement any changes in the approved IRB application, study protocol, or informed consent process without prior IRB approval (except in an emergency, if necessary to safeguard the well-being of a human participant).
- If unavailable to conduct this research personally, as when on sabbatical leave, I will arrange for another investigator to assume direct responsibility for the study. Either this person is named as another investigator in this application, or I will notify the IRB of such arrangements.
- I will obtain Continuing Review approval prior to 12:01 am on the date the approval for the study expires. I understand if I fail to apply for continuing review, approval for the study will automatically expire, and all study activity must cease until IRB approval is granted.
- If protected health information is used or created as part of this research project, the research team agrees NOT to reuse or disclose the information to any other person or entity (beyond the named research team) except as required by law, for authorized oversight of the research project, or unless subsequent IRB approval is obtained for such reuse or disclosure.
- If members of the research team access protected health information from a covered component in order to seek consent/authorization for research, such access is necessary for the research, is solely for that purpose, and the information will not be removed from the covered component.
- Neither I nor any member of the research team has a significant financial interest, as defined by the University of Iowa Operations Manual, whereby the value of the interest to me or any member of the research team could be influenced by the outcome of the study.
- *EFFECTIVE 10/1/09* If the above stated research study has a plan to compensate the research subjects participating in this project, I acknowledge that our unit has a Cash Handling Procedure that has been approved by Accounting Services.
- I further assure that the proposed research is not currently being conducted and will not begin until IRB approval has been obtained.

Gwenneth G Jensen 12-21-09

Signature of Principal Investigator Date

Gwenneth A. Jensen

Printed Name of the Principal Investigator

DEO (Department Chair) - *My signature assures that the investigator:*

- Is qualified to conduct the research as described in this application.
- Has adequate resources, facilities, and numbers of qualified staff to conduct the research as described in this application.
- Has used sound study design consistent with the standards of the investigator's area of research.
- *EFFECTIVE 10/1/09* If the above stated research study has a plan to compensate the research subjects participating in this project, I acknowledge that our unit has a Cash Handling Procedure that has been approved by Accounting Services.
- Has available time to oversee and conduct this project.

Kelle Hern 12-16-09

Signature of DEO (Department Chair) Date

Printed Name of the (Department Chair)

Gwenneth Jensen, BSN, MSN, RN
Outcomes of Heart Failure Discharge Instructions

Faculty Supervisor (If PI is a student) The faculty sponsor must be a member of the UI faculty and is considered the responsible party for legal and ethical performance of the project.

As the faculty supervisor on this research application, I assure that:

- I will meet with the student investigator on a regular basis and monitor study progress.
- The student is knowledgeable about the regulations and policies governing research with human subjects and has sufficient training and experience to conduct this particular study in accord with the approved protocol.
- If I will be unavailable to supervise this research personally, as when on sabbatical leave, I will arrange for an alternate Faculty Supervisor to assume direct responsibility in my absence and I will advise the IRB by letter in advance of such arrangements.
- *EFFECTIVE 10/1/09* If the above stated research study has a plan to compensate the research subjects participating in this project, I acknowledge that our unit has a Cash Handling Procedure that has been approved by Accounting Services.

[signature] 12/16/09

Signature of Supervising Faculty Date

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