A Comparison of Quality of Life in Adult Patients with Heart Failure in Two Medical Settings: A Heart Failure Clinic and a Physician Practice

Janet Bischof

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A Comparison of Quality of Life in Adult Patients with Heart Failure in Two Medical Settings: A Heart Failure Clinic and a Physician Practice

by

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Submitted to the Doctoral Program Faculty
of the School of Nursing in partial fulfillment
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November 6, 2006
APPROVAL OF FINAL DEFENSE OF DISSERTATION

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A Comparison of Quality of Life in Adult Patients with Heart Failure in Two Medical Settings: A Heart Failure Clinic and a Physician Practice.

Janet Revay Bischof RN PhD

Heart Failure (HF), a major chronic disease that affects 4.8 million Americans, traditionally is managed by a primary care physician, with acute treatment at hospital emergency rooms often followed by inpatient admission. Ongoing support (prevention, diagnosis, treatment, intervention, symptom management, and end of life care), education, and intervention over the continuum are important to manage HF. The Modeling Role Modeling theory (Erickson, Tomlin, and Swain), is the study’s conceptual framework. When an individual knows about their illness, they mobilize internal/external resources to gain, maintain, or promote equilibrium. These resources affect daily activities. The purpose of this descriptive study is to compare perceptions of quality of life (QOL) in adult HF patients in two different settings: a HF clinic and physician practices. IRB approval was obtained. Inclusion criteria included adults ages 18 or older, HF diagnosis for greater than six months, current medical management of HF, ability to read/write English, and verbal validation of orientation to time, place, person. Quantitative analysis was conducted using SPSS and SF Health Outcomes Software.

Convenience samples were used. Subject age (n=60) ranged from 24 to 85 years of age. Mean age in the HF clinic was lower (56.3) than the physician practice (72.9). In the total sample 41(68.3%) were male and 19(31.7%) were female. The majority of the sample 53 (68.3%) were white and seven (11.7%) were black (p=.044). There were no Asian or Hispanic subjects.

The research questions that were addressed in this study are as follows:

1. Does health-related QOL differ among HF patients who are receiving medical care in two different clinical settings as measured by the SF-36v2 Health Survey using the Physical Component Scale (PCS) and the Mental Component Scale (MCS)? There was no significance difference found in the PCS score (p=.889) or the MCS score (p=.135). Of eight sub-scores only role-emotional showed significance (p=.007).

2. Does disease specific QOL differ among HF patients who are receiving medical care in two different clinical settings as measured by the Minnesota Living with Heart Failure Questionnaire (MLHFQ) total score, physical sub-score, and emotional sub-score? No significant differences in the MLHFQ total score (p=.907) with mean scores of two groups virtually equal, (HF clinic=46.4, physician office=47.2). The physical dimension sub-score was not different (p=.896). Mean sub-scores in the two groups were virtually equal, (HF Clinic=19.6, physician practice=19.3). The emotional dimension sub-score was not significant (p=.953)(HF Clinic=10.4, physician practice=10.5). There was no significant difference in disease specific QOL.

3. Are there differences in self care resources of HF patients that are receiving medical care in two different clinical settings as measured by the Self Care Resource Inventory and the Needs (SCRIN) and Availability (SCRIA) sub scores? Both the internal (p=.003) and external (p=<.001) SCRIN showed a significant difference. The external (p=.004) SCRIA showed a significant difference.

Dissertation Advisor: Kathleen Sekula, PhD, APRN-BC
DEDICATION

This is dedicated to my family without whom I would not have been able to complete this journey.

My parents, Edward and Geraldine Revay, have instilled in me a value for knowledge and lifelong education. As I began my nursing education in a diploma nursing program, I remember promising my parents that I would continue my education and someday get my degree. This was important, especially to my mother, as I would be the first person in her family to get a college degree.

My late mother-in-law and father-in-law, Howard and Beatrice Bischof, were supportive of all my educational endeavors. They shared with me the greatest gift of all, their son.

My husband, Mark W. Bischof, has supported me in so many ways throughout this journey. His willingness to assist me in school, home, and life projects is immeasurable. Whether the task was to proofread papers, help with xeroxing of articles, verification of data entry in SPSS, doing laundry, cooking supper, or the words of encouragement needed at just the right time; he was always there. Love and thanks Mark.
ACKNOWLEDGMENTS

I would like to express my deepest appreciation to the 60 subjects who participated in this study. Their willingness to talk about their life and health provided me with valuable insight into the daily lives of patients with heart failure. Their unique stories have broadened and enriched my understanding of dealing with chronic disease.

I would like to express my sincere thanks to my entire dissertation committee: Dr. Kathleen Sekula (chair) for her expertise in quantitative methodology and statistical analysis, Dr. Carl Ross for his expertise in cardiology, and Dr. Linda Baas from the University of Cincinnati for her expertise in heart failure and the Modeling Role-Modeling Theory. Thank you so much for moving a novice researcher through the research journey and helping me to become comfortable and confident with the process. I'm grateful for the new opportunities, the new doors that have opened for me due to this research experience. My deepest appreciation for all the time, effort, and valuable input Dr. Sekula put into making the final dissertation paper such a professional product.

A special thank you to Dr. Frank D’Amico for sharing his statistical knowledge and expertise with me. I would like to thank my data collection sites for their patience, their assistance, and their encouragement. A special thank you to Dr. William E. Noble, Robin Ledergerber RN, Dr. Richard Terry, Mrs. Jo Terry, Vera Barton-Caro RN, FNP, Judy Germani RN, Dr. George Sokos, and Dr. T. Barry Levine.

The support of my co-workers has been invaluable. Their encouragement, their patience, and their willingness to listen have made this accomplishment possible. So
thank you: Denise Lucas, RN, FNP and Dr. Joyce Knestrick RN, FNP, fellow WJU faculty members; Deb Walker RN and Teresa Gagliardi, RN for their ongoing encouragement; to Jason Fritzman for his computer expertise; and to Roanne Whanger RN BSN, wish you were here to share this with me.

I would also like to acknowledge financial support through scholarship moneys from the West Virginia Nurses Association District I, Sigma Theta Tau Omicron Mu chapter, and the Mended Hearts Steubenville chapter. I would also like to acknowledge Trinity Health System and their tuition reimbursement program.

And I would like to acknowledge my family support, my parents, my sisters and brothers and their families, my brother-in-law and sister-in-law, and my nieces and nephews. And to my husband, who has been supportive from the very first class to the final reading of my dissertation.

“To every thing there is a season, and a time to every purpose under the heaven”, Ecclesiastes, Chapter 3, Verse 1. With God all things are possible. With God’s enduring love and patience I have completed this goal and ended this journey. And another season begins.
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I. INTRODUCTION

A. Background of the Study

Advances in medical treatment of chronic diseases have led to the increase in the average age of the chronically ill patient and the quality of health care provided during the course of the disease. More than 90 million Americans live with some form of chronic disease which accounts for 70% of all deaths in the United States. The Center for Disease Control and Prevention broadly defines chronic disease as those illnesses that are prolonged, do not resolve spontaneously, and are rarely cured (Nordenfelt, 1995). Common chronic diseases include arthritis, chronic obstructive lung disease, diabetes, epilepsy, and many cardiovascular diseases including heart failure (HF). The challenges and multiple uncertainties of adapting to chronic disease are profoundly personal and require frequent adjustments to management regimens (Landis, 1996; Rich, 2002).

People are living longer and the probability of developing a chronic disease increases with longevity. In 2000, people over the age of 65 represented nearly 13% of the population compared to 8% in 1950. Those who survive to age 70-75 can expect to live approximately 14 additional years; those who live to age 80-85 can expect to live approximately six more years (McKenna, 1994).

Increased access to medical interventions and medications has influenced the quality of health care available to the chronically ill population. Increased access to chronic disease care in the United States has increased the overall cost of chronic disease treatment. One major chronic disease is cardiovascular disease. The cost of all
types of cardiovascular disease in the United states in 2003 was estimated at $351.8 billion (2006 Heart and Stroke Statistical Update, 2005). There are 21 million cases of cardiovascular disease reported annually with an estimated 725,000 deaths annually. Cardiovascular disease encompasses a number of cardiac diagnoses including cardiomyopathy, coronary artery disease, acute coronary syndrome (acute myocardial infarction), cerebrovascular accident, dysrhythmias, rheumatic heart disease, valvular heart disease, congenital defects, and HF (Heart disease, 2002).

Definitions of HF vary. HF is defined as a clinical syndrome or condition characterized by (1) signs and symptoms of intravascular and interstitial volume overload, which may include shortness of breath, crackles, and edema, or (2) manifestations of inadequate tissue perfusion, such as fatigue or poor exercise tolerance. These signs and symptoms result when the heart is unable to generate a cardiac output sufficient to meet the body's oxygen demands (AHCPR, 1994; Carelock & Clark, 2001). Professional organizations offer more complex definitions. The Heart Failure Society of American (HFSA) describes HF as a complex clinical syndrome with a complex pathophysiology that has multiple potential etiologies (Adams & Lindenfeld, 2006). The American College of Cardiology (ACC) in conjunction with the American Heart Association (AHA) defines HF as a complex clinical syndrome that results from any structural or functional cardiac disorder that impairs the ability of the ventricle to fill with or eject blood (Hunt et al., 2005). This definition allows for HF to have a systolic and diastolic etiology.
The etiology of systolic HF is contractile failure of the myocardium leading to reduced left ventricular end function. This can be due to coronary artery disease, ischemia, hypertension, metabolic disorders, or infection. It affects 50 to 60% of patients and is most common in men under the age of 65. The etiology of diastolic HF is left ventricular stiffness in which the ventricle does not fill at normal diastolic pressures. The ventricular muscle loses compliance and elasticity. It is most common in women over the age of 75 (Carelock & Clark, 2001).

HF pathophysiology is recognized clinically by a group of signs and symptoms produced by complex circulatory and neurohormonal responses to cardiac dysfunction. The hallmark clinical symptoms of HF are shortness of breath, fluid retention, and exercise intolerance (Adams, 1999). HF is a complex disease to manage in view of its multiple pathologies. Pathophysiologically, HF is characterized by structural remodeling and dilation of the left ventricular chamber, reduced myocyte shortening and wall motion, sodium retention, systemic vasoconstriction, impeded ventricular ejection, and neurohormonal activation (Adams, 1999). HF can develop in response to various diseases including myocardial ischemia, injury, necrosis, cardiomyopathy, or pulmonary disease. The major concern is that HF is often the end result of any cardiovascular disease.

There are many risk factors for developing HF which can include advancing age, left ventricular dysfunction, valvular heart disease, hypertension, diabetes, tobacco/alcohol abuse, obesity, high or low hematocrit, dysrhythmias, and genetic predisposition. Any of the listed risk factors in combination with the presence of
myocardial infection or myocardial infarction increases the risk of developing HF. The most common cause of HF in the elderly is coronary artery disease. Determining the cause of HF and correcting any underlying etiology is essential for long-term, effective disease management (Stanley, 1999).

The term HF is often used interchangeably with congestive heart failure (CHF), but HF is the more correct term as the symptom of pulmonary congestion may not always be present (Davis, 2002). In recent literature the abbreviation CHF is used to denote chronic heart failure. In the acute phase of HF, pulmonary congestion may be the presenting symptom. Symptoms can range from minimal shortness of breath to pulmonary edema requiring ventilatory support. In CHF, pulmonary congestion may be controlled and not in evidence. For the purposes of this research, the term HF will be used.

The New York Heart Association (NYHA) Classification System (classes I to IV) is commonly used to stage symptomatic HF (Table 1). First developed in the 1950’s, it was updated in 1994 (Ganiats, Browner, & Dittrick, 1998). This classification system uses functional capacity to categorize severity of HF. It is a common subjective measurement reported in published cardiovascular and HF studies (Deaton, Exner, Schron, Riegel, & Prevost, 2001). Alternative words and classifications have been defined more recently to stress the evolution and progressive nature of HF (Caboral & Mitchell, 2003). The ACC/AHA task force identified four stages of HF, stages A through D (Table 1), which complements rather than replaces the NYHA classification system. The stages A through D target HF risk factors, screening, and treatment recommendations.
Table 1: Heart Failure Classification Systems

<table>
<thead>
<tr>
<th>NYHA Classification</th>
<th>NYHA Functional Description</th>
<th>Alternative Heart Failure Classification</th>
<th>ACC/AHA Heart Failure Stages</th>
<th>ACC/AHA Description</th>
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<tbody>
<tr>
<td>Class I (Mild)</td>
<td>Symptoms with more than ordinary activity</td>
<td>Asymptomatic</td>
<td>Stage A</td>
<td>High risk for developing HF. No structural disorder of the heart</td>
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<tr>
<td></td>
<td></td>
<td>Asymptomatic</td>
<td>Stage B</td>
<td>Structural disorder of the heart present. Has never developed symptoms of HF</td>
</tr>
<tr>
<td>Class II (Mild)</td>
<td>Patient with slight, mild limitation of activity; they are comfortable with rest or with mild exertion. Ordinary physical activity results in fatigue, palpitation, or dyspnea.</td>
<td>Asymptomatic</td>
<td>Stage C</td>
<td>High risk for developing HF. No structural disorder of the heart</td>
</tr>
<tr>
<td>Class Ila (Moderate)</td>
<td>Patient with marked limitation of activity; they are comfortable only at rest; no dyspnea at rest</td>
<td>Symptomatic</td>
<td>Stage C</td>
<td>Past or present symptoms of HF. Associated with underlying structural heart disease</td>
</tr>
<tr>
<td>Class IIib (Moderate)</td>
<td>Patient with marked limitation of activity; they are comfortable only at rest; recent dyspnea at rest</td>
<td>Symptomatic with recent dyspnea at rest</td>
<td>Stage C</td>
<td>Past or present symptoms of HF. Associated with underlying structural heart disease</td>
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<tr>
<td>Class IV (Severe)</td>
<td>Patient who should be at complete rest; confined to bed or chair; any physical activity brings on discomfort and symptoms occur at rest. Symptoms of cardiac insufficiency at rest.</td>
<td>Symptomatic with dyspnea at rest</td>
<td>Stage D</td>
<td>End-stage disease. Requires specialized treatment strategies</td>
</tr>
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1 NYHA New York Heart Association  
2 (Ganiats et al., 1998)  
3 (NYHA Heart Failure Classification, 2000)  
4 ACC/AHA American College of Cardiology/American Heart Association  
5 (Hunt et al., 2001)
Stages stress prevention through early recognition and timely treatment of HF, even prior to structural heart changes.

This research utilized the NYHA Classification System when discussing stages of HF.

HF is a major chronic disease that is a burden on all aspects of the health care system. A decade ago, The National Heart, Lung, and Blood Institute estimated that more than five million Americans have HF (Hunt et al., 2005). HF is a chronic disease of 2,360,000 males and 2,440,000 females (2006 Heart and Stroke Statistical Update, 2005) and each year there are approximately 550,000 new cases diagnosed. The annual incidence of HF approaches 10 per 1,000 individuals over the age of 65. It has been described as an epidemic increase (Barker, Mullooly, & Getchell, 2006). The incidence of HF is twice as common in individuals with a co-diagnosis of hypertension (stage I defined as a systolic blood pressure greater than 140 to 159 mm Hg and a diastolic blood pressure greater than 90 to 99 mm Hg) as compared to normotensive individuals (normal defined as a systolic blood pressure less than 120 mm Hg and a diastolic blood pressure less than 80 mm Hg) (Chobanian et al., 2003). The incidence of HF is five times more likely in individuals who have had a previous heart attack. About 22% of male and 46% of female acute myocardial infarction (AMI) patients will be disabled with HF within six years (2006 Heart and Stroke Statistical Update, 2005).

Of the five million Americans with HF, about 1.4 million are under 60 years of age. HF is present in two percent of individuals ages 40 to 59, more than five percent in individuals ages 60 to 69, and 10 percent in individuals aged 70 or older. Among the black population the prevalence is greater (2006 Heart and Stroke Statistical Update, 2005). The five-year mortality rate for HF is about 50%. From 1979 to 1999 HF deaths
increased by 14.5 percent. In 1993 there were 42,000 deaths where HF was identified as the primary cause of death and another 219,000 deaths where HF was listed as a secondary cause of death. If the patient is initially diagnosed as a Class IV HF, 70-95% of individuals die within the first year and 90% die in the second year of diagnosis. From 1979 to 2001 HF deaths increased 155 percent (2006 Heart and Stroke Statistical Update, 2005).

From 1993 to 2003, deaths from HF increased 20.5 %. For the individual under the age of 65, 80% of men and 70% of women will die within eight years of a HF diagnosis. The survival rate for HF is about equal to the survival rate with most forms of cancer. In patients diagnosed with HF, sudden cardiac death occurs at 6-9 times the rate of the general population primarily due to lethal dysrhythmias (2006 Heart and Stroke Statistical Update, 2005).

For patients with cardiovascular disease, including all age groups, the top three reasons for hospitalizations are atherosclerosis, heart attack, and HF. Approximately 80% of all emergency room visits for HF results in hospitalization. Hospital discharges with HF listed as the primary discharge diagnosis increased 159.4% from 1979 to 1998 (438,000 males and 540,000 females). The number of patients with HF discharged in the United States rose from 377,000 in 1979 to 995,000 in 2001, an increase of 264 percent (2006 Heart and Stroke Statistical Update, 2005). HF was listed as a secondary diagnosis in another 1.8 million hospital discharges. In 1999 there were 4.5 million hospital discharges for patients with cardiovascular disease with an average length of stay of 4.7 days (Heart disease, 2002). In 1998 this translated to $3.6 billion paid to Medicare beneficiaries for the treatment of HF or $5,471 per discharge. Published
hospital readmission rates within two days of discharge is two percent and that increases to 50% within six months of discharge (2006 Heart and Stroke Statistical Update, 2005).

