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# DO SOCIAL ISOLATION AND DEPRESSION AFFECT RATES OF HOSPITAL READMISSION FOR PATIENTS WITH HEART FAILURE?

Irma Samaniego

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**DO SOCIAL ISOLATION AND DEPRESSION AFFECT RATES  
OF HOSPITAL READMISSION FOR  
PATIENTS WITH HEART FAILURE?**

**BY**

**IRMA ALVARADO SAMANIEGO**

B.S.N., University of Texas at El Paso, 1979  
M.S.N. Administration, The University of Texas at El Paso, 1989

DISSERTATION

Submitted in Partial Fulfillment of the  
Requirements for the Degree of

**Doctor of Philosophy  
Nursing**

The University of New Mexico  
Albuquerque, New Mexico

**July, 2010**

## **DEDICATION**

**This work is dedicated to my children Adam and Adrian Samaniego.**

**And to my mother and father Carmela and Heriberto Alvarado.**

**And to the millions of people who suffer from depression, whose pain becomes  
unbearable, there is treatment, there is hope.**

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It is with deep appreciation and gratitude that I write this brief acknowledgement. It has been a humbling and traumatic journey in my life that is now complete. I hope to continue to grow and learn, professionally, as well as personally.

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- 4) The patients of Memorial Hermann who allowed me to speak with them
- 5) To my family, thanks for everything.
- 6) Finally, I thank God.

Thank you!

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## ABSTRACT

Heart failure (HF) is a syndrome that primarily affects the aged and is the most common hospital discharge diagnosis for adults in the United States. Readmission is common following discharge from an acute hospital stay for HF. Patients with HF suffer more depressive morbidity than other patients with cardiovascular disease, and many age 65 or older experience social isolation.

This prospective exploratory study examined whether readmission within 30 to 60 days of discharge from an index hospitalization for HF was associated with depressive symptoms or social isolation. A convenience sample of 101 patients participated during an index hospitalization for HF. Participants were followed-up for any readmissions within 30 or 60 days of discharge. Depressive symptoms were measured with the 15-item Geriatric Depression Scale (GDS-15) and social isolation with the Lubben Social Network Scale (LSNS).

At least one readmission for HF occurred for 27 participants within 30 days and for 31 within 60 days. Cronbach's alpha for the GDS-15 was extremely low (.39), and few participants ( $n = 9$ ) had scores consistent with risk for depression; hence, GDS-15 scores were inadequate for testing any association with readmission. The LSNS was reliable ( $\alpha = .77$ ), and 13 participants (13%) had scores consistent with social isolation. There was no association between social isolation and readmission within 30 or 60 days. However, responses to the LSNS helped to identify several patients whose need for social services had not been identified by hospital staff. In exploratory analyses, b-type natriuretic peptide (BNP) within 24 hours of the index admission was associated with



readmission, median = 3327 vs. 852 pg/ml,  $p=.056$ , and 3782 vs. 845 pg ml,  $p=.016$  for any vs. no readmission within 30 or 60 days, respectively.

Limitations include convenience sampling and possible sampling bias as well as a relatively brief follow-up period. Despite the lack of association with readmission, there may be other reasons for screening patients hospitalized for HF for depression or social isolation. The association between BNP and readmission merits further investigation in a study designed for that purpose.

## TABLE OF CONTENTS

|  |             |
|--|-------------|
| <b>LIST OF FIGURES .....</b>   | <b>XIII</b> |
| <b>LIST OF TABLES .....</b>  | <b>XIV</b>  |
| <b>CHAPTER 1 INTRODUCTION.....</b>   | <b>1</b>    |
| <b>Demographics.....</b>   | <b>5</b>    |
| <b>Social Isolation .....</b>  | <b>6</b>    |
| <b>Depression.....</b>   | <b>7</b>    |
| Major depression.....  | 9           |
| Minor depression .....   | 10          |
| Depression in older adults.....  | 11          |
| <b>Heart Failure Exacerbation .....</b>  | <b>11</b>   |
| <b>Conceptual Framework.....</b>   | <b>12</b>   |
| <b>Specific Aims of the Study.....</b>   | <b>16</b>   |
| <b>Potential Significance.....</b>   | <b>16</b>   |
| <b>Limitations.....</b>  | <b>17</b>   |
| <b>CHAPTER 2 REVIEW OF THE LITERATURE.....</b>   | <b>19</b>   |
| <b>Antecedent Factors .....</b>  | <b>21</b>   |
| Physiological.....   | 21          |
| Systolic vs. diastolic dysfunction or classification by ejection<br>fraction (EF)..... | 21          |
| Coexisting factors. ....   | 23          |
| Vasculature .....  | 24          |

|  |           |
|--|-----------|
| Cardiac adaptation .....   | 25        |
| Circulation.....   | 26        |
| Categorizing HF .....  | 27        |
| <b>Psychosocial and Situational / Environmental Antecedent: Social Isolation</b> ..... | <b>29</b> |
| Social isolation and race or ethnicity .....   | 31        |
| Social isolation and gender .....  | 32        |
| <b>Symptom Experience</b> .....  | <b>34</b> |
| Fatigue.....   | 35        |
| Dyspnea.....   | 36        |
| Depression.....  | 39        |
| Somatic awareness .....  | 41        |
| <b>Outcomes</b> .....  | <b>43</b> |
| Readmissions and depression .....  | 43        |
| <b>Mortality and Social Isolation</b> .....  | <b>44</b> |
| <b>CHAPTER 3 METHODS</b> .....   | <b>46</b> |
| <b>Specific Aims and Research Questions</b> .....                                      | <b>46</b> |
| <b>Research Design</b> .....   | <b>47</b> |
| <b>Sample and Setting</b> .....  | <b>47</b> |
| Sample.....  | 47        |
| Setting .....  | 48        |
| <b>Variables and Measures</b> .....  | <b>49</b> |
| Demographic data .....   | 49        |

|  |           |
|--|-----------|
| Cognitive status.....                            | 49        |
| Independent variable.....                        | 51        |
| Dependent variables.....                         | 51        |
| Lubben Social Network Scale.....                 | 56        |
| <b>Protocol and Data Collection .....</b>        | <b>57</b> |
| Recruitment and consent.....                     | 57        |
| <b>Data Analysis.....</b>                        | <b>59</b> |
| <b>Protection of Human Subjects .....</b>        | <b>61</b> |
| <b>Summary.....</b>                              | <b>62</b> |
| <b>CHAPTER 4 RESULTS.....</b>                    | <b>64</b> |
| <b>Descriptive Statistics .....</b>              | <b>64</b> |
| Demographic characteristics.....                 | 64        |
| Clinical characteristics .....                   | 67        |
| Readmissions .....                               | 69        |
| <b>Geriatric Depression Scale .....</b>          | <b>71</b> |
| <b>The Lubben Scale.....</b>                     | <b>72</b> |
| <b>Exploratory Analyses of Readmission .....</b> | <b>76</b> |
| <b>CHAPTER 5 DISCUSSION .....</b>                | <b>79</b> |
| <b>Statistical Assumptions.....</b>              | <b>79</b> |
| <b>Theoretical Assumptions .....</b>             | <b>80</b> |
| Physiological factors.....                       | 81        |
| Situational factors .....                        | 83        |

|  |            |
|--|------------|
| Psychological factors .....  | 83         |
| <b>Limitations</b> .....   | <b>86</b>  |
| <b>APPENDICES</b> .....  | <b>91</b>  |
| Appendix A Geriatric Depression Rating Scale (English Version).....                                      | 92         |
| Appendix B Geriatric Depression Rating Scale (Spanish Version).....                                      | 94         |
| Appendix C Lubben Social Isolation Questionnaire (English Version).....                                  | 96         |
| Appendix D Lubben Social Isolation Questionnaire (Spanish Version) .....                                 | 100        |
| Appendix E Consent to Participate in a Research Study (English) .....                                    | 104        |
| Appendix F Consent to Participate in a Research Study (Spanish).....                                     | 110        |
| Appendix G Authorization for the Use and Disclosure of Protected Health Information<br>for Research..... | 115        |
| <b>REFERENCES</b> .....  | <b>124</b> |

## LIST OF FIGURES

Figure 1: Theory of Unpleasant Symptoms; adapted from Lenz et al. (1997). 35

## LIST OF TABLES

|         |   |    |
|---------|---|----|
| Table 1 | Demographic characteristics of sample (N = 101)                               | 65 |
| Table 2 | Marital status by gender (N = 101)  | 66 |
| Table 3 | Age ranges of participants (N = 101)  | 67 |
| Table 4 | Length of stay (LOS) for enrolled sample (N= 101)                             | 67 |
| Table 5 | Left ventricular ejection fraction by sex (N= 100)                            | 68 |
| Table 6 | Discharge diagnosis (N=101)   | 70 |
| Table 7 | Readmissions (N = 101)  | 71 |
| Table 8 | Admission BNP values (pg/ml) by readmission status at 30 days and 60 days     | 77 |
| Table 9 | Left ventricular ejection fraction by readmission status at 60 days (N = 100) | 78 |

## **Chapter 1**

### **Introduction**

Heart failure (HF) is the most common adult cause of hospitalization, with more than a million hospitalizations annually in the U. S. (Rosamond et al., 2007; Writing Group Members, Lloyd-Jones, Adams, Brown, Carnethon, Dai, S., et al. 2010). According to the American Heart Association (Writing Group Members et al., 2010), over 5 million Americans have heart failure, and the direct and indirect costs of HF exceed \$39 billion per year in the U. S. (Writing Group Members et al.). Among this population, heart failure readmission rates range from 25 to 50% within six months of a hospitalization (Jerant, Azari, & Nesbitt, 2001). The AHA recommends implementing strategies to reduce preventable readmissions to reduce their impact on the economic burden of HF to society. This, in turn, requires greater understanding about factors that may influence readmissions. The purpose of this investigation is to explore emotional and social issues that may influence readmission of individuals with HF.

Heart failure is a syndrome that primarily affects the aged. It exists when the heart muscle is weakened sufficiently to impair its capacity to fill with or pump sufficient blood to meet the body's physiologic demands (Hunt et al., 2005). According to the Heart Failure Society of America (HFSA) (2006a, 2006b):

HF is a syndrome caused by cardiac dysfunction, generally resulting from myocardial muscle dysfunction or loss and characterized by left ventricular dilation or hypertrophy. Whether the dysfunction is primarily systolic or diastolic or mixed, it leads to neurohormonal and circulatory abnormalities, usually resulting in characteristic symptoms such as fluid retention, shortness of breath,



and fatigue, especially on exertion. In the absence of appropriate therapeutic intervention, HF is usually progressive at the levels of cardiac function and clinical symptoms. The severity of clinical symptoms may vary substantially during the course of the disease process and may not correlate with changes in underlying cardiac function. Although HF is progressive and often fatal, patients can be stabilized and myocardial dysfunction and remodeling may improve, either spontaneously or as a consequence of therapy.

In physiologic terms, HF is a syndrome characterized by elevated cardiac filling pressure or inadequate peripheral oxygen delivery, at rest or during stress, caused by cardiac dysfunction. (HFSA, 2006b, p. 14).

The causes of heart failure can be classified into four categories 1) work overload of the ventricle 2) oxygen deprivation of the myocardium such as hypoxia, ischemia, infarction, and or fibrosis 3) cardiomyopathies and 4) altered cardiac rhythm (Hunt et al., 2005). Work overload refers to increased preload (e.g., increased venous return as in fluid overload, or mitral or tricuspid regurgitation) or afterload (e.g., systemic arterial hypertension, pulmonary arterial hypertension, stenosis of the aortic or pulmonic valves; Hunt et al.).

Ischemia is a condition of oxygen deprivation and subsequent inadequate removal of metabolites. The oxygen demand of the heart may be affected by atherosclerotic disease. Atherosclerosis may result in loss of myocardial contractility, increased wall stress, and decreased ventricular compliance (Hunt, et al. 2005). Heart failure is a common sequela of long-term ischemic coronary artery disease, commonly, though not always, following myocardial infarction (Hunt et al.).

Cardiomyopathies are characterized by hypertrophy or hyperplasia of the myocardium, and are generally classified as dilated, hypertrophic, restrictive, arrhythmogenic right ventricular, and unclassified (Elliott, et al., 2008; Richardson, et al., 1996). Although it is common in clinical practice to make inferences about etiology (e.g., ischemic vs. nonischemic based on cardiac catheterization), formal classification schemes focus more on structural and functional characteristics of myocardium, whether or not etiology is known (Elliott, et al.; Richardson, et al.). Dilated cardiomyopathies are characterized by ventricular chamber dilation, systolic dysfunction, elevated left ventricular filling pressure and diminished systolic ejection fraction (Cohn, 2007). These cardiomyopathies often result from myocardial injury due to alcohol or drug abuse, toxic exposures, or viral infections. Restrictive cardiomyopathies may be idiopathic or associated with other diseases (e.g., amyloidosis, scleroderma; Elliott et al.). They are characterized by the impairment of diastolic filling and relaxation which results in depressed cardiac output. Hypertrophic cardiomyopathy (HCM) is characterized by marked hypertrophy of the left ventricle. HCM often has a genetic basis, and is a common cause of sudden death in young, apparently healthy, athletes (Cohn, 2007). However, all classifications can have familial / genetic or non-familial / non-genetic etiologies (Elliott et al.).

Lastly, altered rhythms can be associated with HF or cardiomyopathy, either as an etiological factor or as a consequence or correlate. For example, atrial fibrillation occurs frequently in the presence of systemic arteriolar hypertension and mitral valve disease. Atrial fibrillation results in near-complete loss of effective atrial contraction (sometimes called ‘atrial kick’). In the presence of rapid or impaired ventricular response, this may

reduce cardiac output substantially (Cohn, 2007). Tachydysrhythmias may shorten diastolic filling time and result in decreased stroke volume. Rapid heart rate also increases oxygen demand in patients with atherosclerotic coronary artery disease (CAD), tachycardias may induce or worsen myocardial ischemia, further depressing myocardial function (Cohn).

In the U. S., functional capacity of patients with HF is commonly graded according to the New York Heart Association (NYHA) four-level classification scheme (NYHA, 1994, as cited in American Heart Association, 2007).

- Class I: The patient has no limitation of activities, and ordinary physical activity does not provoke symptoms of dyspnea, fatigue, palpitations or angina.
- Class II: The patient has slight, mild limitation of activity but is comfortable at rest; ordinary physical activity provokes symptoms of dyspnea, fatigue, palpitations or angina.
- Class III: The patient has marked limitation of activity, comfortable only at rest. Less than ordinary physical activity provokes symptoms of dyspnea, fatigue, palpitations or angina.
- Class IV: Inability to perform any physical activity without discomfort and symptoms may occur at rest.(American Heart Association, 2007)

In keeping with the heterogeneous etiologies and presentations of heart failure symptoms, the classification is based primarily on symptoms and their impact on activities, but all categories presume there is objective evidence of cardiovascular disease (American Heart Association, 2007).

It is well documented that co-morbidities such as renal dysfunction, chronic obstructive pulmonary disease, diabetes, and hypertension increase the risk of readmission among patients with HF. Indeed, it has been estimated that 40% of patients with heart failure have five or more noncardiac comorbidities, and that this group accounts for 81% of total inpatient hospital days (Braunstein et al., 2003). Braunstein and colleagues also concluded that, following hypertension and diabetes, the noncardiac co morbidities most frequently experienced by patients included chronic obstructive pulmonary disease (26%), osteoarthritis (16%), chronic respiratory failure or lower respiratory failure (14%), thyroid disease (14%), Alzheimer's disease or other dementia (9%), depression (8%), chronic renal failure (7%), asthma (5%), osteoporosis (5%), and anxiety disorders (3%).

### **Demographics**

In the United States there are approximately 35 million persons over the age of 65, and the most rapid growth in population is occurring in those over the age of 85 (Centers for Disease Control & Merck Company Foundation, 2007). The aging of the population, due in part to increases in life expectancy, including those due to medical advances, means that more Americans than in the past survive to an age at which HF is common (Cohn, 2007). As a person ages the risk of age-dependent heart failure begins to increase, in particular from abnormalities of ventricular relaxation, aging of the vasculature structures, and increased prevalence of coronary artery disease (Cohn). Moreover, as survival from myocardial infarction improved over the last several decades, due to advances in emergency cardiac care, interventional cardiology, and cardiac surgery, some of those saved go on to develop HF. Even improvements in the treatment

of HF itself have contributed to the rising prevalence of HF, to the extent such treatments are effective in extending life expectancy.

### **Social Isolation**

With the general increase in life expectancy, there has also been a dramatic increase in the number of elders living alone. In 1910 only 12% of widowed elders lived alone; nowadays, approximately 40 percent of elders live alone (Hays & George, 2002). Demographers attribute the trend to generally lower fertility rates and a growing preference for privacy. However, there appears to be a significant pattern among elders who live alone. Many are frail, disabled, and widowed; they are also more likely to be economically deprived, lonely, and suffer from depression ( Bertera & Bertera, 2008). Additionally, social isolation has become such a concern that the World Health Organization (WHO) has recognized the prevention of social isolation as necessary for good health (WHO, 2002).

Social isolation can be defined in two ways. One reflects the type and frequency of social contacts. The other reflects the degree to which a person perceives that certain types of support are available. A person is only socially isolated if he or she defines the amount of contact with others as inadequate (Aquino, Altmaier, Russell, & Cutrona, 1996). It is important to remember that living alone does not necessarily make someone isolated; solitude can be a personal choice. For example, social isolation may refer to a physical separation from other people, such as living alone or living in a rural or isolated area. But, it may also refer to a person who chooses to be socially isolated, for example the elder who has chosen to live at some distance from family and friends.

Also, the number of persons or personal daily contacts may be a factor related to adequate social support. Social isolation appears to affect persons with fewer than three people in their social support network (Stuart-Shor, Buselli, Carroll, & Forman, 2003). Individuals with smaller social support networks report the lack of a confidant, and attending fewer social functions. When elders over the age of 85 were asked about the number of friends, 42% reported a decrease in the size of their network. The mean size of an active social network for an elder has been reported to be from five to seven people (Stuart-Shor et al.) with older persons consistently reporting fewer people in their social support groups.

### **Depression**

Heart failure patients suffer significant depressive morbidity; characterized by identifying symptoms of depression (Turvey, Shultz, Arndt, Wallace, & Herzog, 2005). Some symptoms may be attributed to the deterioration in health status (Fitzsimons et al., 2007). In one qualitative study examining patient needs in chronic illness, one heart failure patient described his depression in the following manner:

I don't feel like going out. I have been feeling depressed.... I just didn't want to get out of bed. I felt the same way as I did when I went into the hospital. I feel absolutely rotten. I couldn't care less about anything. (Fitzsimons et al., 2007, p.320)

In the same study, the clinical staff identified depression as a problem for the heart failure population:

Well, perhaps there is something proactive that we could do? Are we under assessing our patient's moods? I know we treat them with our evidence based

medicine for their physical condition; maybe there is something else we could do to help psychologically? (Fitzsimons, 2007, p 320)

Nurses and other providers have recognized that depression is a common problem in patients with HF (Fitzsimons et al., 2007). Major depression is present in 17% to 37% of patients with HF, and minor depression is present in 16% to 22% (Koenig, 2006; Lang & Mancini, 2006). Among heart failure patients, depression is associated with more frequent hospital readmissions, a decline in activities of daily living, and worse New York Heart Association (NYHA) functional classification (Vaccarino, Kasl, Abramson, & Krumholz, 2001; Murberg & Bru, 2001).

Based on the information currently available, it is important for nurses who care for patients with HF to begin to explore in detail the perspective of the heart failure patient. It is important to begin to account for chronology of events or experiences of the heart failure patient, to determine where and when assistance should begin. Without further exploration the potential for continued high readmission rates for HF will continue.

This study is intended to further the knowledge related to symptom identification of patients with heart failure. Managing symptoms of the patient with heart failure is key to a positive outcome. As patients move through the continuum of acute to palliative care, the focus of the interventions may change, but the importance of treating depression and of identifying social isolation remains. This study should increase the awareness that depressive symptoms and social isolation are common among patients with heart failure and should add to the growing body of knowledge for the care and support of people undergoing heart failure treatment.

**Major depression.** The standard psychiatric definition of major depressive disorder (MDD or major depression) as defined by the Diagnostic and Statistical Manual of Mental Disorders-Fourth edition-Text Revision (DSM-IV-TR; American Psychiatric Association, 2000) entails axis 1 criteria that require confirmation by a trained therapist. A diagnosis of MDD implies confirmation that a person has been experiencing at least five of nine possible symptoms, for at least two weeks and that this is a departure from the individual's prior level of functioning. At least one of those symptoms must be a depressed mood or a loss of interest or pleasure (anhedonia) in all or nearly all activities most of the time (nearly every day). Depressed mood and anhedonia may be ascertained by self-report or by report of others (American Psychiatric Association, 2000). Other symptoms may include:

- Considerable loss or gain of weight (5% change in a month, when not dieting.) There may also be a decrease or increase in appetite.
- Difficulty falling asleep or staying asleep (insomnia), or sleeping more than usual (hypersomnia).
- Agitated behavior or slowed down behavior. Others should be able to observe this behavior change.
- Feelings of fatigue or diminished energy.
- Thoughts of worthlessness or extreme guilt.
- Reduced or impaired ability to think, concentrate, or make decisions.
- Frequent thoughts of death or suicide (with or without a specific plan), or an attempt of suicide. (American Psychiatric Association, 2000)



These symptoms cause great distress or difficulty in functioning at home, work, or in personal areas of daily life. According to the DSM- IV-TR criteria, the person's symptoms are not caused by substance abuse, are not due to normal grief or bereavement over the death of a loved one, or by another diagnosis such as schizophrenia (American Psychiatric Association, 2000).

