FACTORS ASSOCIATED WITH ALL-CAUSE REHOSPITALIZATION AND MORTALITY IN PATIENTS WITH HEART FAILURE

By

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Abstract

Background and Significance: Heart failure is diagnosed in over 5.7 million Americans. Despite substantial scientific advancements in the field of heart failure management this disease continues to be a primary cause of death in 50,000 patients and noted in the death findings of an additional 250,000 individuals annually. Over 6.5 million hospital days and over 668,000 emergency room visits. Depression is prevalent in over 20% of HF patients and in 45% of HF patients following an acute exacerbation of their disease.

Purposes: To explore the effect of reactive depression on all-cause rehospitalization and all-cause mortality in NYHA Class III and IV patients during the 12 month following an index hospitalization for HF exacerbation. The study aims were: (a) describe the effect of depression, (b) explain the variance of depression, and (c) determine the moderator effect of depression on patient preparedness to manage complex HF home care all-cause rehospitalization and/or all-cause mortality in HF patients.

Theoretical Framework: The Chronic Care Management Theory will guide the study.

Methods: Secondary Data Analysis of data obtained from the longitudinal NIH funded SMAC-HF trial.

Data Analysis: Descriptive statistics, logistic regression, and multiple linear regression analyses with and with/out interaction effects were performed to address the study purpose and aims.

Findings: Descriptive statistics, logistic regression, and multiple linear regression analyses with and with/out interaction effects were performed to address the study purpose and aims.

Discussion/Conclusion: Depression as measured by CES-D score greater than 16 has a significant relationship with all-cause rehospitalization p=.09 and all-cause rehospitalization and mortality p=.09. In this study, depression did not demonstrate a relationship with mortality alone. In addition, depression did not have an interaction effect between preparedness and all-cause rehospitalization and/or mortality. Screening for depression should be part of heart failure management. Management of depression may decrease rehospitalization in HF patients.

Acknowledgements

I am humbled and blessed to have had the support, encouragement, guidance, editing, and redirection from one of the most talented Dissertation Committee's a student could ask for. Dr. Smith's vision, expectations for excellence, and persistence have been instrumental to my success. She has been a mentor, teacher, colleague, and friend. I am so thankful that she agreed to chair my committee. Dr. Piamjariyakul's vast knowledge of the research process and ability to clarify concepts kept me on track on countless occasion. Dr. Ebbert's enthusiastic passion for clinical excellence and academic growth gave me the courage to enter and remain in this program. Dr. Wick, has been an amazingly patient and helpful throughout my odyssey into the world of statistics. Her ability to transform complex stats into knowledge that can be used by a novice such as I, is nothing short of miraculous. Dr. Ford's strong organizational and administrative knowledge has been a consistent source of wisdom throughout my entire nursing education.

I am also appreciative of the financial support from the Kansas Board of Regents and The University of Kansas Hospital.

To my family and friends: Thank you for believing in me, being patient while I studied at countless hours, carried around articles from birthday parties, movies, choir practice, and shopping and then returning them when I sat them down.

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Chapter I

Introduction

Over 5.7 million Americans are affected by heart failure (HF) (Hall et. al., 2012; Rogers, 2012). HF is taking a sizeable toll on the United States population both in the number of people impacted and also in the magnitude of expense required to treat those afflicted (American Heart Association(AHA), 2012). Annually, HF is the primary diagnosis for over 3 million physician office visits and 668,000 emergency room visits (Yancy, et. al., 2013; Hall et.al., 20012). Persons with heart failure seek outpatient care over 12 million times and have over 6.5 million hospital days (Hunt, 2009). Notably, depression is known to be a comorbidity in over 20 percent of patients with HF and in over 45 percent in patients with more severe decompensated HF (Joynt et. al, 2004). Thus, HF does not only exert a fiscal cost related to multiple health services and hospitalizations, but also carries the significant burden of patient depression (Wu et al, 2008; Joynt et. al, 2004; Jimenez, J. A., et al. (2012); Jiang et al, 2001, Kao et al, 2012).

Literature indicates that as symptoms of depression worsen, heart failure patients have poorer clinical outcomes (Sherwood, 2011). Reactive depression is a type of clinical depression triggered by a stressor in a person's life such as decline in health status, a death in the family, loss of a job, or a personal financial catastrophe (Davis, 1993 & Saunders, 2007). Reactive depression is related to the severe physical limitations, extreme fatigue, breathlessness, and poor social support in HF patients (Koenig, 1988; Luttik, et. al., 2005; Sarkur & Chen, 2012). Repeated multiple hospitalizations and depression is posited to lead to early mortality in HF patients (Ahmed et al., 2008). By determining moderator effects on HF, possibly depression or other relieving interventions can be part of the solution.

In this study, depression has been posited to increase all-cause rehospitalization and morbidity in patients with severe HF. The study examined the moderating effect of depression on all-cause rehospitalization and mortality in HF patients for 12 months following an index hospitalization for HF.

Research Questions

1. What effect does reactive depression have on all-cause rehospitalization and/or all-cause mortality in previously hospitalized heart failure (HF) patients during a 12-month follow up time period?
2. Controlling for demographic characteristics (race, gender, marital status, length of time of HF diagnosis, comorbidity index), what social (social support), financial (income adequacy), and preparedness for HF homecare characteristics explain the variance of reactive depression as measured by the CES-D in patients with HF?
3. Does reactive depression have a moderator effect on patient preparedness and/or all-cause rehospitalization and/or all-cause mortality in HF patients?

Secondary analysis research methods were used to address these research questions. The existing data set for the secondary analysis included over 200 patients who required hospitalization for severe HF and were followed across 12 months.

Background and Significance

Heart failure impacts one to two percent of the adult population in western cultures (Hunt, 2009, Rogers, 2012). Each year, over 550,000 new cases of heart failure will be diagnosed in the United States. Worsening symptoms are the primary cause for rehospitalization in heart failure patients. And often HF patients are admitted for other illnesses which then lead

these patients to also experience an HF exacerbation and increased length of an all-cause hospital stay (Heidenreich et al., 2011).

HF is a chronic disease that continues to increase in prevalence annually despite current advancements in pharmacological and therapeutic treatments. Each year, HF is listed as the primary cause of over 50,000 deaths and contributes to another 250,000 deaths in the United States (Heidenriech et al., 2011; Go et al., 2013). The cost for HF treatment is over $34.4 billion annually (AHA, 2012). These expenses are reflective of the severity of the illness and the impact that this disease has on the quality of life for the individuals who live with HF (AHA, 2012).

Depression is identified in 45% of patients with severe HF, the population in this study (Artinian, 2003; Faller, 2009; Gluck et al, 2003). In contrast, depression is reported in only 10% of the general U.S. adult population. Reactive depressive symptoms include a decreased interest in activities, unplanned change in weight, fatigue, concentration lapses, and low mood (APA, 2013).

Depression also impacts patients affect and their ability to attend to detail (Guck, et. al., 2003). Such decreases in mood and attention can lead to poor medication adherence (Dunus et. al., 2004). Patient adherence to medication and to their restricted fluid and salt intake are the primary cause of fluid retention (Jiang et al., 1999). Fluid retention leads to exacerbation of HF (Lichtman et al., 2008). Increased exacerbations of HF result in frequent hospitalization and death (Joseph et al., 2009). Depression may also interfere with HF patients engaging with their health care providers (Pozuelo, 2009).

Depressed patients are less able to engage in learning behaviors and may not retain discharge education. HF patients are at risk for recurrent HF exacerbation if they do not understand and implement recommended discharge plans (Evangelista, 2003; Phillips et al

2004). The value of patients understanding and receiving appropriate discharge planning was validated when The Joint Commission and Centers for Medicare & Medicaid Services included discharge planning as part of the HF ORYX® Core measures. ORYX Core measures are publicly reported data that all The Joint Commission participating hospitals must measure and track (The Joint Commission, 2013).

Providing patients with discharge instructions is the act of a proactive provider promoting patient preparedness. Currently hospitals only measure the act of giving the instructions, not the effectiveness of those instructions. The effectiveness of that interaction is manifested in the patient's preparedness (Archbold et al, 1990). In addition, nurse practitioners led the nation in developing a policy recommendation that all cardiac patients, including those with HF, be screened for symptoms of depression. This has now become standard practice over the last 5 years (Lichtman, Bigger, Blumenthal et al., 2008).

Statement of the Problem

As symptoms of depression worsen, HF patients, in all New York Heart Association HF Classifications I-IV (NYHA, HF III-IV) have poorer clinical outcomes (Sherwood, 2011). This study will address links between depression and all-cause rehospitalization and/or mortality in the very sickest HF patients with severe impairments (NYHA, HF III-IV). Depressed HF patients are more likely to have additional medical illnesses and severe functional impairment (Freedland & Carney, 2003). Paukert et al., (2009) found depressive symptoms were significantly associated with physical limitations from HF. A study by Atlantis et al, found that depression co-occurs with chronic disease and poor functional health (Atlantis et al, 2011). Functional impairment is a major symptom in HF (NYHA, HF Class III-IV, but not in nondepressed or HF patients in NYHA Class I-II (Koenig, 1998). The additional medical illnesses and the functional

impairments lead to additional hospitalizations. A study by Macabasco-O'Connell found men have worse health perceptions and more depressive symptoms. In addition, low-income patients have poor health perception and more depressive symptoms. As a result, gender and income adequacy ratings will be included in this study (Macabasco-O'Connell, 2010).

Understanding the modifying effect of depression on HF is necessary to develop effective interventions to reduce these individual patient costs and improve clinical outcomes of rehospitalization and mortality. These studies support the concept that depression moderates the relationship between preparedness and HF outcomes.

Study Purpose

The purpose of this study is to explore the effect of reactive depression on all-cause rehospitalization and mortality in NYHA Class III and IV patients during the 12 months following an index hospitalization for HF exacerbation.

Additional understanding of reactive depression in HF patients can lead to better management of the disease. Disease management of HF and depression is based also on professional delivery of services. An empirically-verified theoretical framework that joins both professional and individual patient factors relative to clinical outcomes is the chronic care model.

Theoretical Framework for Improving Chronic Care Delivery Systems and HF Patient Self-Management

The Chronic Care Model (CCM) is illustrated in figure 1 (Bodenheimer et. al, 2002, Coleman et. al, 2009;). CCM uses community resources and organizes the Health Care System to support patient self-management and, as the circles at the bottom of the figure illustrate, promotes productive interactions between an 'informed, activated patient' and a 'prepared, proactive practice team.' Thus, CCM is a health systems model. Wagner and colleagues

validated this model in 1998 and, again in 2003, conducted extensive reviews during which they identified elements common to successful disease management programs. Additional validation of CCM has been conducted by researchers unaffiliated to Wagner (Drewes et al., 2012). The goal of the CCM model is quality patient outcomes guided by well-prepared practice teams providing services to engaged activated patients (Arkansas.gov, 2011). However, if the patient is not engaged due to depression; clinical outcomes suffer.

The CCM model is a systems level model that depicts a comprehensive perspective on health services needed to engage the chronically ill patients in their own care. There is limited information on how to use this systems level model at the individual patient level. This study provides a conceptual model based on the foundations of the CCM at the patient level to evaluate individual HF patient outcomes. Thus, this study will extend the information on how a systems level perspective intersects individual patients. Therefore, CCM was used as a foundation for designing the conceptual framework that guides this study.

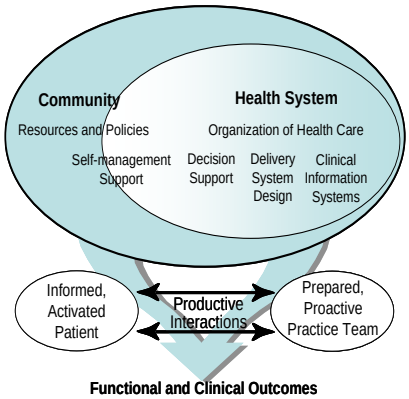


Figure 1. The Chronic Care Model
From: Wagner EH. Eff Clin Prac. 1998; 1(1):2-4

Conceptual Framework Guiding This Study

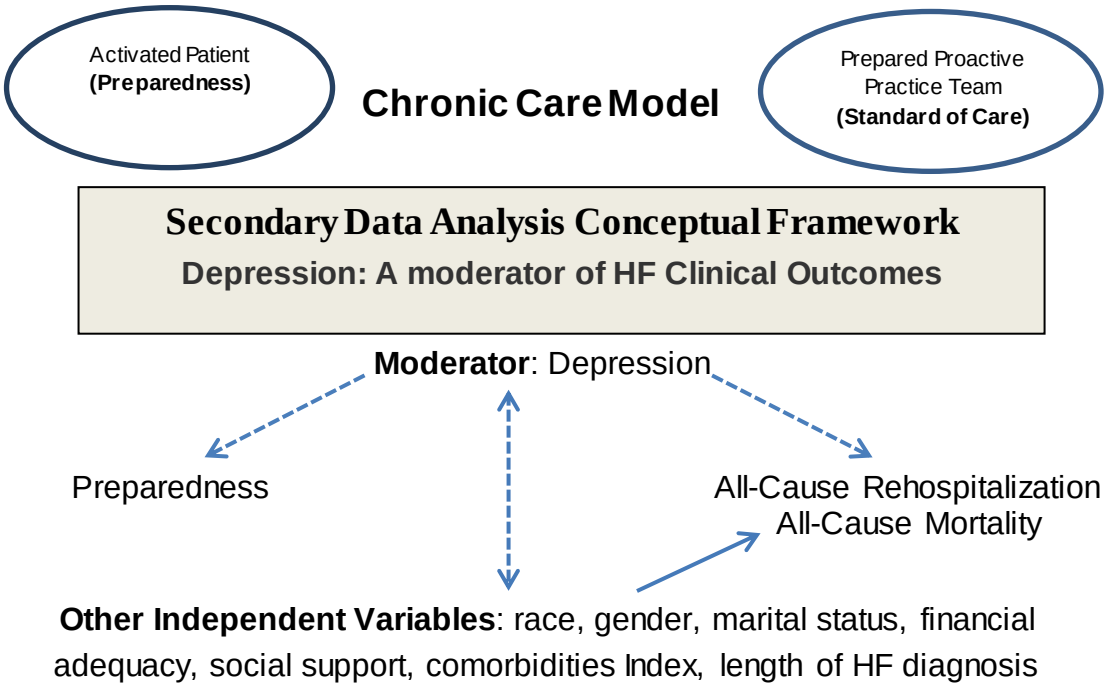
The two circles at the bottom of the CCM are key components of the conceptual framework that guides this research from the system level to individual patient factors that impact clinical outcomes (Figure 1). The Prepared Proactive Practice Team (bottom right hand circle) was operationalized in this study as the standard of care provided to the patients at the academic medical center where data was collected. The bottom left hand circle in the CCM

(Figure 1) indicates a patient must be informed and activated (or engaged in their own care). Yet, depression is known to decrease engagement and impedes learning or being informed.