Traditional medical management of the patient with HF is provided by a primary care physician and with urgent care of symptoms through treatment at local hospital emergency rooms followed by inpatient admission. While this remains a primary pattern for medical care, alternative settings for care are being used. Various settings collaborate to accommodate the entire continuum of care ranging from prevention, initial diagnosis, treatment/interventions, and emergency management of symptoms, and include the private physician office, disease specific clinics, outpatient clinics, hospitals, home health, and hospice (McCauley & Naylor, 2001).

The focus on disease management across the continuum is evident in the literature (Anderson, Pena, & Helms, 1998; Bertel & Conen, 1987; Bither & Apple, 2001; Fonarow, Creaser, & Livingston, 2001; Singh, 1995). The continuum includes prevention, diagnosis, treatment, intervention, symptom management, and end of life care. The provision of ongoing support, education, and intervention over the continuum of HF care is important to the management of the disease and its symptoms. Care can be provided to the patient with HF as a clinic outpatient, in the physician office, during emergency interventions or hospitalization, or in the home (Riegel & LePetri, 2001).

Starting in October of 2001, a national database was established to prospectively study characteristics, management, and outcomes in a broad sample of patients hospitalized with heart failure. The Acute Decompensated Heart Failure National Registry (ADHERE) is a multicenter registry with participation of more than 275
hospitals providing 100,000 patient cases. It is sponsored by Scios, Inc. and overseen by an independent scientific advisory committee of nationally recognized specialties. Patient eligibility is not linked to a specific therapeutic agent or regimen (ADHERE Registry, 2004).

The use of patient rated Quality of Life (QOL) tools as an outcome measure of chronic disease has been included in study designs with increasing frequency (al-Kaade, 2001). QOL can be defined as an individual's satisfaction with his role at work, at home, and in his community (Bonomi, Patrick, Bushnell, & Martin, 2000; Dracup, Walden, Stevenson, & Brecht, 1992; Packa, 1989). QOL encompasses four major domains (physical/functional status, psychological status and well-being, social interaction, and economic/vocational status) and is measured by health related or disease specific QOL tools (al-Kaade & Hauptman, 2001; Cramer & Spilker, 1998). Health related QOL tools, such as the Short Form 36v2 Health Survey (SF-36v2), measure the above domains of QOL as it relates to an individual health perceptions (Cramer & Spilker, 1998). Disease specific QOL tools measure the above domains in relation to a specific disease condition. Illness and treatment affect QOL to the extent that they impact an individual's ability to independently perform the four domains satisfactorily. Clinicians and researchers have to consider QOL measures in assessing the effects of an illness and its treatment (Levine & Croog, 1985). As the population ages and chronic disease becomes even more prevalent in health care, measures of functional loss and disability assume greater importance in the assessment of both QOL and the cost-effectiveness of care (Kane, Rockwood, Finch, & Philp, 1997).

The delivery of medical and nursing care for the patient with HF affects not only
their acute and chronic care, but their day to day self care activities. Day to day activities such as bathing, cooking dinner, shopping, house cleaning, and driving are affected by chronic diseases such as HF. Self care resources are defined as internal and external resources that help an individual to maintain and promote an optimal level of well being (H. C. Erickson, Tomlin, & Swain, 1983). Examples of self care resources could include family support, friends, social support, financial assistance, hope for the future, control, or environmental conveniences (Baas, Trupp, & Abraham, 2001). Self care resources are identified by the individual patient and are given importance by the patient. Self care resources are used to cope with the stress of health care problems in daily life (Baas et al., 2001).

The financial consequence of chronic disease interventions and treatment on health care dollars is staggering. HF treatment has expanded to new and more complex interventions in order to manage the disease and symptoms and can increase the number of office visits, medications, surgical procedures, heart transplant candidates, or artificial heart implantation candidates. Total treatment costs for HF; including physician visits, drugs, and nursing home stays were more than $10 billion in 1990 (AHCPR, 1994), $17.8 billion in 1993, and this cost continues to increase each year. HF costs in 2004, both direct and indirect, were $28.8 billion (2006 Heart and Stroke Statistical Update, 2005). Visits to physician offices for HF increased from 1.7 million in 1980 to 2.9 million in 1993. More than 65,000 individuals received home health care visits for HF each year.

Health care professionals and insurance companies closely manage the utilization of HF interventions. Although the treatments may be more expensive, the
treatments become more cost effective because of the decreasing length of stay of acute care hospital days and decreasing hospital readmission rates. (S. J. Bennett et al., 1999; Fonarow et al., 2001; "Here's how education saved $173,000," 1997; Mark, 1997; McDonald et al., 2002; Polanczyk, Newton, Dec, & Di Salvo, 2001). With the improved access through alternative programs and new technology, correct utilization of interventions may end up saving the health care system dollars (Mark, 1997; Rector, 2000).

B. Purpose of the Study

The purpose of this descriptive study was to compare quality of life in adult patients with HF in two different HF treatment settings: a disease specific HF clinic and physician run private practices. The data from the two samples is compared and contrasted.

C. Research Questions

The research questions that were addressed in this study are as follows:

1. Does health related QOL differ among patients with HF who are receiving medical outpatient care in two different clinical settings: a multi-disciplinary (nursing, medicine, pharmacy, physical therapy, social work, nutrition) disease specific HF clinic and physician run private practices as measured by the Medical Outcomes Study Short Form 36v2 Health Survey (SF-36v2) using the Physical Component Summary Scale and the Mental Component Summary Scale?

2. Does disease specific QOL differ among patients with HF who are receiving medical outpatient care in two different clinical settings: a multi-disciplinary (nursing, medicine, pharmacy, physical therapy, social work, nutrition) disease specific HF clinic
and physician run private practices as measured by the Minnesota Living with Heart Failure Questionnaire (MLHFQ) total score, physical sub-score, and emotional sub-score?

3. Are there differences in self care resources of patients with HF that are receiving medical outpatient care in two different clinical settings: a multi-disciplinary (nursing, medicine, pharmacy, physical therapy, social work, nutrition) disease specific HF clinic and physician run private practices as measured by the Self Care Resource Inventory (SCRI) and the sub-scales Self Care Resource Inventory Needs (SCRIN) and Self Care Resource Inventory Availability (SCRIA) sub-scores?

D. Operational Definitions

**Chronic Disease**: Illnesses that are prolonged, do not resolve spontaneously, and are rarely cured (Nordenfelt, 1995).

**Heart Failure**: A cardiovascular clinical syndrome that has been diagnosed by a physician using a history of symptoms including shortness of breath and activity intolerance that has led to complex circulatory and neurohormonal responses causing cardiac systolic or diastolic dysfunction (Dracup et al., 1992; Funk, Milner, & Krumholz, 2001) as measured by the NYHA HF Classification System (Ganiats et al., 1998).

**Health Related Quality of Life**: An individual's satisfaction with his role regarding health, physical functioning, psychological status, and social interaction at work, at home, and in the community (Grady et al., 1995; Packa, 1989) as measured by the SF-36v2 sub-scores.

**Disease Specific QOL**: An individual with HF’s perceptions concerning the effects of HF on his life (work, home, and community) as measured by the MLHFQ total score,
physical and emotional dimension sub-scores (Rector, Kubo, & Cohn, 1987).

**Disease Management HF Clinic:** A designated clinic providing medical outpatient care with multidisciplinary health care personnel who have expertise in caring for patients with a specific diagnosis of HF (Fonarow et al., 2001).

**Physician run private practice:** A private physician practice that provides outpatient medical care to patients with varying cardiac diagnoses including HF.

**Self-Reporting:** Using a questionnaire format, the patient self-rates their responses to the questions without influence from other sources (Rector & Cohn, 1992).

**Functional Status:** Ability to perform activities of daily living as measured by the SF-36v2 (physical functioning sub-scale) and MLHFQ physical sub-scale (Ware, Kosinski, & Gandek, 2000).

**Emotional Status:** Perception of mental health and social functioning as measured by the SF-36v2 mental health sub-scale (Ware et al., 2000).

**Self-Care Resources:** The internal and external resources of a patient that are mobilized through self-care action to help gain, maintain, and promote an optimum level of holistic health (H. C. Erickson et al., 1983).

**E. Assumptions**

1. The medical outpatient settings provide the services that are needed to care for patients with HF.
2. Patients' have the right to define their own QOL.
3. Patients' have the ability to define their own QOL.
4. Patients' will give honest answers to the questions.
F. Conceptual Framework Overview

Of the many theories utilized in published QOL research, the Modeling Role Modeling (MRM) theory by Erickson, Tomlin, and Swain was chosen as a conceptual framework for this research. Developed and published in 1983 as Modeling and Role-Modeling: A Theory and Paradigm for Nursing (H. C. Erickson et al., 1983), the intent was to develop a holistic nursing theory. Three health professionals worked on the development of the theory: Erickson, a registered nurse with varied experiences in nursing practice, education, and research; Tomlin, a registered nurse also with varied professional experiences in nursing practice and education; and Swain, a non-nurse with an educational background and with an expertise in psychology who has worked extensively with nursing colleagues in research and education (M. E. Erickson et al., 1998).

In developing this holistic nursing theory, the authors were influenced by multiple theoretical works. The influences of Abraham Maslow, Erik Erikson, Jean Piaget, George Engle, Hans Selye, and Milton H. Erikson were integrated and synthesized into the model. Theories involving stress response were used by Erickson and Swain to lead to the development of the MRM theory of the Adaptive Potential Assessment Model (APAM) in 1976. Erickson, Tomlin, and Swain (1998) synthesized the work of Maslow into their MRM theory and used the Maslow hierarchy of needs to define nursing interventions in the nursing relationship.

The MRM theory also included input from the works of Winnicott, Lein, Mahler, and Bowlby. Their description of object attachment helped to define the concept of
affiliated-individuation. Affiliated-individuation is identified as the relationship between object attachment and need satisfaction. Affiliated-individuation is essential to need satisfaction, adaptive coping, and healthy growth and development. It explains the ability of the individual to mobilize resources when confronted with stressors such as loss, grief, or disease. (M. E. Erickson et al., 1998).

Other nursing theorists have also influenced the development of the MRM theory. Peplau in 1952 and Travelbee in 1966 identified the interpersonal process between the patient and the nurse which is significant in providing nursing care. Orem in 1959 defined self care as the care which all persons require each day. The MRM theory uses the above concepts to address the patient self care resources that are available to assist the individual in health and daily life activities. Orlando in 1961 identified that the aim of nursing was to provide assistance to meet the patient’s needs which ties in the concept of self care resources (H. C. Erickson et al., 1983).

The MRM theory identifies self-care as the individual’s knowledge, resources, and action. When the individual knows what has caused the stressor or illness, they can then mobilize the internal and external resources they will need to gain, maintain, or promote a level of equilibrium. The importance of self care and self care resources in the daily lives of patient with HF effects their daily activities.

**Major Concepts and Definitions**

The terms and concepts used within the MRM theory are:

- **Adaptation** occurs as a client responds to stressors, both internal and external, to mobilize coping resources. Maladaptation occurs when a stressor taxes the individual’s energies and the person is unable to engage in constructive coping or mobilize
appropriate resources and results in biophysical vulnerability (H. C. Erickson et al., 1983).

Holism implies that the whole is greater than the sum of the parts. Body, mind, emotion, and spirit are multiple subsystems that interact to affect and control the individual. Holism also encompasses both conscious and unconscious processes within this dynamic process (H. C. Erickson et al., 1983).

Affiliated Individuation is the ability to be dependent on support systems while at the same time maintain independence from those support systems which is referred to as the “I” and “we” states, the ability to be a part of and yet separate (H. C. Erickson et al., 1983).

Self-care is defined as the knowledge, resources, and actions to help the individual gain, maintain, and promote an optimal level of holistic health. Self-care resources are both internal and external. The nurse facilitates the individual in identifying and developing these resources (H. C. Erickson et al., 1983).

Nurturance assists the client in moving towards holistic health and is a cognitive, physiological, and affective process. Nurturance appreciates the value of the clients world from the client’s perspective (M. E. Erickson et al., 1998). It implies that the nurse seeks to know and understand the client’s personal model of his world (H. C. Erickson et al., 1983).

Facilitation is the role of the nurse when engaging or providing care to clients and is an interactive, interpersonal process which assists the individual to develop their own strengths. It allows the individual control or input into developing a plan of care and in decision making (H. C. Erickson et al., 1983).
Unconditional acceptance is defined as being accepted as a unique, worthwhile, and important individual. The individual is accepted and respected as they are. This acceptance facilitates mobilization of resources and helps the individual to reach adaptive equilibrium (M. E. Erickson et al., 1998).

Nursing is defined as an interactive, holistic, interpersonal process with a goal for optimum health. In the MRM theory the nurse is a facilitator (M. E. Erickson et al., 1998).

Modeling is the process the nurse uses to develop an image or understanding of the client’s world from the client’s perspective. There is an art and science to modeling. The nursing art is being able to mirror the client’s perspective of the situation. The nursing science is the scientific collection and analysis of data about the client’s world (M. E. Erickson et al., 1998).

Role-modeling is planning and implementing interventions that are unique for that client. It is the facilitation of the individual in attaining, maintaining, or promoting health. It is both an art and a science. Role-modeling becomes the essence of nurturance (H. C. Erickson et al., 1983).

Environment is not explicitly defined in the MRM theory, but is seen in the social subsystems within the theory. Those social subsystems would include the biophysical stressors which are part of the environment (M. E. Erickson et al., 1998).

Person is described as both a patient and client in the MRM theory. A patient is given treatment and instructions. A client participates in his own care and is a member of the decision making team. A client has some control over the planned regimen. The individual is also described in the theory as having likes and differences. Individuals are
alike in the need for affiliated-individuation, holism, and lifetime growth and
development. Individuals are different in their need for endowment, adaption, and self-
care knowledge (M. E. Erickson et al., 1998).

Health is defined as a state of physical, mental, and social well-being, a state of
dynamic equilibrium, not just the absence of disease. Dynamic equilibrium between
various subsystems must be maintained (H. C. Erickson et al., 1983).
II. REVIEW OF THE LITERATURE

Chapter II will present an overview of the heart failure (HF) literature. A review of health related and disease specific quality of life (QOL) literature will be reviewed as it relates to HF. Tools used to measure HF QOL will be reviewed. The study's conceptual framework will be discussed and how it affects this research.

A. Heart Failure

Overview

The significance of a HF diagnosis is considerable. As more cardiac patients survive their initial event they can expect to live longer with cardiovascular disease. This longevity increases the opportunity for an individual to develop HF due to pathological changes within the cardiovascular system. The increasing elderly population will result in increasing numbers of HF patients regardless of trends in cardiac disease morbidity and mortality. From 1989 to 1999 the death rate from coronary artery disease decreased 24 percent and the actual number of deaths decreased 6.8 percent (2004 Heart and Stroke Statistical Update, 2003). Complex therapeutic strategies are prescribed to manage HF symptoms which affect HF daily life.

Therapeutic strategies

Treatment strategies for the management of HF depend on the type of HF and underlying etiology. With the complex management of ongoing symptoms, vigilant, frequent monitoring is the key to maintaining optimum health. Treatment strategies for the management of HF could include all or a combination of the following: neurohormonal blockade, hemodynamic management, ensuring adequate myocardial perfusion/metabolism, maintenance of electrical stability, and lifestyle modifications

**Neurohormonal blockade**

The syndrome of HF affects the normal autonomic and hormonal responses by causing sympathetic overactivity and parasympathetic withdrawal (Burger & Aronson, 2001). With the activation of vasoconstrictor systems (such as renin-angiotensin, vasopressin, and norepinephrine) in HF, a deleterious effect on heart rate and contractility is produced. There are four main pharmacologic avenues for neurohormonal blockade: angiotensin-converting enzyme (ACE) inhibitors, angiotensin II receptor blockers (ARB), aldosterone antagonists, and beta-blockers.

**ACE inhibitors.** Ace inhibitors are recommended for all patients with systolic HF to improve exercise tolerance, symptom relief, and reduction in mortality (Hunt et al., 2001; Iwata et al., 2006). They suppress angiotension II and aldosterone production, decrease sympathetic nervous system stimulation, increase parasympathetic tone, decrease left ventricular filling pressures, and decrease systemic vascular resistance. The Assessment of Treatment with Lisinopril and Survival (ATLAS) trial concluded that if ACE inhibitors were used in patients with Class II - IV HF, it would save 100,000 lives, would prevent 250,000 hospitalizations, and reduce costs by $2 billion (Barcina Sanchez, Martin Cortes, & Fernandez Fernandez, 1995; Ess, Luscher, & Szucs, 2002; Richardson, Cockburn, & Cleland, 1999). These findings were also confirmed in the Cooperative North Scandinavian Enalapril Survival Study (CONSENSUS) trial when the addition of an ACE inhibitor (enalapril) was added to HF therapy (Pitt, 2000). There was a 16% reduction in mortality when enalapril was added to therapy in the Studies of Left Ventricular Dysfunction (SOLVD) trial.
**Angiotensin II receptor blockers (ARB).** ARB’s block angiotensin II receptors (A-1 and A-2) at the cellular receptor sites and are often added to ACE inhibitor therapy or provide an alternative when the patient is ACE inhibitor intolerant (Eisenberg & Gioia, 2006). The Valsartan Heart Failure (Val-HeFT) study (n=5,010) showed that the addition of valsartan was associated with a decrease in the need for hospitalization admission by 27.5% and a decrease in mortality by 13.2% (Cohn & Tognoni, 2001). The Evaluation of Losartan in the Elderly (ELITE) study (n=3,152) also confirmed these statistics (Carson, 2000). The Losartan Intervention for Endpoint reduction (LIFE) study (n=9,193) suggested that the efficacy of ARB’s in patients with HF remains unanswered (Massie, 2002).