Complicating the assessment of depression in patients with HF, many of the symptoms of depression are common symptoms of heart failure. Hospitalized HF patients frequently report low energy, fatigue, and difficulty enjoying themselves. In addition, sleep disturbances and sleep disorders are common among patients with HF (Turvey et al., 2005). Many patients and providers assume such symptoms are to be expected in anyone with HF, or as a part of getting old; accordingly, depression in patients with HF may remain undiagnosed and untreated or under treated.

**Minor depression.** Minor depression is less disabling than major depression and may last up to two years. It is defined as having 2 to 4 depressive symptoms, of which at least one must be depressed mood or anhedonia, in either case, the symptoms should be occurring most of the day, more often (more days) than not (American Psychiatric Association, 2000). Minor depression is also referred to as subsyndromal depression, mild depression, subclinical depression, and subthreshold depression. Minor depression that has persisted for more than two years (with no episodes of suicidal ideation or attempts) may be indicative of dysthymic disorder (another axis one mood disorder). In general, minor depression among the elderly is more common than major depression (Lyness, King, Cox, Yoediono, & Caine, 1999), but this may not always be the case among patients with HF (Koenig, 2006; Lang & Mancini, 2006).

**Depression in older adults.** Major depressive disorder in older adults can be divided according to time of onset: early life major depression onset, and late life onset (after age 65). The early life onset of major depression typically recurs before age 65 and continues as the person continues to age. Late life depression is depression occurring after age 65, and it may be associated with biological, psychological and social factors (Lapid & Rummans, 2000). Late life depression may occur more frequently in the context of severe or chronic medical illness. Major depression is a serious comorbidity for heart failure patients, with the more depressed dying sooner (Murberg & Furze, 2004).

Murberg & Furze (2004) conducted a longitudinal study of mortality in community-residing patients with HF in Norway. The Zung self rating depression scale (SDS) was utilized to assess for symptoms of depression. In this study 51 out of 119 patients died during a six year follow up period, all from cardiac causes. Patients who were depressed were two and a half times more likely to die within six years than those who were not depressed. The increase in relative risk (RR) for each 1-point increase on the SDS was 1.05 (95% CI, 1.00 to 1.08,  $p = .016$ ), controlling for sex, age, trait neuroticism, and natriuretic peptide levels (a surrogate marker for HF severity).

### **Heart Failure Exacerbation**

Heart failure exacerbation is also known as acute decompensated heart failure; it represents new or worsening signs and symptoms of dyspnea, fatigue or edema that may lead to hospitalization or an unscheduled medical visit. Acute decompensated heart failure is a common problem for patients over the age of 65, and it is associated with major morbidity and mortality (Allen & O'Connor, 2007). Heart failure exacerbations

occur for a variety of reasons (Knox & Mischke, 1999), not all of which are ascertainable. Cardiac causes may include ischemia, pressure or volume overload, or abnormally high or low cardiac output. Other causes of exacerbations may include poorly controlled hypertension, inflammation or infection, lack of adherence with medications, or substance abuse. According to Knox and Mischke, problems in adhering to medications or dietary restrictions and failures of social support are commonly implicated in exacerbation. However, I believe that the potential difficulty adhering to HF medical regimens may also be due to increased difficulty in identifying the symptom origin. A clearer understanding is needed of the combination of physiological and psychosocial symptoms that occurs in HF patients, as well as situational and environmental factors that affect their symptom experience and most importantly the joint effects of combinations of these factors.

### **Conceptual Framework**

The conceptual framework for this investigation is the theory of unpleasant symptoms (TOUS), (Lenz, Pugh, Milligan, Gift, & Suppe, 1997; Lenz, Suppe, Gift, Pugh, & Milligan, 1995). The theory of unpleasant symptoms (TOUS) was developed initially by nurses who had been conducting research on two different symptoms: dyspnea and fatigue. In collaborative discussions, they realized that there were many common elements across these symptoms such that if a nurse understood one symptom, much of that knowledge might apply to the other, and possibly to any unpleasant symptom (Gift et al., 2004). The TOUS addresses symptom recognition and symptom reporting. It is believed that people are able to identify symptoms as a departure from normal functioning (Lenz et al., 1997, 1995), attach a meaning, and make decisions or

take some action (including deciding not to take action). Additionally, the TOUS assumes that persons or their caregivers are able to communicate or correctly interpret the symptoms.

According to the TOUS, symptoms are fundamentally unpleasant sensory perceptual experiences in relation to illness or altered health status that can be characterized in terms of their intensity, sensory quality, timing (duration and frequency), and concomitant distress (Lenz et al., 1997, 1995). Symptoms can be further characterized as being influenced by physiological, psychosocial, and situational or environmental factors (antecedent or influencing factors) and as having consequences or impacts on performance, functioning, or quality of life (Lenz et al., 1997, 1995).

The physiological component of the model includes factors such as the involved organ systems, tissues, and cells, pathological alterations, and metabolic status (e.g., nutrition, elimination of waste products). Psychosocial influencing factors or antecedents could include personality traits, pre-existing depression or other mood disorders, and reactions to an illness state, such as help-seeking or marshaling of social support. Situational factors might include type of employment, occupational or environmental exposures, cultural beliefs, and living situation (e.g., social isolation). Consequences or impacts on performance relate to physical, cognitive and role functioning and also quality of life (Lenz et al., 1997, 1995). A refinement of the original model (Lenz et al., 1997) also took into account that symptoms often occur in combinations or clusters, not in isolation, and emphasized more explicitly the potential for feedback among the three levels of the model (influencing factors, symptom experience, and performance or impact).

In terms of this dissertation, it should be noted that social isolation is viewed under the TOUS as primarily an antecedent or influencing factor (whether conceived of as psychosocial, situational / environmental, or both). In contrast, although depression can be a pre-existing / influencing factor, it may also be a concomitant symptom (i.e., part of a cluster or constellation of concurrent symptoms), or a reaction or consequence of acute or disabling symptoms (e.g., after a myocardial infarction or an exacerbation of chronic HF). On the other hand, distress is a somewhat ambiguous term that refers either to the unpleasantness of sensation or to a person's emotions and evaluative judgments about the possible meaning of what is felt (Armstrong, 2003; Price, 2000; Wells & Ridner, 2008). Regardless, under the terms of the TOUS, distress is held to be part of the symptom experience itself, not a separate symptom. When multiple symptoms interact, as in a symptom cluster, distress may become amplified.

Diseases and syndromes are commonly characterized by groups of symptoms (clusters) that alert the patient that something is wrong and which commonly serve the health care professional as a starting point for history taking and diagnostic testing. In the psychological and psychiatric literature, clinicians have historically used symptom clustering (multiple symptoms) to diagnose and better understand psychological disorders (Faustman & Ficek, 2002). Indeed, one of the main rationales for the DSM axis system was to systematize what combinations of symptoms were necessary for a diagnosis and which and how many others had to be present for a diagnostic label to apply. In medicine, symptom clusters are also characteristic of syndromes such as heart failure or chronic obstructive pulmonary disease that may be heterogeneous in terms of etiology or phenotype. Symptoms of HF may vary to some degree depending on whether it primarily

involves systolic or diastolic dysfunction or right or left ventricular failure. However, common signs and symptoms of HF include fatigue, dyspnea (especially dyspnea on exertion, orthopnea, or paroxysmal nocturnal dyspnea), and peripheral or pulmonary edema.

It wasn't until the late 1990's that a new approach was sought to assist in the management of multiple symptoms: how they were expressed and experienced (Dodd, Miaskowski, & Lee, 2004, Miaskowski, Dodd & Lee, 2004). The belief is that understanding synergistic relationships and interactions among symptoms can optimize symptom management. The TOUS assists in explaining what the symptom experience consists of as well as factors that influence symptoms and outcomes that symptoms influence. The theory views symptoms as interactive, rather than simply additive.

In summary, experiencing multiple symptoms is an integral aspect of living with HF. The TOUS helps to examine each symptom as an interactive component. The theory is based on the assumption that sufficient commonalities exist among symptoms, and acknowledges potential interactions among multiple symptoms. In heart failure, the physiological, psychosocial, and situational factors implicated in classic symptoms of heart failure, such as dyspnea and fatigue, may also be responsible for producing secondary symptoms (e.g., depression). In addition, medications taken for heart failure management may also contribute to depressive symptomatology.

In contrast, social isolation is not a symptom per se, but it could influence either the severity of symptomatology or how effectively or ineffectively the patient copes with HF symptoms and treatment. Alternatively, in some cases, it could be a response to or outcome of depression and other symptoms. Patients with depression may begin to

exhibit behaviors that adversely affect social activities. For example, unmanaged depression may lead to inactivity, and inactivity may lead to withdrawal from friends and family.

### **Specific Aims of the Study**

The specific aims of this exploratory study were to determine whether readmission in elderly patients with heart failure is associated with differences in depressive symptoms, social isolation, or both. The primary independent variable was readmission status at 30 and 60 days following discharge from an index hospitalization for heart failure. For the dependent variables, depressive symptoms were measured with the Geriatric Depression Scale (15-item version; GDS-15; Sheikh & Yesavage, 1986; Yesavage et al., 1983), and social isolation was measured with the 18-item version of the Lubben Social network Scale (LSNS-18; Lubben & Gironde, 2003). Hypotheses for the study were that patients readmitted within 30 to 60 days of discharge from an index hospitalization for HF would differ from patients who are not readmitted in terms of depressive symptoms (GDS-15 scores) and social isolation (LSNS-18 scores) during the index hospitalization. Other patient characteristics to be assessed in exploratory analyses included gender, race and ethnicity, age, educational level, ejection fraction (preserved vs. reduced), NYHA classification level, and b-type natriuretic peptide (BNP) levels drawn within 24 hours of admission.

### **Potential Significance**

The treatment of heart failure centers on complex medication and dietary regimens. For adequate symptom management, patients must be motivated and be willing to learn their treatment regimen, should weigh themselves daily, and should be cognizant

of any changes in their symptoms or activity tolerance. On any given day, symptoms may vary in number and in the intensity, duration or frequency, quality, and the amount of distress associated with them. The symptom and economic burdens of HF may be substantial; causing patients to become depressed or the heart failure treatment itself may cause patients to become depressed. Either way, untreated depression potentially affects the lives of heart failure patients adversely. Furthermore, patients who are depressed may remove themselves from social activities, or the physiological symptoms of heart failure may begin to remove heart failure patients from social activities. When social isolation is experienced, a person may be psychologically challenged by lack of social contacts, friendships, or motivation in ways that may interfere with recognition of heart failure symptoms or with self-management (Brummett et al., 2001). This descriptive study, comparing levels of depression and social isolation between patients with and without a readmission for heart failure may provide insight into the potential importance of assessing depressive symptoms and social isolation when patients with HF are hospitalized. If it turns out there are systematic differences in either depression or social isolation scores between those who subsequently are versus are not readmitted within 30 to 60 days, it would support the need for a larger, prospective study of the predictive utility of measures of depressive symptoms or social isolation in this population in the setting of an acute hospitalization for HF.

### **Limitations**

The limitations of this study include:

1. The study is observational and will necessarily involve a convenience sample of inpatients willing to participate.



2. This study includes only participants from one health care system in southeast Texas therefore, the findings may not be generalizable beyond that locale.
3. Participation is limited to patients who are able to speak and write in English or Spanish and who are not cognitively impaired.
4. It is assumed that self reported scores for depressive symptoms and social isolation are accurate, and that those willing to participate in an observational study are motivated to self-report honestly.

## Chapter 2

### Review of the Literature

Symptoms are subjective experiences of illness that are typically described in terms of alterations in physiological, psychosocial, or behavioral functioning as perceived by the person experiencing them (Hegyvary, 1993). Typically symptoms are contrasted with signs, objective manifestations of illness detectable or measurable by others. However, it is not uncommon for there to be considerable ambiguity between symptoms and signs, and in some cases the same term may be used to label either a symptom or a sign. For example, patients may report having edema on the basis of subjective sensations (e.g., shoes or jewelry not fitting) or on the basis of an increasing trend in daily weights; both can carry the same label, edema, but the former is edema as symptom, the latter is edema as a sign. Either could indicate a possible worsening of heart failure. Similarly, angina pectoris, per se, is a symptom, but when a patient reports its occurrence during a stress test, it is a sign that further diagnostic and, perhaps, interventional activities are called for.

Despite important conceptual distinctions between symptoms, signs, and disease, from the patient's perspective, these are often fused at the experiential level such that the signs (e.g., peripheral edema) and symptoms (e.g., dyspnea and fatigue) *are* the disease or, at least, surrogates for it (Hegyvary, 1993). Patients are unlikely to present for care with complaints about their ejection fraction or oxygen saturation; they are far more likely to complain that they can no longer walk short distances without becoming severely anginal, fatigued, or breathless.

The most basic definitions of symptoms are disturbances of sensation or function that a person experiences as unpleasant, out of the ordinary, or distressing in relation to a usual or ideal state of health or functioning. By themselves, however, symptoms are generally nonspecific with respect to any particular disease or condition (Aronowitz, 2001). Hegyvary (1993) suggested that symptoms potentially are what a person takes to be “red flags” (p.146) that something is not right and that may prompt help-seeking activities.

Within the theory of unpleasant symptoms (TOUS; Lenz et al., 1997, 1995), symptoms are characterized as disturbances in sensation or function that are perceived as unpleasant by the person experiencing them and that have: (a) *physiological*, *psychological*, and *situational* (social and physical environment) antecedents; (b) elements of *intensity*, *sensory quality*, *distress*, and *timing* (e.g., frequency and duration); and (c) impacts or consequences for behavior, affect, cognition, physical functioning, and perceived health status (collectively termed *performance* in the model). Importantly, the model posits feedback and interaction among the various levels and among multiple more or less concurrent symptoms (Lenz et al., 1997). For example, if symptoms lead to inactivity (a behavioral consequence) deconditioning or depression may ensue, and these, in turn may worsen the patient’s underlying physiological and psychosocial condition. On the other hand, if symptoms lead to appropriate help-seeking and treatment of underlying etiologies (hypertension, ischemic coronary artery disease), particularly if combined with structured physical activity as in a rehabilitation program, underlying physiological and psychosocial functioning may stabilize or even improve to some degree.

In this chapter heart failure will be examined from the standpoint of the TOUS (see Figure 1). First, I will provide a brief overview of physiological, psychosocial/behavioral, and situational factors. Then symptoms will be examined. It should be understood that the levels and categories within levels of the TOUS do not represent hard and fast distinctions, let alone imply mutually exclusive categories. For example, social isolation has both psychological and situational/environmental aspects; therefore these will be approached jointly below. Depression can have both physiological and psychological aspects, it can be a pre-existing (antecedent) condition, but it is also a common symptom among patients with HF, many of whom may not have suffered from depression previously. Lastly, the impacts and outcomes of HF will be examined in terms of cognitive, affective, and behavioral consequences or outcomes.

### **Antecedent Factors**

**Physiological.** Common causes of HF include ischemic coronary artery disease, hypertension, and cardiomyopathy, or cardiac remodeling often in conjunction with aging, chronic ischemia, and myocardial injury (e.g., following infarction) (American Heart Association, 2005; Hunt et al., 2005). Heart Failure often develops slowly over time and symptoms begin to appear as the heart loses its ability to fill with or pump blood (Heart Failure Society of America, 2006a. 2006b; Hunt et al.).

### **Systolic vs. diastolic dysfunction or classification by ejection fraction (EF).**

What traditionally used to be referred to as congestive heart failure (CHF) was categorized clinically as primarily left sided (characterized by diminished left ventricular function and pulmonary congestion) or right sided (characterized more by peripheral edema, often in a setting of chronic pulmonary or renal disease). Nowadays, the more

general term, *heart failure*, is preferred, and HF is more often characterized as either systolic versus diastolic dysfunction or, in terms of ejection fraction, as either decreased or preserved.

Systolic dysfunction implies impaired ability of the ventricle (primarily the L ventricle) to empty, as manifested by a reduced ventricular ejection fraction. Criteria for reduced left ventricular ejection fraction (LVEF) are somewhat variable. There is general agreement that LVEF of 50% or above is preserved. Some classify LVEF less than 50% as diminished (Owan et al., 2006), whereas others consider an EF between 40 and 50% to be borderline and reserve the term 'reduced ejection fraction' for those with an LVEF less than 40% (Bhatia et al., 2006).

Diastolic dysfunction implies an impairment of ventricular filling, typically from reduced distensibility or impaired ventricular relaxation of the left ventricle, regardless of whether ejection fraction is preserved or reduced (Aurigemma & Gaasch, 2004).

Diastolic heart failure or heart failure with preserved left ventricular (LV) systolic function (ejection fraction) is recognized as a major growing epidemiological problem (Aurigemma & Gaasch, 2004; Bhatia et al., 2006; Owan et al., 2006), with at least one third to nearly half of HF patients presenting initially with preserved LV systolic function (Aurigemma & Gasch; Bhatia et al.; Chen, Lainchbury, Senni, Bailey, & Redfield, 2002; Owan et al.). The diagnosis of diastolic dysfunction is complex and is best made by Doppler imaging and by assessing the architecture of the heart by echocardiography.

All patients with heart failure and preserved EF can be considered to have diastolic dysfunction, and all patients with systolic dysfunction have reduced ejection fraction. However, some patients with reduced ejection fraction can have mixed systolic

and diastolic dysfunction, although the usual net result is that the former predominates. Therefore, the primary distinction between classifications by type of dysfunction versus by ejection fraction is that systolic vs. diastolic dysfunction refers to a presumed underlying mechanism, whereas classification by ejection fraction is based on the net consequence as estimated by echocardiography, nuclear scintigraphy, or, in some cases, during coronary angiography. While classification by ejection fraction is more objective, all measures of EF require interpretation and depend on the skill and experience of those performing and reading the test.

Recent community and population based studies (Bhatia et al., 2006; Owan et al., 2006) suggest that reduced LVEF is more common in men, whereas HF with preserved EF is more common in women. In these two studies, patients with preserved EF were, on average, slightly but significantly older than those with reduced EF. The prevalence of coronary artery disease and ischemia in those two studies was significantly higher in patients with reduced compared with preserved LVEF, but CAD was still present in one third to one half of patients with preserved EF (Bhatia et al.; Owan et al.). Systemic hypertension was significantly more prevalent in patients with preserved compared to reduced LVEF, but was still present in approximately half of patients with reduced LVEF (Bhatia et al.; Owan et al.). Atrial fibrillation was, likewise, significantly more prevalent in patients with preserved LVEF (approximately 30 to 40%) compared with reduced LVEF (approximately 24 to 28%) (Bhatia et al.; Owan et al.).

**Coexisting factors.** There are a variety of coexisting factors that may contribute to heart failure. In recent years, the importance of ventricular remodeling secondary to increases in circulating catecholamines and chronic over stimulation of the renin-

angiotensin system has been recognized. Increasingly, angiotensin converting enzyme (ACE) inhibitors and  $\beta$ -blockers have become mainstays of HF treatment, especially in systolic dysfunction (Hunt et al., 2005; HFSA, 2006a). In addition, aging is associated with numerous molecular, biochemical, cellular, and biomechanical changes in the heart and the cardiovascular and respiratory systems. For example, cardiac aging results in changes in vasculature, systemic and pulmonary perfusion, and pulmonary function.

In addition, diabetes is commonly associated with hypertension, increased risk for ischemic cardiovascular disease, obesity, and chronic kidney disease. End-stage renal failure is often associated with increased risk for fluid overload. Therefore, the risk for and severity of heart failure are higher in patients with diabetes or renal failure (or both) than in the general population of persons without these conditions. Moreover, in the presence of either or both of these conditions, HF may be more challenging to work up (e.g., increased risks associated with contrast media administered during coronary angiography in patients with decreased glomerular filtration or chronic kidney disease) and more complex to treat (e.g., increased complexity of dietary and medication regimes).

**Vasculature.** Aging may affect both large arteries and smaller resistance vessels (e.g., arterioles). The collagen and elastic elements of the wall matrix may change, and vessel walls may thicken. As a result, vascular stiffness generally increases with age (Francis, Tang, & Sonnenblick, 2004).

Current guidelines (Chobanian, et al., 2003) define hypertension at 140 mmHg systolic and 90 mmHg diastolic; moreover, the risk of adverse cardiovascular events (e.g., myocardial infarction, stroke) is more strongly related to systolic than diastolic

hypertension in older adults (> 50 years of age). From a baseline of 115/70 mmHg, relative risk of cardiovascular disease doubles for each incremental increase of 20 mmHg systolic or 10 mmHg diastolic (National High Blood Pressure Education Program [NHBPEP], 2004). Additionally, there have been studies documenting geographic variations associated with rises in blood pressure and aging. Geographic variations in blood pressure suggest that blood pressure does not rise as much with age as in non industrialized societies (Elford, Phillips, Thomson, & Shaper, 1990).