The conceptual model guiding this study is at the patient level where depression is posited to have a moderator effect on a patient's preparedness, possibly decreasing his/her ability to be informed, activated or engaged; which in turn results in increased rehospitalization and mortality (Figure 2).

Figure 2.

Secondary Analysis Conceptual Framework Aligned with CCM Patient Level Factors Testing Depression as a Moderator of Clinical Outcomes



In Figure 2, dashed arrows reflect research questions being tested in this secondary analysis. The unidirectional dashed arrow on the left of the figure represents the moderator effect of depression on preparedness. The unidirectional dashed arrow on the right of the figure

represents the moderator effect of depression on all-cause rehospitalization and mortality. The solid arrow represents known factors that influence the HF outcomes in this study. The bi-directional dashed arrow demonstrates the interaction effect that depression may have on the other independent variables that are being evaluated in this study. Thus, this study tests the moderating effects of depression on preparedness and outcomes. In addition, this study tests the relationship and degree of variability of reactive depression in HF patients and the other independent variables.

Definition of Terms

The following terms provide the operational definitions of the major concepts in this study. Operational definitions of how each of the following was measured are reviewed in Chapter 2 and described in detail in Chapter 3.

Reactive Depression: a type of clinical depression triggered by a stressor in a person's life (Saunders, 2007). This study evaluates reactive depression at the time of an acute hospitalization for HF. Reactive depression is measured as feelings of fatigue, sleep disturbance, mood disturbance, and decreased attention to detail (Winokur & Pitts, 1964). The American Psychiatric Association defines depression as a person experiencing five or more depressive symptoms for a continuous period of at least two weeks (APA, 2013). Reactive depression will be measured by The Center for Epidemiologic Studies Depression Scale (CES-D). The CESD-10 and revised versions have been demonstrated as effective screening tools in the general population and in persons with chronic disease (Van Dam & Earleywine, 2012; Nishiyama, et al., 2009)

All-cause Hospital Rehospitalization: according to Center for Medicare and Medicaid Services, "an admission to a subsection (d) hospital within 30 days of a discharge from the same or another subsection (d) hospital" (Quality Net, 2012). For the purpose of this study,

rehospitalization will include any admission to an inpatient acute care hospital from index hospital across 12 months. Rehospitalization data was obtained from all patient medical records as part of the original study.

All-cause Mortality: Will be measured as death of the participating patient for any reason after the index hospitalization. Mortality was assessed by hospital records, search of obituaries as well as death records, national death records, and/or contact with the designated contact person for the participant.

Index Hospitalization: The hospitalization where the patient was admitted for HF exacerbation met the inclusion criteria of NYHA Class II-IV and enrolled in the original study. The 12 months of follow-up began at the Index hospitalization.

Assumptions

1. The data collected was obtained as described in the original study research protocols.
2. Medical review with physician adjudication is a reliable measure for all-cause rehospitalization.
3. The National Death Registry provides an accurate record for all-cause mortality.
4. Prepared proactive professionals did provide standard care to the patient in the original study. It is assumed that all patients received standard of care per HF national clinical guidelines as stipulated at the setting of the original study.
5. Data instruments accurately measure major variables in this study.
6. Results will be limited to academic medical center populations of very sick patients.

Summary

HF is a chronic illness that impacts a significant portion of the U.S. population. HF is associated with increased morbidity, mortality, rehospitalization, and increased utilization of

healthcare resources. Depression has been shown to influence rehospitalization and/or mortality in HF patients. The Chronic Care Model (Figure 1) is a validated systems level model that provides a framework for interventions for chronic illnesses, such as HF. A modified conceptual model (Figure 2) was derived from the CCM at the patient level to evaluate individual HF patient outcomes. Thus, this study will extend the information on how a systems level perspective intersects with individual patients.

At the patient level, depression is prevalent in those with HF. Depression is posited to have a moderator effect on patient's preparedness, possibly decreasing their ability to be informed, activated or engaged; which in turn results in increased rehospitalization and mortality (Figure 2). This secondary analysis study uses a descriptive correlational design to answer the research questions. The descriptive correlational design provides a format to describe baseline data and the relationships among the variables. Logistic regression, multiple regression, and multiple regression with interaction terms will be utilized to conduct the data analysis on all-cause rehospitalization and mortality.

Chapter II

Introduction

The Review of Literature Chapter introduces and reviews the major concepts under study and provides their definitions. It includes the state of science regarding depression in chronic illness and heart failure and provides a rationale for the research questions and the selected data analysis plan.

Review of the Literature

The review of literature was conducted using a step-wise method to search the literature and retrieve the relevant articles. The literature was searched using key words related to this study. Key words searched included "heart failure prevalence," "heart failure outcomes," "depression," "heart failure," and "preparedness." The articles were then reviewed to identify reference to heart failure patients only. Databases included in the search were: CINAHL, PubMed, PsycINFO, and Google Scholar. Article relevance was determined based on reviewing the titles and the abstract. An overview of depression and chronic illness will be presented, statement of the problem, and a review of the main concepts.

Depression and Chronic Illnesses

Depression is commonly associated with individuals that have chronic diseases. There is a need for further investigation into the role and prevalence of depression in influencing rehospitalization outcomes of individuals with chronic disease. As increased pressure is placed on hospitals to improve the outcomes of patients with heart failure, understanding the role of depression related to rehospitalization is imperative. Individuals with chronic disease may experience any form of depression. Interventions must be designed to assess and treat the specific type of depression the individual is experiencing. Effective management of depression

in older adults first starts with effective assessment. Prompt diagnosis and treatment of depression has been shown to improve patients' quality of life (Hardy, 2013).

There are numerous studies supporting the concept that depression impacts clinical outcomes. For example, a longitudinal retrospective chart review of 1128 patients found that individuals with higher severity of depression scores were less likely to achieve disease remission at 6 months. Severely depressed patients were 29.6% more likely to reach disease remission when compared to moderately depressed patients at 45.6%. In addition it was identified that patients who were unremitted at 6 months, depression increased significantly as measured by PHQ-9 (Angstman, K. B., et al.,2012).

A study by Asuka at al., of 74 patients with COPD identified the prevalence of using the Center for Epidemiologic Studies Depression scale (CES-D). Depression was evident in 48.6% of the participants. The researchers found a greater impairment in respiratory function in patients with depression as indicated on the Modified Medical Research Council dyspnea scale and the St. Georges Respiratory Questionnaire (SGRQ). The researchers also found that a positive correlation existed between depression and BODE index (Asuka et al., 2013). BODE index includes body mass index, degree of air-flow obstruction, dyspnea, and exercise capacity.

A cross-sectional observational study of 1250 patients from 75 primary care practices found that younger, more educated patients achieve higher Patient Assessment of Chronic Illness (PACIC) scores in Chronic Care Model based programs (Rosemann, Laux, Szecsenyi, & Grol, 2008).

Statement of the Problem

Over 5.1 million Americans are diagnosed with Heart Failure (HF) (NHLBI, 2012, Rogers, 2012). HF is listed as the primary cause of over 50,000 deaths and contributes to

another 250,000 deaths in the United States (Go et al, 2013). In the U.S. depression is found in over 20 million persons (NIH, 2012). Depression has been found in 21% of HF patients (Rutledge et al., 2006). As symptoms of depression worsen in HF patients, they also have poorer clinical outcomes (Heidenreich, 2010; Sherwood, 2011; Son, 2009; Trivedi, 2007). Current cost for HF treatment is over $34.8 billion annually (AHA, 2012). Understanding the modifying effect of depression on HF is necessary to develop effective interventions. This increased understanding can lead to a reduction of individual patient costs and improve clinical outcomes of rehospitalization and mortality. Currently, though, there is insufficient research explaining how depression impacts HF outcomes.

Review of the Main Concepts

Definition of HF

Heart failure is a complex clinical disorder that results from the inability of the heart to meet the oxygen demands of the body. Oxygen demand is in constant flux and varies greatly depending on patients' responses to multiple stimuli, creating constant variability in the patients' conditions. Evaluation of the heart's ability to respond to increased oxygen demand is measured by cardiac output. Cardiac output, modified by heart rate, contractility, preload, and afterload, is influenced by multiple systems that contribute to the complex nature of heart failure. There are structural, neuro-hormonal, conduction, and inflammatory mechanisms that contribute to responses to changes in oxygen demand. Heart failure may result from failure of a system or from a combination of two or more system responses (Hunt, 2009).

Diagnosis & Staging of HF

The diagnosis of heart failure is dependent on the clinical picture, a thorough history, and physical examination. Currently, there is no gold standard diagnostic test or definitive biomarker

to judge the confirmation or severity of this condition, but there is the ability to stage HF. A staging system is used to assist with treatment decisions in heart failure. The commonly used New York Heart Association (NYHA) functional classification system consists of four classes of patient symptoms related to everyday activities and quality of life. This is a subjective classification system, and providers need to be aware of potential inconsistencies among themselves. By knowing the stages of HF, nurses can understand patients' functional limitations and can also direct nursing care based on those limitations. It provides a baseline for measuring progress and deterioration. The four stages of the NYHA classification system (AHA, 2013) are:

- Class I (Mild): Patients are symptom-free and have no limitation to physical activity or everyday physical activity does not cause dyspnea, palpitations, or fatigue.
- Class II (Mild): Patients have slight limitation in physical activity. They are generally comfortable or asymptomatic at rest, but ordinary physical activity results in fatigue, dyspnea, or palpitations.
- Class III (Moderate): Patients have marked limitation in physical activity. Patients are asymptomatic at rest, but less than ordinary activity results in fatigue, dyspnea, or palpitations.
- Class IV (Severe): Patients are unable to perform any activity without symptoms. They are symptomatic even at rest and symptoms become severe with progression of activity.

Depression

Depression continues to be a prominent affliction for many individuals. In the United States, it is estimated that 1 in 10 individuals have depression (CDC, 2013). The high impact of depression on humanity keeps researchers and scholars studying this phenomenon with the hopes of making a difference, providing healing, and higher quality of life. A recent CINAHL search

of the term depression yielded 75,622 unique findings, demonstrating the high degree of scholarly interest in this area.

The following review of the literature will identify what is known about depression in general as well as the body of knowledge involving depression in chronic diseases, specifically related to heart failure.

Definitions of Depression

The American Psychiatric Association defines depression as a person experiencing five or more depressive symptoms for a continuous period of at least two weeks (APA, 2013). The National Institute of Mental Health identifies that there are 3 primary types of depression: Major Depression, Minor Depression, and Bipolar Depression (NIMH, 2009).

Major Depression is identified when symptoms of chronically sad mood, loss of pleasure in activities, or sleep and appetite disturbance take place. In addition, it can include changes in energy level, excessive guilt, and low self-esteem (NIMH, 2009).

Minor Depression is diagnosed by identifying a mood disturbance or loss of pleasure along with at least two but less than five of the other major depressive disorder symptoms. Symptoms include rapid weight change without cause, insomnia or hypersomnia, daily fatigue, inappropriate guilt, poor concentration, and thoughts of death without intent or plan to commit suicide. Minor depression is episodic and symptoms should not impair activities of daily living (NIMH, 2009).

Bipolar Depression, also known as manic-depressive illness, is a brain disorder that causes unusual shifts in mood, energy, activity levels, and the ability to carry out day-to-day tasks. Symptoms of bipolar disorder are severe. They are different from the normal ups and downs that everyone experiences from time to time (NIMH, 2009).

This study evaluates reactive depression at the time of an acute hospitalization for HF. Reactive or situational depression is defined as a "mental depression usually self-limiting, following severe life disappointments such as a death in the family, loss of a job, or a personal financial catastrophe" (Davis, 1993, p. 520). It is a type of clinical depression triggered by a stressor in a person's life (Saunders, 2007). Reactive depression is measured as feelings of fatigue, sleep disturbance, mood disturbance, and decreased attention to detail (Winokur & Pitts, 1964). The Center for Epidemiologic Studies Depression Scale (CES-D) and revised versions have been demonstrated as effective screening tools in the general population and in persons with chronic disease (Van Dam & Earleywine, 2012; Nishiyama, et al., 2009)

There is a high prevalence of HF. The high prevalence and significance of HF and depression will be fully explored in the review of literature below.

Depression in Patients with HF

A meta-analysis of 27 studies identified that 21% of patients with HF had clinically significant depression (Rutledge et al, 2006). A study of 6730 patients by Caughey et.al found over 97% of heart failure patients had at least one co-morbid condition. Included in that 97%, 55% of them had three or more co-morbid conditions, including depression (Caughey, Roughead, Shakib, Vitry, & Gilbert, 2011). In a study of 155 hospitalized patients with HF, 49% had depressive symptoms (Parissis et al., 2008).

A literature review conducted by Joynt, Whellen, and O'Conner found that depression is four to five times as common in HF patients as in the general population (Joynt, Whellan, & O'Connor, 2004). McGowan found that depression is clearly identified in the literature as a comorbid condition in HF patients but continues to not be a part of treatment guidelines (McGowan, 2013).

A study by Polikandrioti et al, 2010, found most of the HF patients they screened had some degree of depression. Women, age over 60, retired, NYHA Class II or III, and HF diagnosis longer than 1 year had higher levels of depression (Polikandrioti et al, 2010). The prevalence of depression in HF is clearly supported in the literature. Knowledge is increasing about the pathophysiology between the two diagnoses.

Pathophysiological factors between depression and HF

The link between depression and heart failure may not be situational alone. Silver identified that there are similarities in the pathophysiologic mechanisms between the conditions (Silver, 2010). Both heart failure and depression have modified autonomic nervous system function, such as increased sympathetic stimulation and decreased parasympathetic response (Koschke et. al, 2009). Inflammatory processes such as Tumor Necrosis Factor, C-reactive protein and Interleukin-6 are found in both depression and heart failure. Inflammation in heart failure patients is known to further impact cardiac contractility, leading to disease progression and worsening symptom burden (Johansson et. al, 2011; Kumar et. al, 2007; Andrei et. al, 2007; Kupper et. al, 2012).