**Aldosterone antagonists.** Aldosterone antagonists, the most common of which is aldactone, have shown an increase in functional status, decrease in hospitalizations, and decrease in incidence of sudden death in patient with HF. The Randomized Spironolactone Evaluation study (RALES) used 25 mg per day of aldactone which allows it to compete with aldosterone in receptor sites and become cardioprotective (Bozkurt, Agoston, & Knowlton, 2003). The RALES trial (n=104) was stopped early when an interim analysis showed a 30% reduction in the risk of death and a 30% reduction in hospitalization for cardiac causes.

**Beta Blockers.** Beta blockers should be utilized in patients with systolic HF (Adams, 1999). This therapy has been advocated for patients with HF since the 1970’s, but did not become common practice as an intervention until the past few years. Beta blockade improves myocardial function, prolongs survival, and prevents serious dysrhythmias (Foody, Farrell, & Krumholz, 2002). Both the HFSA (Adams, 1999) and
the ACC/AHA guidelines recommend the use of beta blockers in all stages/classification of HF and for those at risk for developing HF (Chizzola et al., 2006; Hunt et al., 2001). This recommendation is supported by the Carvedilol Prospective Randomized Cumulative Survival Trial (COPERNICUS) (Packer, Coats, & M.B., 2001), the Beta-Blocker Evaluation of Survival Trial (BEST) (Bristow, Shakar, Linseman, & Lowes, 2001) and the Metoprolol CR/XL Randomized Intervention Trial in Heart Failure (MERIT-HR) trial (Goldstein & Hjalmarson, 1999). These trials were associated with a consistent 40% reduction in hospitalizations and a 30% reduction in mortality (Foody et al., 2002). It has also been shown that adding carvedilol to existing HF treatment can reverse the remodeling of the cardiac sympathetic nervous system function (Chizzola et al., 2006).

Newer neurohormonal interventions are on the horizon. Vasopeptidase Inhibitors (VPI) are currently in trial (Dawson & Struthers, 2002; Quaschning et al., 2001). They reduce vasoconstriction, increase the body’s vasodilator substances, inhibit ACE, and inhibit neutral endopeptidase. In theory, these drugs should be beneficial in both hypertension and HF. Efficacy in hypertension has been demonstrated, but the role in HF remains unclear. Preliminary results from the Omapatrilat Versus Enalapril Randomised Trial of Utility in Reducing Events (OVERTURE) fail to establish VPI as a first line therapy in HF (Dawson & Struthers, 2002).

Cytokine antagonists control the inflammatory response in the endothelial layer of muscle. Many of the inflammatory cytokines have the potential to negatively influence heart contractility, induce hypertrophy, and promote apoptosis thereby contributing to the cardiac remodeling process in HF (Gullestad & Aukrust, 2001).
Use of intravenous immunoglobulin in one small study enhanced left ventricular ejection fraction in patients with HF which did correlate with the anti-inflammatory effects of the therapy (Aukrust, Damas, & Gullestad, 2003). Further research will be needed to identify if this therapy will be beneficial to large numbers of HF patients.

**Hemodynamic management**

Hemodynamic management provides for the lowest systolic blood pressure that allows cerebration, ambulation, and urination. This involves preload reduction (diuretics, venodilators), afterload reduction (ACE inhibitors, Nipride, hydralazine, isororbide), and adequate fluid status. Inotropic support with the use of digoxin provides for symptom improvement (Davis, 2002).

Diuretics are frequently required to treat fluid retention in patients with HF (Costello-Boerrigter et al., 2006). Through their effects on sodium and water balance, diuretics decrease blood volume and venous pressure. Diuretic classes commonly include loop diuretics, thiazide diuretics, and potassium-sparing diuretics.

While the monitoring of hemodynamic status in acute care patients is common place, new technology is allowing for monitoring of patients in the outpatient setting. Using an implantable hemodynamic monitor (IHM), heart rate, activity, right ventricular systolic pressure, right ventricular diastolic pressure, and estimated pulmonary artery diastolic pressures are continuously monitored (Adamson et al., 2003; Magalski et al., 2002; Mehra, 2006; Ohlsson et al., 2001). The measurements obtained are useful in day to day clinical monitoring of HF patients to proactively intervene with appropriate interventions in a timely manner.

Digoxin provides inotropic support. Digoxin is added to the medication regimen
after ACE inhibitors, beta blockers, and diuretics are in use and the patient remains symptomatic. It is also used in patients with atrial fibrillation to slow the heart rate (Ammon, 2001). Digoxin increases myocardial contractility by inhibiting sodium-potassium adenosine triphosphatase and sensitizes cardiac baroreceptors to reduce sympathetic stimulation from the central nervous system (Davis, 2002). Other inotropic agents used include dopamine, dobutamine, and milrinone. Long term outpatient use of dopamine and dobutamine remains controversial (Hunt et al., 2001). While it does seem that pharmacological therapy can improve symptoms and improve quality of life, especially in the home setting, concern about increased mortality remains (Kellum, 2001).

Nesiritide is a human B-type natriuretic peptide and is manufactured from escherichia coli using recombinant DNA technology. Approved by the Federal Drug Administration in 2001, it is the first in a new class of drugs. Nesiritide is the same as the endogenous peptide produced by the ventricular myocardium as a result of volume expansions and pressure overload (Colbert & Greene, 2003). The Vasodilation in the Management of Acute Congestive Heart Failure (VMAC) study was a randomized, double-blind trials of subjects (n=489) with dyspnea at rest that showed that short-term intravenous infusion of nesiritide is associated with hemodynamic and symptomatic improvements in patients with acutely decompensated HF (Keating & Goa, 2003).

**Adequate myocardial perfusion and metabolism**

Adequate myocardial perfusion and metabolism can be accomplished through circulatory assist devices or surgical options. Circulatory assist devices support the circulation when the injured myocardium cannot generate adequate cardiac output.
They decrease the left ventricular workload and enhance oxygen supply to the myocardium (Oz, 2001). Devices could include intra-aortic balloon pump (IABP) or ventricular assist devices (VADS). VADS are a bridge to transplant, but are now being trialed as a bridge to recovery (short term therapy), bridge to bridge (short term to allow for implantation of a long term device), or as destination therapy (VADS as an implanted device instead of cardiac transplant) (Oz, 2001; Smart & Palanichamy, 2005). The Randomized Evaluation of Mechanical Assistance for the Therapy of Congestive Heart Failure (REMATCH) study showed that VADs can prolong life and improve the quality of life in a patient group awaiting transplant (Rosen, Contrada, Gorkin, & Kostis, 1997).

There are various surgical options for improving cardiac function in the patient with HF with or without heart replacement. Coronary artery bypass grafting (CABG) is used to improve vascularization of the cardiac muscle in patients with reversible ischemic myocardial defects. CABG is needed when restoration of coronary blood flow is necessary. Approximately 500,000 CABG procedures are done annually and 50% of patients have Class III or IV HF. Several studies show good long term survival in the use of CABG to improve outcomes in patients with HF (Baron et al., 2002; Elefteriades & Edwards, 2002; Miller, 1993).

Mitral valve reconstruction to correct mitral valve regurgitation is another surgical procedure for patients with HF. Mitral valve regurgitation leads to progressive left ventricular dysfunction and volume overload of the left ventricle. It also increases the severity of HF and increases the risk of clot formation (due to blood stasis in the left atrium and ineffective emptying of the left ventricle) which further complicates the treatment regime. Mitral valve replacement or reconstruction is often performed in
conjunction with CABG when mitral value regurgitation is significant. While valve reconstruction procedures in the patient with HF have traditionally been avoided due to a higher mortality rate, newer studies are showing improved functional status and NYHA functional class improvement (Bolling, Smolens, & Pagani, 2001).

Surgical procedures such as the Batista (Abe, Fukada, & Morishita, 2001; Blanche, Frota Filho, Trento, & Lucchese, 1998; Bridges & Bogen, 2001) and Dor (Di Donato et al., 2001; Dor, 2001) procedures have also been developed to improve outcomes in HF. The Batista Procedure, or partial left ventriculectomy, is a heart reduction surgery developed by a Brazilian surgeon, Dr. Randis Batista. Heart muscle is cut out using a linear incision in an attempt to return the ventricle to optimal size and function by changing geometry. Many of the studies indicate the use of this procedure for bridge to transplant or for those patients for whom transplant is either cost prohibitive or unavailable (Abe et al., 2001; Bolling et al., 2001; Bridges & Bogen, 2001; Brouwer et al., 1999; Garcia, Barril, Manapat, Lopez, & Luna, 1999; Sankar, Baruah, Ninan, Rajan, & Cherian, 2001).

The Dor Procedure or endoventricular circular patch plasty has been used to excise ventricular aneurysms and improve ventricular shape. Studies have shown improved systolic function post procedure (Di Donato et al., 2001; Dor, 2001). Both the Batista and Dor procedures remain controversial (Abe et al., 2001; Moreira & Noedir, 2001). Overall, outcomes have been less than desirable and these procedures are rarely done today.

Cardiac transplantation is the gold standard to resolve the physiological changes in the patient with HF (Zeltsman & Acker, 2002). There are 50,000 Americans who need
a new heart transplanted for a variety of diseases, and 95% will die without getting the transplant. There are approximately 7,700 names on the transplant list. It is available to only a small number of patients (Baas, Fontana, & Bhat, 1997; El-Zaru & DeNofrio, 2002). The cost of cardiac transplantation versus VADS is about the same, $100,000 to $125,000. Current estimations of a 10 year survival rate of 50% remains superior to all available mechanical devices (Haverich & Gorler, 2002). Recipient selection is key to maintaining survival rates (Deng, Smits, & Packer, 2002; Gradaus et al., 2002; Tsai et al., 2002). Follow up post transplant including medications adds an additional $10-18,000 per year.

Newer state of the art technology to improve myocardial perfusion and metabolism are being investigated. Angiogenesis, using vascular endothelial growth factor and fibroblast growth factor to produce new growth of coronary blood vessels, is being trialed. In animal and human trails, several compounds are showing promise. Prostaglandin E is a potent vasodilator and induces angiogenesis in animal tissue (Mehrabi et al., 2001). Gene transfer using vascular endothelial growth factor to stimulate angiogenesis and improve perfusion is being used on ischemic myocardium (Lathi et al., 2001). Use of human hepatocyte growth factor combined with cellular cardiomyoplasty is being tested in rats and hamsters as a possible strategy for the treatment of HF (Miyagawa et al., 2002; Taniyama et al., 2002). Other types of cell transplantation are being considered with potential yet to be determined in the treatment of HF (Ahmedzai, 1995). The investigation into the use of both embryonic stem cells and adult somatic stem cells to augment myocardial performance is ongoing (Hughes, 2002).
Maintenance of electrical stability

Sudden death due to dysrhythmias in HF is 6-9 times the rate of the general population (2004 Heart and Stroke Statistical Update, 2003). Dysrhythmias can include tachy dysrhythmias, brady dysrhythmias, pulseless electrical activity, or ventricular dysrhythmias. Predisposing factors that contribute to the development of electrical instability can include electrolyte imbalance, myocardial tissue changes, ischemia, sympathetic nervous system activity, and other therapeutic interventions (beta blockers). The decision to treat the dysrhythmia is based on the answer to the question “Is the patient symptomatic?” Treatment options can include electrical cardioversion, pharmacologic interventions, revascularization, ablation, internal cardiac defibrillator (ICD), or biventricular pacing. The Multicenter InSync Randomized Clinical Evaluation (MIRACLE) (Saxon, 2002) study looked at biventricular pacemaker devices with and without ICD. This study showed reversal of ventricular remodeling in those patients with successful implant which could affect the overall long term effects of HF on the ventricle over time.

Lifestyle modifications

Life style modifications are aimed at improving oxygen consumption in HF patients. Extensive patient education and close follow-up is provided which often includes a combination of exercise, sleep enhancement, and dietary modifications.

Through exercise training, peak oxygen consumption can be improved. Neither the amount of exercise necessary to produce functional improvement nor the best training strategy has yet to be defined (Uretsky et al., 1998). Rehabilitation exercise programs focus on both aerobic and strength training. Although the Agency for Health
Care Policy and Research in 1994 recommended cardiac rehabilitation guidelines and exercise therapy for HF patients, insurance reimbursement has not materialized due to the resulting increase in cost (AHCPR, 1994). With a low level exercise program, benefits are seen within the first four months. The individual must continue to exercise to maintain the benefits, but after four months there is usually no further improvement (Uretsky et al., 1998).

Improvement of sleep patterns in patients with HF improves oxygenation and lifestyle. An improvement in left ventricular ejection fraction is noted with the use of continuous positive airway pressure (CPAP). Problems common with the patient with HF are sleep apnea (Javaheri, 2006), snoring, and daytime sleepiness, often in conjunction with overwhelming fatigue. Administration of diuretics at night may also disrupt sleep patterns and timing may need to be adjusted (S. J. Bennett, Cordes, Westmoreland, Castro, & Donnelly, 2000). The fear of ‘not waking up’ in the morning disrupts nightly sleep patterns (S. J. Bennett et al., 2000).

Guidelines regarding sodium restriction in the diet of patients with HF are well documented (Volpe et al., 1993). Due to the inability of the body to excrete sodium, sodium is retained thereby retaining fluid. The degree of sodium restriction is less clear, ranging from a two gram sodium or less diet to no added salt in cooking. The dosage of diuretics usually increases as the sodium restriction decreases (Dracup et al., 1994; Uretsky et al., 1998). While patients report that adherence to the diet lessens symptoms, most report difficulties in maintaining the diet.

Body, mind, spirit connections and interventions are also used. Emotions such as depression, hostility, anxiety, anger, and hopelessness play an important part in the
daily life of the patient with HF (S. J. Bennett et al., 2000). While the use of professional therapists has been suggested in the literature, the inclusion of professional therapists as part of the interdisciplinary team has not been widely reported (Bither & Apple, 2001; Uretsky et al., 1998). The use of HF support groups led by physicians and nurses were evident in the literature (S. J. Bennett, Pressler, Hays, Firestine, & Huster, 1997; Rich et al., 1995).

The term counseling was used interchangeably with patient information/education (Bours, Ketelaars, Frederiks, Abu-Saad, & Wouters, 1998; Dracup et al., 1994; Uretsky et al., 1998). Research has focused on the reporting of physical symptoms and self-management techniques. The negative emotional symptoms are just as important in looking at the patient with HF holistically (S. J. Bennett et al., 2000).

Patient education is a key component in implementing lifestyle modifications for the patient with HF (Michalsen, Konig, & Thimme, 1998; Rich et al., 1995). Inclusion of the family or significant others can also greatly influence the implementation of patient education strategies (Uretsky et al., 1998). Adherence may fail due to multiple reasons: patients do not understand how to integrate the information into their activities of daily living, they may forget the instructions, they may not be convinced that the strategies will improve their symptoms, or the interventions prescribed may not be followed due to their burden on family finances (Dracup et al., 1994; Michalsen et al., 1998).

**Preventative Care**

The HF literature is just starting to focus on the prevention of HF rather than the management of HF. Primary prevention is based on the identification of HF risk factors
such as hypertension and cardiovascular disease, and the development and implementation of patient specific strategies to decrease their effect on the individual’s overall health (Logeart, Guiti, Ennezat, & Cohen-Solal, 1998). Primary care providers, especially nurses, play an important role in HF prevention when they perform routine medical check-ups and health education (D. W. Baker, 2002).

The importance of wellness education is an example of how the nurse can help to delay the onset of HF. Cardiovascular risk factors (hypertension, myocardial ischemia, obesity, diabetes) that are addressed early or prior to a diagnosis of HF can affect the spread of this chronic disease. By changing the HF paradigm to include prevention, health care professionals can truly care for the patient across the continuum (Francis, 2000). Addressing the Stage A patient with HF (Table 1) risk factors, as well as coronary artery disease risk factors, is the first important step in preventing HF (Caboral & Mitchell, 2003).

**B. Treatment Locations**

There are multiple treatment locations that can be used by the patient for the treatment of HF. The emergency department is a frequent location for initial treatment of decompensated HF and is usually followed by acute care hospital admission (Butler et al., 2006). The development of observation units in the emergency department is a new, temporary treatment location (Peacock, Young, Collins, Diercks, & Emerman, 2006).