**Cardiac adaptation.** Arterial stiffening triggers a variety of cardiac adjustments, for example, chronically elevated left ventricular afterload causes left ventricular wall thickening from an increase in the size of cardiac myocytes (i.e., as opposed to hyperplasia, an increase in the number of myocytes; Francis et al., 2004). Also, the combination of late augmentation of aortic impedance and left ventricular hypertrophy prolongs myocardial contraction. The prolonged contraction time can contribute to preserved left ventricular pump function, and thus, to a point, may be compensatory (Francis et al.).

With aging comes a decline in diastolic filling of up to 50% (Francis et al.). While this may occur because of mechanical reasons (prolonged contraction time), the decrease in early diastolic filling may be caused by a prolonged relaxation time between aortic valve closing and the mitral valve opening (Lakatta, 1999).

In aging men, an elevated end diastolic volume may tend to maintain cardiac output by increasing stroke volume in the presence of an age-related decline in heart rate. In women, there tends to be little or no increase in end diastolic volume, and so, cardiac output decreases with increasing age (Lakatta, 1999). For women, menopause is



associated with an increase in risk of heart disease. However, there is, at best, no cardiovascular benefit from hormone replacement therapy (HRT) for menopausal women (Hsia et al., 2006); at worst, HRT actually increases risk of cardiovascular events (Writing Group for the Women's Health Initiative Investigators, 2002). Therefore, HRT is not recommended as prophylaxis against cardiovascular disease in menopausal women.

**Circulation.** Aging is also associated with structural and functional changes in coronary vasculature. There is an age-related decline in coronary flow reserve which may be a result of elevated baseline cardiac work and myocardial blood flow (Priebe, 2000). Additionally, the vasodilator capacity of coronary circulation has been shown to have higher coronary resistance in older subjects, suggesting that some impairment of vasodilatation may contribute to impaired vasodilator capacity (Czernin et al, 1993). It is also believed that as the heart ages, the heart rate reflex response to alterations in arterial pressure is impaired. This may compromise arterial pressure homeostasis in response to diuretic therapy, altered fluid intake and postural stress (Priebe, 2000).

One of the major alterations in the aging heart is a decreased ability to respond to exercise. There is a decrease in heart rate and contractile response with age as evidenced by decreases in peak heart rate and peak ejection fraction. The age associated decline in heart rate and LV contractility is due to diminished beta adrenergic modulation of contractility, and vasomotor tone (Francis et al, 2004). In the elderly, the increased demand for peripheral blood flow in exercise or exertion is met primarily by activation of the preload reserve. Thus, increased demand results in reduced cardiovascular reserve and coronary insufficiency which are important underlying risk factors for acute and chronic heart failure in the elderly (Francis et al).

Overall, heart failure is characterized by a downward trend in physical functioning. Patients with heart failure experience not only functional losses but erratic patterns of physical functioning. The HF failure patient must learn to appropriately identify, cope with, and manage symptoms (Redwine et al., 2007).

**Categorizing HF.** There are several methods to categorize the limitations of physical activity causing discomfort. One method is the categorical system of the New York Heart Association (NYHA). The NYHA classification scale was developed in 1928. Since that time two major revisions have been made (AHA, 2007). The current recommended use for the NYHA (Bonow, 2005; Hunt, 2005) involves a two part grading process involving subjective and objective observation. From the subjective perspective, patients are asked to describe the symptoms they experience during physical activity. Then data from specific medical examinations such as echocardiograms, electrocardiograms, or cardiac catheterizations are used to measure cardiac structure and function. From an objective point of view, clinicians are asked to categorize patients on four levels: 1) no objective evidence of cardiovascular disease 2) objective evidence of minimal cardiovascular disease 3) objective evidence of moderately severe cardiovascular disease and 4) objective evidence of severe cardiovascular disease.

NYHA Class I describes patients with cardiovascular disease but without any physical limitations. Class II describes a person with slight limitation of physical activity. Class III describes a person with limited physical activity and Class IV describes a person unable to carry on any physical activity without becoming incapacitated by symptoms (e.g., dyspnea, fatigue, chest pain) or myocardial ischemia or infarction.

Additionally, a newer classification system developed by the American Heart Association and the American College of Cardiologists (Hunt et al., 2005) attempts to recognize earlier stages in the disease process. It too, consists of four stages: Stage A includes patients who are at high risk for HF but do not have structural heart disease or symptoms of HF. For example this would include patients with hypertension, atherosclerotic cardiovascular disease, dyslipidemia, diabetes (or risk factors such as obesity or metabolic syndrome) or patients with cardiomyopathy or a family history thereof. While these patients might not have signs or symptoms of HF, hypertension and other risk factors would need to be controlled. Patients should be counseled to avoid behaviors that may increase the development of HF (smoking, illicit drug use). If cardiac rhythms are abnormal, they would need to be controlled among this group. Also any secondary prevention strategy should be employed: monitoring thyroid disorders as well as atherosclerotic disease.

Stage B includes patients with structural disorders or a functional abnormality of the pericardium, myocardium, or the cardiac valves who have never shown signs or symptoms of HF, but whose structural or functional abnormality is commonly associated with the development of HF. This group should also have all the interventions of stage A, in addition to monitoring for and treatment to prevent possible myocardial infarction. If the patient has a reduced left ventricular ejection fraction, then guideline-based pharmacological treatment should also be initiated (e.g.,  $\beta$ -blocker, angiotensin converting enzyme [ACE] inhibitor or both).

Stage C patients have structural disease and current or prior symptoms of HF, such as shortness of breath, fatigue, and reduced exercise tolerance. These patients may

benefit from all the above interventions. Additionally, diuretics may also be added to their regimen. A cardiac rehabilitation program may be beneficial if symptoms warrant. Stage C patients may require implantable cardioverter-defibrillators (Hunt, 2005).

Finally, stage D patients have refractory HF. These patients require major interventions as listed above and, possibly, biventricular pacing, cardiac resynchronization therapy, or even heart transplantation (Hunt et al., 2005).

To summarize the four classifications of HF vary in severity from stage A in which the person with HF can carry on most usual activities to stage D in which the patient's functioning is so severely compromised as to require major or multiple interventions to survive. If medical therapy has been maximized and the patient is unable to tolerate a major intervention (or they have not succeeded), then at some point, palliative care may be required to manage symptoms.

### **Psychosocial and Situational / Environmental Antecedent: Social Isolation**

Nearly half of persons over the age of 85 years in the U. S. live alone (Lichtenberg, MacNeill, Lysack, Bank, & Neufeld, 2003). However, social isolation is not just living alone; it comprises perceptions that one is alone or without social networks or social support. The North American Nursing Diagnosis Association (NANDA, 2000) defines social isolation as aloneness experienced by the individual. Social isolation is perceived as a negative or threatening state. Some defining characteristics include not having interactions with close friends, neighbors, or family members. Other descriptors include not having interactions with members of work groups or church groups. Social isolation varies according to the degree of physical and emotional separation from other people. While physical distance may be a predisposing factor, it is neither a necessary or

sufficient condition for social isolation. A person can feel lonely and socially isolated despite living in close proximity to significant others, and a person can live at some physical remove from family, friends, and other supports yet not necessarily feel isolated, alone, or lonely (Tomaka, Thompson, & Palacios, 2006).

For many elders, their usual social network of close friends may begin to diminish because of ill health or death. In addition, elders may move to live with or closer to family members, which may entail living further away from close friends and having to adjust to a new environment and new routines

In Murberg's and Bru's (2001) research, 153 Norwegian elders participated in a study to examine the influence social support and social isolation has on heart failure patients. The sample was predominantly male, with men averaging 69.9 years of age, and most were classified as NYHA category II heart failure. In Murberg's and Bru's research, social isolation was assessed using four items: "Do you feel the disease makes it difficult to visit family and friends?" "Do you feel that the disease makes it difficult to receive visits from family and friends?" "Do you feel the disease makes it difficult to participate in social events?" and "Do you feel that the disease makes it difficult to go on holiday with family and friends?" The researchers found that there were significant associations between social isolation and mortality among HF patients within a two year follow-up period. The relative risk of mortality for a 1 point increase in social isolation score was 1.5 (95% CI 1.0 to 2.2,  $p < .04$ ), after controlling for age, depression, NYHA class, and atrial natriuretic peptide levels. Murberg and Bru also found that the lack of social support from a spouse was more strongly related to fatal outcome compared with lack of social support from a primary or secondary network.

Research has shown that when elders face disability, they favor home and community based settings, not institutional settings (Coleman, Kassner, & Pack, 1996). Compared with white elders, minority elders have been found to prefer home and community settings more strongly. This has been attributed to social cultural differences in kinship relations or expectations of filial responsibility and differences in socioeconomic status and access to services (Peng, Navaie-Waliser, & Feldman, 2003).

**Social isolation and race or ethnicity.** Living alone is not uncommon among some groups. Peng et al. (2003) examined over twenty thousand records of patients registered in the Outcomes Assessment Information Set (OASIS) between 1999 and October 2000 and found that African American female elders were more likely than Whites, Hispanics or Asian elders to be alone with no form of supportive care, either formal or informal, after a hospitalization.

Hays and George (2002) used a prospective cohort study to describe race differences among 4,132 elders to estimate ten year prevalence, incidence, and predictors of living alone among Black or African American and White elders. The sample was a stratified four stage random sampling of households from five counties in north central North Carolina. Listing areas were stratified by racial characteristics to generate a sample in which approximately 55 percent of the respondents would be African American and 45 percent would not. Hays and George found three out of every five elders lived with others at the beginning of the study and continued to do so for the next 10 years or until their death. Younger and better educated African American elders lived alone more frequently. They also reported higher incomes, fewer biological children, and fewer living children.

Hispanic elders commonly expect to live with family in old age (Tomaka, et al, 2006). Tomaka and associates telephone interviewed 765 Southwestern U. S. inhabitants over the age of 60. Twenty three percent of the respondents reported their ethnicity as Hispanic. According to Tomaka et al, it is well known that the family and extended family play a central role in Hispanic culture and social lives. As such, one might expect family support to play a particularly critical role in the health and well being of the elder Hispanic (Tomaka, et al.). From a cultural perspective, as Hispanics assimilate to the American culture, and young Hispanics move away from their nuclear families searching for employment or educational opportunities, the elders may be left behind to live alone.

The number of Asian elders living alone has also risen, and there is scant research addressing the mental health of those who live alone versus those who live with family (You & Lee, 2006). Shih, Gau, Lo, and Shih (2005) studied the health needs of elders living alone in Taiwan. Fifty four patients participated in the study; 48 were males and 61% of them (n=33) were unmarried. The principal diagnosis of 48% of subjects was coronary disease. The unmarried male elders reported that a perception of powerlessness occurred either in the preadmission or hospitalization stage or was expected to occur after discharge. This group of Taiwanese elders living alone was found to have a low self image and have greater needs from health care providers versus other elders who live with their significant other (Shih et al).

**Social isolation and gender.** Social isolation also disproportionately affects women. In 2003, 44.3% of women ages 65 or older were widowed; 78.3% of women older than 84 were widowed and living alone (He, Sengupta, Velkoff, & DeBarros, 2005). In part, these statistics reflect the longer life expectancy of women compared with

men in the U. S. However, there are also elements of choice. For example, it has been reported that women with higher incomes chose to live alone more frequently than women with lower incomes (Cheng, 2006).

According to Baker (2000), older Americans have the same desire for independence as young Americans. Independence is equated with life itself. Independence allows older adults greater autonomy to continue to define themselves and avoid feeling they are a burden to others. Letvak (1997) studied eight women living alone, all of whom expressed a desire not to change their life style. Living alone was highly valued and equated with power, freedom, and making one's own decisions.

Bellin (2000) studied older women: these women reported combating loneliness through prayer, working part time, keeping busy, and raising pets to decrease their feelings of loneliness. Bellin's study also demonstrated that having to face difficult tasks or health issues did not affect a woman's decision to live alone. In general, most women found they could tolerate the feelings of being lonely. The risk for physical functional decline and mental health problems may also be lower for women who live alone compared with women who live with family members (Michael, Berkman, Colditz, & Kawachi, 2001).

The most frequent related health problems reported by older women living alone were hypertension, vision changes, arthritis, and incontinence (Austin, Devine, Dick, Price, & Bruce, 2007). According to Austin and colleagues, falling was most concerning to most women living alone. Older women also reported having their own ways to maintain their health: staying active, eating right, getting enough sleep and using folk medicines to relieve bothersome symptoms (Cheng, 2006). In White's (1997) study older

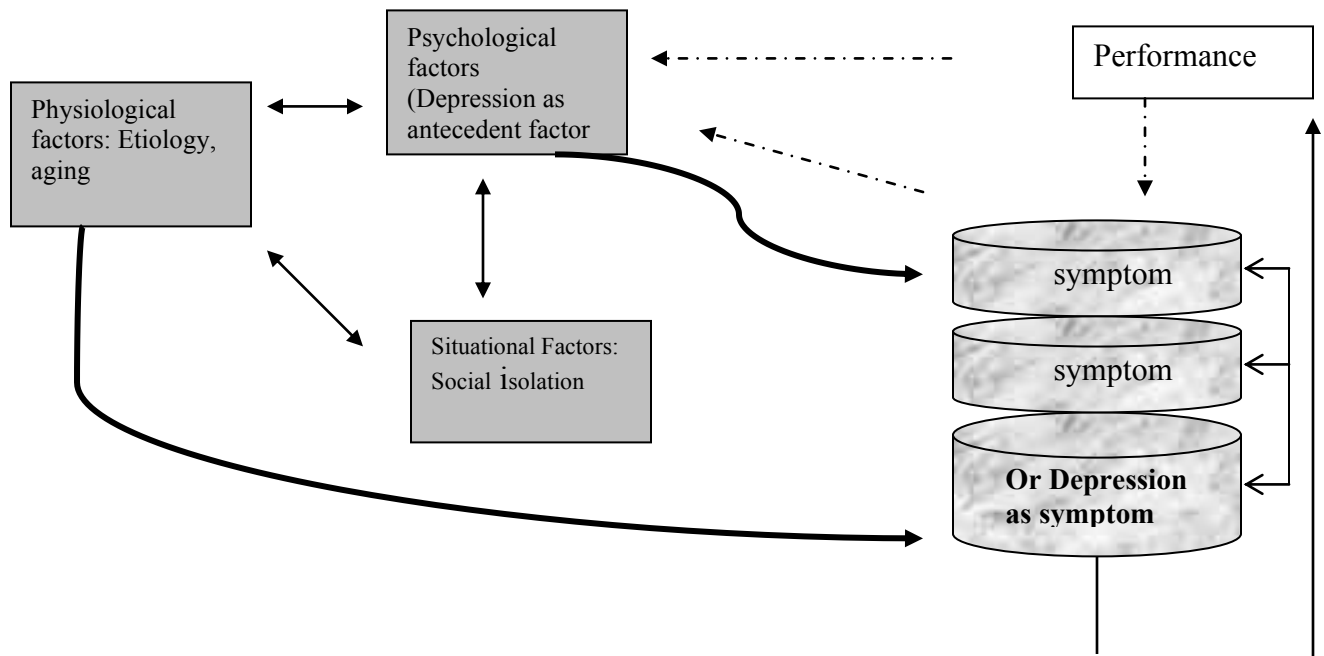


women living alone had an increased use of hospital and community services. Bellin's (2000) study demonstrated that most women did not receive care according to their actual health status. This brings up an interesting point, that health, and isolation may be viewed differently by the elder as compared to the health provider. Decreased use of services may be due to income or transportation difficulties, not necessarily from noncompliance or dissatisfaction with the provider-patient relationship.

Social networks are believed to have a beneficial effect, provide positive interactional support, and affirmation that leads to an overall sense of self worth, self esteem and positive affect. Social support is also believed to buffer the effects of stress and disease (Lincoln, Chatters, & Taylor, 2005). In the stressful situations that occur with disease, supportive networks can help an elder to reappraise and cope more effectively with stressors.

### **Symptom Experience**

In the TOUS (Lenz et al., 2005, 2007), symptom experience comprises both individual symptoms and symptom clusters (See Figure 1). Among patients with HF, symptoms of fatigue, dyspnea, and often, though not always, angina pectoris may also be common. Depression is common, but often is not a symptom that patients explicitly complain about to their health care providers (Frank, Asp, & Dahlberg, 2009).



**Figure 1: Theory of Unpleasant Symptoms; adapted from Lenz et al. (1997). (ANS: Advances in Nursing Science, 19[3], 14 [Figure 1]. Used with permission, Lippincott Williams & Wilkins).**

**Fatigue.** Fatigue has been described by patients as a multidimensional phenomenon involving physical mental sensations and affecting feelings that influence functional ability (Ekman & Ehrenberg, 2002). The NANDA (2001) describes fatigue as an overwhelming sustained sense of exhaustion and described capacity for physical and mental work to occur at a person's usual level. Defining characteristics of fatigue according to NANDA also include:

- a) The inability to restore energy even after sleep
- b) Lack of energy or inability to maintain usual level of physical activity
- c) Increase in rest requirements
- d) Tired

- e) Inability to maintain the usual routine
- f) Verbalization of an unremitting and overwhelming lack of energy
- g) Lethargic listless
- h) Perceived need for additional energy to accomplish routine tasks
- i) Increased physical complaints
- j) Drowsy
- k) Feelings of guilt for not keep up with responsibilities
- l) Compromised concentration
- m) Lack of interest in surroundings
- n) Decreased performance (NANDA, 2001, page 735)

Patients with chronic HF may become so accustomed to fatigue as a symptom of HF that they may not mention it unless they are specifically asked. When a patient complains of fatigue it is usually because it interferes with self care or the ability to function normally. Friedman and King (1995) examined correlates of fatigue in older women with HF and found that fatigue was the most frequently occurring symptom. It has also been speculated that fatigue may be a contributing factor related to patients' inability to follow the prescribed treatment regimen. That is, patients are so fatigued that they do not or cannot get up to take medications, or prepare the appropriate meals. Some of the descriptors of fatigue are very similar to descriptors of depression: lethargy, lack of interest in surroundings.

**Dyspnea.** Dyspnea is the second most prevalent symptom occurring among HF patients. Dyspnea refers to sensations of unpleasant, uncomfortable breathing. It has been defined as “a subjective experience of breathing discomfort that consists of qualitatively

distinct sensations that vary in intensity....” that are derived “from interactions among multiple physiological, psychological, social, and environmental factors, and may induce secondary physiological and behavioral responses” (American Thoracic Society, 1999, p. 322). In heart failure, dyspnea may be the symptom that is most likely to prompt patients to seek help (Mahler, Fierro-Carrion, & Baird, 2003). For example, dyspnea is the most common reason for emergency department visits by patients with HF (Parshall, 1999).

Dyspnea has been examined using cluster analysis. That is, sampling patients of known diagnoses and asking them to describe dyspnea. Among ambulatory HF patients the three most consistent descriptors of dyspnea were found to be “work/effort”, trouble exhaling, and trouble inhaling (Mahler et al, 2003). Others have described dyspnea as air hunger (Peterson, Orth & Ritz, 2008). Parshall et al. (2001) found that HF patients, recalling a specific emergency department visit, commonly referred to sensations of “smothering,” “choking,” and “can’t breathe” (p51). Among the chronic obstructive pulmonary disease population dyspnea is commonly described in terms of work or effort (Mahler et al., 1996). However, during periods of exacerbation, descriptors such as smothering or suffocating are common (Parshall, 2002). People with asthma commonly describe dyspnea in terms of tightness or constriction in addition to work or effort; moreover, the sensations of tightness (which is thought to be primarily due to bronchoconstriction) respond more rapidly to treatment with bronchodilators compared with work or effort (which may persist, even after relief of bronchoconstriction due to increased impedance from inflammation, which generally takes longer to resolve than bronchoconstriction), hence tightness is mechanistically separable from work/effort (Moy, Lantin, Harver, & Schwartzstein, 1998). Thus, qualities of dyspnea may vary not

only by diagnosis but by the setting and context (e.g., whether patients are asked about usual dyspnea or about a specific episode severe enough to lead to an emergency department visit, or how breathing feels before, during, or after acute treatment).

Gift (1987) described acute dyspnea as having a rapid onset and chronic dyspnea as being persistent or occurring over time. Gift argued that environmental stimuli, situational factors and depression are factors affecting chronic dyspnea. She describes people who cope with dyspnea as always being aware of intensity changes, living with a fear of having a bout of dyspnea, and reducing physical activities accordingly. This reduction in physical activities can lead one to reduce or cease altogether one's work, social activities, or nonessential activities of daily living. The reduction in activity can lead to deconditioning, worsening activity intolerance, social isolation and possibly depression (Giardino, et al., 2010; Gift, 1993; Sassi-Dambron, Eakin, Ries, & Kaplan, 1995).

In a study of 57 HF patients who presented to an emergency room complaining of dyspnea; 88% indicated their symptoms ordinarily interfered with activities that were meaningful to them (Parshall et al., 2001; Welsh et al., 2002). The sample was predominantly female (54%), and approximately 2/3 lived with others, but this was not broken down by gender (Welsh et al.). The researchers described two general duration profiles of dyspnea at presentation to the emergency department: those who had experienced dyspnea for 3 days or less at approximately the same severity as when they came to the emergency department, and those who had endured that severity of dyspnea for at least one week before seeking medical assistance. However, there was no

difference between these profiles in the percentage of patients admitted to the hospital (Parshall et al.).