A study of 180 patients by Parissis et al., found that serum prolactin is an independent predictor of prognosis (death or hospitalization) in heart failure (<4.5 vs. ≥ 4.5 ng/mL; odds ratio, 0.368; 95% confidence interval 0.148-0.913; $p = 0.031$). Serum prolactin is also associated with neurohormonal activation and depressive symptoms (Parissis et. al, 2013).

In addition, depressive symptoms are associated with decreased heart rate variability, a major cause of HF exacerbation (Guinjoan, 2007). Low heart rate variability, a modified autonomic response, may also be a contributing factor to poor exercise tolerance in HF patients, a major intervention that maintains heart strength.

The high prevalence of depression in HF patients and the supporting pathophysiological changes provide a basis for understanding the relationship between depression and HF on clinical outcomes.

What is Known about HF and Depression on Clinical Outcomes?

The impact of depression on heart failure patients exceeds beyond the psychosocial and emotional toll expected into physiologic burden as well. Worsening depression symptoms were found to be explanatory risk factors for adverse clinical outcomes in HF patients, independent of HF disease severity (Sherwood et al., 2011). In a retrospective study of community HF patients, patients with depression were found to use more services and had higher costs than HF patients that were not depressed (Gary et al., 2004).

A study of thirty-six HF patients that were referred for outpatient palliative care consultation after discharge showed improvements in symptom burden, depression, and QOL in both groups (Evangelista et al., 2012). Poor quality of life, social isolation, depression, and anxiety all have been linked to increased risk of rehospitalization and mortality in patients with heart failure (Moser, 2002).

HF Rehospitalization and Depression

The Heart Failure Adherence and Retention Trial (HART) a randomized behavioral trial found depressed HF patients were hospitalized for HF 1.45 times more often than non-depressed HF patients. Depression was measured with the Geriatric Depression Scale in this study. A score of greater than 10 was used as an indicator for depression (Johnson et. al, 2012).

Depression is a major factor influencing rehospitalization among HF Patients (Son, 2009; Trivedi, 2007). Characteristics of depression include poor attention to detail which often results

in missing symptoms that should be reported to the health care providers. Other characteristics include feelings of worthlessness that lead to non-adherence to prescribed exercise and medication, plus lack of sleep which decreases the immune system (Bryant, 2004; Cacioppo et al., 2003; Phillips et al, 2005; Liss et al, 2008; Kiloh & Garsid, 1977).

The depressive mechanism that leads to non-adherence is complex. Increased depressive symptoms were linked to carelessness in medication compliance (Cholowski & Cantwell, 2007) as depression alters the desire and the ability to perform tasks such as medication scheduling. Most HF patients have an average of 12 medications to take at varying times throughout a day. Depression can interfere with effective self-implementation of this medication schedule (Krumholz, 2013). In addition, depressive symptoms are associated with decreased heart rate variability, a major cause of HF exacerbation (Guinjoan, 2007). Low heart rate variability, a modified autonomic response, also may be a contributing factor to poor exercise tolerance in HF patients, a major intervention that maintains heart strength.

Depression results in frontal lobe dysfunction which controls dependent executive tasks (Fassati et.al, 2002), including planning and execution of complex actions, abstract reasoning, language and expression (National Academy of Neuropsychology, 2000). Additional research with HF patients shows medial temporal lobe atrophy was related to cognitive dysfunction involving memory impairment whereas white matter hyper-intensities was related to depression and anxiety (Vogels et al, 2007). The neurologic impacts of both HF and depression further decrease the patient's ability to engage in proactive self-care.

HF Mortality and Depression

Mortality is also influenced by depression. A study of 2711 HF patients found patient depressive symptoms were a significant predictor of mortality (Brummet, 2005). Brummet also

found that social support, smoking, sedentary behavior, and depressive symptoms were significant predictors of mortality. Sedentary behavior, a common area of concern in depression, was found to interfere with support and mortality. In Brummet's study, smoking status and depressive symptoms did not interfere with the relationship between support and mortality (Brummet, 2005).

In other research, all-cause mortality in HF patients was predicted in the presence of high somatic/affective depressive symptoms (Confidence Interval, 1.03-3.07; $P = .04$), while cognitive/affective and total depressive symptoms did not (Schiffer et al, 2009). Lee et al, 2012 studied the predictability of depression on cardiac event-free survival. Cardiac event-free survival data included: cardiac death, cardiac hospitalization, or cardiac emergency department visit. Depression predicted time to the first cardiac event (hazard ratio = 1.12, 95% confidence interval = 1.03-1.22) (Lee et al, 2009).

Other Independent Variables and Depression

The literature also indicates there are other independent variables and is posited to impact all-cause outcomes in HF patients. The independent variables selected for review are: preparedness, financial adequacy, social support, comorbidity index, and demographics (race, gender, marital status, and length of HF diagnosis).

Preparedness

Preparedness is operationally defined as the ability to manage HF homecare which is related to information in which the patient must engage to learn (Archbold et al., 1990). Preparedness is a concept first identified by nurse researchers who observed elderly persons challenged with complex home care (Khunti et al., 2002). Those elders who were able

to perceive their ability to manage at home talked about feeling "prepared" which gave them confidence and skills to master the complexity of home care.

These components were placed into a qualitative instrument, with reliability and validity determined (Khunti et al., 2002). Others have used the instrument and its simpler concise form, a one item instrument that asks the person to rate how well prepared they feel to manage HF home care (Smith, 2005). It has been identified that low preparedness scores are correlated with increased re-hospitalization (Henriksson et al. 2012).

Although not extensive, the instrument is consistently found easy to administer and reliable. There is no known case of this measure being used in relationship to the outcomes of all-cause mortality. Use in this study will generate new knowledge.

Financial Adequacy

Also financial adequacy is an important aspect of HF management because the monthly HF medications often run up to $800 (Smith et al., 2006). Thus, reports frequently occur of patients stopping their medications due to cost. A study of thirty-two women with HF found that lower socioeconomic status and advancing age increase vulnerability for poor self-care and negative clinical outcomes (Gary, 2006). Income has been shown to impact clinical outcomes such as when patients are not able to comply with expensive medication regimens (Jencks, 2000; Joynt et al, 2011). A study of 265 heart failure patients found that perceived sufficiency of income was one of six variables that were significant independent predictors of Overall Perceived Health (Carolson, 2013).

Social Support

A study by Huang found that perceived social support had a moderator effect on New York Heart Association Classification System and level of dyspnea in HF ($B = 0.08$, $t = 2.15$)

(Huang, 2013). Friedmand found, in 103 heart failure patients, that the social support amount had contributed to changes in depression (P = .044). Depression increased over time for patients who had lower baseline social support amounts. In contrast, depression did not increase for those with higher initial social support amount (Friedmand, 2013). Koenig identified social support as a significant predictor of depression that impacts mortality in HF patients (Koenig, 1998). Marital status, which is seen as a presumable form of social support, impacts mortality in HF patients, as well (Chung et al, 2009; Park et al, 2011). Depression was found to be associated with a higher risk of noncompliance and lower levels of social support. Depression was also found to be an independent predictive of poor clinical outcomes (Joynt et al., 2004).

Comorbidity

Comorbidity is well known to increase the risk of hospitalization and mortality. The presence of multiple diseases and the resulting medical management complicates the treatment options for patients. The comorbidity Index is a useful tool for subscribing comorbidity risk to a patient. Saver et al., (2012) found that comorbidity (congestive heart failure, chronic obstructive pulmonary disease, diabetes, and hypertension) is predictive of hospitalization.

A study of 211 patients found that patients hospitalized for an acute cardiac event had at least one major geriatric syndrome including: frailty, cognitive impairment, severe dependence and depression present on admission. (Sánchez, Vidán, Serra, Fernández-Avilés, & Bueno, 2011). Ajmera et al., found that co-morbidity with or with out mental illness has an independent and significant association with any hospitalization. However, presence of mental illness alone was not associated with hospitalization (Ajmera et al., 2012).

Demographic (Race, Gender, Length of HF diagnosis)

In addition to considering the comorbidity impact, the individual patient demographics can influence the patients' prognosis. Lastly, some demographic variables have been associated with depression, including race and length of HF diagnosis. Gottlieb at al., studied depression in HF patients (NYHA Class II, III, & IV). A total of 48% of the patients scored as depressed. The Beck Depression Inventory (BDI) was used to evaluate for depression in this study, a score of 10 or more was defined as depression in Gottlieb's study. Gottlieb found that depressed patients tended to be younger, more likely to be women (64%), and Caucasian (54%). Ejection fraction and treatment was similar in both groups (Gottlieb et al., 2004). HF patients of African American descent have been found to have increased mortality and have earlier disease onset (LaVeist et al., 2009).

Length of HF diagnosis is correlated with increased frequency of hospitalization (Au et al, 2012). Length of diagnosis of heart failure has been shown to impact mortality. Fifty percent of patients that have HF and are Medicare beneficiaries are not expected to live 3 years of after an HF exacerbation hospitalization (Barker et. al, 2006).

The study design was selected to allow a comprehensive analysis of the research questions. In addition, it was necessary to select statistical analysis that was within the scope of knowledge of the researcher. Both the study design and analysis plan is crafted to address the aims of the study.

Overview of Design

Secondary Analysis is a research process that utilizes data from a previous study. As a result, the new research is conducted on data already collected and does not include primary data collection (Kiecolt & Nathan, 1985). In secondary analysis, the researcher does not collect that data, but she/he must be fully versed in how, when, and why the data was obtained and how this

data can address the secondary research questions (Cook, 1974; Nicoll & Beyea, 1999; Glass, 1976; Rew et al,. 2000). Secondary data analysis is a cost-effective and time-efficient research method that can maximize the knowledge potential of a study beyond the initial principal aims (Castle, 2003). This form of research can be useful for beginning researchers as they are able to gain experience in data analysis and interpretation (Herron, 1989; Miles & O'Sullivan; Rew et. al, 2000). Secondary analyses are also beneficial for further hypothesis generation (Kiecolt & Nathan, 1985).

Moderator Effect

A moderator effect occurs when the impact of one independent variable depends on the value of another independent variable (Aiken & West, 1991; Fairchild & MacKinnon, 2008; Lewis-Beck, 1980, MacKinnon et al., 2000). Moderator effects serve as a third variable that interacts with the relationship of other variables (Baron & Kenny, 1986). When a moderator effect is present the value of the outcome variable depends on the value of the moderator variable (Cohen & Cohen, 1983). The presence and/or evaluation for moderator effect in research allow a more precise consideration of the relationship between the variables (Bennett, 2000). In this study much is known about the individual variables, but little is known about "when" they relate to each other.

Many of the independent variables selected for this study (depression, social support, comorbidities index, and preparedness to manage HF homecare) have been found in the literature to be associated with hospitalizations and mortality in HF patients. Also, these selected variables are known to be associated with depression (Alosko, 2012; Barnes, 2008; Heo et al, 2008; Loeb et al, 2012; Park et al, 2006; Reschke, 2001; Vaccarino, 2008). However, there is no known

study of preparedness for HF home care relative to all-cause outcomes and the potential moderator effects of depression.

Variable selection for moderator effect should be based a robust conceptual model should be incorporated into the study design. The conceptual model for this study was created based on the premises of the Chronic Care Model.

CCM in the Literature as a framework for Depression and Heart Failure

The Chronic Care Model (as shown in Figure 1, Chapter I) is used as a foundation for chronic disease management for conditions such as diabetes, heart failure, and asthma. However, depression care receives less attention as a primary area of focus in chronic care management (Zafar & Mojtabai, 2011). A meta-analysis of research between 1998-2005 that contained 1 or more elements of the CCM for asthma, congestive heart failure (CHF), depression, and diabetes found that interventions that contain at least one CCM element improved clinical outcomes (Tsai, Morton, Mangione, & Keeler, 2005).

A study of 628 home care patients showed improved self-care behaviors, knowledge, and clinical outcomes when home health nurses used computer based reminders as part of the program of care (Feldman, Murtaugh, Pezzin, McDonald, & Peng, 2005). A study by Solberg and colleagues demonstrated that implementation of CCM based programs resulted in quality improvements (Solberg et al., 2006). A meta-analysis of 112 studies found that interventions that contain at least 1 CCM element improved clinical outcomes and processes of care patients with chronic illnesses (Tsai et al., 2005). The Chronic Care Model was used to develop collaborative care interventions to provide depression care to 55 Latina patients with cancer and depression. The patients that received treatments based on CCM principles had improved

outcomes than standard of care, noting a 2.15 increase in emotional well-being scores (Johnson, Ell, & Lee, 2005).

A modified model is proposed where depression impacts a patient's self-management effectiveness decreasing their ability to be an informed, activated patient, which in turn results in poorer clinical outcomes such as rehospitalization and mortality (Figure 2). The value and efficacy of CCM based programs is apparent in the literature. The challenge is it's a systems level model. The CCM model is a systems level model that allows a comprehensive perspective on how to engage the heart failure population. There is limited information on how to take this systems level model to the individual patient level. A qualitative study by Jeffs et. al, (2013) identified that nurses expect research to be applied at the practice level. Creating a conceptual model that is founded in the principles of the CCM but at the patient level will bring this valuable conceptual model to the bedside to evaluate individual HF patient outcomes and interventions.

Summary

The review of the literature demonstrates that depression and HF have a significant impact on the U.S. population. Limited research exists about the interaction of preparedness on depression and the clinical outcomes of HF patients.

Chapter III

Methodology

This chapter includes a description of the study design, sample, setting, procedures, measures, and data analysis. The chapter also addresses details of the original clinical trial including the setting from which data for this study was drawn. Finally, the chapter discusses ethical considerations as well as limitations.

Research Questions

1. What effect does reactive depression have on all-cause hospital rehospitalization and/or all-cause mortality in previously hospitalized heart failure (HF) patients during a 12-month follow up time period?
2. Controlling for demographic characteristics (race, gender, marital status, length of time of HF diagnosis, comorbidity index), what social (social support,), financial (income adequacy), and patient preparedness for HF homecare characteristics explain the variance of reactive depression as measured by the CES-D in patients with HF?
3. Does reactive depression have a moderator effect on patient preparedness and/or all-cause rehospitalization and/or all-cause hospital mortality in HF patients?

Overview of Design

Secondary Analysis is a research process that utilizes data from a previous study. In this study, a secondary analysis will be conducted on data from the "HF Group Clinic Appointments: Rehospitalization Prevention Clinical Trial." This National Institute of Health grant R01 HL085397 from the Heart, Lung, and Blood Institute was referred to as self-management and care of HF (SMAC-HF). The trial was a randomized longitudinal experimental study conducted to examine the impact of group clinic visits on patients' HF related re-hospitalization or death.