The two major health care settings in which long-term patients with HF are treated are the physician office and disease specific HF clinics. The primary treatment location of the physician office to provide care for the patient with HF has been expanded in recent years. New and diverse treatment providers which include HF
clinics, telephone monitoring, case management, home health, and hospice are instrumental in treating and caring for the patient with HF. The medical model of disease management of HF patient care has been expanded. Treatment for HF is an evolving plan that can change from day to day, week to week, and month to month. To maintain a level of wellness the patient with HF and family require intense education, monitoring, and follow-up. Research is now showing the financial benefits of multidisciplinary HF care over the traditional disease management model (McDonald et al., 2002). The disease management model is a vague term which deals with acute illness and physician directed care (Havranek, Masoudi, Rumsfeld, & Steiner, 2003).

The physician office has been the primary site for care of the patient with chronic disease. Face to face physician visits are based on current problems and symptoms reported by the patient. Visits are scheduled based on the practitioner's judgment. Patients with chronic illnesses, like HF, have infrequent physician contact. In the literature it is reported that patients see a physician on the average of once a month for 15 minutes. The patient is on their own the remainder of the time (Rich, 2002). Another report sets the average at 15 minutes in a physician office every six months (Bertel & Conen, 1987). This time frame does not facilitate the needed individualized interaction and intervention adjustment needed to optimally manage the HF population.

Using a multidisciplinary approach to HF management allows for discipline expertise to improve the overall patient outcomes (Fonarow et al., 1997; Fourny, Neuder, Tranchant, & Francois, 2006; Hanumanthu, Butler, Chomsky, Davis, & Wilson, 1997; Rich, 1999; Ventura, Smart, & Loyalka, 2000). The multidisciplinary team consists of physicians, nurse practitioners, social workers, dietitians, home health nurses,
occupational and physical therapists, pharmacists, and case managers. The medical management of HF involves the prescribing of medications, interventions, and follow-up of existing co-morbidities. Financial counseling is integrated into defining existing and potential resources. Patient and family education is provided to integrate the medication and intervention regimen into daily life routines. (Rich, 1999; Ventura et al., 2000).

HF clinics in various forms are becoming the primary multidisciplinary form of delivering HF care. They exist in several formats: community hospital based, free standing, nurse managed, physician managed, teaching hospital based, and integrated in other disease outpatient clinics (Akosah, Moncher, Schaper, Havlik, & Devine, 2001; Hershberger et al., 2001; McMurray & Stewart, 1998; Paul, 2000; Pitt & Nicklas, 2000; Stromberg, 1998). While standardization of resources (available health care professionals, services provided, interventions provided) in HF clinics vary from clinic to clinic (Riegel & LePetri, 2001), there is proven financial and emotional benefit to the individualized care and follow-up (Akosah et al., 2001; Hershberger et al., 2001; McDonald et al., 2002; Paul, 2000).

Common resources that could be available in the clinic setting include access to physicians, cardiologists, registered nurses, pharmacists, dieticians, home health nurses, occupational and physical therapists, cardiac rehabilitation personnel, and social workers. While some resources vary from program to program, there are certain features and activities that are common to most programs. Essentials would include a case manager or coordinator, patient education activities, enhancement of patient self-management skills, optimization of medications, and close follow up (Rich, 2002). The goals of any HF clinic would be to optimize clinical and economic management of the
patient with HF (Paul, 2000). The HF clinic model attempts to move HF management from reactive care to proactive care (Hershberger et al., 2001).

Case management models have been used in both the inpatient and outpatient HF settings. There is a focus on patient progress toward specific outcomes with subsequent modifications in care based on the evaluation of patient improvement. This standardization of expectations of patient progress prepares the patient for timely discharge while keeping resource use at acceptable and appropriate levels (Lynn & Kelley, 1997).

Community based home monitoring models are also being implemented. Patient data is obtained daily by the patient at home (weight, vital signs, and symptoms such as shortness of breath, fatigue) and entered into a data system via phone or computer (Heidenreich, Ruggerio, & Massie, 1999). Telephone monitoring consists of practitioner initiated calls or call-in systems for patients and care givers. Phone calls are used as adjunct visits in between face to face visits (Shah, Der, Ruggerio, Heidenreich, & Massie, 1998). Use of home health visits as the face to face visits are also utilized, but the number of insurance covered visits may be limited.

Hospice interventions for the patient with HF are mainly for palliative care and symptom management. The hospice care concept was established in London, England in 1968 to improve the QOL of the terminally ill. Care focuses on symptom control (Masters & Shontz, 1989). Criteria for hospice is a NYHA Class IV designation and a prognosis of less than six months.

C. Quality of Life

The definition of QOL in the literature varies. Researchers define QOL using
concepts such as well-being (Dracup et al., 1992), overall physical and psychological well being (Rideout, 1992), or satisfaction with life in general (Riedinger, Dracup, & Brecht, 2002). Studies dealing with chronic disease including HF include QOL measurements in combination with physiological measurements to measure patient outcomes change. When studies regarding treatments, interventions, or medications are developed, the outcomes studied include both the physiological measures as well as their effect on life (S. J. Bennett & Pressler, 1995).

The use of various tools to measure QOL is addressed in the literature. Many QOL tools focus on functional ability in terms of activity and have not taken into account other dimensions of QOL (Jalowiec, 1990). A more comprehensive QOL tool encompasses physical, psychological, and the social aspects of a person’s life. Studies that integrate physiological and QOL measurements to show benefit from an intervention are more commonplace in current research.

The subjectivity of the QOL measurement has been questioned when earlier tools were completed by the health care professional about the patient’s QOL rather than by self-report of the patient. The increasing role of the patient participating in health care decision making enabled the patient evaluated QOL score to be a truer indication of patient perception based on their individual social, home, work, and health status (Christ & Siegel, 1990). Work on The effect of treatments such as chemotherapy, radiation therapy, and radical surgeries on activities of daily living was studied. Some of the earliest integration of QOL studies with treatment regimens were with cancer patients (Ganz, 1994).

Global QOL measurements, also called health related QOL, are used to measure
satisfaction or dissatisfaction with life in general. QOL is an individual's satisfaction with his role regarding health, physical functioning, psychological status, and social interaction at work, at home, and in the community (Grady et al., 1995; Packa, 1989). Their use in diverse populations gives an overall measure of satisfaction with their QOL (Ormel, Lindenberg, Steverink, & Vonkorff, 1997).

Disease specific QOL tools have been developed with questions specific to a particular chronic disease (Moy, Ingenito, Mentzer, Evans, & Reilly, 1999; O’Conor, Johannesson, Hass, & Kobelt-Nguyen, 1998; Plaza, Serra-Batlles, Ferrer, & Morejon, 2000; Rector & Venus, 1999). Disease specific tools address the quality of activities of daily living in patients with diabetes, arthritis, pulmonary disease, and cancer. They measure an individual's perceptions concerning the effects of HF or any chronic disease on their life at work, at home, and in the community (Rector, Kubo et al., 1987).

There have been several tools developed for or used in the HF population. The Short Form-36v2 Health Survey (SF-36v2) was developed as a health related QOL tool and has been used in the HF population. The Minnesota Living with Health Failure Questionnaire (MLHFQ) was one of the first HF disease specific tools developed (Rector, Frances, & Cohn, 1987) and is frequently used in the HF population. The Kansas City Cardiomyopathy Questionnaire (KCCQ) (Green, Porter, Bresnahan, & Spertus, 2000) is one of the newest tools developed to quantify health status and QOL in HF patients. The KCCQ is a new, self-administered, 23-item questionnaire that quantifies physical limitations, symptoms, self-efficacy, social interference and QOL. It was administered with the Short Form-36 (SF-36) and MLHFQ. The researcher felt that the sensitivity of the new questionnaire was substantially greater than that of the
MLHFQ or the SF-36 (Green et al., 2000). However, the KCCQ tool was not selected for this research because of minimal published studies in the literature and the predominance of the MLHFQ in HF studies.

The Self-Management of HF Questionnaire was developed to evaluate self-management of HF (Riegel, Carlson, & Glaser, 2000). Face and content validity of the tool were demonstrated adequately with internal consistency scores of the six sub-scales of the instrument ranged from .79 (measured ease of evaluating treatment) to .92 (evaluating the change over time). Reliability could not be calculated for one sub-scale (evaluating the treatment) because of missing data that resulted from patients skipping sections because they had not experienced a symptom.

The tools chosen for this research are the MLHFQ, the SF-36v2, and the Self Care Resource Inventory (SCRI). The literature will be reviewed from the standpoint of overall information, clinical research, and patient populations.

**Minnesota Living with Heart Failure Questionnaire**

The MLHFQ was developed in 1986 (Appendix A). It is a 21-item questionnaire with a Likert rating scale of 0 - 5 (6 point response range) extending from ratings defined as no, very little, to very much. A total possible score of 0 to 105 is obtained with physical and emotional sub-scores. The MLHFQ tool is a commonly employed disease specific health status measure for HF (Green et al., 2000).

The MLHFQ instrument was designed for use as a self reporting tool with patients with HF and has been used extensively with this population over the past 10 years. Rector and Cohn (1992) conducted a randomized, double-blind, placebo-controlled clinical trial of pimobendan to measure patient outcomes using the MLHFQ.
As a disease specific tool that measures QOL for the HF population, the MLHFQ has been reported to be valid, reliable, and effective (Cohen-Solal, Caviezel, Laperche, & Gourgon, 1994; Green et al., 2000; Guyatt, 1993). This tool will be used to collect HF disease specific QOL information and patient perceptions in this study.

Questions focus on impairments that patients frequently attribute to the diagnosis and symptomatology of HF, and evaluates the patient’s perceptions of the effect of HF treatments. It does not represent all facets of life that can be affected by the chronic disease of HF. The self-report questionnaire is completed by the patient rather than a health care provider and the patient rates the presence or absence of therapeutic benefit. When health care providers rate QOL or therapeutic benefit, the scores do not always agree with the perceptions of the patient (Rector & Cohn, 1992).

The MLHFQ was compared to the NYHA Functional Classification System for HF (Dracup et al., 1992). In the development of the MLHFQ a comparison with the NYHA classification was done with 83 patients. A correlation of .80, \( p<0.01 \) was established. (Guyatt, 1993). As a disease specific tool that measures QOL for the HF population, it has been shown to be valid, reliable, and effective. (Berry & McMurray, 1999; Cohen-Solal et al., 1994; Guyatt, 1993; Havranek et al., 1999; Shively, Fox, & Brass-Mynderse, 1996). It has been used extensively in medication research with patients with HF.

Research was conducted regarding the addition of the drug flosequinan to the therapeutic regimen for patients with HF (n=322) currently on a diuretic, digoxin, and an ACE inhibitor (Massie et al., 1993). Efficacy was evaluated with serial measurements of treadmill exercise time, responses to the MLHFQ, and clinical assessments during a baseline phase and a 16-week treatment period. Results showed that the addition of
flosequinan 100 mg once daily improved the overall MLHFQ score significantly when compared with placebo.

The physiologic effects of ACE inhibitors was studied to determine if their effects, in conjunction with all other aspects of ACE inhibitor treatment, favorably alter QOL as judged by the patients (Rector, 1995). The available data suggest that symptomatic patients who have a limited QOL of life can be improved by ACE inhibitors. The research also showed that it was reasonable to assume that avoidance of episodes of decompensated HF and ischemic events would have some yet-to-be-defined effect on maintenance of patients' QOL.

A randomized, double-blind crossover study design (n=15) was used to determine whether supplemental oral L-arginine can augment peripheral blood flow and improve functional status in patients with moderate to severe HF (Rector et al., 1996). Subjects were given six weeks of oral L-arginine hydrochloride and six weeks of matched placebo capsules in random sequence. With the 15 patients in the study, results showed lower physical sub scores on the MLHFQ. Supplemental oral L-arginine had beneficial effects in patients with HF.

A quinolone inotropic agent (OPC-8212) was studied in 17 patients with moderate to severe HF (Kubo, Rector, Strobeck, & Cohn, 1988). The MLHFQ was administered prior to and after one month of treatment. The MLHFQ scores showed patients reported an improvement in total scores (49 to 38, respectively with \( p < .05 \)) in daily functioning.

The MLHFQ has also been used to study the effects of severity of HF symptoms in relation to HF interventions. The relationship between exertional symptoms,
ventilatory and skeletal muscle dysfunction, and circulatory function in patients with HF was studied in 52 ambulatory patients (Wilson, Rayos, Yeoh, Gothard, & Bak, 1995). The level of perceived exercise intolerance during daily activities was evaluated using MLHFQ scores. All groups in the study exhibited similar levels of fatigue and dyspnea at comparable workloads and had comparable total scores for the MLHFQ.

The effect of exercise on patients with HF QOL has been studied using the MLHFQ. A study to compare exercise training on a cycle ergometer (focusing on major muscle mass) and aerobic knee-extensor training (focusing on minor muscle mass) was conducted in 24 patients with HF who had completed their first exercise training more than one year previously (Tyni-Lenne et al., 1999). Subjects were randomized into control and exercise groups. Physiological measurements such as citrate synthase activity, blood lactate concentration, peak oxygen uptake, and plasma norepinephrine concentration were measured. QOL was measured using the MLHFQ. MLHFQ scores showed improvement in the health-related quality of life \( (p < 0.05) \) only after knee-extensor training. Physical training was beneficial in previously trained patients with HF and aerobic training involving minor muscle mass showed greater efficiency than training involving major muscle mass.

In a study with 22 ambulatory males, the effects of an exercise training program on patients with HF (NYHA functional class II-III) attributed to left ventricular systolic dysfunction and dilated left ventricle were studied (Tokmakova, Dobreva, & Kostianev, 1999). Subjects were randomized into control and training groups. The reduction in scores from baseline and at eight weeks as measured by the MLHFQ \( (p < 0.001) \) reflect the reduction of symptoms and the improvement in health-related QOL.
Using the MLHFQ, QOL was studied with implanted device interventions (Gras et al., 1998). The Medtronic InSync pacemaker left ventricular pacing lead was implanted and studied with 68 patients. There was a clinical benefit among surviving patients, which was corroborated by a significant improvement in NYHA functional class, significant narrowing of the paced QRS complex, a significant decrease in the interventricular mechanical delay, a trend toward an increase in the duration of ventricular filling, and a longer distance covered during a 6-minute walk test. Improvement was noted in all MLHFQ scores.

**Short Form-36v2 Health Survey**

The SF-36 (Appendix B) was developed by John Ware in 1992 as part of the Medical Outcomes Study (MOS) which was supported by the Rand Corporation. It is a patient self-report survey of general health status that has been used to assess overall QOL in a variety of patient populations. It has been used to measure QOL in chronic disease conditions such as cancer, arthritis, stroke, diabetes, pain, coronary disease, HF, hip and knee replacements, and chronic obstructive pulmonary disease.

Initially comprised of 108 questions, which was determined to be too lengthy to be effective (Brazier et al., 1992). Using question analysis and further research it was reduced to 36 questions and renamed the SF-36. In 1996 the SF-36 (SF-36v2) was revised to correct minor deficiencies identified in the original version. Five level response choices were added in two role functioning scales, mental health scale, and vitality scale. Improvements were also made in instructions to participants (Ware et al., 2000).

With only 36 questions it is estimated to take approximately 5 to 10 minutes to
complete (Brazier et al., 1992; Martin, Engelberg, Agel, & Swiontkowski, 1997; Moy et al., 1999). It was constructed to measure eight health attributes using eight multi-item scales containing two to ten items each. The eight sub-scales measure physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional, and mental health. MOS researchers developed the questions from a variety of instruments already in use: the General Psychological Well-Being Index, the Health Perceptions Questionnaire, the Health Insurance Experiment, and the Well-Being Profile (Cramer & Spilker, 1998). There is a three, five, or six point rating scale that can be used for each of the 36 questions.

The SF-36 has had rapid acceptance as a measurement tool for health related QOL because of its brevity and favorable psychometric properties (Stadnyk, Calder, & Rockwood, 1998). There is a large body of literature to support the reliability and construct validity of this tool using both internal consistency and test-retest methods (Vickrey, Hays, Genovese, Myers, & Ellison, 1997). This tool has been used in a variety of chronic disease populations.

Functional outcomes at an average of six months after outpatient rehabilitation were investigated in a pilot study with a sample of 42 patients receiving physical therapy for low back, neck, and other musculoskeletal problems (J. G. Baker, Fiedler, Ottenbacher, Czyrny, & Heinemann, 1998). For predicting improvement verses no improvement using the SF-36 sub-scales, the physical functioning sub-scale was predictive of change in general health.

Chronic obstructive pulmonary disease (COPD) outpatients (n=472) were surveyed to evaluate change on both the Chronic Respiratory Disease Questionnaire
(CRQ) and the SF-36 (Wyrwich, Tierney, & Wolinsky, 1999). Among SF-36 sub-scales demonstrating acceptable reliability and reasonable variance, the percent of individuals within each change category was consistent with those seen in the CRQ dimensions. The SF-36 and two disease-targeted health related QOL instruments were administered to 171 adults with multiple sclerosis (Vickrey et al., 1997). Results indicate that the disease-targeted scales provided unique information not captured by the generic measure. Additional information was gained by supplementing the SF-36 with selected disease specific scales.

Patients with severe chronic airway limitation being assessed for home oxygen therapy (n=60, 32 males and 28 females) at the Flinders Medical Centre, Adelaide, South Australia were administered two generic QOL instruments, the Nottingham Health Profile and the SF-36 (Crockett, Cranston, Moss, & Alpers, 1996). Patients with severe chronic airway limitations were experiencing severe impairment in their QOL in comparison to age-matched South Australian norms, with physical disability the major limitation. There were several significant correlations between the domains of the SF-36 and the Nottingham Health Profile which were predominantly gender-specific.