**Depression.** Under the TOUS, depression could be an antecedent factor (e.g., a psychosocial pre-existing condition prior to a diagnosis of HF or even a risk factor for cardiovascular disease), a consequence or outcome of other symptoms (e.g., reactive depression in response to diminished functional capacity), or a symptom itself, either in isolation or in a cluster with other symptoms (as is common in chronic conditions such as HF). Because the nature of the proposed dissertation study is essentially cross-sectional, it will not be possible to determine the extent to which depression, if present, may have been a pre-existing condition or a symptom(s) outcome. Therefore, for the purposes of this chapter it will be discussed as a symptom that may coexist with other HF symptoms.

Depression is one of the most common symptoms in the primary care setting and the World Health Organization predicts that by the year 2020 major depression and coronary disease will be the two leading contributors to the worldwide burden of disease (Brody et al., 1998). The prevalence rate of depression ranges from 4.3 % to 26 % in general populations (Kessler, 2004). Among the heart failure population depression has been studied among outpatients, and the incidence rate has been reported to be as high as 42% (Skotzko et al., 2000).

Koenig (1998) found the prevalence of depression to be 36.5% in 543 inpatients age 60 years or older. Romanelli, Faverbach, Bush, & Ziegelstein (2002) studied a group of elders with recent myocardial infarction (MI). They found that almost one in four older patients were depressed soon after an MI. Older patients with depression had a fourfold increased risk of death within the first 4 months after an acute MI.

Several biological factors have been examined and proposed as potential mechanisms by which depression may lead to cardiovascular disease. One mechanism that has been suggested is the dysregulation of the autonomic nervous system (ANS). In early heart failure, cardiac sympathetic activation often predominates over vagal tone, and norepinephrine levels are increased (Esler & Kaye, 2000), potentially increasing risk for tachydysrhythmias. High levels of circulating catecholamines may contribute to recurrent endothelial inflammation or injury, increased vascular and cardiac wall stress, and increased platelet activation. Both inflammatory and platelet coagulant processes are associated with depression (Esler & Kaye). Among patients with cardiovascular disease there is evidence that altered autonomic tone associated with depression is associated with increased heart rate and reduced heart rate variability. Carney et al. (2000) found that there is a higher heart rate and a lower heart rate variability rate in depressed patients with stable coronary disease compared with non-depressed patients with stable coronary disease. The more depressed the patient, the lower the heart rate variability. They also studied heart rate variability among patients with depression and found that cognitive behavioral treatment of depression was associated with a decrease in heart rate of approximately 5 beats per minute, but the effects on heart rate variability were equivocal. Carney and colleagues concluded that their results were similar to those found when beta blockers were administered to patients with coronary artery disease (i.e., a reduction in sympathetic tone and decreased mean heart rate), especially during the day time.

Jonas, Franks, and Ingram (1997) studied a cohort of men and women for 7-16 years and found that there was an association between high anxiety and depression with hypertension. The National Health and Nutritional Examination Survey I (NHANES)

follow up study found that symptoms of depression at baseline were associated with a higher risk of developing hypertension over a 20 year follow up (Mussolino, 2005). Similarly, in the coronary artery risk development in young adults (CARDIA) study, investigators followed over 1500 African-American and 1800 White men and women patients for 5 years (Davidson, Jonas, Dixon, & Markovitz, 2000). They concluded that depression was associated with hypertension. Depressive symptomatology was measured using the Center for Epidemiologic Studies-Depression (CES-D) questionnaire (Radloff et al., 1977) at the enrollment and at the 5 year period. Study patients with depression scores greater than 16 at enrollment were significantly more likely to develop hypertension during 5 years of follow-up.

**Somatic awareness.** Somatic awareness is the sensitivity to physical sensations and bodily activity secondary to physiological change (Jurgens, 2006). HF patients are asked to learn, recognize and to distinguish symptoms that need to be addressed or reported on a daily basis (Grady et al., 2000). Somatic awareness in HF is made more difficult by the daily fluctuations in symptoms of HF. Elders may experience symptoms of HF, such as fatigue and dyspnea, but they may believe they are due to old age. When the elder begins to “monitor” heart failure symptoms that are insidious, ambiguous, and non-specific, uncertainty occurs, and with uncertainty comes hesitancy to report and a delay in treatment may occur (Jurgens). Low somatic awareness is associated with increased severity of coronary disease and longer delays in care seeking (Jurgens).

Symptom identification occurs when a person has a pattern, a certain degree of familiarity with the symptom and has given the symptom meaning and a label (Mishel, 1988). The identification process has been shown to be delayed when persons have low



somatic awareness (Dracup & Moser, 1997) or when a person begins to exhibit clusters of symptoms (Ryan & Zerwic, 2003). A symptom cluster occurs when three or more symptoms are experienced together, and the symptoms arise from various etiological factors (Dodd, Miaskowski, & Paul., 2001).

Relatively little is known about symptom identification in HF; symptoms may vary in number or severity and from stable to unstable over a relatively short interval, often without obvious precipitating cause. Some may not seek assistance believing that the symptom will resolve itself. Some HF patients consistently have a longer duration of dyspnea, edema, cough, and orthopnea prior to hospital admission, suggesting that such symptoms are relatively constant in number and severity or that these patients either become inured to their symptoms or are unaware of their severity (Friedman, 1997; Parshall et al. 2001).

Patients who are depressed in addition to having symptoms such as dyspnea and fatigue may develop an attitude that their symptoms can't be helped. This is exemplified among patients with end stage heart failure. This population has been reported to have fewer social contacts, more limited support networks, and to be more noncompliant with treatments. Zipfel, Lowe, and Paschke (1998) attributed the increase in depression directly to psychological distress that is experienced in later stages of HF, particularly among patients on a waiting list for a heart transplant.

Da Canhota and Piterman (2000) report that emotional and psychological distress may not be spontaneously expressed by elders who may prefer to communicate only physical symptoms. Often they may be abetted by health care providers who, in a busy practice setting, may not inquire about psychological symptoms unless a patient or family

member brings up the topic. This patient physician/provider communication breakdown may lead to psychological symptoms being under treated and under reported among the elderly. This communication breakdown may lead to treatment delay for symptoms of HF. It is believed to be a factor associated with preventable hospital admissions (Vinson, Rich, Sperry, Shah, & McNamara, 1990).

A number of reliable and valid questionnaires are available that can help to determine if HF patients have secondary symptoms of depression or are experiencing social isolation. A detailed description of the instruments to be used in this study is in Chapter 3.

## Outcomes

**Readmissions and depression.** Heart failure is a progressive, debilitating disease. It is of no surprise that depression rates are high among this group. Jiang et al. (2001) studied 374 heart failure patients 18 years or older, and assessed depression using the Beck depression inventory (BDI). A total of 126 patients (35.3%) scored 10 or higher (indicative of depression). Of the entire sample 40.2% had one or more readmissions. Those experiencing major depression (n= 46) had the highest readmission rates at 3 months and 1 year. Persons with major depression had readmission rates of 52.2% at three months. At one year the readmission rate was 80.4%. Persons with mild depression had the next highest number of readmissions at 42.6%. at three months and 55.6% at one year. Relative to the non-depressed (n=231), those with major depression were nearly twice as likely to be readmitted at 3 months (OR =1.9, 95% CI 1.0 to 3.59,  $p = .04$ ). Those with major depression were 3 times more likely to be readmitted at the one year mark (OR = 3.1, CI 1.4.- 6.66,  $p = .005$ ). Patients with a BDI of 10 or higher had mortality

rates of 11.9% at 3 months. At 12 months the mortality was 20.8%. Comparing patients with BDI scores of ten or less the mortality rate was 5.7% at 3 months. At twelve months the mortality was reported to be 13.7%. Also, in this study advanced age was associated with increased mortality at 3 months (OR =1.05 for each 1 year increase above age 63; 95% CI, 1.011-1.091,  $p = .01$ ). NYHA class was not significantly associated with either outcome at 3 months, but was associated with both outcomes at one year. The odds ratio favoring death was 1.85 for each ascending class; 95% CI, 1.21-2.82,  $p =.05$ . The relative odds favoring readmission were OR = 1.77 for each one stage increase in NYHA class, 95% CI: 1.25-2.53,  $p =.002$ .

### **Mortality and Social Isolation**

Friedman, et al. (2006) studied the relationship between mortality and HF. In this study, participants had NYHA class II or III heart failure and left ventricular ejection fractions of less than 35%. Several instruments were used to assess various psychosocial variables. The tool used to assess social support was the social support questionnaire 6 (SSQ-6). The SSQ-6 provides a list of six situations potentially requiring social support and asks the respondents on whom they could rely for help, the amount of help, and their perceived satisfaction with help in each situation. Individual item scores range from 0 to 1, with higher scores indicating more social support. The participants were predominantly men, ranging in age from 35 to 85 years of age. Satisfaction with social support scores ranged from 0 to 54 (Mean = 32.1, SD= 6.1). Mortality was 7% among patients above the mean on social support and 14% among those below the mean. Mortality was 8% among patients with high social support and without depression or anxiety, 16% for socially isolated patients with either anxiety or depression, and 20% for socially isolated patients

with both anxiety and depression. Both depression and social isolation were predictors of mortality after controlling for demographic and clinical predictors of mortality. Friedman and colleagues also found that the number of people the patients could ask for support in specific situations was a predictor of survival, independent of demographic and clinical status. Most importantly, the interrelationship of depression and social isolation is consistent with HF outpatients living alone. Depression and social isolation are related to mortality in this patient population: depression and social isolation predict mortality independent of demographic and clinical status and perceived functional status (Friedman, et al., 2006).

In summary, the TOUS demonstrates the complexity of psychological and situational factors that may interact with symptoms. There is at least some indirect evidence that readmission rates among patients with HF may be related to depressive symptoms and social isolation. If depression or social isolation is found in this dissertation study to be more severe or prevalent among readmitted HF patients compared with those who are not readmitted, then it may be prudent to assess more systematically for depression and social isolation during hospitalizations.

## **Chapter 3**

### **Methods**

This chapter is divided into the following sections: 1) Specific Aims and Research Questions; 2) Research Design; 3) Sample and Setting; 4) Variables and Measures; 5) Protocol and Data Collection; and 6) Data Analysis.

#### **Specific Aims and Research Questions**

The specific aims of this exploratory study were to determine whether readmission of elderly patients with heart failure was associated with differences in depressive symptoms, social isolation, or both. The primary independent variable for the study was 30 and 60 day readmission following discharge from an index hospitalization for heart failure. For the dependent variables, depressive symptoms were measured using the 15 item version of the Geriatric Depression Scale (GDS-15; Sheikh & Yesavage, 1986; Yesavage et al., 1983), and social isolation was measured using the 18-item version of the Lubben Social Network Scale (LSNS-18; Lubben & Girona, 2003). Hypotheses for the study were: 1) patients readmitted within 30 and 60 days of discharge from an index hospitalization for HF will have differed in depressive symptom scores (GDS-15 scores) during the index hospitalization from patients who are not readmitted; and 2) patients readmitted within 30 and 60 days of discharge from an index hospitalization for HF will have differed in social isolation (LSNS-18) scores during the index hospitalization from patients who are not readmitted. Other patient characteristics to be assessed in exploratory analyses included gender, race and ethnicity, age, educational level, ejection fraction (preserved vs. reduced), NYHA classification, and b-type natriuretic peptide level.

## **Research Design**

The study used a descriptive comparative design with prospective data collection. The study was approved by the Committee for the Protection of Human Subjects at the University of Texas Houston Health Science Center, and by the Memorial Hermann Health Care System Center for Clinical and Translational Sciences. Informed consent was obtained from all participants.

Those consenting to participate were screened for cognitive status with the Mini-Mental State Exam (MMSE; Folstein, Folstein, & McHugh, 1975), and those with MMSE scores of at least 24 completed the GDS-15 and LSNS-18 during a hospitalization for HF. Data were collected by interview and chart review. Following discharge, participants were followed by checking readmission history on the daily census to determine whether or not there was a readmission for heart failure within 30 or 60 days of discharge. For both follow-up intervals, those who were readmitted for HF were compared with those who were not in terms of their demographic characteristics, their clinical characteristics during the hospitalization in which they enrolled (the index hospitalization), and differences in GDS-15 and LSNS-18 scores during the index hospitalization. There was no follow-up beyond 60-days.

## **Sample and Setting**

**Sample.** The target population for this study was English or Spanish speaking patients with heart failure (HF), aged 65 years or older. Informed consent was obtained from all participants. Criteria for inclusion in the sample were: adults at least 65 years of age admitted for a diagnosis of heart failure for which there was adequate clinical confirmation (e.g., evidence of systolic or diastolic dysfunction by echocardiogram,

nuclear scan, or cardiac catheterization, or evidence of a well-documented history of heart failure). Participants had to be able to speak and understand English or Spanish. Exclusion criteria were a history of dementia or substantial cognitive deficits or the investigator's judgment that an individual's capacity for consent was diminished or uncertain. A convenience sample of 120 participants was enrolled during an inpatient admission for heart failure, but 12 were excluded for MMSE scores less than 24; one was excluded after finding that a power of attorney (POA) for health care decisions had previously been executed. Six persons who enrolled were discharged before completing either of the study questionnaires, leaving a final sample of 101 participants who completed at least one of the study questionnaires.

**Setting.** Participants were recruited from three large acute care hospitals that are part of a single health care system in the greater metropolitan area of Houston, Texas. One facility is centrally located and serves a large portion of the city indigent and uninsured. The other two facilities are located in an economically stable urban setting. Houston is the fourth largest city in the United States, and the state of Texas has the fourth largest population of older adults (2.7 million). In Harris county alone, there are 424,000 persons residing who are over the age of 60 (Department of Aging and Disability Services [DADS], 2007). Harris county also has a large older Hispanic and African American population, 78,000 and 72,000 respectively.

The inpatient units where recruitment and data collection took place were a 45 bed cardiology unit with an average admission rate of 40 HF patients per month, and two general medicine telemetry units with an average admission rate of 30 HF patients per month. The facilities are part of the same multi-hospital health system. The investigator

had an administrative position within the system, hence already had clinical privileges and approved direct access to administrative and clinical data pertaining to admissions. In addition, participants expressly consented to accessing records for purposes of determining readmissions.

### **Variables and Measures**

**Demographic data.** Demographic data were obtained both from the medical record and the patient. For patients who gave informed consent to participate, identifiers needed for the follow-up for readmissions included the patient's name, medical record number, and dates of hospitalization. Demographic data collected included age, gender, income, ethnicity, marital status, and highest level of education. Clinical data obtained from the medical record during the index hospitalization included admitting and discharge diagnoses, ejection fraction, NYHA classification, b-type natriuretic peptide (BNP) level within  $\pm$  24 hours of admission, etiology of HF (ischemic or non ischemic), and medications prior to, during, and at discharge from the index hospitalization. Medications of interest included beta-blockers, an angiotensin receptor blocker (ARB) or angiotensin converting enzyme (ACE) inhibitor, nitrates, diuretics, and antidepressants.

**Cognitive status.** The presence of gross cognitive deficits or dementia was determined during eligibility screening. Heart failure patients with documented dementia or impaired decisional capacity (e.g., for whom a guardianship or durable power of attorney is already operative) were peremptorily excluded without contact. Among potentially eligible patients, the investigator used her expert clinical judgment during the initial contact with the patient to determine whether the patient had adequate capacity for



consent, and she excluded from participation any who, in her judgment, had questionable decisional capacity.

Among patients who agreed to participate the mini mental state examination (MMSE) was used to assess cognitive status (Folstein et al., 1975). The MMSE consists of eleven items assessing orientation, recall, registration, attention, calculation, language, and praxis. Scores range from 0 to 30, with a score of less than 24 indicating cognitive impairment. Participants scoring less than 24 were excluded from further participation.

Parker and Phillip (2004) found that people who belong to a minority group are at greater risk than non minority persons of being misclassified as cognitively impaired when, in fact, they are not. It has been demonstrated that older minorities who have not assimilated to the U. S. tend to score lower than European Americans on the MMSE (Espino, Lichtenstein, Palmer, & Hazuda, 2001). In particular, Hispanics who live in low-income barrio neighborhoods are more likely to score lower than those in middle income transitional or high income suburban neighborhoods (Espino et al., 2001). A Spanish translation of the MMSE was used for Spanish-speakers, paying close attention to differences in wording among various Latin American residents. Actual responses were documented, rather than simply marking responses as correct or not.

Highest level of education is also a concern in testing with the MMSE. Wood, Giuliano, Bignell, and Pritham, (2006) screened 323 African Americans and 91 Whites with the MMSE and found that African Americans consistently scored lower than White participants. The average years of school completed was less for African American participants ( $M = 10.2, \pm 4.2$  years) than for White participants ( $M = 11.7, \pm 4.1$ ). Problem areas of performance on the MMSE for African Americans included: 38% of

African Americans participants could not complete the serial 7s item beginning at 100 and counting back by 7s, whereas only 19% of White participants could not complete it. Twenty five percent of African American participants compared to 18% of White participants had difficulty with copying the design on the MMSE (overlapping pentagons). The most common missed items among African Americans on the MMSE were the serial 7's, copy design, and the day of the week. The serial 7's is a calculation task, and copying a geometric design is a visual spatial task. Both involve mathematical ability that is dependent on educational and cultural characteristics. The findings of the Wood et al. study suggest that highest level of education should be assessed as part of the baseline demographics, in addition to race and ethnicity.

**Independent variable.** The primary independent variable for the study was whether or not a participant was readmitted for HF within 30 or 60 days of discharge from the index hospitalization for HF. Determination of readmission status was accomplished by review of administrative data and by contacting patients via telephone to determine if they may have been admitted somewhere outside of the system. Contacting patients proved to be difficult as many respondents did not answer their phones or had answering machines. Because of privacy concerns, messages were not left on answering machines.

**Dependent variables.** *Geriatric Depression Scale-15.* Depressive symptoms were measured using the Geriatric Depression Scale (GDS)-15. The original Geriatric Depression Scale (GDS) was designed specifically for screening depression in the elderly (Yesavage et al., 1982-1983). In the initial testing, Cronbach's alpha for the GDS was .94, which was comparable to the Zung Self-Rating Depression Scale (SDS;  $\alpha = .87$ ) and

Hamilton Rating Scale for Depression (HRS-D;  $\alpha = .90$ ). The median corrected item-total correlation for the GDS was  $r = .56$  (range 0.32-0.83). The mean inter-correlation for the GDS items was  $r = .36$ . The GDS was concurrently valid in relation to the HRS-D and the SDS, as well as with the number of depressive symptoms as determined by Research Diagnostic Criteria for depression (Yesavage et al.) All three of these scales discriminated significantly between normal (non depressed), mildly depressed, and severely depressed elderly,  $F(2, 97) = 99, p < .001$ , and all three scales discriminated significantly across all three pairwise comparisons by post hoc pair wise t-tests ( $p < .001$  for all comparisons; Yesavage et al.)

The scale that was used in the present study was the fifteen item short version of the GDS (GDS-15) (Sheikh & Yesavage, 1986). The short form is correlated significantly with the long form,  $r = 0.84; p \leq .001$  (Sheikh & Yesavage) and internally consistent (Cronbach's  $\alpha = .80$ , D'Ath, Katona, Mullan, Evans, & Katona, 1994;  $\alpha = .79$ , Koehler et al., 2005;  $\alpha = .78$ , Weeks, McGann, Michaels, & Pennix, 2003). D'Ath et al. (1994) also found the area under the receiver operating characteristic curve (ROC) against a criterion diagnosis of depression was 0.73 for the 15-item version compared with 0.79 for the 30 item version. D'Ath et al. concluded the 15 item scale was an adequate substitute for the full 30-item scale.

The geriatric depression scale has been used with HF patients in outpatient (Koenig, 2006) and in acute care inpatient settings (Fulop, Strain & Stettin, 2003). In one acute care setting Weeks et al. (2003) evaluated 816 HF patients for depression using the GDS-15. The GDS-15's internal consistency reliability was marginal (Cronbach's  $\alpha = .72$ ).

As with the full version, the GDS-15 discriminates between depressed and non depressed elderly (Sheikh & Yesavage). The GDS-15 is available in both English and Spanish (Carrete et al., 2001). The GDS-15 uses a dichotomous response (yes/no) format for each item. There are no negatively worded items. Ten of fifteen items when answered affirmatively indicate depression; whereas five items indicate depression if answered in the negative and are reverse-scored before calculating reliability estimates or a total score. The higher the score on the GDS-15, the greater the number of depressive symptoms. Sheikh & Yesavage (1986) recommended a criterion of 5 or greater as indicating the potential presence of depression when using the 15 item scale; however, in other studies, cut points have ranged from 4 to 7 (Wancata, Alexandrowicz, Marquart, Weiss, & Friedrich, 2006).

A potential limitation of a dichotomous response format is that some people may have a tendency toward only positive or negative answers, irrespective of the question (Streiner & Norman, 2003). However, dichotomous items are often preferred by older respondents (i.e., compared with ordinal or continuous item scale types; Yesavage et al., 1982-1983). Another reason for preferring the GDS-15 scale for the elderly is that it does not contain somatic symptoms which can be related to physical disorders that may be common in the elder population, not just depression e.g., loss of appetite, loss of energy, and fatigue (Alexandrowicz et al., 2006). Also the GDS scale does not ask questions related to long term outlook on life, which may not be appropriate for all elderly persons (e.g., near the end of life). Another advantage of the GDS-15 is brevity and ease of completion- approximately 5-7 minutes (Sheikh & Yesavage, 1986).