The SMAC-HF dataset includes data elements collected across 12 months from 198 patients with HF. The primary aims of the SMAC study have been met, but additional knowledge can still be harvested from this dataset as all-cause rehospitalization and mortality was not studied in SMAC-HF trial.

Secondary analysis is an extension of data sharing where research data is made available to other researchers for further exploration to address new research questions (Bullock, 2007; Glass, 1976; Leske, 1990; Vogt, 2005). As a result, the new research is conducted on data already collected and does not include primary data collection (Kiecolt & Nathan, 1985). In secondary analysis, the researcher does not collect that data, but she/he must be fully versed in how, when, and why the data were obtained and how the data can address the secondary research questions (Cook, 1974; Nicoll & Beyea, 1999; Glass, 1976; Rew et al,. 2000). Secondary data analysis is a cost-effective and time-efficient research method that can maximize the knowledge potential of a study beyond the initial principal aims (Castle, 2003). This form of research can be useful for beginning researchers as they are able to gain experience in data analysis and interpretation (Herron, 1989; Miles & O'Sullivan; Rew et. al, 2000). Secondary analyses are also beneficial for further hypothesis generation (Kiecolt & Nathan, 1985).

Secondary Analysis Study Design

In this secondary study, a descriptive correlational design will be used to answer the research questions. This descriptive correlational design provides a format to describe baseline data and the subsequent linear relationships among the selected variables (Burns & Groves, 2001; Polit & Beck, 2010). This design is suitable to address the new research questions from the original dataset through this examination of relationships, identification of explained variance, and determination of the linear effects among selected variables.

In this original study, outcome variables of all-cause rehospitalization and mortality were collected across 12 months. But, the other variables used come from the baseline prior to any intervention. Per statistical advice, one variable may be created that codes patients as control or experimental.

Secondary Descriptive Analysis

An advantage of the secondary analysis is the new description of the data selected to address the research questions that will be reported. A report of the raw data frequencies, central tendencies, and outliers will be generated. This report will provide new knowledge on the secondary analysis variables including the frequency of all-cause rehospitalization (which has not been described elsewhere). Subsequently, there will be a raw data description and the statistical data analysis results. Based on the new results, there may be recommendations for new interventions related to depression, social support, comorbidity management, or preparedness approaches. Finally, new hypotheses or research questions may be generated.

Moderator Effect

A moderator effect occurs when the impact of one independent variable depends on the value of another independent variable (Aiken & West, 1991; Fairchild & MacKinnon, 2008; Lewis-Beck, 1980, MacKinnon et al., 2000). Many of the independent variables selected for this study (depression, social support, comorbidities index, and preparedness to manage HF homecare) have been found in the literature to be associated with hospitalizations and mortality in HF patients. These selected variables are known to be associated with depression (Alosko, 2012; Barnes, 2008; Heo et al, 2008; Loeb et al, 2012; Park et al, 2006; Reschke, 2001; Vaccarino, 2008). However, there is no known study of preparedness for HF home care relative

to all-cause outcomes and the potential moderator effects of depression. This moderator analysis is unique to this secondary study.

To test the moderator effects, the data analysis requires acceptable reliability among studied variables to decrease the risk of Type II error (Lubinski and Humphreys, 1990). Type II error occurs when a researcher accepts the null hypothesis when it is false and the research hypothesis is true (Ott & Longnecker, 2001; Rosenthal & Rosnow, 2008; Sheskin, 2004). According to Cohen and other statisticians, failure to reject the null requires investigation into whether the failure is from poor instrument reliability, insufficient power, or absence of the phenomenon (Cohen, 1977; Howard, Maxwell, & Fleming, 2000; Mone et al, 1996). Low powered studies decrease the consistency of findings in the literature (Howard, Maxwell, & Fleming, 2000). This study will have sufficient power. In addition, only reliable instruments are used in this study as seen in Table 1. The next sections describe the known relationships between the studied variables.

Review of Setting

The SMAC-HF study was conducted at the University of Kansas Hospital's Mid-America Cardiology Clinic. It is a hospital-owned practice that employs over 40 cardiologists. The organization has multiple clinic sites throughout the Kansas City Metropolitan Area and in the surrounding rural communities. In addition, Mid-American Cardiology has nurse practitioners that specialize in heart failure and see 20-30 patients daily (Smith et. al., 2008). The University of Kansas Hospital is the primary acute care hospital for patients receiving care from this cardiology practice.

The setting also includes The Heart Failure and Cardiomyopathy Center, which is the first in the region to focus on heart failure and cardiomyopathy. This Center features the most

experienced cardiologists in the multi-state region. The University of Kansas Center for Advanced Heart Care opened in 2006 and was completed in 2011. Mid-America Cardiology was ranked 30th by the *US News & World Report* for 3 consecutive years (UKH, 2013). The research division of the Center is directed by Dr. Vacek, a cardiologist who recently completed his master's degree in clinical and translational research. Dr. Vacek is a consultant on Dr. Smith's NHLBI heart failure clinical trial. Notably, the American Heart Association recently recognized the hospital with performance achievement awards for 36 consecutive months of compliance with national guidance measures for stroke care and for treating heart failure patients (UKH, 2013).

Lastly, the setting includes The White Heart Learning and Resource Center, a specifically designed learning environment located on the second level of the Center for Advanced Heart Care. It is one of the most comprehensive facilities of its kind in Greater Kansas City. Patients, their family members, and community residents can visit the Center to learn about the heart and the importance of heart health. The SMAC-HF clinical trial was conducted in this center.

Review of Original Study Enrollment

Enrollment into the original study occurred after completing informed consent and gathering the initial baseline data. Interventions were conducted at The University of Kansas Hospital and outpatient clinic. Initial screening for participants included all patients that were admitted to The University of Kansas Hospital with an exacerbation of HF across the five year enrollment period (see Study flow chart in Appendix). At the time of enrollment, the practice was caring for over 3000 heart failure patients annually. Investigators that were trained to screen, recruit, and/or enroll patients to the study were blinded to group assignment to support objectivity. A total of 5,538 patients were screened for eligibility. The inclusion criteria were:

age greater than 18 years, ability to read and speak the English language, access to a telephone, recent hospitalization for acute decompensated heart failure. Exclusion criteria were: dialysis, transient reversible HF, anticipated heart transplants in 12 months, and anticipated survival less than 12 months. All screened patients who met eligibility were invited for participation (Dalton et. al., 2009).

Participants in the SMAC-HF Trial were randomly assigned to Arm 1 (Experimental Group) or Arm 2 (Standard of Care Group). Both groups had data collected at baseline prior to viewing the evidence-based educational videotapes based on national heart failure education standards (Smith et. al, 2005). Post-discharge data were collected at 4 months, 6 months, 9 months, and 12 months. The baseline data were obtained before intervention and within 3 weeks of the index hospitalization for an HF exacerbation (New York Heart Association Classification III and IV).

Review of Sample

The final number of subjects enrolled in the study was 198. The intervention group had 92 subjects assigned whereas the standard care group had 106 subjects assigned. There were 74 experimental and 90 standard of care subjects that completed the study at 12 months. The reason for this reduction of subjects was similar in both groups and resulted from 22 to deaths and 12 withdrawals. There was a 91% completion rate in the clinical trial of those surviving.

Sample characteristics from the SMAC-HF Trial are described below. At baseline, patients reported having been diagnosed with heart failure, for a median 6.2 years. Five patients had HF greater than 30 years. Patients' ranged in age from 24 years to over 89. Sixty-one percent of the patients were male. Only 32 of these patients reported they were employed. Education ranged from college graduates (35.7%), to having completed some college (27.8%), to having

completed the 8th grade (3%). The index hospital length of stay was, on average, 4.86 days (range = 1 – 34 days). All patients were discharged from the hospital to home (Smith, 2013).

Income Adequacy is a single-item scale was reported at baseline. The scale asks subjects to indicate their financial ability to manage within their current monthly income. Income has shown to impact clinical outcomes such as when patients are not able to comply with expensive medication regimens (Jencks, 2000; Joynt et al, 2011).

Income data was reported at baseline and at the 6 month follow up appointments. There were 26 missing fields due to withdrawing from the study or death. This included 35 (20.3%) who reported an annual household income of less than $10,000. Five patients reported they had no financial income. Nearly half of the patients reported an annual household income less than $20,000. Two-thirds of the sample reported an annual income of less than $30,000 and over 75% of the sample reported annual incomes of under $40,000 (median annual income = ($20,112).

The poverty level in the United States in 2012 was set at $23,050 (total yearly income) for a family of four (HHS, 2012). Households that have income below the poverty level are assumed to have difficulties meeting basic care needs such as food, housing, and monies for illness. There is extensive fiscal burden with HF medications, frequent office visits, home care, and special dietary requirements. Income adequacy instead of reported income will be used for this analysis.

Sample Representativeness

When compared to national HF registries at baseline, enrolled subjects in the SMAC-HF Trial were slightly younger than those found in other national HF clinic trials (age 62.2 years vs. 66 and 71 years, respectively). Also, the SMAC-HF trial sample consisted of slightly more men

than the national HF registries (61.6% vs. 48% and 51%), but less men than other large clinical trials (61.6% vs. 62% and 68%). Notably, patients in this SMAC-HF clinical trial had a slightly greater number of co-morbidities (including hypertension, diabetes mellitus, cerebrovascular accident, and chronic obstructive pulmonary disease) than those enrolled in both the national registries and multi-site clinical trials.

Despite these differences, patient clinical characteristics (left ventricular ejection fraction and left ventricular internal dimension-diastole, diabetes, previous acute myocardial infarction, dyspnea) are comparable to those described in large, multi-site HF studies including the CHARM, OPTIMIZE-HF, and COACH trials (Appendix). It may be that populations at academic, tertiary referral medical centers include patients who are sicker than the general population of patients with HF. In addition, current national reports reveal younger populations are being given a diagnosis of HF more often than in previous years. Overall, SMAC-HF has a representative sample compared to HF patients at The University of Kansas Hospital who did not enroll in SMAC-HF, patients in large HF trials and national registry comparisons.

Data Monitoring and Quality Management Controls for the SMAC-HF Trial

All data in the SMAC-HF Trial were handled in a manner to support quality data management and security. All data were entered twice by independent individuals and compared to confirm accuracy. Double entry of data by independent operators allowed a comparison of each data input with the final verification of accuracy being the actual data found in each subject's responses or clinical data from the medical record. The original study used quality assurance data integrity techniques including data protocols and maintaining an audit trail of the decisions made in managing the data (Boyington et. al, 1999; Roberts et. al, 1997; Wynd et al, 2003).

The SMAC-HF clinical trial also utilized the National Institute of Health (NIH) Required Data Safety and Monitoring Committee (DMSC) including a physician, officer, and statistician who were external to the School of Nursing. These 3 individuals met annually with the SMAC-HF researchers to review the IRB re-certifications, protocols being followed, and the data accumulated up to that point. As a part of the process, any adverse effects or deaths were reviewed to assure these were not due to the research or to the intervention. It was determined mortality was not impacted by the research. The DMSC annual review summary was acknowledged by IRB as a thorough exemplary process and used SMAC-HF as an example for the University of Kansas Medical Center. Finally, tests for balanced randomization (Dougherty et al, 2002) to confirm equivalencies at baseline occurred for patients in both groups on clinical symptoms, demographics, depression, social support, and preparedness (Smith, 2013).

Procedures and Methods for Current Study

This study will utilize similar quality control measures. Data for this study will be extracted from the original database into a separate dataset based on the identified criteria noted in the introduction. All subjects will remain de-identified and the secondary dataset will be managed in a secure manner respective to the confidential and sensitive nature of the data. The data will be transmitted only in secure emails on the University of Kansas Medical Center firewall-protected server. Data selected for inclusion will be analyzed for distribution, including the need for transformations, and adequacy of meeting statistical assumptions prior to quantitative analyses (Keppel & Wickens, 2004; Lentz, 1990; Stevens, 1994). Rules for managing any missing data will be discussed with the dissertation committee (Musil et al., 2002; Patrician, 2002). Any missing variables will be labeled as sporadic, random, or systematic

(occurring repeatedly) and reported (Brown, Baumann, & Cameran, 1996; Newell, 1992; Tsiatis, 1990; Verbeke & Molenberghs, 2001).

Missing data is a major problem in all longitudinal clinical trials. Rubin classifies missing data patterns into missing at random (MAR), missing completely at random (MCAR), and non-ignorable (NI) (Rubin, 1976). In most longitudinal clinical trials, missing data patterns fall into the MCAR and MAR categories. As noted, the SMAC-HF Trial had approximately 2-5 % of missing data. Thus, researchers may handle this problem using imputation techniques such as last observation carried forward as is consistent with intent-to-treat analysis or the mean of the observed data (Hollis et al., 1999). Reporting of missing data patterns in this analysis may make the imputing rules unnecessary. A detailed data analysis will be provided for each research question in the data analysis section.

Variables Included in the Secondary Analyses

The variables selected for this secondary analyses were based on the conceptual framework and the literature review. Variables include demographics (age, gender, race, marital status, length of HF diagnosis), social support, income sufficiency, preparedness for HF home care, and a Comorbidity Weighted Index Score. Also included is the moderator variable under study, depression (CES-D). The outcome variables are all-cause rehospitalization and all-cause mortality. These variables are all continuous except gender, marital status, rehospitalization, and mortality.

Study Instrumentation

Well-known empirical instruments were utilized to obtain the data for this study. The instruments included a demographic sheet, the Center for Epidemiological Studies Depression Scale (CES-D), the Dartmouth Primary Care Cooperative Information Project Chart System

Functional Assessment Charts (COOP Charts) that measures types of social support availability, an Income Adequacy rating scale, Preparedness for HF Home Care, and a medical record review for determining the comorbidities index score. Copies of the instruments are available in the appendix. Internal reliability was established with these multi-item instruments with Cronbach's alpha scores ranging from .829 and .887 respectively (Walters, 2011). These reliability results were consistent with previous studies utilizing these multi-item instruments.

Table 1.