The SF-36 has been used in measuring QOL in heart related diseases. A prospective, repeated-measures design was used to examine functional status in patients with a coronary artery bypass graft (CABG) over time (Barnason, Zimmerman, Anderson, Mohr-Burt, & Nieveen, 2000). Baseline data was obtained by patient interview in the hospital setting after CABG surgery, at three months, at six months, and at 12 months after surgery. Baseline scores on seven of the eight sub-scales of the SF-36 were significantly lower than at three, six, and 12 months after surgery. Role-
emotional functioning baseline scores were not significantly lower than three month scores; however, baseline scores were significantly lower than six and 12 month scores. Three month scores were also significantly lower than six or 12 month scores except for the scales measuring social and general health functioning. The results of the study provide a basis for determining areas of functional limitations during recovery from CABG surgery. Study results are also the foundation for evaluating outcomes of patients with a CABG when specific interventions (pain management, psychosocial support, physical strengthening, fatigue management) are implemented during hospitalization, home recovery, and rehabilitation to target optimal psychosocial and physiologic functioning of patients post CABG.

The relationship between patients with chronic stable angina (n=55) ratings and current health status was studied using multiple tools including the SF-36 (Chen, Daley, & Thibault, 1996). Correlations between ratings for both health states and scales of the SF-36 were positive, with some reaching statistical significance. The study concluded that having patients rate current health and symptom free health is a useful measure of treatment effectiveness for specific symptoms in clinical trials and patient care. It can help patients and clinicians prioritize multiple health problems.

In another study, 51 patients with sleep apnea were administered the SF-36 before treatment for sleep apnea was initiated and at four weeks into treatment (L. S. Bennett, Barbour, Langford, Stradling, & Davies, 1999). Compared with general population data, the dimensions of energy and vitality and physical role limitation were abnormal before treatment (p<0.05) and normalized with treatment. Sleepiness and pretreatment SF-36 values correlated significantly.
QOL in sleep apnea patients (n=108) treated with nasal continuous positive airway pressure was studied (Jenkinson, Stradling, & Petersen, 1997). The baseline SF-36 scores revealed substantial adverse effects on subjective health of patients with obstructive sleep apnea. Treatment with nasal continuous positive airway pressure improved scores on the SF-36.

The health status of bone marrow transplant survivors (n=251) was compared to age-adjusted population health-related QOL with the SF-36 (Sutherland et al., 1997). On average, survivors had some diminished QOL relative to the health status of the population in general. Time post transplant had a significant influence on QOL. Patients with less than three years from transplant experienced considerable impairment while those who had survived beyond this point were indistinguishable from the normal population in most domains and significantly better in certain psychosocial aspects of health. The study concluded that 81% of patients were satisfied with the QOL outcome that they had achieved and 94% would recommend a bone.

In a study of 85 patients with musculoskeletal tumors, the population experienced health status and functional deficits in each of the eight SF-36 assessed scales (Bruckner, Cluett, & Conrad, 1998). Data showed that the most severe deficits were experienced by patients who had diagnoses of bone tumors and malignant tumors. The data allows the physician to understand the presenting condition from the patient's perspective and is an important and often neglected aspect of the overall assessment of the health of the patient on presentation. This study shows that the SF-36 is a practical and effective method for documenting perceived deficits in health status in patients with musculoskeletal tumors.
The SF-36 has been used in a variety of patient ages including the adult population. In a study of 13,042 randomly selected subjects ages 18 to 64 years, the SF-36 was administered in a community setting to obtain normative values (Jenkinson, Coulter, & Wright, 1993). The survey achieved a response rate of 72% (n = 9332). Internal consistency of the different dimensions of the questionnaire was high. Normative data broken down by age, sex, and social class were consistent with those from previous studies.

The SF-36 has been administered in the elderly population (ages 65 and older). Elderly patients with osteoarthritis were compared with that of their peers with no chronic illnesses to investigate the associations between analgesic use and QOL (Briggs, Scott, & Steele, 1999). Osteoarthritis patients had significantly ($p < .05$) lower scores than control patients in all QOL scales. Osteoarthritis patient scores were lowest for the scales of role-physical, bodily pain, and physical functioning.

The SF-36 has been used in the HF population. In a study to assess the functioning and well-being of older patients presenting with HF, the SF-36 was administered before ACE inhibitor treatment was initiated (Jenkinson, Jenkinson, Shepperd, Layte, & Petersen, 1997). The conclusion was that ACE inhibitor treatment, while lengthening life, has a relatively limited impact on QOL.

The QOL of women HF patients (n=691) was compared with women with other chronic conditions (Riedinger et al., 2002). Compared with the normative group of women, women with HF had significantly lower QOL, especially in the areas of vigor, activities of daily living, social activity, and general health. The study concluded that women with HF had poorer QOL than do other chronic disease populations.
A QOL study of gender differences among patients (n=435) admitted with HF was measured. Health-related QOL was measured by the SF-36 (Chin & Goldman, 1998). The study concluded that one year mortality in both genders was high and QOL was low in patients admitted with HF. Women had less improvement in physical health status and perceived their QOL to be lower than male subjects, thus they may require different HF interventions.

QOL scores for HF patients were measured in a study of 50 patients (Havranek et al., 1999). The SF-36 and the MLHFQ were administered. There were significant ($p<0.05$) curvilinear relationships between the physical function scale of the SF-36 and the MLHFQ physical sub score. The study concluded that these tools are valid measures of QOL in patients with HF, and cost-effectiveness analyses of HF treatments incorporating tools in the outcome measure can be meaningful.

Another study (Pilote et al., 1995) compared functional status and QOL in Americans and Canadians with and without prior symptoms of heart disease. QOL was generally better in the 934 Americans than in the 278 Canadians, with overall health rated as excellent or very good in 30% of Americans versus 20% of Canadians ($p = .0001$). Similar emotional and social health scores were obtained. The functional status of patients without prior symptoms of heart disease is similar in Americans and Canadians. However, among patients with previous symptomatic heart disease, functional status is higher in Americans than in Canadians. This difference may be due to different patterns of medical management of heart disease in the two countries.

**Self Care Resource Inventory**

The SCRI tool was developed by Baas in 1992 to fill a gap in instrumentation to
measure self care from the MRM perspective (Baas, 1992; Baas et al., 1997). The tool (Appendix C) is a 35 item, Likert scale (rating from 0 which is none to 4 which indicates a great deal), self-reporting instrument that measures biophysical, psychological, cognitive, spiritual, and social needs. Using the MRM concepts of internal and external self care resources, the sub-scales measure what patient resources are needed by the internal and external self care resource inventory needs (SCRIN) and the internal and external self care resource inventory availability (SCRIA) (Baas et al., 1997). Each sub-scale is summed with a possible total 0 to 140 (Baas et al., 1997). At present this tool has only been utilized in the cardiac population (in both patients with HF and myocardial infarction) and has been used in a limited number of studies.

One of the first published studies using the SCRI surveyed patients with HF (n=38) regarding various dimensions of QOL. No differences were found in the resources needed or available, physical or emotional symptoms, total activity or health related QOL among the groups (Baas et al., 1997). Patients post myocardial infarction (MI) (n=84) were studied between three and six months post discharge regarding activity levels. There was no difference reported in activity level between those who participated in cardiac rehabilitation sessions and those who did not (Baas, 2004).

D. Modeling Role Modeling Theory

The Modeling Role Modeling (MRM) theory has been applied in many research studies dealing with the promotion and maintenance of an individual's health. The theory has been used in studies of chronic diseases and their impact on the daily lives of individuals.

The theory was first used to study hospitalized medical surgical patients (n=46)
(H. Erickson & Swain, 1982). Three classes of significantly different adaptive potential were identified: the alarm and impoverished states were considered as stress states, while the equilibrium state was considered a non-stress state. Although it was possible to distinguish stress from nonstress states, using only physiological parameters, psychological parameters were required to distinguish between the stress states of arousal or impoverishment. The study concluded that nursing interventions based on differentiated assessments of individuals adaptive reserve would be more effective than nursing interventions that do not take this into account.

COPD patients were studied (n=109) to test the MRM theory describing the relationships among psychosocial resources (strength of psychosocial attributes and basic need satisfaction), perceived stress, disease severity, and symptomatic experience (Leidy, 1990). The psychosocial attributes variable was a significant predictor of basic need satisfaction for both sexes. For males, basic need satisfaction and stress were significant predictors of symptomatic experience, while psychosocial attributes were not. For females, the psychosocial attributes variable was a significant predictor of symptomatic experience, while basic need satisfaction and stress were not.

In a study of diabetic patients (n=94) research was undertaken to assess spiritual well-being as an internal coping resource to buffer the effects of uncertainty on psychosocial adjustment (Landis, 1996). The findings suggest that spiritual well-being may be an important internal resource for persons forced to adjust to uncertainty related to long-term health problems such as diabetes mellitus.

In the cardiac population the MRM theory has been utilized in HF studies. Thirty-eight individuals undergoing different treatment regimens for HF were surveyed
regarding various dimensions of QOL (Baas et al., 1997). Results suggested that by using the MRM theory to develop nursing interventions it could enhance resources that could improve QOL in patients with HF.

An exploratory study was conducted with patients with HF (n=138) on the physical limitations imposed by a chronic illness (Baas, Beery, Fontana, & Wagoner, 1999). The participants reported an overall high level of satisfaction with their lives, despite the presence of a chronic disease. It was felt that by successfully dealing with past developmental challenges (as per the Erikson’s developmental stages), the individuals had residual positive energy to overcome their current health problems. The MRM theory was supported by the linkages between the mood states, life satisfaction, and developmental residual.
III. METHODS

This chapter will discuss the study design, setting, sample, instruments, and procedures for data collection and analysis.

A. Design

A descriptive design was used to determine quality of life (QOL) measurements when studying patients with heart failure (HF) in two different settings for medical management and follow-up. Using the settings as independent variables, QOL scores (dependent variables) were compared between HF subjects from the disease specific HF clinic and the HF subjects from physician run private practices.

B. Setting

Two settings were compared, a disease specific HF clinic and private physician practices. These settings were studied because they are the primary settings utilized for the medical management of the HF population.

Disease Specific Heart Failure Clinic

The HF clinic is a more recent approach to disease specific care. The HF clinic provides patient management utilizing a multidisciplinary approach (nursing, medicine, pharmacy, physical therapy, social work, nutrition) with a focus on the specific HF diagnosis. One HF clinic setting was studied in this research. The university based clinic had services and interventions that are delineated as they pertain to the needs of the patient with HF. As a designated clinic space within the university hospital, the clinic has a reception/sign-in area, patient/family waiting area, six exam rooms, adjacent areas for cardiac diagnostic testing (echocardiogram, cardiac stress testing, electrocardiograms), patient education space with written materials, and staff areas (conference room,
medical record area, office areas). Other medical clinics (pacemaker, anticoagulant, cardiac device, general cardiology) utilize the same areas, but are scheduled on different weekdays and times. Family/significant other involvement was encouraged through attendance at office visits and participation in educational opportunities.

Staff permanently assigned to the HF clinic include physicians, cardiologists, medical residents, cardiology fellows, registered nurses (RN’s), secretarial support, and cardiac technicians. Adjunct staff can be utilized from hospital resources which include pharmacists, dieticians, other physician specialists, social workers, physical therapists, and cardiac rehabilitation staff. Staff did not include advanced practice nurses. Designated cardiologists scheduled time slots throughout the week in which HF patient appointments are specifically scheduled. Patients with HF are routinely followed by a primary physician. Staff members (physicians, RN’s) are on call 24 hours a day to answer patient questions in order to provide early intervention, direction, and information. Patients and families/significant others are provided with phone numbers so they can access staff members at any time.

HF interventions available through the clinic include (a) pharmacologic therapy adjustment (experimental and non-experimental medications) that can be administered orally or intravenously, (b) behavior modification (smoking cessation, weight reduction, sleep enhancement, Dean Ornish program), (c) dietary intervention (weight reduction, sodium restriction, fluid management), (d) patient education (written materials, audiovisual teaching adjuncts, verbal discussion), (e) device therapies for dysrhythmia control (atrial ventricular synchronous pacemakers, biventricular pacemakers, automatic internal defibrillators), (f) cardiac devices (ventricular assist devices),
(g) surgical intervention (coronary artery bypass graft, valve replacement, ventricular mesh), (h) screening for cardiac transplant candidates, and (i) post cardiac transplant follow-up. All patient evaluation, screening, education, and interventions (with the exception of cardiac transplant) ordered in the HF clinic are provided through the services of the hospital.

**Physician Private Practice**

The private physician practice has been the mainstay for providing medical care to patients with chronic diseases. The private physician practices in this study involve two private physician offices that provided care to patients with a HF diagnosis. Both physicians are board certified cardiologists with intervention privileges in area hospitals. Located in a non-university setting, the physician practices also provided medical care for a wide range of patients with medical conditions.

The private physician practices are free standing physician offices. The offices have a reception/sign-in area, patient/family waiting area, from three to six exam rooms, cardiac diagnostic testing area (for electrocardiograms, cardiac stress testing, echocardiogram), and staff areas (medical record area, conference room, office space). Office staff included the physician, registered nurse, physician assistant, family nurse practitioner, and secretarial support.

HF interventions available at the office included (a) pharmacological therapies and adjustment (administered orally), (b) behavior modification, (c) patient education (written materials for patients/families regarding diet, smoking cessation, weight control), (d) screening for device implantation, (e) follow up checks for implanted devices, (f) cardiac surgery evaluation, and (g) other types of cardiovascular consults.
Referral to outside resources is possible and can be scheduled as additional appointments. The outside resources included cardiac rehabilitation, Dean Ornish program, smoking cessation, and weight reduction.

**Summary**

While there are many similarities between the two settings (staffing, cardiac testing accessibility, access to cardiologists, and patient education materials), there are several differences between the two study settings. The physician office has a family nurse practitioner on staff while the HF clinic is staffed with entry level registered nurses. Access to interventions varied between the two settings. The HF clinic has access to ventricular assist devices, ventricular mesh, transplant screening, and experimental drugs. The physician office can refer to an outside cardiologist for these interventions, which necessitates an additional appointment and travel.

Another difference is the diagnosis specific patient population. At the HF clinic, all patients have a diagnosis of HF and appointments are grouped on specific days. In the physician office all types of medical and cardiac diagnoses, including HF, can be scheduled on all office days which necessitates a patient to patient shift in practice standards and critical thinking.

Access to 24 hour health care personnel is different between the two treatment locations. At the HF clinic, 24 hour access for questions and concerns is available by both physicians and nurses. At the physician office 24 hour access is available for physician services only.

**C. Sample**

Convenience samples from the HF Clinic and private physician practice were
used. Inclusion criteria included:

1. Adult males and females ages 18 or older
2. Diagnosis of HF for greater than 6 months
3. Current enrollment in HF medical management (either a disease specific HF clinic or private physician practice)
4. Ability to read and write English in order to complete the questionnaire
5. Successful verbal validation of orientation to time, place, person

D. Instruments

The instruments used for data collection consisted of the Minnesota Living with Heart Failure Questionnaire (MLHFQ) to identify disease specific QOL, the Short Form 36v2 Health Survey (SF-36v2) to identify health related QOL, and the Baas Self Care Resource Inventory (SCRI) to identify the effect of self care resources on QOL. Each tool will be discussed from the standpoint of statistical assessment, patient populations, and reliability and validity.

*Minnesota Living with Heart Failure Questionnaire*

The MLHFQ is the most validated questionnaire for measuring QOL in the HF population at present (Cohen-Solal et al., 1994; Green et al., 2000; Guyatt, 1993). The 21 questions were identified from a comprehensive list of sickness-related dysfunctions from the Sickness Index Profile, a health related QOL tool (Rector, Kubo et al., 1987). The questions can be grouped into two categories with two sub-scores: physical dimension and emotional dimension. The physical dimension sub score is calculated with eight questions (question number 2, 3, 4, 5, 6, 7, 12, and 13). Questions contributing to this sub-score take into account activities such as walking, climbing
stairs, doing errands, working around the house, and engaging in recreational activities. The emotional dimension or psychological sub-score is calculated with five questions (question number 17, 18, 19, 20, and 21) and addresses sleeping problems, fatigue, and overall well-being. The psychological and emotional dimension sub-scores were identified by factor analysis and can be examined to further characterize the effect of HF on a patient’s life (Rector & Cohn, 1992). The MLHFQ has been translated into other languages and the resulting QOL scores tested for reliability and validity (Briancon et al., 1997).

The questionnaire was tested for internal consistency using a Cronbach Alpha statistic. In 1987 subjects with left ventricular dysfunction (n= 83) were surveyed using the MLHFQ (r= .80). The results suggested that this tool is a valid representation of patient impairment (Rector, Kubo et al., 1987). A weighted Kappa statistic of 0.84 was cited in this study for the two baseline self-assessments. Internal consistency was also evaluated using the Spearman Rank Order correlation coefficients between each item and the overall score. Item scores ranged from 0.35 to 0.86 (Rector, Kubo et al., 1987). A study of HF patients in a randomized, double-blind, placebo-controlled 3-month trial of pimobendan (n=198) was used to measure the reliability and validity of the MLHFQ (r= 0.93) (Rector & Cohn, 1992).