Wancata et al. (2006) conducted a systematic review of both the GDS 15- and the 30-item version (21 studies and 32 studies, respectively). The pooled sensitivity of the GDS-15 was 0.805 and specificity was 0.750 against a valid criterion measure or diagnosis of depression. These were comparable to the GDS-30 (.753 and .770, respectively; Wancata et al.). In studies in which the Center for Epidemiological Studies Depression (CES-D) scale was used in addition to either or both versions of the GDS against a valid diagnostic criterion for depression, both versions of the GDS were more sensitive and less specific than the CES-D, but the differences were not large (Wancata et al.). Overall, Wancata et al. concluded that the criterion-referenced validity of either version of the GDS was comparable to the CES-D (Wancata et al.).

The GDS was translated by a group in Spain (Ramos Brieva, Montejo Iglesias, Lafuente Lopez, Ponce de Leon Hernandez, & Moreno Sarmiento, 1991). They found that one particular question, which asks, “Do you prefer to stay at home, rather than going out and doing new things?” was consistently answered as *yes* in certain cultures. They speculated that normal daily life of elders in certain populations may involve staying at home. They recommended that the cut point might need to be adjusted for different populations. For Chinese and Turkish versions of the GDS the same question was correlated with depression, but the respondents themselves did not view their answer as being indicative of depression (Chan, 1996; Ertan & Eker, 2000).

Carrete, et al. (2001) translated and validated a Spanish version of the GDS-30. Using a random sample of 252 ambulatory Argentinean patients, they compared their GDS translated telephonic version (GDS-T) with the same scale administered two weeks later in a face to face interview. The face to face interview consisted of two parts. First an

interviewer conducted the history and physical, determining activities of daily living, instrumental activities of daily living, and a mini mental state examination. A different interviewer, blind to the previous results, administered the GDS in person (GDS-P). Carrete et al. reported item to item correlations between the two versions ranging from 0.32 to 0.85. Of the 169 elders who followed up with the person to person interview Carrete and associates reported a Cronbach's  $\alpha$  coefficient of 0.85 (GDS-P) and 0.88 for the GDS-T. Sensitivity and specificity were 88% and 82%, respectively for the GDS-P, and 84% and 79%, respectively for the GDS-T.

In Texas, Baker and Espino (1997) translated and assessed the reliability of the GDS-15 among Mexican Americans with known DSM –III-R psychiatric diagnoses. In this sample 23 men and 18 women ranging in age from 62-98 were screened. Then the elders were divided into two groups: those with major depressive disorders ( $n=28$ ) and those with other DSM-III-R depressive disorders ( $n=13$ ). In this sample the GDS-Spanish scores ranged from 1-14. When the cut point for depressive symptoms was a score greater than 5, the sensitivity for major depressive disorders group (MDD) was only 39% (11 of 28 screened positively for symptoms of depression). Among the other depressive disorders (ODD) group 10 of 13 (Sensitivity = 77%) screened positively for depressive symptoms. When the cut point was lowered to a score of 4 or greater, the sensitivity improved to 75% for MDD (21/28) and 85% (11/13) for ODD.

Fernández-San Martín et al., (2002) translated the GDS-30 into Spanish. The internal consistency of the GDS (Cronbach's  $\alpha$ ) was .82. In this study 14% of the subjects were illiterate and 50% had received no education. The comprehension of the questions was believed to be high.

The translated version that was used in the present study was the Spanish version by Fernández-San Martín et al. This version was selected because the Spanish translated version is estimated to be at a sixth grade level by facility translators for the health care system where the study was conducted. Translators used the Fernandez-Huerta Readability Calculator (n. d.), which estimated the readability level, not syllable count and determined the GDS was easy to read. Only the GDS-15 questions will be selected from the GDS- 30 Fernández-San Martín et al. version (Appendix B); the same 15 items were used by Baker & Espino (1997).

In the present study, participants scoring greater than or equal to 5 were considered positive screens reflecting depressive symptomology (Meara, Mithelmore, & Hobson, 1999; Sheikh & Yesavage, 1986). The admitting physician was notified via progress note if persons were reporting symptoms of depression or scoring a five or higher.

*Lubben Social Network Scale.* Measurement of social isolation was with the 18-item version of the Lubben Social Network Scale (LSNS; Lubben scale; Lubben & Girona, 2003). The LSNS is a brief self reported inventory designed to gauge social isolation in older adults by measuring perceived social support received by family and friends. It was developed in 1988 and revised in 2002. The original version (Lubben, 1988) was a ten item scale. It consisted of an equally weighted sum of 10 items used to measure size, closeness, and frequency of contacts of a respondent's social network. Items are rated using Likert-type scoring with 5 ordinal response categories. The revised scale consists of an equally weighted sum of 18 items used to measure size, closeness and frequency of relatives, friends, and neighbors (LSNS-18; Lubben et al., 2006). The longer

version has three separate subscales for friends, family, and neighbors and has the highest level of internal consistency alpha 0.82 for the total score (Lubben & Gironda, 2003).

The subscales for friends, family, and neighbors can be used to determine whether major differences in network characteristics exist between groups.

The LSNS-18 is computed by summing the 18 items with total scores ranging from 0-90. Lower scores indicate smaller networks (Lubben & Gironda, 2003). However, one validation study by Rutledge, Matthews, Lui, Stone and Cauley (2003) found that the Lubben possessed poor internal consistency levels ( $\alpha = 0.55$ ). Scores lower than 36 reflect social isolation (Emlet, 2006). The physician was notified via progress note if a patient's score was 36 or less, possibly reflecting social isolation.

### **Protocol and Data Collection**

Prior to data collection the protocol for this study was approved by the Committee for the Protection of Human Subjects at the University of Texas Houston Health Science Center and by the Memorial Hermann Health Care System Center for Clinical and Translational Sciences. The researcher also met with the Cardiology Division Chiefs and administrative directors to explain the study and seek general approval and support.

**Recruitment and consent.** The procedure for recruiting patients involved acquiring a daily census with a working diagnostic code (DRG) indicative of heart failure. The investigator had access to census and admitting data by virtue of her employment position in the health care system. Once the patient was identified, the admitting orders were checked to verify the diagnosis. The patient's physician was approached and permission was obtained to approach the patient.



Next, the nurse taking care of the patient was asked if the patient was awake, alert and oriented. If yes, then the patient was approached and asked if he or she would like to participate. At this time the study was explained and questions answered. Patients who expressed interest in possibly participating were given consent form (Appendix E or F) and HIPAA forms (Appendix G); these were explained and the patient was asked to read them or have them read. Patients were given reasonable time to read and consider whether or not they wished to agree to participate. Signed informed consent was obtained from patients who agreed to participate. The original was placed in the medical record in the consent section; a copy was maintained by the investigator. A third copy was given to the patient.

After consent was obtained, the researcher administered the questionnaire packet beginning with the mini mental state exam (MMSE). If the patient scored at least 24 on the MMSE, the LSNS-18 and the GDS-15 were then administered. A progress note was written explaining the scores; it was then up to the discretion of the provider to determine if a referral was needed.

After discharge the patient was followed in the readmission database, an electronic administrative record, for up to 60 days. The investigator had access to these administrative data by virtue of her employment position, and participants explicitly consented to that access. In addition, when the readmission telephone call was made, participants were asked if they had been admitted to an outside facility. The follow up period was divided into two 30 day intervals, and the focus of the study was on how many patients were readmitted at least once in either period, not on multiple readmissions.

## Data Analysis

Statistical power and sample size were estimated by a biostatistician using PASS software, based on a preliminary review of administrative data for the three study hospitals suggesting an overall 30-day readmission rate of .20. To date, no studies using the LSNS have been conducted with patients with HF; therefore, estimates were based on the GDS-15 which has been used in HF and other chronic diseases. Because readmission is dichotomous, initially, the approach taken was to estimate power and sample size for an odds ratio of 2.0, assuming a 20% readmission rate and a median split on the GDS-15 as predictor (i.e., a relatively large effect size), but the sample size requirements for a power of at least .80 were prohibitive for a dissertation study ( $N \approx 400$  overall,  $\approx 200$  each, above and below the median on the GDS-15), given the expected acuity of a hospitalized HF population.

Therefore, the approach taken for purposes of sample size and power estimation (and, hence, for the data analysis plan) was to treat readmission as a dichotomous *independent* variable and the GDS-15 scores during the index hospitalization as the *dependent* variable. For a range of standard deviations, consistent with published reports on the GDS-15 in HF and other chronic diseases (2.0-4.0 points), a sample size of 120 was sufficient for power  $\geq .80$  to detect a mean score difference of at least 2.6 points on the GDS-15 using a two-tailed two-sample t-test at a significance level of  $p < .05$ . Because the overall expected readmission rate was relatively low (.20), the expected number of readmissions in a sample of 120 was only 24. If the actual rate were lower, enrollment would continue to a minimum of 20 readmission events.

Data analysis was conducted using PASW Statistics (Version 17). Data were screened for accuracy of data entry and missing data by the researcher. Descriptive statistical analyses included frequencies and proportions or percentages for categorical variables (nominal or ordinal), means and standard deviations for continuous (interval or ratio) level data that are at least approximately normally distributed, and medians with interquartile ranges for continuous variables that are not normally distributed (or ordinal variables with  $> 7$  categories).

Analyses of bivariate associations include chi-square analyses for nominal variables and parametric (Pearson product moment) or nonparametric (Spearman rank order) correlation coefficients according to the level of measurement and distributional characteristics of variables at an ordinal, interval, or ratio level of measurement.

The GDS and LSNS scales were analyzed for inter item and adjusted item-total correlations and assessment of internal consistency (Cronbach's alpha for the LSNS and the Kuder-Richardson variant [KR-20] of Cronbach's alpha for the GDS-15). Item analysis was conducted with the goal of achieving a minimum alpha (or KR-20) of 0.80 which Nunnally and Bernstein (1994) describe as sufficient for an already developed instrument.

Initially, two-tailed, two-sample t-tests were used to determine whether participants who were readmitted within 30 or 60 days differed from those who were not in their GDS-15 and LSNS-18 scores during the index hospitalization. Two-way analysis of variance with fixed factors was used to determine if there was any interaction between gender and readmission status. Contingency table methods were used to determine

whether there was a significant association between readmission and the proportions of participants above and below the respective cut points of the GDS-15 or LSNS-18.

### **Protection of Human Subjects**

The study was approved by the Committee for the Protection of Human Subjects at the University of Texas Houston Health Science Center and by the Memorial Hermann Health Care System Clinical Innovation and Research Institute. Once site and IRB approvals were obtained, meetings were held with care giving staff in the units where data collection occurred. The purpose of these meetings was to explain the general purposes of the study to the staff and to secure their cooperation. Actual recruitment and consenting were the responsibility of the investigator, but care giving staff were asked to confirm that a patient was sufficiently stable to recruit or to facilitate introducing the investigator to the patient.

The consent addressed: a) study title, b) sites of study, c) name and telephone numbers of investigator, d) purpose of study, e) description of study, f) benefits to respondents, g) risks to respondents, h) alternatives to participation in the study, i) subject withdrawal j) subject's right to refuse, k) subject's right to privacy, l) release of information, m) financial information, and n) acquisition of signatures. Consent also authorized the investigator to use administrative data for purposes of determining if there were any readmissions for heart failure within 30 or 60 days of discharge from the index hospitalization.

As this was an observational study, there were no direct benefits to participation. Risks and discomforts of participation were not beyond those ordinarily experienced in inpatient clinical interviews, and mechanisms were put in place for notification of a

participant's physician if scores on either the GDS-15 or the LSNS-18 were indicative of a potential problem.

A copy of the consent was given to each study participant. A locked filing cabinet containing study information was maintained by the investigator in the hospital facility, in the department of performance improvement. The office was secured when the investigator was not present. Results will be communicated only in aggregate, with no identifying information to be reported.

In terms of confidentiality, all participants were given an anonymous study identifier number at enrollment. It was necessary for the duration of the study to maintain specific identifiers of the participant's name, medical record number, and dates of hospitalization. These were maintained on a separate face sheet to the demographic data record. Any data entered electronically into a database or statistical program used only the anonymous study ID number, not the patient's name or medical records number, and only the LOS in days, not the actual dates of hospitalization. At the completion of the study, the face sheets were removed and shredded, at which point the only record of participants' names were the consent and HIPAA forms, which do not have the study ID number on them.

### **Summary**

It is hoped that this study will add to the body of knowledge about readmissions for heart failure exacerbations. Patients who are sometimes labeled as "frequent flyers" may represent failures to recognize a potentially treatable comorbidity (depression) or problems with social support, either of which could begin to be addressed during an index hospitalization, and both of which have implications for case management. For

example, for hospital case managers or social workers, it may signal that more community-based nursing case management may be needed to assist this group of patients in the effective treatment of their heart failure. An acute hospitalization episode is an opportunity to begin appropriate screening and to make appropriate referrals. The use of short, quick, reliable assessment tools may assist in this preventive role and may help reduce hospital readmissions for this population.

## Chapter 4

### Results

This chapter will present the results of the data analysis in the following sections: descriptive statistics for demographic and clinical characteristics and for readmission; results pertaining to the research questions; and exploratory analyses.

Between January 2009 and August 2009, to reach the target sample size of 120, physicians were contacted about potentially eligible patients on 200 occasions. On 130 occasions, physician permission was granted and patients were contacted. Ten of those patients declined participation. Of the 120 participants who were enrolled in the study, 12 had MMSE scores under 24 and one was subsequently excluded due to an existing power of attorney ( $n = 13$  excluded). A total of 7 were discharged before completing all study measures, but 101 (84.2% of all who enrolled) completed at least one of the two study questionnaires ( $n = 101$  for the GDS-15;  $n = 100$  for the Lubben scale). Descriptive demographic and clinical data will be given for all participants who completed at least one of the questionnaires ( $N = 101$ ).

### Descriptive Statistics

**Demographic characteristics.** The participants were age 65 or older hospitalized for treatment of heart failure in one of three acute care hospitals of a multi-hospital network in a metropolitan area in southeast Texas. Upon admission, the preliminary or working diagnosis was HF as identified by the charge nurse, case manager, or patient's nurse. Only one participant (with preserved ejection fraction) had a principal discharge diagnosis other than HF (myocarditis); this participant was not excluded because myocarditis is associated with dilated cardiomyopathy, and acute inpatient treatment for

myocarditis is generally similar to treatment for heart failure (Cooper, 2009). Data on gender, race and ethnicity, and educational attainment are summarized in Table 1.

**Table 1**

*Demographic characteristics of sample (N = 101)*

| Variable                          | Frequency (%) |
|-----------------------------------|---------------|
| Sex                               |               |
| Male                              | 50 (49.5)     |
| Female                            | 51 (50.5)     |
| Race / Ethnicity                  |               |
| White                             | 46 (45.5)     |
| Black/African-American            | 41(40.6)      |
| Hispanic                          | 14 (13.9)     |
| Education                         |               |
| ≤8 <sup>th</sup> grade            | 6 (5.9)       |
| 9 <sup>th</sup> -12 <sup>th</sup> | 54 (53.5)     |
| Some college                      | 29 (28.7)     |
| College Graduate                  | 11 (10.9)     |
| Did not answer                    | 1 ( 1.0)      |

There was no substantial difference in race, ethnicity, or educational status by gender, but there was a very substantial difference in marital status by gender (Table 2). Nearly 2/3 of the men were currently married compared to approximately 30% of the



women,  $\chi^2$  (df = 3) = 17.32,  $p < .001$ ;  $\phi = 0.41$ . Other than that, there were no striking differences in other demographic characteristics according to gender.

**Table 2**

***Marital Status by gender (N = 101)***

| Variable              | Frequency (%)     |                     |
|-----------------------|-------------------|---------------------|
|                       | Male ( $n = 50$ ) | Female ( $n = 51$ ) |
| Marital Status        |                   |                     |
| Currently married     | 32 (64)           | 15 (29)             |
| Not currently married | 18 (36)           | 36 (71)             |

Compared with those who did not complete at least one of the study questionnaires ( $n = 6$ ), those who were excluded ( $n = 13$ ) were more likely African-American or Hispanic (1/6 vs 12/13, Fisher Exact Test  $p = .003$ ). There was no significant difference between those who completed at least one of the study questionnaires ( $n = 101$ ) and those who were excluded ( $n = 13$ ) in gender, age, marital status, education, EF (preserved vs diminished), or LOS. Those who were excluded were more likely to be African-American (8/12; 67%) or Hispanic (3/12; 24%) than those with a MMSE of at least 24 who completed at least one of the study questionnaires (41% and 14%, respectively),  $\chi^2$  (df = 2) = 7.26,  $p = .026$ ,  $\phi = 0.25$ .

The mean (SD) age of the participants was 76.3 (7.6) years. The median was 77 and the mode ( $n = 12$ ) was 80 years of age. Age ranges by decade are shown in Table 3.

**Table 3***Age ranges of participants (N = 101)*

| Age Range | Frequency (%) |
|-----------|---------------|
| 65-74     | 43 (42.6)     |
| 75-84     | 44( 43.6)     |
| ≥ 85      | 14 (13.9)     |

**Clinical characteristics.** Length of stay (LOS) for the index admission (Table 4) ranged from 1-29 days for the initial hospitalization and was markedly skewed in a positive direction and extremely kurtotic. The median LOS was 4 (25<sup>th</sup> %ile = 3, 75<sup>th</sup> %ile = 7) days and the mode (n = 101) was 3 days. Approximately 16% (n = 16) had a LOS of 10 days or longer. One participant died before discharge. Length of stay did not differ between men and women and had only a weak positive correlation with age that was not statistically significant (Spearman rank-order correlation,  $r_s = .18, p = .07$ ).

**Table 4***Length of stay (LOS) for enrolled sample (N= 101)*

| LOS in days | Frequency (%) |
|-------------|---------------|
| 1-3         | 37 (36.6)     |
| 4-6         | 36 (35.6)     |
| 7-9         | 12 ( 11.9)    |
| ≥ 10        | 16 (15.8)     |

Fifty five percent of participants ( $n = 56$ ) did not have a b-type natriuretic peptide (BNP) ordered within 24 hours of admission. For the other 45 participants, BNP levels ranged from 33 -16,847 pg/ml, median = 939 (25<sup>th</sup> %ile = 581; 75<sup>th</sup> %ile = 3480). The only BNP value less than 100 pg/ml was from a patient with myocarditis. Only one patient, with unspecified heart failure, had a BNP value greater than 11,000 pg/ml. The BNP distribution was positively skewed and extremely kurtotic.

Left ventricular ejection fraction (LVEF) ranged from 10 to 75 percent. The range for men ( $n = 49$ ; 1 not documented in chart) was 10% to 55%; for women ( $n = 51$ ), the range was 19% to 75%. Median (25<sup>th</sup>, 75<sup>th</sup> %ile) was 34 ( 25, 40) for men and 34 ( 25, 45) for women. Approximately 14% of men had preserved ejection fraction ( $> 40\%$ ) compared with 29.4% of women. (Table 5)

**Table 5**

*Left ventricular ejection fraction by sex (N = 100)*

| Range       | Men ( $n = 49$ )<br>$n$ (%) | Women ( $n = 51$ )<br>$n$ (%) |
|-------------|-----------------------------|-------------------------------|
| $\leq 20\%$ | 9 (18)                      | 5 (10)                        |
| 21-25%      | 9(18)                       | 8 (16)                        |
| 26-30%      | 6 (12)                      | 3 (6)                         |
| 31-35%      | 9 (18)                      | 10 (20)                       |
| 36-40%      | 9 (18)                      | 10 (20)                       |
| $>40\%$     | 7 (14)                      | 15 (29)                       |

A higher proportion of men (86%) than women (71%) had an ejection fraction less than 40%, but overall, there was no significant difference by sex across categories of

ejection fraction,  $\chi^2$  (df=5) = 5.18,  $p = .39$ ,  $\phi = .23$  or by whether LVEF was preserved (> 40%) or not, Fisher exact test,  $p = .09$ . Neither BNP nor LVEF was correlated significantly with LOS,  $r_s \leq .20$ . BNP was negatively correlated with LVEF,  $r_s = -.35$ ,  $p = .016$ .

The principal discharge diagnosis occurring most frequently was unspecified heart failure ( $n = 35$ ). The next most frequent was acute-on-chronic systolic heart failure ( $n = 24$ ; Table 6).

**Readmissions.** Readmission within 30 and 60 days of discharge was assessed for all participants with complete data on at least one study questionnaire ( $N = 101$ ). During the 30 day study period, there were a total of 27 patients (27%) who were readmitted for HF. By 60 days, there were an additional 8 readmissions, but 4 were among patients who were also readmitted within 30 days. Therefore, a total of 31 patients (30.6%) were readmitted within 60 days. Readmission was more common for men than women (Table 7), but the difference was not statistically significant at 30 days or 60 days. The participant whose discharge diagnosis was myocarditis was not readmitted at 30 or 60 days.

At 30 days all patients received a follow up phone call to ask if they had been admitted to an outside facility. The majority of the respondents did not answer the telephone or had answering machines. To be HIPAA-compliant, phone messages were not left for the participants. Only 15 participants were successfully contacted by phone; none had been readmitted.