Measure Descriptions

Scale Name	**Definitions**	**Citations**	**When Obtained**
Income Adequacy	Single item that measures perceived income adequacy	Macabasco-O'Connell, 2010; Baik, 2012; Ware,1996	Baseline Index hospitalization
Demographic Sheet	Race, gender, marital status, # of years since HF diagnosis.	Macabasco-O'Connell, 2010;Pena, 2010; Barnes 2008	Baseline Index hospitalization
Preparedness for Home Care 8-item, summed score.	Perceived ability to manage HF home care; low scores associated with rehospitalization,	Archbold et al, 1990	Baseline Index hospitalization
Center for Epidemiological Studies - Depression Scale (CES-D)	Reactive depression, associated with cardiac disease mortality. 10-item-Likert	Comstock et. al., 1976, Radloff & Locke, 1986, Radloff & Rae, 1979; Milette et. al., 2010, Ondine van de Rest et. al., 2010, Zausniewski & Graham, 2009	Baseline Index hospitalization
COOPS: Social Activities, Social Support (To Listen) and Social Support (To Help)	Limitation of social activities with friends and families due to health. Someone to listen and someone available when help is needed.	Kinirons; Watson; Rai, 1997, Bronfort; Bouter, 1999; Gilliland et. al., 1998; Nelson et al., 1996 Uebelacker,2013	Baseline Index hospitalization

Comorbidity Score	This scale measures severity of multiple illnesses and is weighted by age.	Charlson et al., 1987 Burns,1991 Rutledge, 2009	Baseline Index hospitalization
Outcome variables:			
All-Cause rehospitalization	All hospitalizations for all-causes	(Trivedi, 2007).	Retrospective review and across 12 months
All-Cause Mortality	All deaths for any reason	(Trivedi, 2007).	Retrospective review and across 12 months

The Center for Epidemiologic Studies Depression Scale

The Center for Epidemiologic Studies Depression Scale (CES-D) is considered a gold standard for screening for reactive depressive symptoms (Bowden et al., 2010) and is the dependent variable for this analysis. The original CES-D was developed by Laurie Radloff at Utah State University in 1977 and has had two extensive revisions since it is inception. The scale was designed to assess symptoms of depression in the general and chronically ill populations. The CES-D allows assessment of disease symptoms in individuals with or without a diagnosis of depression. This was unique as previous scales were designed to assess severity of depression (Radloff, 1977). The CES-D scale has been used in many large research projects including the National Health and Nutrition Examination Survey and the Community Mental Health Assessment Survey (Comstock et. al., 1976, Radloff & Locke, 1986, Radloff & Rae, 1979).

The CES-D is a 10-item scale with one open-ended question that asks the subject to report how often they felt a certain way in the last week. This is a time-specific assessment

which inherently presents limitations in assessing test/retest correlations due to risks of bias from repeated measuring (Radloff, 1977). Radloff separated the symptoms of depression into components and each component has a few individual items that measure it. The components included are: "depressed mood, feelings of guilt and worthlessness, feelings of helplessness and hopelessness, psychomotor retardation, loss of appetite, and sleep disturbance" (Radloff, 1977, p. 386). The individual response items are worded in such a way to prompt a recollection of the frequency of past feelings. The list of responses is as follows:

During the past week…I felt

Rarely or none of the time (less than a day)

Some or a little of the time (1-2 days)

Occasionally or a Moderate Amount of Time (3-4 days)

Most or all of the time (5-7 days)

Content validity was established by the associated presenting symptoms of the participant. It was noted that 85% of individuals who scored high on the CES-D will have clinical depression (Radloff, 1977). The CES-D items are summed to create scores that range from zero to 40, (0-7 being no depressive symptoms, 8-10 mild, 11-19 moderate, 20-25 moderately severe, and greater than 26 indicates severe depressive symptoms). Test-retest reliability ranged from r=.45-.70. In addition, the scale had high correlation with clinician assessment of severity of depression (Craig & Van Natta, 1977). Reproducibility was evaluated as .71 and intra/inter-rater ratio was .99 (Ondine van de Rest et. al., 2010).

Reliability has been established in adults with a Cronbach's alpha of .90, .84, .87 and .89 identified on previous studies (Milette et. al., 2010, Ondine van de Rest et. al., 2010,

Zausniewski & Graham, 2009). The original CES-D validation studies identified internal consistency at .85 in the general population and .90 in the psychiatric population.

Social Support (COOP Charts)

COOP charts are the product of The Dartmouth-Northern New England Primary Care Cooperative Information Project, a group of medical practices that partner together in research endeavors (Nelson et. al., 1987). The COOP charts have been edited and revised over the last 10 years to maximize their effectiveness as a simple tool to measure aspects of social support. Each chart is designed to be either self-administered or clinician-administered. The basic elements of the COOP charts include a title that is reflective of what is intended to be measured, a visual representation, and five questions relating to the area of focus.

Research has demonstrated the addition of the visual cue does not change the way participants respond (Larson, Hays et al. 1992). However, research has shown the addition of visual cues does increase test-retest reliability (Hadorn, Hays et al. 1992). A score of four or five is considered abnormal (Nelson, et. al, 1987) or having a lack of social support. COOP Charts have been shown to be easy to administer, can be completed quickly, and have high inter/intra-rater reliability (Bouter, 1999; Rai, 1997). Test-retest reliability was assessed at .73-.98 (Spiker, 1996). Intra-class correlation coefficients ranged between .5-.98 (Keller et. al., 1992).

COOP figures are simple and intuitive to complete while maintaining robustness. The COOP charts have been shown to be as dependable at measuring functional health as more complicated metrics. A limitation of the COOP charts is the lack of precision compared to the complex charts (Nelson, et al, 1996). However, the simplicity and ease of scoring of COOP charts makes them a relevant option used in primary care offices as well as in this study.

The COOP charts have been successfully adapted to work with specific cultures and populations while maintaining internal consistency (Gilliland et. al., 1998). Qualitative assessment indicated that 93% of participants felt the charts were easy to answer (Gilliland et. al., 1998). Social Support is the concept evaluated in this secondary analysis that utilized COOP charts.

Social Support was measured by three different COOP single items. The respondent was asked to rate the scales based on whether they felt nervous, lonely or blue, needed help with daily chores, got sick and had to stay in bed, and/or needed help just taking care of them in the last week. The single item scales ask the subject to rate the availability of support if the subject needed it in the last 4 weeks (Bennett, 2001). The first scale asks, "If you needed someone to listen or to help you, was someone there for you? The item response options range from one to five (1 = being as much help as they wanted, 2= quite a bit of help available, 3= some help available, 4 = a little help available, and 5=no help available). There is a corresponding character image: 1 = two happy characters making contact, 2 = two happy characters close but not making contact, 3 = 2 neutral affect characters not making contact, 4 = 1 neutral character and 1 sad character not making contact, and 5 = 1 sad character alone.

The second scale asks, "Was someone available to help you if you needed and wanted help? The item response options range from one to five (1 = being as much help as they wanted, 2 = quite a bit of help, 3 = some help available, 4 = a little help available, and 5 = no help available). There is a corresponding character image: 1 = multiple characters surrounding the primary character, 2 = a few characters surrounding the primary character, 3 = a couple of characters surrounding the primary character, 4 = a single character with the primary character, and 5 = the primary character is alone.

The third scale is titled Social Activities and asks, "Has your physical and emotional health limited your social activities with family, friends, neighbors, or groups?" The item response options range from one to five (1 = Not at all, 2 = slightly, 3 = moderately, 4 = quite a bit, and 5 = extremely). There is a corresponding character image: 1 = multiple characters surrounding the primary character, 2 = a single character with the primary character and a few characters in the background, 3 = primary character standing contently off to the side of three characters interacting, 4 = the primary character alone watching the other characters, and 5 = the primary character alone sadly watching the other characters.

Charlson Comorbidity Weighted Index Score (CCI):

The Charlson Comorbidity Weighted Index Score (CCI) measures the number of multiple illnesses a patient has and is weighted by age. The overall index of comorbid diseases was initially developed in internal medicine patients and validated in 588 patients with cancer (Charlson et al., 1987). In the weighted score, the mean number of comorbid diseases each patient has is used with addition of weighting for age. One point is added to the CCI score for each decade of life after age 40 years (with age 40 years = 0, 50 years = 1, 60 years = 2) and age-weighted score is used.

Preparedness for Home Care

Preparedness for HF Home Care (modified from the Preparedness for Home Caregiving Scale) is an 8-item Likert-type instrument that asks respondents to rate their readiness to perform home care (Archbold et al., 1990). It is designed to be self-administered. This scale defines the concept of preparedness to manage the complexities of heart failure at home. Preparedness is measured as the perceived readiness for the different domains of home care activities. The domains of home care assessed in this instrument include providing physical care, managing the

emotional elements, setting up services, managing stress, and managing the chronic illness. The respondent will then rate each of the domains. The ratings are as follows:

0 = Not at all prepared

1 = Not too well prepared

2 = Somewhat prepared

3 = Pretty well prepared

4 = Very well prepared

The summed preparedness scores have a range of 0-32 with higher scores suggesting better preparedness in either the patient or family member providing care at home. The items are designed to assess how the respondent is feeling at the present time. For example, the first question states, "How well prepared do you think you are now to take care of the physical parts of managing heart failure in the home?" The preparedness scale is designed to allow the practitioner to modify the language to address a specific condition (i.e.: Heart failure, diabetes, and wound care) and not just vague disease states. In addition, the Preparedness for Care Scale has been adapted successfully in Swedish (Henriksson, Andershed et al. 2012). Internal consistency has been reported as high with Cronbach alphas of 0.88 to 0.93 reported in the literature (Carter et al., 1998; Hudson & Hayman-White, 2006).

Demographic Variables

The demographic characteristics that will be used in this analysis will be race (African American, Caucasian, or Non-African American), gender (self-reported), marital status (single, married, separated, and divorced), income adequacy, and length of time since HF diagnosis. Income Adequacy is a single-item scale that asks the subject to indicate their financial ability to manage within their current monthly income. The item ranges from one to four (1=they can't

make ends meet, 2=just enough, 3=enough with a little left extra sometimes, and 4=always have money left over). Previous studies have demonstrated that single item instruments can be just as effective as multi-item instruments and that single item instruments increase test-retest reliability (DeBoer, 2004).

Outcome Variables

The outcome variables for this study are all-cause hospital rehospitalization and all-cause mortality during 12-month follow-up. All-cause rehospitalization and all-cause mortality will be evaluated as a composite variable. Chart review was used to obtain all rehospitalization data. The medical record review included physician adjudication of all-cause rehospitalization and mortality (Pfeffer et al., 2003).

All-cause Hospital Rehospitalization

All-cause hospital rehospitalization, according to Centers for Medicare and Medicaid Services, is a subsequent hospitalization that occurs after a discharge from the same or another subsection of the hospital (Quality Net, 2012). For the purpose of this study, rehospitalization will include any admission to an inpatient acute care unit within 12 months of the index or baseline hospitalization for HF. Rehospitalization data was obtained from the patient medical record at the University of Kansas Medical Center and other hospitals as part of the primary study (Smith et al, 2005). All-cause rehospitalization was selected due to the tenuous physiologic nature of heart failure patients. Many causes of hospitalization, regardless of the indication, have been found to worsen heart failure (Patel, 2008).

All-cause Mortality

All-cause Mortality will be measured as death of the participating patient for any reason. This variable was retrieved using the Medical Record Data Retrieval Form and public death

records as part of the original study (Smith et al, 2005). The literature continues to support the need and desire to reduce hospital rehospitalization and mortality in HF patients, but there is limited knowledge about which characteristics lead to or moderate these outcomes.

Statistical Considerations

Data was analyzed using Statistical Package for Social Science (SPSS) Version 23. The data was evaluated for missing data and outliers and were handled accordingly. Even a small proportion of outliers can have a significant impact on statistical analysis so this was evaluated closely for potential impact (Yuan & Bentler, 2001). Cutoffs and transformations were utilized to mitigate the impact of outliers on the data (Ratcliff, 1993). Statistical assumptions of normality, linearity, homoscedasticity, and multicollinearity were assessed. An evaluation of the descriptive statistics of each variable was performed including measures of central tendency and frequency distributions.

Power Analysis

A power analysis was conducted for each of the three research questions utilizing a-priori method. An online power analysis calculator by Dr. Daniel Soper (2013) was used for the multiple regression analysis.

Research Question 1. What effect does reactive depression have on of all-cause rehospitalization and/or all-cause mortality in previously hospitalized HF patients during a 12 month follow up time period? The following inputs included: an alpha of .05, medium effect size of .15 (indicating a small effect could be ascertained) and, 3 variables (CES-D, all-cause rehospitalization, and all-cause mortality). The CES-D inputs included: population mean of 15, population standard deviation of 10, and an expected mean of the sample 8.69. This calculation determined that a minimum sample size of 33 would be necessary to gain the desired effect.

Research Question 2. Controlling for demographic characteristics (race, gender, marital status, length of time of HF diagnosis, comorbidity index), what social (social support), financial (income adequacy), and patient education (preparedness for HF homecare) characteristics explain the variance of reactive depression as measured by the CES-D in heart failure patients? The following inputs included: an alpha of .05, medium effect size of .15 (indicating small effect could be ascertained), 9 variables (CES-D, race, gender, marital status, income sufficiency, social support, preparedness for HF homecare, number of years having heart failure, and Charlson weighted comorbidities index). This calculation determined that a minimum sample size of 167 would be necessary to gain the desired effect.

Research Question 3. Does reactive depression have a moderator effect on patient preparedness and all-cause rehospitalization and/or all-cause mortality in heart failure patients? The following inputs included: an alpha of .05, medium effect size of .15 (indicating small effect could be ascertained), 4 variables (CES-D, preparedness for HF home care, all-cause rehospitalization, and all-cause mortality). This calculation determined that a minimum sample size of 129 would be necessary to gain the desired effect.

The original dataset included a final sample size of 198 subjects which provided a sufficient sample size with acceptable power. Evaluating the entire study population also protects against loss of power due to attrition.

Data Analysis Plan

A detailed analysis plan is presented for each research questions below. Descriptive statistics will be used to describe the sample and outcome variables frequencies.

Research Question 1. **What effect does reactive depression have on of all-cause rehospitalization and/or all-cause mortality in previously hospitalized HF patients during a**

12 month follow up time period? A multiple logistic regression model will be used to answer this question. The dependent variable—a composite indicating either all-cause rehospitalization or all-cause mortality—will be computed as a yes/no outcome. It will be modeled using the independent variable depression as measured by CESD. An odds ratio will be calculated to describe the relationship between varying levels of depression and the odds of being rehospitalized or dying due to any reason. Model assumptions and fit will be assessed to ensure the analysis method is appropriate. Similar individual models will be built for mortality and rehospitalization, separately, considering intervention.