The MLHFQ was compared to the New York Heart Association (NYHA) Functional Classification System for HF (Dracup et al., 1992). This functional classification system has long been used to measure the physical ability of a patient to engage in daily activities in relation to the degree of symptoms. In the development of the MLHFQ, a comparison with the NYHA classification was done with 83 patients and
a correlation of .80, \( p<.01 \) was obtained. It has a correlation statistic of .80 with a global rating of .60 (Guyatt, 1993).

The MLHFQ was specifically designed for use in patients with HF and has been used extensively with this population over the past 10 years. As a disease specific tool that measures QOL for the HF population, it has been shown to be valid, reliable, and effective (al-Kaade & Hauptman, 2001; Green et al., 2000; Guyatt, 1993; Sheth et al., 2002; Shively et al., 1996). Permission was obtained from the University of Minnesota (Appendix D) to administer the tool to measure the perception of disease specific QOL in patients with HF for this research.

**Short Form-36v2 Health Survey**

The SF-36 Health Survey (SF-36) and SF-36v2 Health Survey are comprised of 36 items with 8 sub-scales: physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional, and mental health and consists of two major summary scales, physical and mental. The Medical Outcomes Trust provides standard instructions and/or computer programs for scoring the questionnaire (Ware et al., 2000). The scoring program “SF Health Outcomes Scoring Software - Basic Module” was used to calculate the sub-scores for this research (Saris-Baglama et al., 2004).

The tool can be self-administered, administered by computer, or administered by an interviewer in person or by telephone. For this research the tool was administered by an interviewer. Permission from QualityMetrics Incorporated (Appendix E) was obtained to administer the tool to measure health related QOL in patients with HF.

The SF-36v2 gained rapid acceptance as a measurement tool for health related QOL because of its brevity and favorable psychometric properties (Stadnyk et al.,
There is a large body of literature to support the reliability and construct validity of this tool using both internal consistency and test-retest methods (Vickrey et al., 1997). In a general population study (n=11,186) the tool had a correlation value of .68 (Stewart, Hays, & Ware, 1988). In 1993, a study of 9,332 working age adults showed an internal consistency with the 8 sub-scales as ranging from .76 (social functioning scale) to .90 (physical functioning) (Jenkinson et al., 1993). Internal consistency was rated as good. Baas et al (1997) studied chronic HF patients (n=38) using the SF-36 and measured the alpha coefficient as >.80 (with a range from .75 to .91), and stability as r=.79 with the eight sub-scales (Baas et al., 1997). Patients with HF were studied in the Studies of Left Ventricular Dysfunction (SOLVD) trial (n=308) and the study reported high values of internal consistency with a Chronbach's alpha of >.80 (Berry & McMurray, 1999).

Content validity has also been addressed. Symptoms and issues that address a specific condition are not included because the SF-36v2 is a generic measure. Studies to date addressed content and concurrent criterion, and construct and predictive validity. It is primarily designed for persons age 14 and older (S. J. Bennett et al., 1999; Chrispin, Scotton, Rogers, Lloyd, & Ridley, 1997; Mosconi, Cifani, Crispino, Fossati, & Apolone, 2000). Although it was developed in the United States, it has been translated into other languages (for example French, German, Swedish, and Dutch).

**Self Care Resource Inventory**

The Self Care Resource Inventory (SCRI) tool was developed by Baas in 1992 to fill a gap in instrumentation to measure self care from the Modeling Role Modeling (MRM) theory perspective. Internal consistency was assessed using Chronbach’s alpha
with results ranging from .79 to .91 in a study of 38 patients with HF (Baas et al., 1997). In a study of 84 post myocardial infarction subjects the SCRI was administered with a Chronbach alpha of .93 for the SCRIN and SCRIA scales (Baas, 2004). As a newer instrument, published information on this tool is limited.

The SCRI is utilized in this dissertation research to measure self care resources, (both internal and external) in patients with HF based on the Modeling Role Modeling (MRM) theory which is the conceptual framework for this study. Internal self care resources can be described as those factors which make the individual unique. This tool measures such factors as hope, control, self-efficacy, future orientation, and knowledge of the illness. External self care resources are those social factors which are separate from the individual. Measurement of such factors as social support, social network financial assistance, health care provider support, and help with driving/shopping were measured by the tool (Baas et al., 2001).

The Self Care Resource Inventory Needs (SCRIN) sub-scale score is the sum measure of the amount of resources the individual perceives to be needed for recovery. The internal needs sub-score is calculated with 12 questions (question numbers 3, 6, 7, 8, 9, 13, 15, 24, 26 29, 30, and 31) and the external needs sub-score with seven questions (question numbers 4, 11, 16, 18, 21, 32, and 35). The Self Care Resource Inventory Availability (SCRIA) sub-scale score is the sum measure of the perceived amount of resources that the individual has accessible to help cope with the stressors during recovery (Baas, 1992). The internal availability sub-score is calculated with 13 questions (question numbers 3, 6, 7, 8, 10, 12, 17, 19, 21, 23, 26, 29, and 30) and the external availability sub-score is calculated with 11 questions (question numbers 4, 5,
11, 15, 16, 18, 20, 32, 34, and 35). Permission from Dr. Linda Baas (Appendix F) was obtained to administer this tool to measure self care resources.

**Patient Demographic Questionnaire**

A list of demographic questions about medical history focusing on HF diagnosis and treatment was completed by the participants (Appendix G). Subject information did not include any specific patient identifiers (name, address, medical record number, social security number). Content validity for the demographic questionnaire was obtained through completion of a pilot study of the study questionnaires.

A pilot study was conducted to review the questionnaire presentation, to review the demographic questions, and to obtain time requirements for the study participants. A convenience sample of 14 subjects was obtained to review the questionnaires. Subjects were approached from each decade of life from age 40 to 70. Instructions requesting written input was included in a letter to the participants (Appendix H). The ages of participants in the pilot study ranged from 48 to 79 with a mean age of 60.2. There were at least three subjects from each decade of life.

The participants were asked to record their start and finish time in completing the questionnaires. The time needed to complete the questionnaires ranged from 18 minutes to 67 minutes with a mean of 37 minutes. Questions about the format of the questionnaires were asked. The participants were asked if they were able to read the size of print (font) without problems. The size of print (12 point) was deemed adequate by 14 (93%) of the 15 participants. No changes in the overall print size were made.

One of the pilot study questions involved the shading of every other question to improve readability. The alternate questions on the MLHFQ and SCRI were shaded in
the pilot study while the SF-36v2 questions were not. The alternate question shading was deemed helpful by 10 (71%) of the 14 participants. The SF-36v2 questionnaire was subsequently revised to include the shading of alternate questions. The pilot study questionnaires were printed on white paper and 14 (100%) of the respondents deemed this adequate. The participants were asked if having the questionnaires printed front and back made it harder to complete the questions. Eleven or 79% responded that it did not make completing the questionnaires more difficult. The questionnaires in the research study were printed front and back.

The content of the demographic questionnaire was evaluated by the participants. It was suggested that for clarification the questions should be numbered. If the respondent had a concern about a question, the number would make the question easier to identify. Question numbers were added to the patient demographic questionnaire. Several comments were noted regarding the medical condition listing (question number 10). Some of the diseases listed were abbreviated and some had an explanation while others did not. The disease list was edited and made consistent with both the abbreviation and explanation. Input was received regarding the list of treatments the patient was currently receiving (question number 18). A question regarding which HF treatments or category of drugs were part of the treatment regime was found to be confusing for respondents. Respondents placed multiple question marks in drug category options and questions arose regarding the disease abbreviations. The drug category question was deleted and a decision was made that the researcher would evaluate the treatment and medication list and determine the categories prescribed for the subjects.
Comments were requested pertaining to the presentation of the questionnaires. Five of the respondents provided input on the format of the pages which was incorporated into the final questionnaire draft. The pilot study participants felt the questions were very clearly stated on the MLHFQ. They also commented that having the 0 to 5 scale with definitions listed was beneficial. The font size of the SCRI instructions (10 point) was reported to be too small. The font was enlarged to a 12 point font to make the size consistent on all four of the questionnaires. The SF-36v2 questionnaire also received several format comments. Three of the participants suggested that the major questions should be bolded for ease of reading. All of the above suggestions were incorporated into the revised questionnaire packet.

**Medical Chart Questionnaire**

Medical information was obtained from study participants and validated by the researcher through review of the subject’s medical record (Appendix I). This included medication history, medical history, and number of office/clinic visits. Additional information obtained from the medical record included ejection fraction, type of HF (systolic, diastolic, combined), echocardiogram results, cardiac catherization results, NYHA classification, presence of left bundle branch block, date first seen in office/clinic, failed treatments, insurance agency, and pacemaker information. Validation of patient information on the demographic questionnaire was obtained for the patient medical history, medication history, and number of physician/clinic visits or calls.

**E. Sample Size**

Sample size for this research study was determined by review of previous studies using the questionnaires, review of the literature, and calculation using a power
analysis formula. Review of the literature showed a wide variety of sample sizes in studies using the MLHFQ from 15 (Rector et al., 1996) to 322 (Massie et al., 1993). Studies utilizing the SF-36v2 included sample sizes ranging from 61 (Jenkinson, Stradling et al., 1997) to 216 subjects (Riedinger et al., 2002). With such a wide variety of samples sizes in the literature, a power analysis was conducted.

Sample size was calculated using two different methods. A sample-size estimation formula for testing for the mean of a normal distribution (two sided alternative) formula (Rosner, 1995) was calculated using prior HF studies (Appendix J). Using an alpha of .05 with a power of .80, initially a sample size estimation of 150 with 75 subjects from the HF clinic and 75 subjects from the private physician offices was calculated. A second method was conducted using an on-line computer calculator from DSS Research (Researcher’s Toolkit, 2005) to calculate sample size. Using an alpha of .05 and a beta of .50, a sample size of 56 (28 in each group) was obtained. It was determined to use a total sample size of 60 (30 in each group) for this research.

Using the inclusion criteria, a convenience sample was obtained. The patient information brochure (Appendix K) was placed in the HF clinic and physician offices prior to the beginning of data collection to inform patients of the study. Each patient received a copy of the patient brochure at the time of data collection.

**F. Protection of Rights of Human Subjects**

Prior to data collection, approval was obtained from the Duquesne University Institutional Review Board (IRB) Committee (Appendix L). On-line education regarding the protection of human subjects was completed (Appendix M). Additional approval was obtained from West Penn Allegheny Health System Institutional Review Board.
Committee for the HF clinic site data collection (Appendix N). Additional mandatory education regarding the protection of human subjects was required and completed for IRB approval (Appendix O). The data collection sites for the private physician offices felt the research had been adequately reviewed by the two IRB offices and did not require additional approval.

To maintain confidentiality, each subject was identified by a study identification number. The results of the study were reported as group information only, and no subjects were identified. The data is kept in a locked file at the researcher's home. The data (including consent forms) will be maintained in a locked file by the researcher until the study and dissemination of the findings is complete.

The subjects reported no discomfort or risks associated with this research. The only inconvenience was the 30 to 40 minutes of time required to complete the questionnaires. There was no cost to the subjects participating in this research.

There was no direct benefit to the subjects for participating in this research. One indirect benefit was the gathering of quality of life information that could help medical professionals improve HF care in the future.

G. Procedure for Obtaining Data

1. A flyer (Appendix K) was distributed to the HF clinics and private physician offices prior to the data collection phase to provide study overview information to patients about the research study. The flyer was left in waiting areas as preliminary information for patients in the event they would like to participate.

2. Patients were informed in writing that data collection would take place immediately prior to or after their scheduled visit or they could set up a specific time for
data collection. A phone number of the researcher was provided for any questions or to arrange a meeting for scheduled data collection.

3. Potential subjects who met the inclusion criteria were identified from the appointment schedule. To facilitate the identification of patients already enrolled in the study, a list of enrolled patients at the data collection site was maintained. This assisted the clinic/office staff in easily identifying those patients who were potential study subjects and to identify those patients who had already enrolled and completed the study. The list was shredded on the last day of data collection.

4. Patients were screened for orientation to time, place, and person by the office staff. This was done through verbal questions to the subject during their clinic/office visit. They were asked their name, where the interview is taking place, the date (day, month, year), and name of the current president.

5. If orientation was not verified, no further questions were asked and the subject was thanked for their participation. No subjects were excluded from participating in the study due to orientation.

6. If the questions were answered correctly the staff of the clinic/office then asked if they would like to talk to the researcher about the study. If they chose not to participate, nothing more was done. If they had additional questions about the study, the questions were answered by the researcher.

7. If they chose to participate in the study, the participants were escorted to a designated data collection area (private conference room in physician offices, room adjacent to the waiting area at the HF clinic).

8. The informed consent form (Appendix P) was then reviewed with the
prospective subject. The consent was read by or read to each prospective subject. There was one subject who declined to participate in the study at this point because review of the medical record was included in the consent. This subject was not included in data collection. All subjects were given an opportunity to ask questions and have their questions answered. All other subjects who were identified agreed to participate. Several subjects (n=10) could not complete the questionnaire at their appointment time due to other commitments, but indicated they would like to participate in the study. A date and time was agreed upon for the researcher to contact the subject by phone at a later time. The researcher made the follow-up phone call and the questionnaires were completed via phone interview.

9. The researcher asked if there were additional questions the subject had about the research process and questions were answered.

10. The subject signed three copies of the consent. One copy of the consent was given to the subject. The second copy was kept by the researcher. The third copy was placed in the patient’s medical record. The consent procedure was completed prior to the collection of any data. The copy on the medical record was also used to keep track of patients who had previously participated in the study.

11. Once informed consent was obtained, the subject was assigned a study identification number which would identify the subject and all collected data.

12. The researcher verbally reviewed the instructions for completing the questionnaires (the patient demographic questionnaire, MLHHQ, SF-36v2, and SCRI) and answered any questions that arose at that time. For the first subject, the questionnaires were read by the subject and results recorded by the participant. The
first subject had multiple questions about the instructions and questionnaires and all questions were answered by the researcher. All subsequent questionnaires were read to the subjects in interview style and responses recorded by the researcher. This allowed the researcher to develop one on one interaction with the subjects which made the process more friendly and conversational. The researcher conducted all 60 questionnaire completion sessions, therefore the data collection environment was consistent throughout.

13. The researcher answered any questions that arose during the interview process.

14. When the questionnaires were completed they were reviewed for completeness and any blank questions completed.

15. The subject was asked if they would like a summary of the study results. If the subject answered yes (n=46), an index card was completed with their name and home address. There was no reference to the subjects study identification number on the postcard in order to maintain confidentiality. The summary will be mailed out at the completion of the study and will include a summary of the study findings and a thank you to the subjects for participation.

16. The researcher reviewed the subject’s medical record and completed the chart review data collection tool based on medical chart information and was completed following the questionnaire interviews. Additional information regarding the subject’s medical condition was gathered which included: ejection fraction, cardiac catheterization results, echocardiogram results, NYHA classification, type of HF, number of visits to clinic/office in past 12 months, failed treatments, and referral history. Information
H. Data Analysis

Quantitative analysis of the data obtained was conducted. Quantitative analysis included the use of independent sample t tests to compare the questionnaire QOL scores, SCRI score, and all sub-scores. Descriptive analysis was conducted with the patient demographic questionnaire information. The computer program SPSS version 13.0 was used to record and analyze the research data.

Using the Patient Demographic Questionnaire, results were compared between two groups (a disease specific HF clinic and physician run private practices) and the total sample using mean, range, standard deviation, and independent sample t-test statistics. Health related demographic information was compared in the same manner using frequency, percentage, and Pearson Chi-Square statistics.

Research Questions

Research question 1: Does health related QOL differ among patients with HF who are receiving medical outpatient care in two different clinical settings: a multi-disciplinary (nursing, medicine, pharmacy, physical therapy, social work, nutrition) disease specific HF clinic and physician run private practices as measured by the Medical Outcomes Study SF-36v2. The SF-36v2 was scored using the Quality Metric scoring software “SF Health Outcomes Scoring Software - Basic Module” (Saris-Baglama, 2004) to calculate the 8 sub-scales and the Physical Component Summary Scale (PCS) and the Mental Component Summary Scale (MCS). The PCS and MCS and the 8 sub-scales were compared using an independent 2 sample t-tests to
determine $p$ values.

Research question 2: Does disease specific QOL differ among patients with HF who are receiving medical outpatient care in two different clinical settings: a multi-disciplinary (nursing, medicine, pharmacy, physical therapy, social work, nutrition) disease specific HF clinic and physician run private practices as measured by the Minnesota Living with Heart Failure Questionnaire (MLHFQ). The total score of the questionnaires, physical sub-score, and emotional sub-score was compared between the groups. The MLHFQ sub-scores were obtained using the scoring guidelines and SPSS software.

Research question 3: Are there differences in self care resources of patients with HF who are receiving medical outpatient care in two different clinical settings: a multi-disciplinary (nursing, medicine, pharmacy, physical therapy, social work, nutrition) disease specific HF clinic and physician run private practices as measured by the SCRI for the sub-scales of the SCRIN (internal and external) and SCRIA (internal and external). The two settings were compared using independent t tests for $p$ values. SCRI sub-scales scores were obtained using SPSS syntax calculations developed by Dr. Linda Baas.
IV. Results

This chapter will report all demographic results of the study. It will also present the results from the three research questions.