**Table 6*****Discharge diagnosis (N=101)***

| Diagnosis   | ICD-9  | Frequency |
|---|--------|-----------|
| Unspecified HF                                      | 428.0  | 35        |
| Acute-on-chronic systolic HF                        | 428.23 | 24        |
| Chronic systolic heart failure                      | 428.22 | 7         |
| Acute systolic heart failure                        | 428.21 | 6         |
| Chronic diastolic heart disease                     | 428.32 | 5         |
| Acute-on-chronic diastolic HF                       | 428.33 | 5         |
| Acute-on-chronic combined systolic and diastolic HF | 428.43 | 4         |
| Unspecified systolic HF                             | 428.20 | 4         |
| Acute diastolic HF                                  | 428.31 | 3         |
| Chronic combined systolic heart failure             | 428.42 | 2         |
| Rheumatic congestive HF                             | 398.91 | 2         |
| Hypertensive heart and chronic kidney disease       | 404.00 | 1         |
| Hypertensive heart and kidney disease with HF       | 404.93 | 1         |
| Unspecified diastolic heart failure                 | 428.30 | 1         |
| Myocarditis   | 429.00 | 1         |
| Total   |        | 101       |

**Table 7*****Readmissions (N = 101)***

| Readmission | Male (n = 50)<br><i>n (%)</i> | Female (n = 51)<br><i>n (%)</i> |
|-------------|-------------------------------|---------------------------------|
| ≤ 30 days   | 16 (59)                       | 11 (41)                         |
| ≤ 60 days   | 19 (61)                       | 12 (39)                         |

**Geriatric Depression Scale**

The GDS was completed by 101 participants. The mean GDS score was 2.7 (1.7) points. The median and mode were both 3. Only 9 participants had scores greater than or equal to 5, consistent with at least mild depressive symptoms. This probably reflects a selection bias that likely is attributable to several unanticipated factors. Physicians were less willing to permit the researcher to approach patients who were more seriously ill and who may have been more depressed. In addition among those who were approached, those who were more depressed may have been less inclined to participate.

Among participants, there was no significant difference between men and women in GDS scores. The median (25<sup>th</sup>, 75<sup>th</sup>ile) for women was 3 (2, 4) points; for men, it was 2 (1,4) points, Mann Whitney test, mean rank 54.25 for women and 47.69 for men,  $z = -1.14, p = 0.25$ ). There was no significant difference by age group in GDS scores, Kruskal-Wallis  $\chi^2 (df = 2) = 1.60, p = 0.45$ . Mean ranks were 51.1, 48.27, and 59.4, and medians were 3 (2, 3), 2 (1, 4), and 3 (2, 4), respectively for the 65-74, 75-84, and 85 years or older groups.

The Kuder-Richardson-20 statistic (equivalent to Cronbach's alpha for dichotomous items) was only 0.39 in this sample and the mean interitem correlation was

nearly 0 (mean = .04; range = -0.17 to + 0.31). This probably reflects a floor effect on scores (~ 91%  $\leq$  4 points). Because of the low reliability estimate, it was not possible to test the hypothesis that participants who were subsequently readmitted were more depressed at the time of the initial hospitalization. In an exploratory analysis, participants with scores of five or more ( $n = 9$ ) or 4 or more ( $n = 30$ ) were not significantly more likely to be readmitted at 30 or 60 days, Fisher exact test,  $p > .05$ .

### **The Lubben Scale**

The Lubben scale was completed by 100 participants. The mean score in this study was 48.3 (SD 11.7), the median was 47.5 (25<sup>th</sup> – 75<sup>th</sup> percentiles: 40.0-55.8). Overall, thirteen participants (13%) had scores less than 36. Scores were normally distributed, Kolmogorov-Smirnov test,  $p = .20$

Overall, the Cronbach alpha for the Lubben was 0.77, indicating that about 23 % of the total item variance was attributable to measurement error (DeVellis, 2003). The mean inter-item correlation was low (mean  $r = .15$ , range -.25 to .65). Corrected item-total correlations ranged from 0.03 to 0.59, and squared multiple correlations from 0.22 to 0.61. Only one item if deleted would have increased alpha, but only marginally (#3, “How many relatives do you feel at ease with to talk about private matters?”) Deletion of this item would have raised Cronbach’s  $\alpha$  to 0.785). Overall, internal consistency reliability was adequate for purposes of hypothesis testing.

To test the hypothesis that those who were readmitted at 30 or 60 days had lower Lubben scale scores than those who were not readmitted, a two sample t test was used. There was virtually no difference in Lubben scale scored between those who were or were not readmitted at least once within 30 or 60 days. At 30 days post discharge, the

mean score (SD) for patients who were readmitted was 47.3 (SD 10.1) versus 48.7 (SD 12.3),  $t(df = 98) = 0.53$ ,  $p = .60$ . The mean score for those readmitted at 60 days was 48.3 (SD 10.4) versus 48.3 (SD 12.3) for those who were not readmitted,  $t(df = 98) = -0.03$ ,  $p = .98$ .

Exploratory analyses were conducted to examine if there were significant mean differences between Lubben scores for men versus women, and to determine if there was any interaction between sex and readmission. In a two-way ANOVA with interaction term (gender, total admissions, gender x total admissions) there was no interaction between sex and readmission,  $F(1,96) = .18$ ,  $p = .67$ . The model without interaction showed no significant difference in Lubben scores between men and women,  $F(1,97) = .03$ ,  $p = .87$ .

Several issues relevant to the wording of items of the Lubben scale emerged during data collection. Many participants asked for clarification with questions related to the wording, “How often do you *see or hear from* relatives, friends or neighbors?” Participants wanted to know if email counted as “hearing from”. The same was true of the series of questions asking, “How often do you *see or hear from* relatives, friends or neighbors with whom you have the most contact?” More than 50% of participants were using email with some frequency. The Spanish translation of the Lubben had one word, *pariente*, for which Hispanics in this sample nearly always requested clarification. In general, *parientes* means a relatives or relations. *Familiares* (i.e., family members) appeared to be a more common word among Hispanic participants.

Several questions on the Lubben scale tended to elicit more expansive responses beyond just marking the Likert-type rating. With regard to question 7: *How many*



*neighbors do you see or hear from at least once a month?* Nearly all participants indicated they had 3 or more neighbors. However, four participants indicated that they were referring to neighbors from their past residences because they had recently moved to the city and actually knew no one outside of their immediate family. These four participants were married and had moved to be with a daughter or son. All four had a poor prognosis and felt that the surviving spouse would have an easier time being in close proximity to a son or daughter.

Questions 9 (*How many neighbors do you feel at ease with that you can talk to about private matters?*) and 10 (*How many neighbors do you feel close to such that you could call on them for help?*), though similar in wording, elicited differing responses. The predominant response to Question 9 was *none*. However, African-American and Hispanic participants were somewhat more likely to respond that they felt at ease with one or two neighbors.

In answering these questions, many participants recalled a time when they knew their neighbors well, could talk with them and rely on them for help. Many participants, in contrast, indicated that nowadays they rarely knew their neighbors well. Some noted that their neighbors were younger and appeared too busy to talk, so they did not try to have a friendship with them. Widowed or divorced participants, however, indicated that they tried consistently at least to talk to neighbors.

Even though they did not necessarily confide in neighbors, most participants had at least two consistent persons they could rely on for help. Widowed women in particular, told stories about partnerships they had with neighbors to keep an eye on their property. One stated that her neighbor knew that if the front window blinds were not open, then

something might have happened to her. The neighbor then knew to go ring the door bell or call her and check on her. Another woman described how she and her next door neighbor had a pact: if her newspaper was not picked up by 9am, (which was the time he went to work) then he was to call the police to summon help. Another woman had an understanding with neighbors that she moved her car out of the garage to the driveway every morning and back inside the garage by 5 pm. This signified that all was well. Several neighbors knew they needed to call for help if the car was out past dark. Two women had emergency response alarms that they wore around their necks.

One divorced male participant, living in a trailer park, had two friends he could call on for help. Additionally, they had given him an air horn to use when his breathing became difficult. His neighbors could easily hear the horn, and they would arrive or other nearby neighbors would arrive to help him. His neighbors also rotated cooking meals for him all year long. Another single male veteran reported having one neighbor he could call on for help. Unfortunately he had to pay the neighbor (out of his retirement money) to assist him with his activities of daily living. When asked why he had not solicited assistance from the Veterans Department, he stated he would not take charity. After a long emotional discussion, this veteran finally agreed to talk with social services and he received emergent assistance.

One divorced female, when asked how many neighbors she could call, said she could call on two neighbors, but felt they could not assist her. Her house had lost part of the roof and every time it rained she had water in her kitchen. Also, rats were coming in through the roof. Her two small dogs would fight off the rats, but, she was so afraid to fall asleep in the bed and get bitten by the rats, she was hardly sleeping. All of this was

exacerbating her lung problems, dysrhythmias and HF. The Adult Protective Services department was notified, and she was relocated to clean, decent housing. She was readmitted a second time, but she reported being much happier and felt safe in her new home.

African American participants commonly reported being able to count on church members for help, even if they were not neighbors. While church members may not have lived close by, they felt they could get emergent assistance from their ministers. Ministers were usually involved in a weekly face to face meeting with the patients. In busier churches, the pastor would at least call the member and ask if any assistance was needed. On weekends, volunteers from the Church would visit or transport members to church services. Churches also provided a lunch and activities for these participants. In contrast, Hispanic participants reported having the least amount of social support outside the family.

Thus, in general, the questions on the Lubben scale regarding “neighbors” elicited a great deal of explanatory information regarding the level of social contact patients were having. Even if the scale was not associated with readmission, it may have value as an assessment of social support and possible need for social services.

### **Exploratory Analyses of Readmission**

Exploratory analyses were also conducted to test for any associations between readmission status at 30 days or 60 days and BNP levels at admission (Table 7). Among participants who had a BNP drawn within 24 hours of admission ( $n = 48$ ), 2 were among the 12 enrollees excluded from further analysis due to an MMSE < 24 and one failed to complete the MMSE. The difference in medians was approximately 2475 pg/ml at 30

days ( $p = .056$ ) and approximately 2938 pg/ml at 60 days ( $p = .016$ ). Thus, although the result at 30 days did not reach statistical significance, it was a substantial difference in clinical terms. The difference at 60 days was both statistically significant and clinically substantial. All but one of the cases readmitted by 60 days was among those readmitted within 30 days (Table 8).

**Table 8**

*Admission BNP values (pg/ml) by readmission status at 30 days and 60 days (n = 45)*

| Readmission Status | n   | Percentiles      |        |                  | Ranks |       | Mann-Whitney Test |        |       |      |
|--------------------|-----|------------------|--------|------------------|-------|-------|-------------------|--------|-------|------|
|                    |     | 25 <sup>th</sup> | Median | 75 <sup>th</sup> | Mean  | Sum   | <u>U</u>          | Z      | p     |      |
| 30 days            | no  | 33               | 326    | 852              | 2462  | 20.74 | 684.50            | 123.50 | -1.91 | .056 |
|                    | yes | 12               | 763    | 3327             | 8251  | 29.21 | 350.50            |        |       |      |
| 60 days            | no  | 32               | 315    | 845              | 2249  | 19.98 | 639.50            | 111.50 | -2.42 | .016 |
|                    | yes | 13               | 767    | 3782             | 9247  | 30.42 | 395.50            |        |       |      |

\* For BNP drawn within  $\pm 24$  hours of admission

There was no significant association between ejection fraction and readmission status at 30 days,  $\chi^2$  (df = 5) = 1.73,  $p = .89$ , or 60 days,  $\chi^2$  (df = 15) = 5.11,  $p = .40$  (Table 9, data shown for total readmissions at 60 days). There also was no association between length of stay and readmissions at 30 days, Mann Whitney test,  $z = -0.35$ ,  $p = .72$ , or total readmissions at 60 days, Mann Whitney test,  $z = -0.94$ ,  $p = .35$ .

**Table 9***Left ventricular ejection fraction by readmission status at 60 days (N = 100)*

| Range  | Not Readmitted (n = 69) | Readmitted (n = 31) |
|--------|-------------------------|---------------------|
|        | n (%)                   | n (%)               |
| ≤20%   | 10 (15)                 | 4 (13)              |
| 21-25% | 9(13)                   | 8 (26)              |
| 26-30% | 5 (7)                   | 4(13)               |
| 31-35% | 16 (23)                 | 3 (10)              |
| 36-40% | 14 (20)                 | 5 (16)              |
| >40%   | 15 (22)                 | 7 (22)              |

## **Chapter 5**

### **Discussion**

This prospective descriptive study examined differences in physiological and psychological variables during a 30 to 60 day period following an index hospitalization for HF. It was hypothesized that patients who were readmitted for HF within 30 or 60 days of discharge from the index hospitalization would have more severe depressive symptoms (higher GDS-15 scores) or greater social isolation (lower Lubben scale scores) during the index hospitalization than patients who were not subsequently readmitted for HF. No statistically significant or clinically meaningful association was found between readmission and either depressive symptoms or social isolation.

In exploratory analyses, a significantly higher admission BNP for the index hospitalization was found in those who had been readmitted at least once within 60 days, of discharge compared to those with no readmissions. The difference was large enough to be clinically meaningful in addition to being statistically significant. For readmissions at 30 days, the difference in admission BNP was large enough to be clinically meaningful, although it fell short of the threshold for statistical significance. No statistically significant association was found between readmission at 30 or 60 days ejection fraction or between readmission and length of stay.

### **Statistical Assumptions**

Prior to the study, it was estimated that 120 subjects would be needed for adequate ( $\geq 80\%$ ) statistical power to detect a potentially meaningful difference in GDS scores, based on an expectation of 20% readmission rate (24 readmissions). Due to post-enrollment determination of ineligibility ( $n=13$ ), approximately 90% (107/120) remained

eligible of whom 94% (101/107) completed the GDS. However, the actual readmission rates were higher than the 20% on which the sample size estimate was based; 27% (27/101) within 30 days and 31% (34/101) at least once by 60 days following discharge from index hospitalization. In addition, it was apparent that very few participants had a GDS score consistent with increased risk for depression. Therefore a decision was reached, in consultation with the dissertation chair, to discontinue enrollment. Due to the low reliability of the GDS in this sample, no attempt was made to estimate observed power, so the actual statistical power of the study is unknown. However, there was a moderate to large, statistically significant difference in admission BNP for the index hospitalization between those who were readmitted at least once within 60 days and those who were not readmitted. Therefore there was adequate statistical power to detect a clearly meaningful difference in admission BNP values.

With respect to the unacceptably low reliability of the GDS-15 in this study, Kieffer and Reese (2002) reviewed studies in which reliabilities for the GDS were either reported or could be calculated from the published data. Despite a mean reliability of .85, they found published reports of reliability coefficients as low as 0.41 and calculated some reliabilities to have been as low as .11.

### **Theoretical Assumptions**

For the purposes of this study, social isolation was viewed primarily as an antecedent situational factor and depression was viewed as primarily a symptom. The TOUS (Lenz et al., 1995, 1997) portrays dimensions of intensity, quality, duration, and distress of individual symptoms or symptom clusters. When symptoms cluster, which is common in heart failure, the symptoms may have synergistic effects that exceed the sum

of separate effects. Because symptoms other than depression were not included, any potential synergy between depressive and other symptoms (e.g., fatigue, dyspnea) could not be assessed.

**Physiological factors.** With respect to BNP, Wu, Harrison and Maisel (2004) studied 344 cases in which BNP was ordered on admission. They found that BNP may have enabled more HF patients to be treated properly through proper identification, but BNP served only to reduce the number of incorrectly diagnosed readmissions. Ancheta et al. (2009) also found that clinician's awareness of BNP levels was not associated with improvements in outcomes including quality of life and length of stay.

Bettencourt, et al. (2004) studied 182 patients admitted for HF and followed for six months. They found that variables associated with an increase for readmission or death were heart rate, length of stay, volume overload, no ACE-inhibitor prescribed at discharge and *changes* in BNP levels between admission and discharge (i.e., not just BNP at admission). The median admission BNP level was 6778 pg/ml and the median level at discharge was 4137 pg/ml. The variation in BNP was the strongest predictor of an adverse outcome. Similarly, Lainchbury et al. (2009) studied BNP guided therapy in 384 patients. They found that pharmacotherapy guided by BNP peptides improved mortality at one year.

In the present study, higher BNP levels within 24 hours of the index admission were associated with readmission. The median difference between those readmitted and those not readmitted was approximately 2400pg/ml at 30 days and 2900 pg/ml at 60 days, both of which would be considered clinically meaningful. Thus, it is possible that higher BNP values at admission may be associated with an increase in risk for readmissions.



However, the analysis was limited because a majority of participants (those with an already confirmed diagnosis of heart failure) did not have BNP levels ordered within 24 hours of admission because a result would not have altered clinical decision making.

In the Worcester Heart Failure study (Saczynski, Darling, Spencer, Lessard, Gorre & Goldberg (2009) 4,534 participants hospitalized for possible HF were recruited, of whom only 37% had documented ejection fractions. In this sub-group of participants, patients were younger, had a lower body mass index, and were less likely to have a medical history of diabetes, cancer or renal disease. As in the present study, EF alone was not found to be a predictor of readmission. The thirty day crude mortality rate in patients with documented EF showed that mortality rates increased with age from 5.5% in patients < 65years of age to 17.6% in those aged 85 or older.

With respect to ejection fraction, Torre-Amione et al., (2009) studied acute heart failure and symptoms of worsening heart failure. In this randomized hemodynamic study, they found that patients admitted with acute HF (AHF) were older, about half were women, half had preserved left ventricular ejection fraction and 20% had new onset HF as compared with younger age and significantly male predominance and chronic HF cohorts. They concluded that the pathogenesis and course of AHF could be determined by factors different from those affecting the course and outcome of chronic HF.

McMurray and Pfeffer (2004) also observed that impaired left ventricular ejection fraction correlated with adverse outcome in patients with chronic HF, but did not correlate with worse outcome in patients with AHF. Torre-Amione et al. (2009) believe that AHF may have different end points, for example prevention of a readmission during an acute HF episode is not as important an outcome as clinical stabilization and

improvement in symptoms. No studies demonstrating a significant association between length of stay and readmission were found.

**Situational factors.** This study also found that social isolation was not a predictor for readmission. From a theoretical perspective, the TOUS does not specify the strength or direction of any associations among situational, physiological, and psychological antecedent factors. However, it is reasonable to assume that, in general, worse antecedent or baseline status would be associated with worse performance or outcomes.

Sorkin et al. (2002) studied 180 elderly patients and found that patients who perceived loneliness had longer lengths of stay than persons who did not report perceived loneliness, but this was not specific to patients with heart conditions, and they did not investigate readmissions. Sorkin and associates also examined the possible mediating mechanisms by which loneliness might influence the probability of having a heart condition: the first analysis examined the possibility that physiological factors (serum cholesterol, body mass index) might mediate the association between loneliness and the probability of having a heart condition. Triglyceride levels and BMI did not mediate the relation between loneliness and having a heart condition. Sorkin et al. also examined affect states: depression did not serve as a mediator ( $M_s = 9.26$  vs  $9.17$ ).

**Psychological factors.** With respect to depression, Redwine et al. (2007) followed 18 men with HF over a two year period. They found that certain physiological factors previously thought to be related (e.g. body mass index, level of BNP, and EF) were not correlated to depression scores. Patients who were re-hospitalized over a two year period had higher depression scores at baseline. Redwine and colleagues also found

that there was a negative linear relationship between the number of depressive symptoms and the ratio of Th1/Th2 leukocytes at baseline among the HF patients (Th1 cells promote cellular immunity by rapidly producing a range of cytokines; Th2 cells produce cytokines such as IL-4 and IL-10). Patients who were re-hospitalized and or died due to cardiovascular events over a two year period had higher depression scores as well as reduced Th1/Th2 ratios at baseline. In addition, HF patients with high depression scores had lower cellular immunity, as evidenced by a shift in interferon gamma/interleukin-10 ratios in Th2 cells. These findings by Redwine suggest that an association between depression and compromised immune status may contribute to the relationship between depression and cardiac morbidity and, mortality over a period of several years.

In the present, study the total rate of depressive symptomology was 8.9%, with the depressed sample consisting of 4 men and 5 women. Assuming a reliable measure had been used, it may have been that a much higher severity or duration of depression (greater variability in scores) would have been needed to detect any association with readmission for this population. Alternatively, the readmission interval may have been too short to detect a meaningful relationship.

The TOUS examines symptoms based on intensity/severity, duration/timing, distress and quality. In this study, a score of 5 categorized a person as potentially depressed. Kieffer and Reese (2002) point out that reliability is a property of scores on an instrument (i.e., an interaction between the instrument and the population and setting in which it is used) rather than a property of the instrument independent of the context in which it is used. In this study the reliability of scores may have been adversely affected

by sampling biases that were an artifact of requiring access to patients through their physicians.

Although possible effects of gender are not explicitly localized in the TOUS model, no relationship was found between gender and readmission in the present study. This is consistent with findings of Lee, Capra, Jensvold, Gurwitz and Go (2004) over a twelve month period. D'Ath and associates (1994) studied 194 elders at a single point in time and found the mean GDS-15 scores to be 3.7, but with a range of 0-15 points and approximately one third in the depressed range (34% overall, 35% of men and 33% of women) They found no statistically significant relationships between GDS score and either age group (65-74 years vs. 75 or older) or gender.

In the present study no clinically or statistically significant differences in depression scores were found for race and ethnicity. Again, the ability to detect any such difference was adversely affected by the low score variability and unacceptably low reliability of the GDS-15 in the present sample. However, some similarities to previously reported studies were found.