Table 2.
Types of variables and numbers of parameters needed

Variable	Type of measurement
Dependent Variables	
All-Cause Rehospitalization	Categorical
All-Cause Mortality	Categorical
Independent Variable	
CES-D Score	Continuous

Research Question 2. Controlling for demographic characteristics (race, gender, marital status, length of time of HF diagnosis, comorbidity index), what social (social support), financial (income adequacy), and patient education (preparedness for HF homecare) characteristics explain the variance of reactive depression as measured by the CES-D in heart failure patients? Multiple regression was used to quantify the association between the variables (race, gender, marital status, income sufficiency, social support, preparedness, years of having heart failure, and Charlson weighted score) with CES-D. Prior to the regression analysis, the data was assessed to ensure the main assumptions of regression are met including: normality, linearity, independence, non-multicollinearity, and homoscedasticity.

Table 3.
Types of variables and numbers of parameters needed

Variable	Type of measurement
Dependent Variable	
CES-D	Continuous
Independent Variable	
Race	Categorical
Gender	Categorical
Marital Status	Categorical
Income Adequacy	Continuous
Social Support	Continuous
Preparedness for HF Homecare	Continuous
Years of having heart failure	Continuous
Charlson comorbidities index	Continuous

Research Question 3. Does reactive depression have a moderator effect on patient preparedness and all-cause rehospitalization and/or all-cause mortality in heart failure patients? A multiple logistic regression model that includes an interaction of depression and preparedness was used to evaluate for a moderator effect. This regression also included a

categorical variable indicating if the patient had been in the standard care or the experimental groups. Prior to the regression analysis, the data was assessed to ensure the main assumptions of regression are met including normality, linearity, independence, non-multicollinearity, and homoscedasticity. Adjustments for any confounding variables that might influence survival or HF rehospitalization using the multiple regression method of Cox's proportional hazards model was made.

Table 4.
Types of variables and numbers of parameters needed

Variable	Type of measurement
Dependent Variables	
All-cause Rehospitalization	Categorical
All-cause Mortality	Categorical
Independent Variables	
CES-D Score	Continuous
Preparedness for HF Homecare	Continuous

Study Limitations

General Limitations of Secondary Analysis

Using data that has already been collected can be a very efficient and useful way to expand the body of nursing knowledge, but it does present a unique set of challenges. Primarily, because the researcher did not collect the original data she/he has no control over how or what was collected. The researcher was not able to ascertain some underlying issues pertaining to data collection and is limited to what is available in the dataset as well as where, when, and how it was collected (Boslaugh, 2007). The data may not be able to answer the researcher's specific research questions or contain specific information that the researcher would like to have and they may need to modify their original research aims to continue the study.

The research questions for this study are framed by the conceptual framework illustrated in Chapter 1 Figure 2. To address these limitations for this secondary analysis, previous work on this SMAC-HF data set when the study was at mid completions stage was undertaken. That previous work gave the researcher experience with the instruments, SMAC-HF data set, and using SPSS. There are additional benefits of this secondary analysis that mitigate the limitations. Benefits include the SMAC-HF trial was a randomized clinical trial, DSMC annual review, data quality and integrity, availability at The University of Kansas School of Nursing (easy to access and clarify the variables), and availability of the statistician who was involved in the original study.

Reactive depression is situational and acts on a continuum. In order to explore the degree and variability or other types of depression (i.e.: Bipolar), additional evaluation would be necessary. However other studies including SMAC-HF trial have confirmed that the majority of HF in depression is situational and are not major depressive disorders (Ell et al, 2005; Bowden et al., 2010). The CESD has been validated as an effective tool for evaluating reactive depression in a variety of populations.

The data were collected in a single setting which limits the generalization. The setting is an academic medical center and a regional referral hospital. The designation of a regional referral hospital lends itself to a sicker HF population than you would expect in a community hospital. In addition, many participants did not answer the actual income question but all did answer the question about income adequacy at baseline. Another limitation to this study is that no direction or cause-effect can be drawn from the results. This secondary analysis will provided correlational results, which follows the premise of the conceptual framework.

Ethical Considerations

This study is a secondary data analysis which is considered to be minimal risk research. For this study there are no direct benefits or risks to the participant. Data will be de-identified and maintained in a secure manner in order to protect the confidentiality of the patient. All data will be transferred via encrypted email using The University of Medical Center server only. During the analysis phase, the data will be stored on the researcher's password-protected computer with a back-up copy on the University of Kansas Medical Center server. No copies of the data will be stored on any portable electronic devices such as laptops or thumb drives. Institutional review board approval will be obtained from The University of Kansas Medical Center prior to conducting any research.

Summary

A descriptive correlational design will be used to test the research questions. This is a secondary data analysis of the SMAC-HF Trial data. The sample for this study will be inclusive of all participants (n=198) enrolled in the trial. Each participant completed the full battery of instruments during the defined intervals over a 12-month time period. Logistic regression analysis will be conducted to answer research question 1, multiple regression for research question 2, and multiple regression with an interaction effect will be conducted to answer research question 3. Moderator effects will also be explored between depression and the other variables.

Chapter IV

Findings

The purpose of this study is to examine the moderating effect of depression on all-cause rehospitalization and mortality in HF patients for 12 months following an index hospitalization for HF. Three research questions were devised to fully explore the purpose. This study addresses the following research questions:

1. What affect does reactive depression have on all-cause rehospitalization and/or all-cause mortality in previously hospitalized heart failure (HF) patients during a 12-month follow up time period?
2. Controlling for demographic characteristics (age, gender, race, marital status, length of time of HF diagnosis, Charlson comorbidity index score), what social (social support), financial (income adequacy), and patient preparedness for HF homecare characteristics explain the variance of reactive depression as measured by the CES-D in patients with HF?
3. Does reactive depression have a moderator effect on patient preparedness and all-cause rehospitalization and/or all-cause mortality in heart failure patients?

Description of Sample

The study included data from 198 subjects with an average age of 62.3 years (SD = 13.2). Forty-three percent (87) of subjects identified their race as African American (Table 5). Slightly over half of the participants (51%) were not rehospitalized during the course of this study. The median baseline CES-D score was 7.5 (range = 0, 28). Eighty-three (41.9%) participants were married. Over 61% of the participants were male. The average Charlson Comorbidity Index was 6.65. The median number of years all participants had been diagnosed with heart failure

was 2.3. The control group median number of years diagnosed was 7 whereas the treatment group median was 3.39.

Table 5.
Demographic and Clinical Characteristics of *N* = 198 Subjects

Subject Characteristic		Overall (*n* = 198)	SMAC-HF Intervention (*n* = 92)	Standard of Care (*n* = 106)
Age (in years) (mean, SD)		62.3 (13.2)	62 (13.1)	61(13.3)
Male Gender (*n*, %)		122 (61.1%)	69 (75%)	52 (49%)
Race	African-American (*n*, %)	87 (43.9%)	35 (38%)	52 (49.1%)
	Caucasian (*n*, %)	105 (53%)	52 (56.5%)	54 (50.9%)
	Native American or Alaskan	2 (1%)	1 (1.1%)	1 (.9%)
	More than one background	4 (2%)	4 (4.3%)	0
Marital Status	Married (*n*, %)	83 (41.9%)	40 (43.4%)	42 (39.6%)
	Widowed (*n*, %)	30 (15.2%)	15 (16.3%)	14 (13.2%)
	Divorced (*n*, %)	45 (22.7%)	28 (30.4%)	17 (16%)
	Separated (*n*, %)	10 (5.1%)	5 (5.4%)	5 (4.7%)
	Never Married (*n*, %)	30 (15.2%)	17 (18.4%)	13 (12.2%)
Charlson Comorbidity Index (mean, SD)		6.65 (2.83)	6.0 (2.6)	7 (3.0)
CESD Score (median, range)		7.5 (0, 28)	7 (7.0)	8 (6.0)
Years since HF diagnosis (median, range)		2.3 (0.01, 38.76)	3.39 (6.2)	7 (8.9)
Depressed (CESD $\geq$ 16)† (*n*, %)		48 (24.2%)	21 (22.8%)	27 (25.5%)

†: Radloff, 1977

Research Questions

Question 1. *What affect does reactive depression have on all-cause rehospitalization and/or all-cause mortality in previously hospitalized heart failure (HF) patients during a 12-month follow up time period?*

Mortality rates were relatively low throughout the duration of this study. In total only 18 participants died during this study. Of those that died, 15 had CESD scores of 16 or less

Rehospitalization however was more common effecting 97 participants. Of those 97 participants with rehospitalization events 67 of them had CESD scores of 16 or less. A total of 68 participants with CESD scores of 16 or less experienced at least one rehospitalization and or death.

Table 6.
All-cause mortality and rehospitalizations by Depression.

	CESD	
	< 16	≥ 16
	Not Depressed	Depressed
	(*n* = 150)	(*n* = 48)
All-cause mortality and/or hospitalization (*n*, %)	*68(45.3%)*	*30(62.5%)*
All-cause mortality (*n*, %)	*15 (10%)*	*3(6.3%)*
All-cause rehospitalization (*n*, %	*67(44.7%)*	*30(62.5%)*
# of 12-month rehospitalizations (median, range, S.D.)	*00, 0-10, 1.8*	*1, 0-7, 1.7*

Table 7.
Model Information for Research Questions

	Odds Ratio	95% CI	*p*-value	Wald
Model 1: Composite	1.061	1.015-1.110	.009	6.804
Model 2: Mortality	1.033	.963-1.109	.364	.823
Model 3: Rehospitalization	1.061	1.015-1.110	.009	6.8

The logistic regression model relating CESD to the composite outcome of all-cause death and/or rehospitalization showed the odds of rehospitalization and/or death due to any cause increased by 6% (OR = 1.06, 95% CI = 1.015, 1.11) for every one-unit increase in CESD. In addition, 4.7% of the variation in the outcome can be described by changes in CESD (Wald χ^2 = 6.804, *df* = 1, *p* = 0.009). Goodness of fit was confirmed using the Hosmer and Lemeshow test (p = 0.7) (Shaw and Barnwell, 2003). When investigated individually, the logistic regression model

relating CESD to all-cause mortality showed the odds of death due to any cause increased by 3% (OR = 1.03, 95% CI = 0.963, 1.109) for every one-unit increase in CESD. When looking at mortality alone, only 0.9% of the variation in the outcome can be described by changes in CESD (Wald χ^2 = .823, *df* = 1, *p* = 0.364). For all-cause rehospitalization, the odds increased by 6.8% for every one unit increase in CESD (OR = 1.061, 95% CI = 1.015, 1.11) and CESD was found to explain 4.7% of the variation in the outcome.

In summary, CES-D was shown to increase the odds of rehospitalization and the composite variable (rehospitalization and/or death), likely due to the strong relationship with rehospitalization and depression. Further for every one-unit increase in CES-D score the odds of rehospitalization increases by 6.8%. This was also consistent with the composite variable which includes all-cause rehospitalization and mortality. As mortality alone did not increase the odds of rehospitalization and/or death. The rate of mortality was very low (8.1%) in this study population which may contribute to the findings.

Question 2. *Controlling for demographic characteristics, what social, financial, and preparedness characteristics help explain variation in reactive depression in patients with HF?* The depressed and nondepressed group both identified as having high percentages of someone to listen 67.3% and 66.6% respectfully. The social support someone to help also included high percentages of perceived support 68.8% and 70%. Income adequacy percentages were also similar between groups. Always have enough or a little extra 39.6% and 47.4%. The nondepressed group had the highest percentage of participants reporting that they "Can't make ends meet" at 25% compared to the depressed group at 18%. Preparedness to manage heart failure care very well was 50% in the group with CESD scores less than 16 compared to 32% in those scoring 16 or higher.

The analysis of variance table further confirms that neither the first model (demographics alone) nor the second model (demographics and social support, income sufficiency, patient preparedness, and reactive depression) predicted scores. None of the predictors in this analysis were significant. Neither model was deemed significant; model 1 p-value .08 and model 2p-value .848.

Table 8.
Model Summary for Research Question 2

	R	R^2	Adj. R^2	*Std. Error*	F Change	Sig
Model 1	.222	.049	.024	6.46	1.973	.084
Model 2	.227	.056	.011	6.52	1.234	.848

Table 9.
Social, Financial and Preparedness Characteristics by CESD.

	CESD	
	≤ 16 (*n* = 48)	> 16 (*n* = 150)
Social Support (Someone to listen)	2.02	2.21
1= No, not at all (*n*, %)	3(6.3%)	13(8.7%)
2 = Yes, a little (*n*, %)	4(8.3%)	14(9.3%)
3 = Yes, some (*n*, %)	9(18.8%)	21(14%)
4 = Yes, quite a bit (*n*, %)	7(14.6%)	45(30%)
5 = Yes, enough (*n*, %)	25(52.1%)	56(37.3%)
Social Support (Someone to help)	1.90	2.13
1= No, not at all (*n*, %)	1(2.1%)	10(6.7%)
2 = Yes, a little (*n*, %)	4(8.3%)	14(9.3%)
3 = Yes, some (*n*, %)	10(20.8%)	21(14%)
4 = Yes, quite a bit (*n*, %)	7(14.6%)	45(30%)
5 = Yes, enough (*n*, %)	26(54.2%)	60(40%)
Preparedness	21.66	27.27
1 = Not at all (*n*, %)	1(2.1%)	3(2%)
2= Not too well (*n*, %)	3(6.3%)	8(5.3%)
3= Somewhat well (*n*, %)	6(12.5%)	40(6.7%)
4= Pretty well (*n*, %)	14(29.2%)	50(33.3%)
5= Very well (*n*, %)	24(50%)	48(32%)
Income Adequacy	2.28	2.44
1 = Can't make ends meet (*n*, %)	12(25%)	27(18%)
2 = Just enough (*n*, %)	16(33.3%)	51(34%)
3 = Little extra (*n*, %)	13(27.1%)	49(32.7%)
4 = Always have extra (*n*, %)	6(12.5%)	22(14.7%)

Multiple regression analysis confirmed that the proposed model was not predictive for depression in heart failure patients.

Question 3. Does reactive depression have a moderator effect on patient preparedness and all-cause rehospitalization and/or all-cause mortality in heart failure patients?

To determine if depression has a moderator effect on the relationship between preparedness and the outcome variables (mortality and/or rehospitalization) a regression analysis was conducted. The analysis was conducted in three steps to individually assess for moderation in all three of the outcome variables.