A. Demographics

Results of the Patient Demographic Questionnaire are presented in Tables 2, 3, 4, and 5. Results were compared between two groups (a multi-disciplinary disease specific HF clinic and two physician run private practices) using mean, range, standard deviation, and independent t-test or Chi-Square. A summary of all study subjects is included.

General demographic information is compared in the same manner in Tables 2 and 3. Subject age in the total sample ranged from 24 to 85 years of age with a mean of 64.7. The mean age of the subjects in the HF clinic group was lower ($p<.001$), at 56.3 (range 24-79), than the physician practice group at 73 (range 41-85). In the total sample 41 (68.3%) of subjects were male and 19 (31.7%) were female. There was not a significant gender difference ($p = .405$) between the two groups. The HF clinic subjects were 73.3% male (n = 22) and 26.7% female (n = 8) and the physician practice subjects were 63.3% male (n = 19) and 36.7% (n = 11) female.

Race/ethnicity was surveyed. In the total sample the majority of subjects were Caucasian. Fifty-three subjects (68.3%) were Caucasian and seven (11.7%) were African American. There was a significant difference between the two groups ($p=.044$). The HF clinic group had a greater number of African American subjects at 6 (20%) than the physician practice group at 1 (3%).
Table 2: Health Related Information of Heart Failure Subjects

<table>
<thead>
<tr>
<th></th>
<th>Multi-Disciplinary Disease Management HF Clinic n=30</th>
<th>Physician Run Private Practices n=30</th>
<th>Total Subjects n=60</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>Range</td>
<td>SD</td>
</tr>
<tr>
<td>Age (years)</td>
<td>56.3</td>
<td>24-79</td>
<td>15.3</td>
</tr>
<tr>
<td>Length of Heart Failure Diagnosis</td>
<td>7.9</td>
<td>1-39</td>
<td>8.0</td>
</tr>
<tr>
<td># Hospital visits in past 12 months</td>
<td>2.0</td>
<td>0-16</td>
<td>3.3</td>
</tr>
<tr>
<td># ED$^1$ visits 12 months</td>
<td>2.4</td>
<td>0-40</td>
<td>7.4</td>
</tr>
<tr>
<td># Physician Calls within 12 months</td>
<td>2.8</td>
<td>0-40</td>
<td>8.0</td>
</tr>
<tr>
<td>Physician/ Clinic visits 12 months</td>
<td>5.5</td>
<td>1-25</td>
<td>4.7</td>
</tr>
<tr>
<td>Total # of Physicians seen</td>
<td>3.5</td>
<td>1-6</td>
<td>1.2</td>
</tr>
<tr>
<td>Miles to clinic/ physician visit</td>
<td>37.9</td>
<td>2-150</td>
<td>36.3</td>
</tr>
<tr>
<td>Initial Ejection Fraction (%)</td>
<td>27.2</td>
<td>9-60</td>
<td>15.1</td>
</tr>
<tr>
<td>Current Ejection Fraction (%)</td>
<td>23.6</td>
<td>7-50</td>
<td>10.4</td>
</tr>
</tbody>
</table>

$^1$ ED - Emergency Department
Table 3: General Demographic Information of Subjects with Heart Failure Subjects

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Multi-Disciplinary Disease Management HF Clinic n=30</th>
<th>Physician Run Private Practices n=30</th>
<th>Total Subjects n=60</th>
<th>Chi-Square</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number (%)</td>
<td>Number (%)</td>
<td>Number (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td></td>
<td>0.698</td>
<td>.405</td>
</tr>
<tr>
<td>Male</td>
<td>22 (73.3)</td>
<td>19 (63.3)</td>
<td>41 (68.3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>8 (26.7)</td>
<td>11 (36.7)</td>
<td>19 (31.7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td></td>
<td></td>
<td></td>
<td>15.33</td>
<td>.032</td>
</tr>
<tr>
<td>&lt; 8 years high school</td>
<td>0</td>
<td>1 (3.3)</td>
<td>1 (1.7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 12 years high school</td>
<td>3 (10)</td>
<td>10 (33.3)</td>
<td>13 (21.7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Graduated high school</td>
<td>13 (43.3)</td>
<td>10 (33.3)</td>
<td>23 (38.3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vocational School</td>
<td>5 (16.7)</td>
<td>3 (10)</td>
<td>8 (13.3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Graduated 2 years College</td>
<td>4 (13.3)</td>
<td>2 (6.7)</td>
<td>6 (10)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Graduated 4 years College</td>
<td>5 (13.7)</td>
<td>0</td>
<td>5 (8.3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Graduate School</td>
<td>0</td>
<td>2 (6.7)</td>
<td>2 (3.3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Post-graduate studies</td>
<td>0</td>
<td>2 (6.7)</td>
<td>2 (3.3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Race/Ethnicity</strong></td>
<td></td>
<td></td>
<td></td>
<td>4.04</td>
<td>.044</td>
</tr>
<tr>
<td>African American</td>
<td>6 (20)</td>
<td>1 (3.3)</td>
<td>7 (11.7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>24 (80)</td>
<td>29 (96.7)</td>
<td>53 (88.3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Marital Status</strong></td>
<td></td>
<td></td>
<td></td>
<td>12.63</td>
<td>.013</td>
</tr>
<tr>
<td>Single</td>
<td>8 (26.7)</td>
<td>2 (6.7)</td>
<td>10 (16.7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>19 (63.3)</td>
<td>18 (60)</td>
<td>37 (61.7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Widow/Widower</td>
<td>0</td>
<td>8 (26.6)</td>
<td>8 (13.3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Divorced</td>
<td>2 (6.7)</td>
<td>2 (6.7)</td>
<td>4 (6.7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Separated</td>
<td>1 (3.3)</td>
<td>0</td>
<td>1 (1.7)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
There were no Asian or Hispanic subjects in the sample.

Marital status of the subjects was surveyed. In the total sample the majority or 37 subjects (61.7%) were married and 10 (16.7%) were single. There was a significant difference between the two groups ($p = .013$). The HF clinic group had eight (27%) single subjects and 19 (63%) married subjects. The physician practice group had two (6.7%) single subjects and 18 (60%) married subjects. Eight subjects in the physician practice group were widow/widowers (13.3%). Four subjects in the total sample were divorced (6.7%) with two in each of the two groups. Seventeen percent of both groups (five subjects each) reported having zero children. The HF clinic subjects had a range of one to four children and the physician practice subjects had a range of one to six. There was no significant difference between the two groups related to the number of children ($p = .317$).

Years of education were varied in the sample and there was a significant difference between the two groups ($p = .032$). Twenty-three (38.3%) of the total sample subjects completed their high school education while 13 (21.7%) completed less than 12 years of schooling. Twenty-three of the subjects completed some type of education post high school. Twenty-seven (90%) subjects in the HF clinic group completed high school or post high school education in contrast to 19 (63%) in the physician practice group.

The overall number of miles subjects in the total sample traveled to the clinic/physician appointment ranged from one to 150 miles with a mean of 28.9 miles. There was a significant difference in mileage between the two groups ($p = .018$). The
HF clinic subjects traveled a mean of 37.9 miles with a range of two to 150 miles. The physician practice subjects traveled a mean of 20.1 miles with a range of one to 72 miles.

All subjects in the total sample had a diagnosis of HF for a mean of 9.4 years with a range of one to 40 years. The HF clinic subjects had a HF diagnosis for a mean of eight years and the physician practice subjects for a mean of 10.9 years. There was no significant difference ($p = .197$) between the two groups.

Initial ejection fraction for the total subjects was 35.9% with range of 9 to 80%. Normal ejection fraction (EF) is 50 - 70% (Burkhoff & Weisfeldt, 2000). There was a highly significant difference ($p=<.001$) between the two groups. The HF clinic group had an initial EF mean of 27.2% and the physician office group had an initial EF of 44.5%. The most current EF mean for all subjects was 32.6% with a range of 7 - 80%. The HF clinic group had a current EF mean of 23.6% (range of 7 - 50%) and the physician practice subjects had a mean of 41.7% (range of 25-80%). There was a highly significant difference ($p=<.001$) between the two groups.

Patients with HF are on a number of medications to improve their health status. In this study subjects were asked to list their medication regime and this was compared to the medication list in the medical record. The HF clinic subjects had a medication list range of three to 14 drugs while the physician practice subjects had a range of four to 18 drugs. The mean number of medications recorded by patients in the total sample compared to those in the medical record differed by less than one medication. The range of differences in the number of medications included on both lists ranged from
zero to six medications.

The number of hospital visits related to problems associated with HF in the past 12 months had an overall mean of 1.2 with the physician office subjects at 0.4 visits and the HF clinic subjects at two. There was a significant difference between the two groups ($p = .017$). The number of physician/clinic visits within the past 12 months had a mean of 4.3 with the physician office group at three and the HF clinic group at 5.5. There was a significant difference between the two groups ($p = .005$).

In Table 4 the standard medicine regime of HF subjects is shown. The frequency of failed medications are included. Failed medications are defined as those medicines that patients have been prescribed, but have been discontinued due to side effects, adverse reactions, or intolerance.

Beta blockers were prescribed in 83.3% of total subjects and there was not a significant difference between the two groups ($p = .757$). The HF clinic group had beta blockers prescribed in 86.7% of subjects and in the physician office group in 80% of subjects.

Diuretics were prescribed in 78.3% of the total subjects (80% in the physician practice group and 76.7% in the HF clinic group). There was not a significant difference between the two groups ($p = .921$). Potassium sparing diuretics were prescribed in 31.7% of all subjects. In the physician office group 10% were prescribed these diuretics and 53.3% in the HF clinic group. There was a significant difference between the two groups ($p = .001$). Eleven percent of all subjects failed on this therapy.
Table 4: Utilization of Standard Heart Failure Medications

<table>
<thead>
<tr>
<th>Medication</th>
<th>Multi-Disciplinary Disease Management HF Clinic n=30</th>
<th>Physician Run Private Practices n=30</th>
<th>Total Subjects n=60</th>
<th>Chi-square</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beta Blocker</td>
<td>Yes (%) 26 (86.7) Failed (%) 1 (3.3)</td>
<td>Yes (%) 24 (80) Failed (%) 2 (6.7)</td>
<td>Yes (%) 50 (83.3) Failed (%) 3 (5)</td>
<td>.056</td>
<td>.757</td>
</tr>
<tr>
<td>Diuretic</td>
<td>Yes (%) 23 (76.7) Failed (%) 4 (13.3)</td>
<td>Yes (%) 24 (80) Failed (%) 3 (10)</td>
<td>Yes (%) 47 (78.3) Failed (%) 7 (11.7)</td>
<td>.164</td>
<td>.921</td>
</tr>
<tr>
<td>Potassium Sparing Diuretic</td>
<td>Yes (%) 16 (53.3) Failed (%) 4 (13.3)</td>
<td>Yes (%) 3 (10) Failed (%) 2 (6.7)</td>
<td>Yes (%) 19 (31.7) Failed (%) 6 (10)</td>
<td>15.9</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Aspirin</td>
<td>Yes (%) 16 (53.3) Failed (%) 0</td>
<td>Yes (%) 24 (80) Failed (%) 1 (3.3)</td>
<td>Yes (%) 40 (66.7) Failed (%) 1 (1.7)</td>
<td>6.86</td>
<td>.032</td>
</tr>
<tr>
<td>Angiotensin Receptor Blockers (ARB)</td>
<td>Yes (%) 21 (70) Failed (%) 5 (16.7)</td>
<td>Yes (%) 10 (33.3) Failed (%) 2 (6.7)</td>
<td>Yes (%) 31 (51.7) Failed (%) 7 (11.7)</td>
<td>14.1</td>
<td>.001</td>
</tr>
<tr>
<td>Angiotensin Converting Enzyme Inhibitor (ACEI)</td>
<td>Yes (%) 3 (10) Failed (%) 7 (23.3)</td>
<td>Yes (%) 12 (40) Failed (%) 6 (20)</td>
<td>Yes (%) 15 (25) Failed (%) 13 (21.7)</td>
<td>7.48</td>
<td>.024</td>
</tr>
</tbody>
</table>

Aspirin was prescribed 66.7% of the time in subjects in the total sample with 10% failing on the therapy. Aspirin was prescribed in 80% of the subjects in the physician office group and 53.3% in the HF clinic group. There was a significant difference between the two groups ($p = 0.32$).

The initiation of angiotensin receptor blockers (ARB) occurred in 51.7% of HF subjects. There was a significant difference ($p = .001$) between the two groups. The HF clinic group was prescribed ARB's 76.7% of the time while the physician practice group prescription rate was 33.3%. Approximately 12% of subjects failed on this therapy. Angiotensin converting enzyme (ACE) inhibitors were prescribed in 25% of all study
subjects. In the HF clinic group three (10%) subjects were currently prescribed an ARB and in the physician practice group 12 (40%) were currently receiving an ARB. There is a significant difference ($p=.024$) between the two groups. Twenty-two percent of the total subjects failed on ARB therapy.

In summary, HF clinic patients were prescribed a regimen of medications that follow the American College of Cardiology and the American Heart Association practice guidelines with a higher percentage of use of beta blockers, potassium sparing diuretics, and ARB’s. The physician office group had a higher percentage of prescribed aspirin and ACE inhibitor therapy.

Co-morbid conditions in the HF subjects (Table 5) showed some significant differences between the two groups. Cardiomyopathy was found in 86.6% of the HF clinic subjects and 30% of the physician practice subjects and was significantly different ($p=<.001$) between the two groups. There was with an overall cardiomyopathy rate of 58.3% in total subjects. A listed diagnosis of angina was found in 38.3% of the total subjects. The HF clinic group had an incidence of 6.7% and the physician practice an incidence of 70% and there was a significant difference ($p= <.001$) between the two groups. Coronary artery disease was found in 50% of the HF clinic group and 93.3% in the physician practice group ($p= <.001$) and the differences between the two groups was highly significant. Implanted cardiac defibrillators were found in 66.7% of the HF clinic group and 16.7% in the physician practice group and the differences between the two groups was significant ($p=<.001$).
Table 5: Co-morbidity Health Related Information in Subjects with Heart Failure

<table>
<thead>
<tr>
<th>Co-Morbidity</th>
<th>Multi-Disciplinary Disease Management HF Clinic n=30</th>
<th>Physician Run Private Practices n=30</th>
<th>Total Subjects n=60</th>
<th>Chi-square</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic Obstructive Pulmonary Disease</td>
<td>6 (20)</td>
<td>7 (23.3)</td>
<td>13 (21.7)</td>
<td>0.10</td>
<td>.754</td>
</tr>
<tr>
<td>Diabetes</td>
<td>17 (56.7)</td>
<td>15 (50)</td>
<td>32 (53.3)</td>
<td>0.27</td>
<td>.605</td>
</tr>
<tr>
<td>Cerebral Vascular Accident</td>
<td>2 (6.7)</td>
<td>1 (3.3)</td>
<td>3 (5)</td>
<td>0.35</td>
<td>.554</td>
</tr>
<tr>
<td>Hypertension</td>
<td>25 (83.3)</td>
<td>25 (83.3)</td>
<td>50 (83.3)</td>
<td>&lt;.001</td>
<td>1.0</td>
</tr>
<tr>
<td>Cardiomyopathy</td>
<td>26 (86.7)</td>
<td>9 (30)</td>
<td>35 (58.3)</td>
<td>19.82</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Myocardial Infarction/Acute Coronary Syndrome</td>
<td>11 (36.7)</td>
<td>20 (66.7)</td>
<td>31 (51.7)</td>
<td>5.41</td>
<td>.02</td>
</tr>
<tr>
<td>Angina</td>
<td>2 (6.7)</td>
<td>21 (70)</td>
<td>23 (38.3)</td>
<td>25.45</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Coronary Artery Disease</td>
<td>15 (50)</td>
<td>28 (93.3)</td>
<td>43 (71.7)</td>
<td>13.87</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Cardiac Stent</td>
<td>6 (20)</td>
<td>3 (10)</td>
<td>9 (15)</td>
<td>1.18</td>
<td>.278</td>
</tr>
<tr>
<td>Coronary Artery Bypass Graph Surgery</td>
<td>7 (23.3)</td>
<td>16 (53.3)</td>
<td>23 (38.3)</td>
<td>5.71</td>
<td>.017</td>
</tr>
<tr>
<td>Dysrhythmias</td>
<td>16 (53.3)</td>
<td>23 (76.7)</td>
<td>39 (65)</td>
<td>3.59</td>
<td>.058</td>
</tr>
<tr>
<td>Atrial Fibrillation/Flutter</td>
<td>13 (43.3)</td>
<td>11 (36.7)</td>
<td>24 (40)</td>
<td>0.28</td>
<td>.598</td>
</tr>
<tr>
<td>Valvular Disease</td>
<td>18 (60)</td>
<td>18 (60)</td>
<td>36 (60)</td>
<td>&lt;.001</td>
<td>1.0</td>
</tr>
<tr>
<td>Congenital Heart</td>
<td>0</td>
<td>1 (3.3)</td>
<td>1 (1.7)</td>
<td>1.02</td>
<td>.313</td>
</tr>
<tr>
<td>Rheumatic Heart</td>
<td>1 (3.3)</td>
<td>2 (6.7)</td>
<td>3 (5)</td>
<td>0.35</td>
<td>.554</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>19 (63.3)</td>
<td>23 (76.7)</td>
<td>42 (70)</td>
<td>1.27</td>
<td>.260</td>
</tr>
<tr>
<td>Sleep Disorder</td>
<td>4 (13.3)</td>
<td>6 (20)</td>
<td>10 (16.7)</td>
<td>0.48</td>
<td>4.88</td>
</tr>
<tr>
<td>Pacemaker</td>
<td>9 (30)</td>
<td>6 (20)</td>
<td>15 (25)</td>
<td>1.96</td>
<td>.375</td>
</tr>
<tr>
<td>Internal Cardiac Debibrillator</td>
<td>20 (66.7)</td>
<td>5 (16.7)</td>
<td>25 (41.7)</td>
<td>15.45</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>
Coronary artery bypass graft (CABG) surgery was present in 23.3% of the HF clinic group and 53.3% of the physician practice group ($p = .017$). The overall CABG surgery rate in the total subjects was 38.3%. History of a myocardial infarction (MI) or acute coronary syndrome was 51.7% in the overall group. Approximately 37% of subjects in the HF clinic group had an incidence of MI as part of their history while 66.7% of subjects in the physician office group had a MI documented ($p = .02$).