Previous research has demonstrated that Hispanic females are at greater risk of depression due to poverty and lack of economic resources (Chiriboga, Black, Aranda, & Markides, 2002). Unmarried Hispanic elder females are 2.5 times more likely to be depressed than their married counter parts (Falcón & Tucker, 2000). While this study, did not ask questions related to family structure, it is worth mention that Hispanic caregivers of adults with dementia have been found to be more likely than Black or White caregivers to have GDS-15 scores of 6 or higher (Covinsky, et al., 2003).

In this study, Hispanics tended to the word *nervios* (“nerves”) to describe symptoms of depression, which has been reported in Puerto Ricans (Guarnaccia, Lewis-Fernández, & Marano, 2003) and Mexican-Americans (Newton, 1978, as cited in Guarnaccia et al., 2003). Guarnaccia et al. assert that such usage is also common in other Latin American cultural groups, although probably with cross-cultural variations in what is meant. Stigma may also influence how elders and minorities self report depression (Interian, Martinez, Guarnaccia, Vega, & Escobar, 2007).

In this study, no African American participants reported feeling depressed. Other studies have reported that African Americans may conceptualize depression differently than Whites (Blazer et al., 1998; Gallo et al., 1998; Kirmayer, 2001), and that the African American population may also attach stigma to mental illness, thus also affecting responses in self rating instruments (Mills, 2004).

### **Limitations**

Limitations of this study include sample size and potential selection bias. The sample size estimate was based on analysis of readmission statistics in the participating hospitals, based on all HF admissions, not just patients 65 years of age or older, let alone those willing to participate in an observational research study. However, the number and percentage of readmissions in the sample (n= 31, 31%) was somewhat greater the prior estimate of a 20% readmission rate. Thus, although the statistical power of the study was almost certainly lower than 80%, there were a sufficient number of readmissions for meaningful analysis of other variables.

Convenience sampling and having to ask provider permission were limiting factors. Providers may have been hesitant to allow the researcher to speak with depressed

patients or sicker patients. Also, self selection bias among people who are depressed may have played a role. For example, among the patients who were actually approached for recruitment, none who stated they had depression agreed to participate in the study. It is reasonable to assume that factors affecting willingness to volunteer introduce a self selection bias especially since this was an observational study with no direct benefit to participants.

Almeida, Kashdan, Nunes et al (2008) reported that more anxious, socially avoidant and depressed people are less likely to volunteer for participation in research studies. All of these factors potentially affect the representativeness of the study sample and impact both internal and external validity. Therefore, the extent to which the study results can be generalized beyond the sample may be quite limited. While these participants may not represent the population of all patients hospitalized for HF in terms of psychosocial characteristics, they were reasonably representative of the HF population served by the hospital system in terms of demographic and clinical variables, for example age, sex, race, ethnicity, BNP at admission, ejection fraction, length of stay, and rate of readmissions.

Another limiting factor was the amount of time the participants were followed. Readmission was assessed at 30 and 60 days post discharge. As it turned out, nearly all of those readmitted within 60 days of discharge had also been readmitted within 30 days (27/31; 87%)., and, in the BNP analysis, a change in readmission status of a single case accounted for the result changing from not statistically significant to statistically significant. No outside readmissions were encountered, however only 15% of respondents were successfully reached by telephone. This potentially could have resulted

in misclassification and undercounting of readmissions. Thus, the actual readmission rates may have been higher. While readmissions were all related to heart failure, it may well have been the case that a longer follow up interval (e.g. 6 months, a year) would have been better.

Although there have been many studies of readmission in heart failure (Krumholz et al, 1997; Gooding & Jette, 1985, Krumholz et al., 2000; and Harjai, Thompson, Turgut & Shah, 2001) there is no consensus across studies as to what an optimal follow-up interval should be. In addition, some studies have recruited HF patients only after a recent hospitalization instead of during an acute hospital stay (Fulop et al., 2003). Some have used a combined endpoint of death or any hospitalization as opposed to readmission alone following a specific hospitalization (Redwine et al., 2007; Vaccarino, et al., 2007) and others have been based entirely on existing administrative data (Anderson, Freedland, Clouse, & Lustman, 2001). Such issues also impact internal and external validity of previous studies of readmission, and differences in design, endpoints, and timeframes for readmission complicate comparing results across studies.

In summary, the study was unable to substantiate that depression or social isolation affects readmissions over a 30 to 60 day interval following discharge from an index hospitalization for HF. The results do not rule out a possible role for screening for depression and social isolation during an admission for HF. Clinical guidelines for cardiovascular care recommend that screening for depression should be considered (Lichtman et al., 2008) and no harm related to screening has been identified (Thombs, de Jonge, Coyne, Whooley et al, 2008). More research on the impact of depression screening is needed and the impact various depression tools may have: different

instruments measure different symptoms, and a self reported instrument varies from an interview or an observer rated instrument for major and minor depression. It is yet to be determined which instrument may be more beneficial among HF patients.

The results of this study also do not rule out a possible need for a longer follow-up interval if readmission is an outcome of interest. It may well be that depression and social isolation do not manifest themselves until several years after a person has had HF, and may require a longer interval than 60 days for an impact on rehospitalization to be detected. Jiang and associates (2001) found that readmissions were high for major depression after 3 months of a previous admission (52%) and after one year the readmission rate was 80%. Future research may also be needed to specify the follow up period needed before manifestation of depression is detectable.

There is also the possibility that several psychosocial variables may need to be measured in addition to depression, for example anxiety and loneliness. The complexity of psychological and situational factors may interact with symptoms leading older adults to judge their health unfavorably and to perceive deficits in their social networks. Future research is recommended to examine which variables may mediate the relationship between social isolation, loneliness and a readmission or a death.

Future research is also recommended at examining physiological symptoms and their interactions and mediating effects among each other, for example, dyspnea and fatigue may also be interacting with each other affecting rates of perceived depression and affecting perceived level of social isolation. It is important to identify which mechanisms account for the poor outcomes: a larger, more representative sample, with a



broader range of depressive scores might show strong evidence that depression and physiological factors mediate each other.

Future research should also be directed at examining the role BNP levels have with relation to readmissions. Serial BNP levels might prove useful in assessing risk for readmissions among HF patients (Wilson Tang et al., 2007) and might even be of value in identifying patients who need more intensive surveillance and treatment to prevent readmission. The concept of BNP guided management of HF is still under investigation.

In closing, it should be noted that the purpose of any screening measurement is to identify individuals for whom more comprehensive and definitive assessment is warranted. Diagnostic and treatment should never rely solely on information provided by a screen. Depression and social isolation may be important enough on their own, even if they do not predict readmission, to be worth screening for during an acute hospital admission. Continued efforts are needed to decrease burden of hospitalization and other adverse outcomes in these high risk patients.

## APPENDICES

|            |  |     |
|------------|--|-----|
| Appendix A | Geriatric Depression Rating Scale (English Version).....   | 92  |
| Appendix B | Geriatric Depression Rating Scale (Spanish Version).....   | 94  |
| Appendix C | Lubben Social Isolation Questionnaire (English Version).....   | 96  |
| Appendix D | Lubben Social Isolation Questionnaire (Spanish Version) .....  | 100 |
| Appendix E | Consent to Participate in a Research Study (English) .....   | 104 |
| Appendix F | Consent to Participate in a Research Study (Spanish).....  | 110 |
| Appendix G | Authorization for the Use and Disclosure of Protected Health Information<br>for Research (English and Spanish) | 115 |

**Appendix A**

**Geriatric Depression Rating Scale (English Version)**

GERIATRIC DEPRESSION RATING SCALE

Brink et al., 1982; Yesavage et al., 1983 - SHORT version - Sheik et al., 1986

Choose the best answer for how you have felt over the past week:

Yes / No

- ]  ] 1. Are you basically satisfied with your life?  
 ]  ] 2. Have you dropped many of your activities and interests?  
 ]  ] 3. Do you feel that your life is empty?  
 ]  ] 4. Do you often get bored?  
 ]  ] 5. Are you in good spirits most of the time?  
 ]  ] 6. Are you afraid that something bad is going to happen to you?  
 ]  ] 7. Do you feel happy most of the time?  
 ]  ] 8. Do you often feel helpless?  
 ]  ] 9. Do you prefer to stay at home, rather than going out and doing new things?  
 ]  ] 10. Do you feel you have more problems with memory than most?  
 ]  ] 11. Do you think it is wonderful to be alive now  
 ]  ] 12. Do you feel pretty worthless the way you are now  
 ]  ] 13. Do you feel full of energy?  
 ]  ] 14. Do you feel that your situation is hopeless?  
 ]  ] 15. Do you think that most people are better off than you are?

TOTAL GDS:

(GDS maximum score = 15)

- 0 - 4 normal, depending on age, education, complaints  
5 - 8 mild  
8 - 11 moderate  
12 - 15 severe

**Appendix B**

**Geriatric Depression Rating Scale (Spanish Version)**

GDS-15 adapted from Fernández-San Martín et al., (2002)

1. ¿En general se siente satisfecho con su vida?
2. ¿Ha abandonado muchas de sus actividades e intereses?
3. ¿Siente que su vida está vacía?
4. ¿Se aburre con frecuencia?
5. ¿Esta de buen humor la mayor parte del tiempo?
6. ¿Tiene miedo que le suceda algo malo?
7. ¿Se siente feliz la mayor parte del tiempo?
8. ¿Siente con frecuencia que nada o nadie le puede ayudar?
9. ¿Prefiere quedarse en casa en vez de salir y hacer cosas nuevas?
10. ¿Siente que tiene más problemas de memoria que los demás?
11. ¿Piensa que es maravilloso estar vivo?
12. ¿Se siente inútil tal y como esta ahora?
13. ¿Se siente lleno de energía?
14. ¿Cree que su situación no tiene salida?
15. ¿Cree que la mayoría de la gente está en mejor situación que usted?

**Appendix C**

**Lubben Social Isolation Questionnaire (English Version)**

LUBBEN SOCIAL NETWORK SCALE – 18LSNS-18

FAMILY Considering the people to whom you are related either by birth or marriage...

1. How many relatives do you see or hear from at least once a month?

0 = none            1 = one            2 = two            3 = three or four            4 = five thru  
eight                5 = nine or more

2. How often do you see or hear from relative with whom you have the most contact?

0 = never            1 = seldom            2 = sometimes            3 = often            4 = very often            5 =  
always

3. How many relatives do you feel at ease with that you can talk about private matters?

0 = none            1 = one            2 = two            3 = three or four            4 = five thru  
eight                5 = nine or more

4. How many relatives do you feel close to such that you could call on them for help?

0 = none            1 = one            2 = two            3 = three or four            4 = five thru  
eight                5 = nine or more

5. When one of your relatives has an important decision to make, how often do they talk to you about it?

0 = never            1 = seldom            2 = sometimes            3 = often            4 = very often            5 =  
always

6. How often is one of your relatives available for you to talk to when you have an important decision to make?

0 = never            1 = seldom            2 = sometimes            3 = often            4 = very often            5 =  
always

NEIGHBORS: Considering those people who live in your neighborhood....

7. How many of your neighbors do you see or hear from at least once a month?

0 = none            1 = one            2 = two            3 = three or four            4 = five thru  
eight                5 = nine or more

8. How often do you see or hear from the neighbor with whom you have the most contact?

0 = never            1 = seldom            2 = sometimes            3 = often            4 = very often            5 =  
always



9. How many neighbors do you feel at ease with that you can talk about private matters?  
0 = none      1 = one      2 = two      3 = three or four      4 = five thru  
eight      5 = nine or more

10. How many neighbors do you feel close to such that you could call on them for help?  
0 = none      1 = one      2 = two      3 = three or four      4 = five thru eight      5 = nine or  
more

11. When one of your neighbors has an important decision to make, how often do they  
talk to you about it?

0 = never      1 = seldom      2 = sometimes      3 = often      4 = very often      5 =  
always

12. How often is one of your neighbors available for you to talk to when you have an  
important decision to make?

0 = never      1 = seldom      2 = sometimes      3 = often      4 = very often      5 =  
always

FRIENDSHIPS: Considering your friends who do not live in your neighborhood....

13. How many of your friends do you see or hear from at least once a month?

0 = none      1 = one      2 = two      3 = three or four      4 = five thru  
eight      5 = nine or more

14. How often do you see or hear from the friend with whom you have the most contact?

0 = never      1 = seldom      2 = sometimes      3 = often      4 = very often      5 =  
always

15. How many friends do you feel at ease with that you can talk about private matters?

0 = none      1 = one      2 = two      3 = three or four      4 = five thru  
eight      5 = nine or more

16. How many friends do you feel close to such that you could call on them for help?

0 = none      1 = one      2 = two      3 = three or four      4 = five thru eight      5 = nine or  
more

17. When one of your friends has an important decision to make, how often do they talk  
to you about it?

0 = never      1 = seldom      2 = sometimes      3 = often      4 = very often      5 =  
always

18. How often is one of your friends available for you to talk to when you have an important decision to make?

0 = never      1 = seldom      2 = sometimes      3 = often      4 = very often      5 = always

LSNS-R total score is an equally weighted sum of these items. Scores range from 0 to 90.

**Appendix D**

**Lubben Social Isolation Questionnaire (Spanish Version)**

LSNS-18

FAMILIARES Incluye las personas con las que usted está emparentado, ya sea por nacimiento o por matrimonio ...

1. ¿Con cuántos parientes se reúne o habla por lo menos una vez al mes?  
0 = ninguno 1 = uno 2 = dos 3 = tres y cuatro 4 = cinco a ocho  
5 = nueve o más
2. ¿Con qué frecuencia se reúne o habla con el pariente con el que tiene mayor contacto?  
0 = nunca 1 = rara vez 2 = a veces 3 = a menudo 4 = muy a menudo 5 = siempre
3. ¿Con cuántos parientes se siente usted en confianza para tratar asuntos privados?  
0 = ninguno 1 = uno 2 = dos 3 = tres y cuatro 4 = cinco a ocho  
5 = nueve o más
4. ¿Con cuántos parientes se siente usted en confianza como para pedirles ayuda?  
0 = ninguno 1 = uno 2 = dos 3 = tres y cuatro 4 = cinco a ocho  
5 = nueve o más
5. Cuando alguno de sus parientes debe tomar una decisión importante, ¿qué tan a menudo le hablan sobre ello?  
0 = nunca 1 = rara vez 2 = a veces 3 = a menudo 4 = muy a menudo 5 = siempre
6. ¿Con qué frecuencia está disponible alguno de sus parientes para hablar cuando usted tiene una decisión importante que tomar?  
0 = nunca 1 = rara vez 2 = a veces 3 = a menudo 4 = muy a menudo 5 = siempre

VECINOS: Incluye aquellas personas que viven en su vecindad....

7. ¿Con cuántos vecinos se reúne o habla por lo menos una vez al mes?  
0 = ninguno 1 = uno 2 = dos 3 = tres y cuatro 4 = cinco a ocho  
5 = nueve o más
8. ¿Con qué frecuencia se reúne o habla con el vecino con quien mantiene mayor contacto?  
0 = nunca 1 = rara vez 2 = a veces 3 = a menudo 4 = muy a menudo 5 = siempre

9. ¿ Con cuántos vecinos se siente usted en confianza para tratar asuntos privados?  
 0 = ninguno 1 = uno 2 = dos 3 = tres y cuatro 4 = cinco a ocho  
 5 = nueve o más
10. ¿ Con cuantos vecinos se siente usted en confianza como para pedirles ayuda?  
 0 = ninguno 1 = uno 2 = dos 3 = tres y cuatro 4 = cinco a ocho  
 5 = nueve o más
11. Cuando alguno de sus vecinos debe tomar una decisión importante, ¿qué tan a menudo le hablan sobre ello?  
 0 = nunca 1 = rara vez 2 = a veces 3 = a menudo 4 = muy a menudo 5 = siempre
12. ¿ Con qué frecuencia está disponible alguno de sus vecinos para hablar cuando usted tiene una decisión importante que tomar?  
 0 = nunca 1 = rara vez 2 = a veces 3 = a menudo 4 = muy a menudo 5 = siempre

AMISTADES: Incluye sus amistades que no viven en su misma vecindad....

13. ¿ Con cuántos amigos se reúne o habla por lo menos una vez al mes?  
 0 = ninguno 1 = uno 2 = dos 3 = tres y cuatro 4 = cinco a ocho  
 5 = nueve o más
14. ¿ Con qué frecuencia se reúne o habla con el amigo con quien mantiene mayor contacto?  
 0 = nunca 1 = rara vez 2 = a veces 3 = a menudo 4 = muy a menudo 5 = siempre
15. ¿Con cuántos amigos se siente usted en confianza para tratar asuntos privados?  
 0 = ninguno 1 = uno 2 = dos 3 = tres y cuatro 4 = cinco a ocho  
 5 = nueve o más
16. ¿ Con cuantos amigos se siente usted en confianza como para pedirles ayuda?  
 0 = ninguno 1 = uno 2 = dos 3 = tres y cuatro 4 = cinco a ocho 5 = nueve o más
17. Cuando alguno de sus amigos debe tomar una decisión importante, ¿qué tan a menudo le hablan sobre ello?  
 0 = nunca 1 = rara vez 2 = a veces 3 = a menudo 4 = muy a menudo 5 = siempre

18. ¿ Con qué frecuencia está disponible alguno de sus amigos para hablar cuando usted tiene una decisión importante que tomar?
- 0 = nunca 1 = rara vez 2 = a veces 3 = a menudo 4 = muy a menudo 5 = siempre

LSNS-R el resultado total es una suma ponderada equitativamente entre estas partidas. La

escala de los resultados es 0 al 90.

**Appendix E**

**Consent to Participate in a Research Study (English)**

## CONSENT TO PARTICIPATE IN RESEARCH

“Non cardiac risk factors and heart failure readmissions”  
CPHS-HSC-GEN-08-0496

You are being invited to take part in a research study conducted by Irma Samaniego, RN, MSN, PhD candidate and Mark Parshall, PhD, RN, Associate Professor University of New Mexico College of Nursing, Albuquerque, NM. You have been asked to take part in this study because you have been admitted to the hospital with heart failure.

Your decision to take part in this study is entirely voluntary. A decision not to take part will not change the services that are available to you from your doctor or Memorial Hermann Hospital.

You may refuse to answer any questions asked or written on any forms. Please read the information below and ask questions about anything you do not understand, before deciding whether or not you would like to take part in this study.

Other eligibility requirements to take part in this study are that you are at least 65 years of age and live at home, you are able to speak and understand English or Spanish, and you are capable of giving informed consent. There will be about 120 men and women who will be in this study. If you agree to take part in this study, you will be interviewed at your convenience, while you are a patient in the hospital. The interview will include several questionnaires and will take approximately 15-20 minutes. In addition, if you agree to take part in this study, some information will be obtained from your medical record. There is no experimental treatment in this study.

### • PURPOSE OF THE STUDY

The purpose of this study is to learn more about psychological factors and social support among patients hospitalized for heart failure. This study is important to nursing because the results may help find better ways to take care of people with heart failure.

*IRB Number:*  
*Date of IRB Approval:*  
*Project Expiration Date:*

Page 1 of 5



IRB NUMBER: HSC-GEN-08-0496  
IRB APPROVAL DATE: 11/7/2008  
IRB EXPIRATION DATE: 10/31/2009



## • PROCEDURES

If you agree to take part in this study, you will be asked to do the following things:

- You will be asked to answer several questions, for example “what day is it”, “what time is it.” These questions are designed to help figure out your level of understanding (cognitive function).
- You will then be asked to complete two questionnaires, one of which has questions that can be answered yes or no, the other has questions that ask for numbers or ratings of frequency.
  - Examples of yes/no questions are:
    - “Are you basically satisfied with your life?” and
    - “Do you think that most people are better off than you are?”
  - Examples of questions that ask for numbers or ratings are:
    - “How many of your friends do you see or hear from at least once a month?” and
    - “How often is one of your relatives available for you to talk to when you have an important decision to make?”
- You will be asked your age, gender, race and ethnicity, marital status and the highest level of school you completed.
- You will be asked for permission to review your medical record.
  - The information to be obtained from your medical record include the type and severity of heart failure you have, results of diagnostic and laboratory tests, medications, and the number of days you are in the hospital.
- One month and two months after your discharge from this hospital, the researcher will also check administrative records to determine if you have had any more hospital admissions for heart failure over that period. In addition, 30 days after you have been discharged, the researcher will contact you by phone or mail (whichever you prefer) to determine if you have had any hospital admissions to any other facility.
  - There is no other follow-up to the study.

- **POTENTIAL BENEFITS TO SUBJECTS AND/OR TO SOCIETY**

This study is not being conducted to improve your condition or health. You have the right to refuse to take part in this study.

One benefit of taking part in this study includes if you are found to have particular symptoms that may suggest depression or isolation your doctor will be notified.

Your taking part in this study may help doctors, nurses, and case managers do a better job of assessing and taking care of patients with heart failure. These questionnaires may help identify patients who may need additional services or referral.

- **POTENTIAL RISKS AND DISCOMFORTS**

You may experience minimal risk during this study. As a result of this research, you may become aware of feelings or things that have bothered you. If any questions make you uncomfortable for any reason, you do not have to answer them. You may become tired during your interview. If this occurs the researcher will stop and let you rest. If you do not wish to continue at all, you can just tell the researcher who will thank you for your time and end your participation in the study.