Table 10.
CES-D Moderation Effect

	B	Std. Error	Z	Sig.
Preparedness and Mortality	.01	.04	.3	.76
Interaction Effect	-.00	.00	-.76	.44
Preparedness and Rehospitalization	-.00	.02	.05	.95
Interaction Effect	-.00	.00	.59	.55
Preparedness and Composite	.00	.02	.1	.91
Interaction Effect	-.00	.00	.56	.57

The first model included preparedness as the predictor, CES-D as the moderator, and mortality as the outcome. The model was not significant and CES-D did not have a significant moderating effect on the relationship between mortality and preparedness (p=.44).

The second model included preparedness as the predictor, CES-D as the moderator, and rehospitalization as the outcome. The model demonstrated a significant relationship exists directly between CES-D and rehospitalization (p=.04). CES-D however did not have a moderating effect on the relationship between preparedness and rehospitalization (p=.55).

The third model included preparedness as the predictor, CES-D as the moderator, and the composite variable (rehospitalization and/or mortality) as the outcome. The model was not significant and CES-D did not have a significant moderating effect on the relationship between the composite variable (p=.57). A significant relationship was found with CES-D and the composite variable directly (p=.03).

In all three models depression as measured by CES-D did not have a moderating effect on preparedness and the outcome variables. Depression did continue to demonstrate a significant relationship with rehospitalization.

Summary

Logistic regression, multiple regression, and moderator analysis were conducted to address the research questions. These analyses demonstrated that depression consistently has a significant relationship to rehospitalization. On the other hand, depression did not have a significant relationship to mortality. In addition, depression did not have a moderating effect on the relationship between preparedness and the outcome variables (mortality and/or rehospitalization).

Chapter V

This chapter presents discussion of the significance of the study, characteristics of the sample, and research findings based on each of the study variables. Findings will be discussed in relationship to current literature. In addition, limitations of the study, recommendations for further research, and conclusions are included.

Substantial literature and research exists into the effects of depression in patients with cardiovascular disease. While previous research supported the conclusion that depression can influence clinical outcomes in patients with heart failure, the exact nature of the influence has not been clear. Limited research was found in the literature that directly assessed the effect of depression on all cause rehospitalization in heart failure patients. This study examined the relationships between depression and social support, depression and preparedness, depression and income adequacy, depression and death, and depression and all cause rehospitalization using the Chronic Care Model (Wagner et al., 2004) as a guiding model. A more in depth understanding of the relationships between these variables is necessary to develop effective protocols to reduce all-cause rehospitalization and mortality in heart failure patients.

Significance of the Study

Heart failure management designed to improve survival and reduce all cause rehospitalization is an area of focus for many acute care hospitals, legislators, and healthcare providers. In fiscal year 2012, the Affordable Care Act established the Hospital All Cause Rehospitalization Reduction Program. This program reduces Centers for Medicaid and Medicare Services (CMS) payments to hospitals that have excess all cause rehospitalizations defined by the Rehospitalization Reduction Program. The program affects patients with hospital discharge dates beginning on or after October 1, 2012. Heart Failure was one of the first three diagnoses to

be included in this CMS program. The Hospital All Cause Rehospitalizations Reduction Program defines all cause rehospitalization as any unplanned all cause rehospitalization within 30 days of a discharge (CMS, 2015). The all cause rehospitalization payment adjustment is calculated based on a hospital's excess all cause rehospitalization ratio (a measure of a hospital's performance compared to the national average that is risk adjusted) over a 3-year period. The repayment penalty started at a maximum of 1% and has increased to 3% of Medicare DRG payments.

The impact of the repayment penalty was significant to the site of this study. The first penalty repayment year resulted in the hospital having a .38 penalty on 75 million dollars of Medicare revenue, the Kansas average penalty is .44 and the national penalty is .61. This .38 penalty related to an estimated $360,000 potential loss of revenue annually at the 1% penalty rate (Marting, 2016). The financial impact of not addressing all cause rehospitalization rates is prohibitive to remaining a fiscally viable organization.

The findings of this study add to the body of knowledge regarding the relationship between heart failure, depression, and all cause rehospitalization and/or mortality. The American College of Cardiology and AHA in-hospital process indicators do improve quality of care but surprisingly do not improve overwhelming disease and rehospitalization rates (Desai & Stephenson, 2015). Even with the growing motivation to improve heart failure outcomes, there is insufficient understanding of what modifiable variables directly impact all cause rehospitalization and mortality. This study directly contributes to the breadth of knowledge surrounding heart failure outcome indicators and their potential interaction variables.

Characteristics of the Sample

Participants in the study were recruited after being admitted to the hospital for acute heart failure decompensation. There were 198 patients with class 3 or 4 heart failure, which is the most severe classification of the disease. The racial distribution of participants was self-reported as follows: 43.9% African American, 53% Caucasian, 1% Native American and Alaskan, and 2% reported more than 1 race background. The racial and ethnic make-up of the sample was likely due to geographic location of the study. The site was located in a major metropolitan area in the Midwest. The city data reported a racial makeup of 39.7% Caucasian, 28.5% Hispanic, 25.8% African American (City-data.com, 2015). The facility has a large referral base from the surrounding suburban and rural areas that may have contributed to the increased percentage of African American and Caucasian participants.

Overall, most of the participants were well educated with 63.5% reporting that they were college graduates or had completed some college. Three percent of the participants had completed formal education up to the 8th grade. The ability to read and write the English language was one of the inclusion criteria for the study, which many Spanish speakers did not meet. Reading inclusion criteria may have skewed the results favorably towards those that are more educated. It would be necessary to evaluate the screening results to determine the percent of participants excluded based on ability to read the English language.

Gender bias has existed previously in cardiovascular research (Wenger, 2012). Gender was further validated as an outcome modifier in this study. Depression has been shown to be a strong predictor of early mortality in a recent longitudinal study in Amsterdam. The Amsterdam prediction was compounded if the men reported being depressed and lonely (Holwerda et. al., 2016). Depression produces proinflammatory factors, hypothalamic-pituitary axis, autonomic

nervous system, and metabolic factors may also contribute to worsening chronic illness (J. Katon , 2011). The literature also confirms that outcomes vary between male and females (Otten, 2013). This study sample was comprised of 61.1% male and 38.9% female. Analysis of Variance indicated significant variance exists between genders in two of the variables: length of years diagnosed with heart failure (.035) and income (.008). Joffe et al. (2013) report heart failure patients are living longer than in the last 10 years. The findings regarding income sufficiency were consistent with 2013 US Census Bureau data which reported females receive less income than males (US Census Bureau, 2015). Specifically, in this sample women reported significantly less income, greater depression, and were diagnosed with heart failure later than their male counter parts. Women have also been shown to be treated with antidepressants more than men. Treatment with antidepressant therapy has been shown to increase mortality in heart failure patients (Veien et al., 2011).

Depression was identified in 35 of the participants. Depression was identified based on CES-D scores. Prevalence of depression in study participants was relatively low with about 17.7% of participants scoring 16 (the cutoff point) or higher. The mean CES-D score was 8.94 (S.D. 6.554). Clinical depression has been shown to be present in over 20% of patients with heart failure (Rutledge et al., 2006). Reactive depression was measured with the CES-D scale in this study. The CES-D measures depressive symptoms 1 week before the completion of the scale. This CES-D scale was found reliable and valid in this sample. However, this measure of reactive depression versus psychiatric depression measure among persons with heart failure may need additional evaluation.

Depression is a common comorbid condition that increases in prevalence as heart failure severity increases (Sullivan et al., 2004). Prevalence of depression varies significantly between

studies. Variability can be contributed to how depression is operationalized in each study. A review of the literature conducted by Chapa et al. noted prevalence of depression between 23.8% to 67% in inpatients with heart failure and 16.7% to 70% in outpatients with heart failure (2015). The studies reviewed used a variety of instruments and techniques to assess for depression. Angermann et al., found that depression was prevalent 4-5 times more in the heart failure population than the general population (2011). These factors may contribute to the wide range of depression scores found in this study (Chapa et. al., 2014).

Discussion of the findings

The main study aim was to explore the relationships among mortality, all-cause rehospitalization, and depression in patients with heart failure. A secondary aim was to evaluate the above mentioned relationships in the context of patient preparedness for managing heart failure and social support. The third aim was to understand the moderating relationship depression has on patient preparedness and among mortality and/or all-cause rehospitalization. Developing education, intervention, and clinical programs to promote patient management of their depression may help reduce all-cause rehospitalization. The findings from this study offer a guide for future research on the relationship of depression on all-cause rehospitalization.

Discussion of findings by research question

Question 1: What effect does reactive depression have on of all-cause rehospitalization and/or all-cause mortality in previously hospitalized HF patients during a 12 month follow up time period?

The logistic regression model was significant for depression as a predictor of all cause rehospitalization and mortality (p=.009). Depression improved the model predictability of an event of all cause rehospitalization and mortality by 6.8%. Further, for every one-unit increase

in depression as measured by CES-D, the odds of all-cause rehospitalization and/or death increase by 6.8%. However, the logistic regression model was not significant for depression being a predictor in mortality alone. Yet, the logistic regression model was significant (p=.009) for depression as a predictor in all cause rehospitalization alone. The model improved the predictability of an event by 6.5%. For every one-unit or one-point increase in the CESD score, the odds of all cause rehospitalization increase by 6.1%.

Question 2: Controlling for demographic characteristics, what social, financial, and preparedness characteristics help explain variation in reactive depression in patients with HF?

The relationship between depression, social support, and patient preparedness was not significant with/without controlling for demographics. The number of variables inputted in the multiple regression analysis has the potential to minimize/suppress a potential relationship. However, the number of variables compared to the N is acceptable in this study (Slinker & Gantz, 2008).

Question 3: Does depression have a moderator effect on patient preparedness and all-cause rehospitalization and/or all-cause mortality?

Depression, as measured by CES-D, did not have a moderating effect on preparedness and mortality (B=.-0033, *p*-value 0.4), preparedness and all cause rehospitalization (B=-.0018, *p*-value 0.5), or preparedness and the composite (B=-.0017, *p*-value 0.5). The model did demonstrate that CES-D has a significant direct relationship between CES-D and all-cause rehospitalization (p=.04) and the composite variable of all-cause rehospitalization and/or mortality (p=.03).

According to Hayes and Mathes, a moderator effect, also called an interaction, provides greater depth of understanding between variables than just testing for simple bivariate cause and effect. Exploring all variables that effect a variable strengthens the knowledge obtained during testing (Hayes and Mathes, 2009).

The Analysis of Variance Table further confirms that neither the first model (demographics alone) nor the second model (demographics and social support, income sufficiency, patient preparedness, and reactive depression) predicted mortality and/or rehospitalization. None of the predictors in this analysis were significant. Neither model was deemed significant (model 1 p-value 0.1 and model 2 p-value 0.3).

Study Limitations

Multiple study limitations were identified during the course of this research. Limitations were found in the areas of sample size, study design, analysis technique, instrumentation, and generalizability. The limitations should be taken into consideration when evaluating the outcomes and findings of this study. The existing limitations do not distract from the value of the findings but rather serve as a foundation for future studies.

Limitation of Sample

Sample size was one limitation of the study. The sample size was adequate to meet the minimum requirements of the data analytics, but it could have contributed to the inability to assess significant relationships or interactions specifically as related to mortality. In this study sample during the timeframe the data was collected, we had a small number of deaths (18 in total) that may have contributed to non-significance. The study population had an 11% mortality rate, which is consistent with the hospital and national average for mortality.

Limitations of Study Design

The study design was a secondary analysis, which offered many benefits. However, there are inherent limitations to all secondary analysis that were present in this study. The dataset had already been cleaned and the individual items verified by second data entered.

Instrumentation Limits

In addition, the data did not have the individual item details from depression but rather subscale and scale scores. This prevented the ability to evaluate any relationships within an instrument item score to the outcomes. Previous conclusions regarding the validity and reliability of the instruments were obtained from the parent study. As a secondary analysis, it was not possible to request additional information or clarification from subject participants. In order to maintain the expectations of the parent study protocol, this research was limited to the timeframe of the parent study.

Preparedness scores appeared to have a ceiling effect. The majority of scores indicated a high degree of preparedness regardless of group enrollment in the parent study. A new inventory to measure this variable may be necessary to further assess a potential relationship.

This researcher was surprised that depression did not appear to have a relationship with preparedness. It was anticipated that depressed participants would report being less prepared to manage their heart failure. The preparedness scale used in this study measures how prepared patients rate their ability to manage heart failure. The study site is recognized by AHA for heart failure quality of care. Perhaps this population is provided more resources than the general population. Another consideration that may have impacted patient preparedness scores was the quality of standard care of all participants. As part of the study all participants were given a

standardized heart failure DVD to watch. This DVD has been proven to be of high quality and an effective teaching tool (Smith et. al, 2014). It is reasonable to assume that this level of patient education may be above the standard education provided to patients. This may have increased the perception of patient's preparedness to care for their heart failure. Heart failure is a progressive disease and this may supersede the impact of how prepared the patient is to manage it.

CES-D overall score was higher in women than men. The mean score for women was 10.08 compared to men who had a mean score of 8.23 (*p*-value =.05). The cut-off that was used to identify a participant as depressed was a score of greater than 16. It may be beneficial to evaluate in this specific population if this metric is relevant. Some research has been found to use a cut off score of 11 to identify persons with mild depression when using the CESD 10 (Miller, et.al., 2008). Depression is known to increase as daily function, extreme fatigue, and breathlessness increases regardless of how well prepared or how much the patient knows about managing their illness.

Study Generalizability

Study generalization was evaluated using the three generalization models described by Firestone, analytic, transferability, and statistical generalization as described (1993). The ability to replicate findings adds to the body of knowledge "knowledge grows through confirmation" (Polit & Beck, 2010).

Analytic generalizability is the process of reviewing and integrating the depth of the data within the breadth of the overarching theory. In other words, how well do the individual findings support the overarching research conclusions?

The statistical generalizability of the study is limited to the sample being selected from a single tertiary academic health center in the Midwest. Academic hospitals consistently have patients with higher CMI (Case Mix Index) than community hospitals. One could conclude that these participants from this academic medical center would be "sicker" than the standard heart failure patient. The initial study recruited participants after a hospital admission. It is worth considering if the results could be replicated or would they change if the study was conducted on patients prior to an admission. The study group had a recent inpatient hospital encounter thus the severity of their heart failure was controlled.

The setting and sample have been described in detail and meet the criteria of a "thick description", which provides a basis for researchers/clinicians to apply the findings in the future. The study sites heart failure quality measures for mortality is no different than the national rates (CMS Hospital Compare, 2015). Mortality rate 11.6% for heart failure patients specifically. Transferability is the ability to take the findings of a study and use it in a different setting or with different users (Lincoln & Guba, 1985).

The hospital site for this study participates with American Heart Association's Get With The Guidelines for Heart Failure (GWTG-HF) and has been recognized for repeated excellence in providing compliant evidence based care (Powell, 2016). GWTG-HF is a program to promote best practice treatment with the management of heart failure patients. The research sites strong adherence to GWTG-HF may have contributed to the overall outcomes of the study participants. This level of evidence based care compliance may decrease the studies generalizability.

Implications

Depression is a comorbid condition that is highly prevalent in patients with heart failure. In addition, recent research from the Nord-Trondelag Health Study suggests that depression may also be a risk factor for developing heart failure (Gustad et. al., 2014). The causal relationship between heart failure and depression is not well understood. This study confirmed that depression has a direct effect on all cause rehospitalization. For every one point increased on the CES-D scale the risk of being rehospitalized increased by 6.8 percent. The findings suggest that by reducing CES-D scores we can reduce the number of hospitalizations a patient will experience. Depression has also been linked to reduction in reported self-care (Kessing et al., 2016). Depression may be linked to poor compliance with medication, decreased provider contacts, less exercise, excess dietary sodium intake, and lack of flu shots but the current research findings do not provide conclusive cause.

The study has implications for healthcare providers, healthcare leaders, heart failure patients, legislature, and researchers that are interested in decreasing all cause rehospitalization and mortality in heart failure patients. Although a statistically significant relationship was not found between: depression and mortality, preparedness and mortality, and preparedness and depression the findings provide insight into the impact of depression on rehospitalization. Providers and hospitals must assess for depression in the heart failure population and provide effective treatment. Treating the symptoms and pathology of heart failure alone is inadequate to improving outcomes in this population.

A significant relationship was identified between depression and all cause rehospitalization. The relationship between depression and the composite variable (all cause rehospitalization and mortality) was also significant. However, it appears that all the explained

variability was due to all cause rehospitalization and not mortality. This further supports the strength of the relationship between depression and rehospitalization.

Suggestions for Further Research

Depression exists in multiple states and on a continuum as such there are a variety of instruments that measure depression. Research that explores the impact of depression in its various forms could provide additional meaning. Specifically, healthcare literature has presented an increase that compare CES-D and PHQ-9 results; as these measure different variables (Bowden et al., 2011). The body of heart failure knowledge would be enhanced and create increased transference of data if consensus could be reached on which depression assessment was most appropriate for this population.

A follow up qualitative study that explored what the main concepts preparedness, social support, depression, and income sufficiency mean to the patient would provide insight into effective interventions. The body of research surrounding heart failure and depression has not accepted a "gold standard" assessment tool. This has created a wealth of metrics to explore, but does not support direct comparisons.

This study confirmed that reactive depression has a relationship with rehospitalization. What is not known and needs further exploration is the impact of the healthcare team on that relationship. Would the healthcare teams' perception, knowledge, and ability to effectively manage depression effect the relationship between depression and rehospitalization? Further understanding of the variables that impact this relationship will promote the development of strategies to improve outcomes.

Another meaningful study is a longitudinal time study analysis of depression in heart failure patients. Ideally the first assessment would occur as initial diagnosis in the outpatient setting prior to an acute hospitalization, which would evaluate the modulating effect and reactive depression throughout the context of a chronic disease state. Now that the parent study is complete and all the data is available for evaluation, further exploration on the causes or rehospitalization and their relationship to depression would provide valuable knowledge.

Summary and Conclusion

This secondary analysis was conducted on the data from a large NIH supported study. Multiple analyses were used to explore the variation of depression. Correlation tests were conducted to test the correlations among the main study variables, which are: social support, income adequacy, Charlson comorbidity, depression, and heart failure preparedness, and various demographics.

Logistic regression analysis was done to test the relationship between reactive depression and all-cause rehospitalization and/or all-cause mortality. A multiple regression analysis was conducted to assess the relationship between depression and social support, depression and income adequacy, and depression and patient preparedness while controlling for demographic characteristics (age, gender, race, marital status, length of time of HF diagnosis, Charlson comorbidity index score). Depression was positively correlated with heart failure all cause rehospitalization. For every single increase in the CES-D score (level of depression) there was a 6.8% increase in the odds of being readmitted.

The findings regarding the nature of the relationship among the study variables supported the concept that depression is prevalent in heart failure patients and impacts rehospitalization.

Wagner's Chronic Care Model provided a substantial foundation for the relationships tested and the recommendations in this study. This included the interplay between the community, individual, social support, and treatment impacts outcomes. This study was not able to replicate the relationship between depression and mortality. However, the moderation effect depression has on the relationship between all cause rehospitalization and heart failure preparedness had not been tested before.

Heart failure is a condition that effects over 5.8 million Americans and is identified in every ninth death certificates annually (284,388 deaths) (Mozzafarian et,al., 2016). Heart failure was determined to be the underlying cause in 20 percent of those deaths. These statistics have remained consistent over the course of multiple decades. Heart Failure accounts for the primary diagnosis in over 1.02 million heart failure admission annually in 2010. The number has not changed significantly from 2000 when 1.008 million (Mozzafarian et,al., 2015). At this pace achieving The AHA Impact Goal "to improve the cardiovascular health of all Americans by 20%, while reducing deaths from cardiovascular disease and stroke by 20%" by 2020 is a daunting task. This expectation has been set in the presence of a known aging population (Go et. Al., 2013). The State of Aging and Health in America 2013 report estimates the American population greater than 65 years of age is expected to exceed 75 million in the next 25 years. This is double the current 65 and older population (CDC, 2013). Incidence of cardiovascular related death rises naturally as a part of the aging process. It is reasonable to assume that heart failure incidence will rise with the growing population.

Patients with cardiac diseases have been shown to have an increase incidence of depression. Depression is thought to have a relationship with heart failure mortality, but that was not validated with this study. The parent study included consultation with a Psychiatric Clinical

Nurse Specialist. This intervention may have contributed to the low depression and high preparedness scores. Complex relationships exist between heart failure demographics, preparedness, social support, and income adequacy. The research supports that differences exist in the outcomes and efficacy of treatment based on gender, African American race, socioeconomic status, self-care ability, and social support. These relationships, the cause of any disparities, and the impact of depression on the heart failure population are not fully understood.

An essential component of managing heart failure is reducing all cause rehospitalization and ultimately reducing mortality. It is essential to explore and understand the contributing and causal variables in order to improve heart failure outcomes. Creating meaningful interventions is essential to addressing this issue, researching contributing variables that can be modified such as preparedness and depression is one potential strategy. Additional, research is warranted to further confirm the findings and explore additional findings.

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Appendix A:

Human Subjects Approval

The University of Kansas Medical Center

Human Research Protection Program

July 1, 2013

Project Title:	Factors Associated with All-cause Re-hospitalization and Mortality in Patients with Heart Failure
Investigators:	Carol Smith, PhD, RN, FAAN Renee Walters, RN, MSN, CCRN, FNP
Department:	School of Nursing
Determination:	Not human subjects research

Dear Investigator:

Thank you for your submission. This letter certifies that the above referenced project has been evaluated by the KUMC Human Research Protection Program (HRPP). The HRPP has determined that your proposal does not involve human subjects.

Your project involves secondary analysis of data obtained from the IRB-approved study SMAC-HF. You will examine the effect of reactive depression on all-cause re-hospitalization and mortality among the subjects who participated in SMAC-HF. Because the data were not collected for your current research project and because they are being provided to you in a way that does not allow for individual identification, your project does not constitute human subjects research. It should also be noted that topic of your research was covered under the original IRB approval for the parent study. For these reasons, your project does not require review or oversight by the KUMC Human Subjects Committee.

Please note that if you revise your activities to interact directly with human subjects, or to obtain identifiable data, you should contact our office immediately. Also, you must notify our office if you inadvertently learn the identity of a study participant, or, for previously unforeseen reasons, you believe that it is important to identify an individual. If this were to occur, the HRPP would re-evaluate your project's regulatory status.

Very truly yours,

Karen Blackwell

Karen Blackwell, MS, CIP
Director, Human Research Protection Program

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Phone: (913) 588-0942 Fax: (913) 588-5771 kblackwe@kumc.edu

Appendix B:

Baseline

IDCODE_____ TCODE 01

Tell us a little about you. Please **Circle the number** that best describes you.

1. Are you male or female?

____ Male $_1$ ____ Female $_2$

2. In what year were you born?

_____

3. Do you have a Hispanic or Latino Ethnic Background or Spanish origin? (Cuban, Mexican, Puerto Rican, South American, Central American or other Spanish culture)

_____ Yes$_1$ _____ No$_0$

4. What is your race?

American Indian/Alaska Native... 1
Asian..... 2
Native Hawaiian/Other Pacific Islander..... 3
Black or African American..... 4
White..... 5
More than one race..... 6
Other..... 7

5. What is the highest grade in school that you completed?

Completed 8th grade or less..... 1
Some high school..... 2
Completed high school..... 3
Vocational/community college... 4
Some college..... 5
Completed college or more..... 6

6. What is your current marital status?

Married..... 1
Widowed..... 2
Divorced..... 3
Separated..... 4
Never married..... 5

7. Do you have children under 18 for whom you have caregiving responsibilities?

_____ Yes$_1$ _____ No$_0$

8. Counting yourself, how many people live in your household? _____ people

9. Are you currently employed for pay?

No..... 1
Yes..... 2
IF NO: Are you retired?..... 3
IF NO: Are you on disability?..... 4
IF NO: Disabled and retired?..... 5
IF YES: How many hours/week? ____

10. What kind of work (occupation) have you done most of your working life?

_____

11. Please circle each type of health insurance you use.

Private-employment based..... 1
Private-direct purchase..... 2
Medicare..... 3
Medicaid..... 4
Military (e.g. VA/Champus)..... 5
Other (Please list)..... 6

_____

IDCODE _____
CESD

TCODE 01

We are wondering about how you have felt over the **past four weeks**. Using the scale below, **circle** the **ONE** number that best describes how often you felt or behaved this way. **During the past four weeks, how often have you:**	Less than 1 day of the week	1-2 days of the week	3-4 days of the week	5-7 days of the week
1. Felt depressed.	0	1	2	3
2. Felt that everything you did was an effort.	0	1	2	3
3. Felt your sleep was restless.	0	1	2	3
4. Felt happy.*	0	1	2	3
5. Felt lonely.	0	1	2	3
6. Felt that people were unfriendly.	0	1	2	3
7. Enjoyed life.*	0	1	2	3
8. Felt sad.	0	1	2	3
9. Felt that people dislike you.	0	1	2	3
10. Felt you could not get "going".	0	1	2	3

11. **In the past three months,** have you had times when you were unhappy, sad, gloomy, depressed, blue, hopeless, or discouraged? If so, please write about the things that made you feel this way. **

_____

_____

Note to interviewer: Proceed to Depression/Suicide Protocol and contact Noreen if either of the following occurs: 1) Total score is 20 or greater (*when scoring, reverse the positive statement items # 4 (Felt happy) & #7 (Enjoyed life), meaning 0=3, 1=2, 2=1, 3=0); 2) Answer to item #1 (Felt depressed), #5 (Felt lonely), or #8 (Felt sad) is 3 (5-7 days of the week).

**Coding: CE 11 _____ 0 = No comments; 1= Comments
CE 11A _____ 0 = No sadness or feelings of discouragement, etc.; 1 = Yes
CE11B ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 Enter code(s) from coding list

Was Noreen Contacted? ____ Yes$_1$ ____ No$_0$ For Official Use Only _____

IDCODE _____ TCODE 01

We know that people feel well-prepared for some parts of home care, and not as well prepared for other parts. **Circle the number** that best shows how well prepared you feel you are to do the following, even if you are not doing that type of care now.

PREPAREDNESS	Not at all	Not too well	Some what	Pretty well	Very well
1. How well prepared do you think you are **now** to take care of the physical parts of managing heart failure at home?	0	1	2	3	4
1a. How well prepared do you think you are **now** to handle the daily heart failure self-management routine?	0	1	2	3	4
2. How well prepared do you think you are **now** to take care of the emotional parts of managing heart failure?	0	1	2	3	4
3. How well prepared do you think you are **now** to find out how to manage your heart failure care?	0	1	2	3	4
4. How well prepared do you think you are **now** for the stress of managing heart failure home care?	0	1	2	3	4
5. How well prepared do you think you are **now** to make activities pleasant for both you and those around you?	0	1	2	3	4
6. How well prepared do you think you are **now** to handle emergencies that involve heart failure?	0	1	2	3	4
7. How well prepared do you think you are **now** to get help and information you need from the health care system?	0	1	2	3	4
8. How well prepared do you think you are **now** to manage your heart failure?	0	1	2	3	4

ID Code _____ **TCode 01**

INS & INC

Tell us a little about you. Please **Circle the number** that best describes you.

1. Do you have insurance that pays for your medication?

_____ Yes$_1$ _____ No$_0$

2. If Yes, how much of the medication cost is paid by insurance? (Circle one number)

None	Some	Half	Most	All
1	2	3	4	5

3. In the **past 3 months**, did you stop using medication because of the cost?*

_____ Yes$_1$ _____ No$_0$

4. Which of the following statements describes your ability to get along on your monthly income?
Circle the number that best describes you.

I can't make ends meet.....	1
I have just enough, no more.....	2
I have enough, with a little extra sometimes...	3
I always have money left over.....	4

*3.1 If answer to question 3 is "yes," read subject the script for "Response to SMAC-HF Subjects who have Discontinued Taking Medication due to the Cost," then complete the form on the next page.

Time Stopped: _____ **Total Time Questionnaire:** _____ **Minutes**

IDCODE _____ TCODE 01

2. Social Support

During the past 4 weeks if you . . .

- felt very nervous, lonely, or blue
- got sick & had to stay in bed
- needed help with daily chores
- needed help just taking care of yourself

If you needed someone to listen or to help you, was someone there for you?

Yes, as much as I wanted		1
Yes, quite a bit		2
Yes, some		3
Yes, a little		4
No, not at all		5

3. Social Support

Was someone available to help you if you needed and wanted help?

Yes, as much as I wanted		1
Yes, quite a bit		2
Yes, some		3
Yes, a little		4
No, not at all		5