- **IN CASE OF INJURY**

If you suffer any injury as a result of taking part in this research study, please understand that nothing has been arranged to provide free treatment of the injury or any other type of payment. However, all needed facilities, emergency treatment and professional services will be available to you, just as they are to the community in general. You should report any injury to Irma Samaniego at 713-704-8006 and to the Committee for the Protection of Human Subjects at (713) 500-7943. You will not give up any of your legal rights by signing this consent form.

- **COSTS, REIMBURSEMENTS, and COMPENSATION**

You will not be paid to take part in this study.



- **CONFIDENTIALITY**

You will not be personally identified in any reports or publications that may result from this study. Any personal information about you that is gathered during this study will remain confidential to every extent of the law. A special number will be used to identify you in the study and only the investigator will know your name. There is a separate authorization form that you will be asked to sign which details the use and disclosure of your protected health information.

- **STUDY WITHDRAWAL**

You can choose whether or not to be in this study. If you agree to be in this study, you may withdraw at any time without consequences of any kind or loss of benefits to which you are otherwise entitled. You may also refuse to answer any questions you do not want to answer. There is no penalty if you withdraw from the study and you will not lose any benefits to which you are otherwise entitled.

The investigator may withdraw you from this research if circumstances arise which warrant doing so, such as a change in your diagnosis or prognosis.

- **QUESTIONS**

If you have any questions or concerns about this research, please contact:  
Principal Investigator- Irma Samaniego, RN, MSN, PhD at 713-704-8006;  
email: [irma.samaniego@memorialhermann.org](mailto:irma.samaniego@memorialhermann.org)  
Faculty Sponsor Mark Parshall, RN, PhD at 505-272-4540;  
email: [mparshall@salud.unm.edu](mailto:mparshall@salud.unm.edu)



**Signature**

Sign below only if you understand the information given to you about the research and choose to take part. Make sure that any questions have been answered and that you understand the study. If you have any questions or concerns about your rights as a research subject, call the Committee for the Protection of Human Subjects at (713) 500-7943. If you decide to take part in this research study, a copy of this signed consent form will be given to you.

\_\_\_\_\_  
Name of Participant

\_\_\_\_\_  
Signature of Participant

\_\_\_\_\_  
Date/Time

\_\_\_\_\_  
Name of Investigator

\_\_\_\_\_  
Signature of Investigator

\_\_\_\_\_  
Date/Time

• **CPHS STATEMENT**

This study (HSC-GEN-08-0496) has been reviewed by the Committee for the Protection of Human Subjects (CPHS) of the University of Texas Health Science Center at Houston. For any questions about research subject's rights, or to report a research-related injury, call the CPHS at (713) 500-7943.

**Thank You**



**Appendix F**

**Consent to Participate in a Research Study (Spanish)**

## CONSENTIMIENTO PARA PARTICIPAR EN UNA INVESTIGACION

Factores de riesgo no cardíacos y readmisión por insuficiencia cardíaca  
CPHS-HSC-GEN-08-0496

Se le invita a un estudio de investigación conducido por Irma Samaniego, RN, MSN, PhD candidata y Mark Parshall, PhD, RN, Profesor Asociado de la Escuela de Enfermería de la Universidad de New Mexico, Albuquerque, NM.

Su decisión en el presente estudio es enteramente voluntaria y no afectara su tratamiento o servicios en el hospital Memorial Hermann o el tratamiento de su medico.

Usted no tiene que contestar preguntas. Le agradecemos leer la información que aparece a continuación y formular sus preguntas sobre cualquier aspecto que no comprenda, antes de hacer una decisión

Algunos de los otros requisitos para ser elegible al estudio incluyen tener por lo menos 65 años de edad y vivir en su casa, hablar y entender ya sea inglés o español, y ser capaz de dar un consentimiento informado. Habrá unos 120 hombres y mujeres. Si usted está de acuerdo, será entrevistado a su conveniencia, durante su estadía en el hospital como paciente. La entrevista incluirá varios cuestionarios y durará aproximadamente 15-20 minutos. Además, obtendremos cierta información de su expediente médico. No existe tratamiento experimental en este estudio.

### • PROPOSITO DEL ESTUDIO

El propósito del estudio es aprender más sobre los factores psicológicos y apoyo social en pacientes hospitalizados por insuficiencia cardiaca. Dicho estudio es importante para la profesión de enfermería debido a que sus resultados pueden ayudar a encontrar maneras más eficaces de atender a las personas con insuficiencia cardíaca.

### • PROCEDIMIENTOS

Si usted accede, se le pedirá lo siguiente:

- Responder varias preguntas, como por ejemplo, ¿qué día es?, ¿qué hora es? Estas preguntas están diseñadas con el fin de ayudar a decidir su nivel de entendimiento (función cognitiva).
- Luego se le pedirá completar dos cuestionarios, uno de los cuales tiene preguntas que pueden responderse con un si o un no, mientras que el otro tiene preguntas que requieren como respuesta números o clasificaciones por frecuencia.
  - Ejemplos de preguntas si/no:
    - “¿Está usted básicamente satisfecho con su vida?” y

- “¿Piensa usted que la mayoría de las personas están en mejor situación que usted?”
- Ejemplos de preguntas que requieren números o clasificaciones:
  - “¿Cuántos de sus amigos le visitan o llaman por lo menos una vez al mes?” y
  - “¿Con qué frecuencia puede usted conversar con alguno de sus parientes o familiares cuando tiene que tomar una decisión importante?”
- Se le preguntará su edad, sexo, raza y grupo étnico, estado civil y el nivel de educación (estudios cursados).
- Se le pedirá permiso para revisar su expediente médico.
  - La información a ser obtenida incluye el tipo y la severidad de la insuficiencia cardíaca que usted padece, los resultados de sus pruebas diagnósticas y de laboratorio, medicamentos, y el número de días que lleva en el hospital.
  - Al mes de su alta del hospital, el investigador comprobará también los expedientes administrativos para determinar si usted fue admitido más de una vez por insuficiencia cardíaca ese mes. Además, el investigador le contactará por vía telefónica o por correo (el que usted prefiera) para determinar si ha sido admitido a cualquier otro hospital en un lapso de 30 días contados a partir de su fecha de alta de este hospital.
  - No existe seguimiento alguno distinto al estudio en cuestión.

## **POSIBLES BENEFICIOS PARA LOS PARTICIPANTES Y/O LA SOCIEDAD**

Este estudio no se conduce con la finalidad de mejorar su condición o salud. Usted está en su derecho a rehusarse de participar en el estudio.

Uno de los beneficios de su participación incluye que si se llega a determinar que usted posee síntomas particulares que pudiesen sugerir depresión o aislamiento, su médico sería notificado.

Su participación en el estudio puede ayudar a médicos y enfermeras a encontrar maneras más eficaces de atender a las personas con insuficiencia cardíaca. Estos cuestionarios pueden ayudar identificar personas que puedan necesitar adicionales servicios.

## **• POSIBLES RIESGOS E INCONVENIENTES**

Puede experimentar un riesgo mínimo durante el presente estudio. Como resultado de esta investigación, podría identificar sentimientos o asuntos que le han venido perturbando. Si alguna de las preguntas le llegase a incomodar por alguna razón, no está

en obligación de responderla. Podría asimismo cansarse durante su entrevista. Si esto ocurre, el investigador hará una pausa y le permitirá descansar. Si no desea continuar con el estudio, tan solo dígame al investigador, quien le agradecerá haber donado su tiempo y finalizará su participación en el estudio.

## **CASOS DE LESIONES FISICAS**

En el caso de una lesión física y/o mental resultante de la participación en este proyecto de investigación, no proveerá seguro alguno médico, hospitalización u otro tipo de cobertura a los participantes de este estudio de investigación. Todas las facilidades para obtener tratamiento de emergencia y servicios profesionales estarán a su disposición, así como a la comunidad. Usted debe de reportar lesiones físicas a Irma Samaniego (713) 704-8006 y al Comité para la Protección de los Sujetos Humanos (CPSH) (713) 500-7943. Usted mantiene sus derechos legales firmando este consentimiento.

- **COSTOS Y COMPENSACION**

Ninguno.

- **CONFIDENCIALIDAD**

Cualquier información obtenida en relación a este estudio y que puede ser identificada con su persona, permanecerá confidencial y será divulgada solamente con su permiso o según exige la ley. La confidencialidad se mantendrá asignando a los participantes un número de identificación anónimo para el estudio.

Existe una forma de autorización que se le solicitara firmar. Esta forma contiene detalles sobre como se divulga información personal.

- **RETIRO**

Usted puede escoger si participa o no en este estudio. Si se ofrece a estar en el estudio, puede retirarse del mismo cualquier momento sin consecuencias de ningún tipo o pérdida de beneficios a los cuales tiene derecho. También puede rehusarse a contestar cualquier pregunta que no desee contestar. No será penalizado si se retira del estudio y no perderá beneficio alguno al cual tiene derecho.

El investigador puede asimismo retirarle del estudio si surgen circunstancias que lo ameritan, tales como un cambio en su diagnóstico o en su pronóstico.

- **PREGUNTAS**

En caso de tener alguna pregunta o inquietud acerca de la presente investigación, le agradecemos contactar a:

Investigador Principal- Irma Samaniego, RN, MSN, PhDc al 713-704-8006;

email: [irma.samaniego@memorialhermann.org](mailto:irma.samaniego@memorialhermann.org)



Patrocinador de la Facultad: Mark Parshall, RN, PhD al 505-272-4540;  
email: [mparshall@salud.unm.edu](mailto:mparshall@salud.unm.edu)

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**Firma**

Firme si ha entendido la información que se le ha dado. Este seguro de que sus preguntas han sido respondidas a su satisfacción, y que usted este de acuerdo con este estudio. Si tiene preguntas sobre sus derechos llame al *Comité para la Protección de los Sujetos Humanos* (CPSH) (713) 500-7943. Si decide tomar parte en este estudio, le daremos una copia de este formulario.

Nombre del Participante

Firma del Participante

Fecha

Nombre del Investigador

Firma del Investigador

Fecha

---

Este estudio (HSC-GEN-08-0496) ha sido revisado por el *Comité para la Protección de los Sujetos Humanos* (CPSH) del *University of Texas Health Science Center*, Houston. Si tiene cualquier pregunta sobre sus derechos en el presente estudio, o para reportar lesiones relacionadas con este estudio llame al Comité para la Protección de los Sujetos Humanos (The Committee for the Protection of Human Subjects) al teléfono (713) 500-7943

**Gracias**

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**Appendix G**

**Authorization for the Use and Disclosure of Protected Health Information  
for Research**

**Authorization for the Use and Disclosure of Protected Health Information  
for Research**

**University of Texas Health Science Center at Houston and/or Memorial  
Hermann Healthcare System (MHHS)**

**Patient Name:**

**Date of Birth:**

**I hereby authorize the following Health Care Provider to release the following information from the medical records of the patient identified above to The University of Texas Health Science Center at Houston (UTHSCH) or Memorial Hermann Hospital System (MHHS) and specifically to the Principal Investigator listed below and the study research staff.**

***I understand I have the right to revoke this authorization in writing at any time except to the extent that action has been taken in reliance upon it. I understand that I may revoke this authorization by sending, via mail or facsimile, a written notice to the following individuals/organizations stating my intent to revoke this authorization.***

**Study Title:**

Non Cardiac Risk Factors and Heart Failure Readmissions

**Principal Investigator:**

Irma Samaniego, PhDc

**Principal Investigator Address:**

**(Please send all records to this address.)**

Irma Samaniego  
6411 Fannin Street  
Robertson 658  
Houston, Texas 77030

**Principal Investigator Phone Number:**

713-704-8006

**Principal Investigator Fax Number:**

713

**Complete the section(s) applicable to this study:**

Memorial Hermann Hospital System

Privacy Officer  
Memorial Hermann Healthcare System  
7737 Southwest Freeway  
Houston, Texas 77074

Fax Number (713) 456-4542

University of Texas Health Science Center

Address:

Fax Number:

---

Other known Health Care Provider (provide information by adding rows below)

---

**Name of Health Care Provider:**      **Health Care Provider Address:**      **Health Care Provider Fax Number:**

No records have been added

Other Health Care Provider (to be identified at time of enrollment)

Name of Health Care Provider:

---

Address:

---

Fax Number:

---

The information to be **released** to the Principal Investigator will include (please check appropriate box):

- Complete Clinical Records
- Other (complete section below)

Please specify portions of records to be **released**:

I understand that the Principal Investigator may disclose information to the Committee for the Protection of Human Subjects (CPHS) and the Clinical Research Billing Compliance Office for the purposes of verifying research data.

In addition, I understand that the Principal Investigator listed above may disclose the information to the following:

List names here:

None

\* The information that may be **disclosed** to (shared with) the parties listed above may include (Please check appropriate box):

- Complete Clinical Records
- Other (complete section below)
- None

Please specify portions of records to be **disclosed** (including any patient identifiers) to the parties listed above:

\* The information that may be **retained** by the parties listed above may include (Please check appropriate box):

- Complete Clinical Records (data must be fully de-identified)  
 Other (Complete section below)  
 None

Please specify portions of the records to be **retained**:

*I understand that UTHSCH or MHHS personnel who obtain access to my health information as part of this research study may not use the information for purposes other than this study, except as otherwise permitted by law. I understand that to the extent any Recipient of this information, as identified above, is not a "covered entity" under Federal or Texas privacy law, the information may no longer be protected by Federal and Texas privacy law once it is disclosed to the Recipient and, therefore, may be subject to re-disclosure by the Recipient.*

*I understand that the University of Texas Health Science Center (UTHSCH) or Memorial Hermann Hospital System (MHHS) may not withhold or condition treatment based on my completion of this authorization form.*

*I understand that the records used and disclosed pursuant to this authorization form may include information relating to: Human Immunodeficiency Virus (HIV) infection or Acquired Immunodeficiency Syndrome (AIDS); treatment for or history of drug or alcohol abuse; or mental or behavioral health or psychiatric care.*

*In the case of an adverse event related to or resulting from taking part in this study, I authorize the researchers listed above to access test, treatment and outcome information about the adverse event from the treating facility.*

*Unless otherwise revoked, this authorization will expire on the 180th day after the signing or as otherwise specified below:*

This authorization is valid until (please list expiration date if applicable):

- Authorization will expire on the 180th day after signing this form.  
 Authorization will expire on:

Expiration date:

**OR**

Authorization will expire (enter number of years below) \_\_\_\_\_ years after the end of the study.  
 1.00

#### Special Instructions:

Use this space to enter any additional information or special instructions:

Only de identified data will be shared with dissertation committee. Biostatistician will received only de identified data for analysis.

#### Signature Section:

\_\_\_\_\_  
 Signature of Subject or Subject's Legal Representative                      Date

---

Printed Name of Legal Representative (if any)

---

Relationship of Legal Representative to Subject

---

Printed Name of Person Obtaining Authorization

---

Signature of Person Obtaining Authorization

Date

### CPHS Section Information

Protocol Number: HSC-GEN-08-0496

Original Approval Date: 11/07/2008

Expiration Date: 10/31/2009

CPHS Stamp: **NOT VALID WITHOUT THE RB STAMP**



**THE UNIVERSITY of TEXAS**  
HEALTH SCIENCE CENTER  
AT HOUSTON

Effective Date of Stamp: 11/07/2008

Comments:

**1.0 Autorización Para el Uso y Acceso de la Información de la Salud Protegida Para Investigación  
Centro de Ciencias de la Salud de la Universidad de Texas en Houston y/o el Memorial Hermann Healthcare System (MHHS)**

**1.1 Nombre del Paciente :**

**1.2 Fecha de Nacimiento:**

**2.0 Yo autorizo al siguiente abastecedor del cuidado médico a descargar la siguiente información de los expedientes médicos del paciente identificado arriba al Centro de Ciencias de la Salud de la Universidad de Texas en Houston (UTHSC-H) o Memorial Hermann Hospital System y específicamente al investigador principal nombrado abajo y el personal del estudio de investigación.**

*Entiendo que tengo el derecho a revocar esta autorización por escrito en cualquier momento con la excepción de que hasta el punto se ha tomado acción con la confianza de tenerla. Entiendo que puedo revocar esta autorización mandando, vía correo o facsímile, un aviso a las siguientes individuos/organizaciones afirmando mi intención a revocar esta autorización.*

**2.1 Título del Estudio :**

Non Cardiac Risk Factors and Heart Failure Readmissions

**2.2 Investigador Principal:**

Irma Samaniego, PhDc

**2.3 Dirección del Investigador Principal:**

Irma Samaniego  
6411 Fannin Street  
Robertson 658  
Houston, Texas 77030

**2.4 Número de Teléfono del Investigador Principal:**

713-704-8006

**2.5 Número de Facsímile del Investigador Principal:**

713-704-6374

**2.6 Complete el sección aplicable a este estudio:**

Memorial Hermann Healthcare System (MHHS)

Oficial de Privacidad  
Memorial Hermann Healthcare System  
7737 Southwest Freeway  
Houston, Texas 77074

Número de Facsímile: (713) 456-4542

Centro de Ciencias de la Salud de la Universidad de Texas

Dirección:

Número de Facsímile:

---

Otro abastecedor del cuidado médico conocido (proporcione la información añadiendo filas abajo)

---

| Nombre del Abastecedor del Cuidado Médico: | Dirección del Abastecedor del Cuidado médico: | Número de Facsimile del Abastecedor del Cuidado Médico: |
|--|---|---|
|--|---|---|

No records have been added

Otro abastecedor del cuidado médico (debe ser identificado al tiempo de inscripción)

Nombre de Abastecedor del Cuidado Médico:

Dirección:

Número de Facsimile:

**2.7 \*** La información que será **descargada** al investigador principal incluirá (por favor seleccione la caja apropiada):

- Expedientes Clínicos Enteros
- Otro (complete sección abajo)

Por favor especifique las porciones de expedientes para **descargar**:

---

**3.0** Además, entiendo que el investigador principal nombrado arriba puede divulgar información al Comité Para la Protección de Sujetos Humanos (CPHS) a los siguientes individuos, comités, organizaciones, y patrocinadores:

**3.1** Incorpore nombres aquí:

---

**3.2 \*** La información que puede ser **divulgada** (compartida con) los partidos antedichos puede incluir (por favor seleccione la caja apropiada):

- Expedientes Clínicos Enteros
- Otro (complete sección abajo)
- Ninguno

Por favor especifique las porciones de expedientes para ser **divulgada** (incluyendo identificadores del paciente):

---

**3.3 \*** La información que puede ser **retenida** por los partidos antedichos puede incluir (por favor seleccione la caja apropiada):

- Expedientes Clínicos Enteros (los datos deben estar completamente de-identificados)
- Otro (complete sección abajo)
- Ninguno



Por favor especifique las porciones de los expedientes para ser retenidas:

---

**4.0** Entiendo que el personal de UTHSCH o MHHS quien obtendrá acceso a mi información de la salud como parte de este estudio de investigación no podrá usar la información para fines más allá de este estudio, con la excepción de que al contrario sea permitida por ley. Entiendo que hasta el punto que el recipiente de esta información, incorporado previamente, no es una "identidad cubierta" bajo la ley de privacidad Federal o Estatal de Texas, la información podría no ser protegida por la ley de privacidad Federal o Estatal de Texas se le es divulgada al recipiente, por lo tanto, puede ser sujeta a divulgar por el recipiente de nuevo.

*Entiendo que el Centro de Ciencias de la Salud de la Universidad de Texas en Houston (UTHSCH) o Memorial Hermann Healthcare System (MHHS) no puede retener o condicionar tratamiento basado en la información que he sometido son esta forma de autorización.*

*Entiendo que los expedientes usados y divulgados conforme a esta forma de autorización puede incluir la información relacionada a: infección del Virus Humano De la Inmunodeficiencia (VIH) o síndrome adquirido de la inmunodeficiencia (SIDA); tratamiento para o historial del abuso droga o de alcohol; o salud mental o del comportamiento o cuidado psiquiátrico.*

*En el caso de que un acontecimiento adverso sea relacionado con o resultado de participar en este estudio, yo autorizo a investigadores nombrados arriba a tener acceso a la prueba, tratamiento e información del resultado acerca el acontecimiento adverso de la facilidad conduciendo tratamiento.*

*A menos que de otra manera esté revocada, esta autorización expirará el 180o día después de firmar o según lo específico de otra manera abajo:*

**4.1** Esta autorización es válida hasta que (incorpore por favor la fecha de vencimiento si es aplicable):

- La autorización expirará en el 180o día después de firmar esta forma.  
 La autorización expirará encendido:

Fecha de vencimiento:

0

La autorización expirará (incorpore el número de años abajo) \_\_\_\_\_ años después del final del estudio.

**4.2 Instrucciones Especiales:**

Use este espacio para ingresar información adicional o instrucciones especiales:

---

**5.0 Sección de Firmas :**

5.1

\_\_\_\_\_  
Firma del sujeto o del representante legal del sujeto      Fecha

5.2

\_\_\_\_\_  
Nombre del representante legal (si alguno)

5.3

---

Relación del representante legal al sujeto

5.4

---

Nombre de la persona obteniendo autorización

5.5

---

Firma de la persona obteniendo autorización      Fecha

### CPHS Section Information

Protocol Number:                      HSC-GEN-08-0496

Original Approval Date:              11/07/2008

Expiration Date:                      10/31/2009

CPHS Stamp:                            **NOT VALID WITHOUT THE RB STAMP**



THE UNIVERSITY of TEXAS

HEALTH SCIENCE CENTER  
AT HOUSTON

Effective Date of Stamp:              11/07/2008

Comments:

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