Dysrhythmias were listed as a co-morbidity in 39 (65%) of total HF subjects. In the HF clinic group 16 (53%) subjects were identified with dysrhythmias, while in the physician practice group 23 (77%) of subjects listed dysrhythmias as a medical problem. The difference between the groups did not reach significance ($p = .058$). The presence of atrial fibrillation or flutter as a dysrhythmia was queried. The HF clinic group had 13 (43%) subjects with this diagnosis and the physician practice group had 11 (37%). There was no significant difference between the two groups ($p = .598$).

Information regarding documentation of the New York Heart Association (NYHA) classification for patients with HF was reviewed. NYHA classification was documented on 30 (50%) of the total sample of medical records (n=60). Two records (7%) in the HF clinic group (n=30) and 28 records (93.3%) in the physician practice group (n=30) had NYHA classification documented. The HF clinic group (n= 28) had 12 subjects (40%) with a Class I (least severe classification) designation, seven subjects (23.3%) had a Class II designation, three subjects (10%) Class III designation, and 6 (20%) subjects were designated Class IV (most severe classification). The physician practice group (n=2) had zero Class I and II, one (3.3%) Class III, and 1 (3.3%) Class IV patient.
Documentation of the type of HF (systolic, diastolic, combined) was reviewed. This information was documented on 21 (35%) out of the total medical records (n=60) reviewed which included 16 (53.3%) of the HF clinic group records and 5 (16.6%) of the physician practice group records. The HF clinic group had 12 (40%) subjects with systolic HF, two (6.7%) subjects with diastolic HF, and two (6.7%) subjects had a combination of the two types. The physician practice group totaled four (13.3%) subjects with systolic HF and one (3.3%) subject with diastolic HF.

In summary, there were significant differences in demographics between the two treatment locations. The HF clinic subject group was younger, single, more highly educated, traveled longer distances to their appointment, and have had HF less number of years. The HF clinic group had poorer heart function at initiation of treatment and with treatment, less incidence of dysrhythmias but more device treatment for the dysrhythmias identified. The HF clinic group had a higher incidence of cardiomyopathy as a cause for HF while the physician office group had a higher incidence of coronary artery disease and myocardial infarction.

B. Reliability of Study Tools

Reliability statistics for this study sample were completed on two of the three tools used in this study. Reliability, the extent to which measures give consistent or accurate results, was calculated using SPSS software. The sub-scale scores of the Minnesota Living with Heart Failure Questionnaire (MLHFQ) and the Self Care Resource Inventory (SCRI) tools used in this study had acceptable Cronbach Alpha’s that demonstrated internal consistency and reliability (Table 6).
Table 6: Cronbach Alpha Statistics for the Study Population

<table>
<thead>
<tr>
<th>Questionnaire Sub-Scales</th>
<th>Number of Items</th>
<th>Cronbach Alpha</th>
</tr>
</thead>
<tbody>
<tr>
<td>MLHFQ Physical Scale</td>
<td>8</td>
<td>.88</td>
</tr>
<tr>
<td>MLHFQ Emotional Scale</td>
<td>5</td>
<td>.77</td>
</tr>
<tr>
<td>SCRI Internal</td>
<td>12</td>
<td>.91</td>
</tr>
<tr>
<td>SCRI Internal</td>
<td>12</td>
<td>.89</td>
</tr>
<tr>
<td>SCRIA External</td>
<td>7</td>
<td>.83</td>
</tr>
<tr>
<td>SCRIA Internal</td>
<td>11</td>
<td>.86</td>
</tr>
</tbody>
</table>

1 MLHFQ - Minnesota Living with Heart Failure Questionnaire
2 SCRI - Self Care Resource Inventory Needs
3 SCRIA - Self Care Resource Inventory Availability

The MLHFQ physical sub-scale had one item, question number 6, “Making your working to earn a living difficult” with an item total correlation of less than .35. Because of the age of the study subjects this question was not as applicable. It was included as this tool has been used extensively in the HF population and has shown good overall reliability in other published studies. The MLHFQ emotional sub-scale item total correlations were all greater than .35.

In three of the four sub-scales of the SCRI there was one question with an item total correlation below the .35 value. The Self Care Resource Inventory Needs (SCRI) internal sub-scale and the Self Care Resource Inventory Availability (SCRIA) internal sub-scale had the same question that scored less than .35 for the item total correlation.
This was identified as question number 3, “Information about my illness and treatment”. Despite the low level of internal consistency on this one item, the question was retained. One possible reason for the low correlation was that the subjects felt they had received enough information. In the SCRIA external sub-scale question number 20, “Assistance so I can do my work or usual activities”, also had an item total correlation below .35. In consultation with the questionnaire author, the question was retained because it did not strongly influence the overall questionnaire quality.

The third tool, the Short Form-36v2 (SF-36v2), has been used extensively in the literature and published reliability statistics with the HF population. Reliability coefficients ranging from .78 to .92 are published for the specific HF population and the Short Form-36 (SF-36) tool (Ware, Kosinski, & Gandek, 2000). Items are weighted in the development of each scale and this makes calculation of a Cronbach Alpha difficult to perform and interpret. Therefore a Cronbach Alpha was not determined for this tool.

C. Results by Question

Research Question 1

Does health related QOL differ among patients with HF who are receiving medical outpatient care in two different clinical settings: a multi-disciplinary (nursing, medicine, pharmacy, physical therapy, social work, nutrition) disease specific HF clinic and physician run private practices as measured by the Medical Outcomes Study SF-36v2 using the Physical Component Summary Scale (PCS) and the Mental Component Summary Scale (MCS)?

Table 7 outlines the results of the SF-36v2 questionnaire in these HF subjects.
Table 7: Health Related Quality of Life as measured by the Short Form-36v2 in Subjects with Heart Failure

<table>
<thead>
<tr>
<th>SF-36v2 Health Survey Scores</th>
<th>Multi-Disciplinary Disease Management HF Clinic n=30</th>
<th>Physician Run Private Practices n=30</th>
<th>Total Subjects n=60</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
</tr>
<tr>
<td>Physical Component Summary Score</td>
<td>35.7</td>
<td>9.4</td>
<td>36.0</td>
</tr>
<tr>
<td>Mental Component Summary Score</td>
<td>47.5</td>
<td>9.5</td>
<td>43.2</td>
</tr>
<tr>
<td>Physical Functioning</td>
<td>35.7</td>
<td>9.8</td>
<td>34.1</td>
</tr>
<tr>
<td>Role-Physical</td>
<td>36.1</td>
<td>11.4</td>
<td>34.2</td>
</tr>
<tr>
<td>Bodily Pain</td>
<td>49.0</td>
<td>11.4</td>
<td>44.9</td>
</tr>
<tr>
<td>General Health</td>
<td>33.2</td>
<td>9.4</td>
<td>36.7</td>
</tr>
<tr>
<td>Vitality</td>
<td>36.4</td>
<td>12.5</td>
<td>35.3</td>
</tr>
<tr>
<td>Social Functioning</td>
<td>44.7</td>
<td>12.2</td>
<td>44.3</td>
</tr>
<tr>
<td>Role-Emotional</td>
<td>47.9</td>
<td>10.4</td>
<td>39.4</td>
</tr>
<tr>
<td>Mental Health</td>
<td>45.0</td>
<td>11.9</td>
<td>42.8</td>
</tr>
</tbody>
</table>

1 QOL - Quality of Life
2 SF-36v2 - Short Form - 36 version 2 Health Survey
3 HF - Heart Failure
No significant differences between the two groups were found on the PCS \((p = .889)\) or the MCS \((p = .135)\). The mean scores of the PCS were virtually equal, the HF clinic group mean score was 35.7 and the physician office group was 36.0 with a total subject mean of 35.8.

The PCS summary score measures physical limitations, energy levels, and pain. The MCS mean score in the HF clinic group was 47.5 and in the physician office group was 43.2 with an overall mean of 45.3. The MSC summary score measures psychological distress and limitations in social roles due to emotional problems (Ware et al., 2000).

Of the eight sub-scores (physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional, and mental health) only the role-emotional sub-score showed a significant difference \((p = .007)\) between the two groups. The mean score in the HF clinic group was 47.9 and the in the physician office group the mean score was 39.4 with an overall subject mean of 43.7. The role emotional sub-score measures problems with work or other daily activities as a result of emotional problems (Ware et al., 2000).

Based on the research question, there were no significant differences in the physical or mental health summary scales between the two groups. Of the eight sub-scale scores of the SF-36V2 tool, there was a significant difference in only one sub-scale score, the role-emotional score between the two groups. The role emotional score defines substantial differences in mental health burden and the score was significantly lower in the physician practice group. Health related QOL was scored similarly in both
groups which could indicate health related QOL is not effected by the treatment location.

**Research Question 2**

Does disease specific QOL differ among patients with HF who are receiving medical outpatient care in two different clinical settings: a multi-disciplinary disease specific HF clinic and physician run private practices as measured by the MLHFQ total score, physical sub-score, and emotional sub-score? Table 8 presents the scores on the MLFHQ.

**Table 8: Disease specific Quality of Life as Measured by the MLHFQ\(^1\) in Subjects with Heart Failure**

<table>
<thead>
<tr>
<th>MLFHQ Scores</th>
<th>Multi-Disciplinary Disease Management HF Clinic n=30</th>
<th>Physician Run Private Practices n=30</th>
<th>Total Subjects n=60</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
</tr>
<tr>
<td>Total Score</td>
<td>46.4</td>
<td>24.7</td>
<td>47.2</td>
</tr>
<tr>
<td>Physical Dimension</td>
<td>19.6</td>
<td>11.0</td>
<td>19.3</td>
</tr>
<tr>
<td>Emotional Dimension</td>
<td>10.4</td>
<td>6.9</td>
<td>10.5</td>
</tr>
</tbody>
</table>

\(^1\) MLHFQ - Minnesota Living with Heart Failure Questionnaire

There were no significant differences in the values of the MLHFQ total scores \((p = .907)\) between the two groups. The mean total scores in the two groups were virtually equal, the HF Clinic group mean total score was 46.4 and the physician office group was 47.2. The physical dimension sub-score was not significantly different \((p = .896)\).
The HF Clinic group physical sub-score was 19.6 and the physician practice group was 19.3. The emotional dimension sub-score did not show significant differences (\( p = .953 \)) between the two groups. The HF Clinic group emotional dimension sub-score was 10.4 and the physician practice was 10.5.

Based on the research question disease specific QOL was scored the same in the two treatment groups. There was no significant difference in disease specific QOL in any of the MLHFQ total or sub-scores among patients with HF who receive medical outpatient care in the two different clinical settings.

**Research Question 3**

Are there differences in self care resources of patients with HF that are receiving medical outpatient care in two different clinical settings, a multi-disciplinary disease specific HF clinic and physician run private practices as measured by the SCRI and the sub-scales SCRIN and SCRIA scores? Table 9 presents the scores on the SCRI questionnaire.

The SCRIN sub-score measures what the patient needs to help them deal with their illness and get better. The SCRIA sub-score measures what the patient has available to them to deal with their illness. The internal sub-score measures factors that make the individual unique such as hope, control, self-efficacy, and future orientation. The external sub-score measure those factors which are separate from the individual such as social support, social network, financial assistance, health care provider support, and help with daily activities such as driving and shopping.
Table 9: Self Care Needs as Measured by the SCRI\textsuperscript{1} in Subjects with Heart Failure

<table>
<thead>
<tr>
<th>SCRI Scores</th>
<th>Multi-Disciplinary Disease Management HF Clinic n=30</th>
<th>Physician Run Private Practices n=30</th>
<th>Total Subjects n=60</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean SD</td>
<td>Mean SD</td>
<td>Mean t test p value</td>
</tr>
<tr>
<td>SCRIN\textsuperscript{2}</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Internal</td>
<td>35.4 6.6</td>
<td>40.3 5.8</td>
<td>37.8 3.047 .003</td>
</tr>
<tr>
<td>External</td>
<td>15.4 5.8</td>
<td>22.5 4.6</td>
<td>18.9 5.187 &lt;.001</td>
</tr>
<tr>
<td>SCRIA\textsuperscript{3}</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Internal</td>
<td>32.9 8.1</td>
<td>35.9 9.3</td>
<td>34.5 1.318 .193</td>
</tr>
<tr>
<td>External</td>
<td>27.6 7.40</td>
<td>33.1 8.5</td>
<td>30.4 3.015 .004</td>
</tr>
</tbody>
</table>

\textsuperscript{1} SCRI - Self Care Resource Inventory
\textsuperscript{2} SCRIN - Self Care Resource Inventory Need
\textsuperscript{3} SRNIA - Self Care Resource Inventory Availability

The HF clinic group overall scored lower on all aspects of the SCRI questions. Three of the four sub-scale scores were significantly different between the two groups. Both the internal ($p = .003$) and external ($p=<.001$) SCRIN sub-scores were significantly different. The internal and external resources measured by the SCRIN were significantly lower in the HF Clinic group than the physician run practice. Needs were also measured by the number of clinic/office appointments and hospitalizations within the past 12 months.

The number of clinic/office appointments between the two groups was significantly different ($p = .005$). The HF clinic group averaged 5.5 visits per 12 months and the physician office group averaged 3 visits. There was a larger range in the number of clinic/office appointments between the two groups with the HF clinic group.
ranging from one to 25 and the physician office ranging from one to six visits.

The number of hospitalizations in the past 12 months was significantly different between the two groups ($p = .017$). The HF clinic group had a mean of two (range of zero to 16) and the physician office group had a mean of less than one (range of zero to three).

The external ($p = .004$) SCRIA sub-score also showed significance. The external resource scores were significantly different with the HF clinic group scoring lower in both the SCRIN and SCRIA scores. Availability was also measured by the number of phone calls the subject made to the clinic/office within the past 12 months. There was no significant difference between the two groups ($p = .136$). The HF clinic group averaged three calls per 12 months (range zero to 40) and the MD office group averaged less than one (range zero to six).

There are significant differences in the internal and external needs and external availability of self care resources of patients with HF that are receiving medical outpatient care in two different clinical settings. Patients in the HF clinic group showed lower internal resource needs and availability and lower external resource availability. What an individual needs and what is available to deal with their illness was different between the two treatment groups.

**D. Descriptive Questions**

Two open ended descriptive questions were asked of all subjects in this study. Results are presented in Table 10.
Table 10: Subject Answers to Open Ended Questions

<table>
<thead>
<tr>
<th>“How do you define or describe heart failure?”</th>
<th>Multi-Disciplinary Disease Management HF Clinic n=30</th>
<th>Physician Run Private Practices n=30</th>
<th>Total Subjects n=60</th>
<th>Chi-square</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>6 (20%)</td>
<td>8 (27%)</td>
<td>14 (23%)</td>
<td>.37</td>
<td>.542</td>
</tr>
<tr>
<td>Shortness of breath</td>
<td>13 (43%)</td>
<td>13 (43%)</td>
<td>26 (43%)</td>
<td>.00</td>
<td>1.0</td>
</tr>
<tr>
<td>Weakness</td>
<td>4 (13.3%)</td>
<td>10 (33.3%)</td>
<td>14 (23%)</td>
<td>3.4</td>
<td>.067</td>
</tr>
<tr>
<td>Tired</td>
<td>7 (23%)</td>
<td>5 (17%)</td>
<td>12 (20%)</td>
<td>.42</td>
<td>.519</td>
</tr>
<tr>
<td>Scary</td>
<td>1 (3%)</td>
<td>0</td>
<td>1 (2%)</td>
<td>1.0</td>
<td>.313</td>
</tr>
</tbody>
</table>

| “What does heart failure mean to you?”         |                                                   |                                     |                     |           |    |
| Dying                                         | 1 (3%)                                            | 3 (10%)                             | 4 (7%)              | 1.1       | .301 |
| Scary                                         | 2 (7%)                                            | 1 (3%)                              | 3 (5%)              | .68       | .410 |
| Slow down                                     | 15 (30%)                                          | 16 (53%)                            | 31 (52%)            | .35       | .554 |
| Do Less - Can’t                                | 15 (30%)                                          | 10 (33.3%)                          | 25 (42%)            | 1.7       | .190 |
| Tired                                         | 2 (7%)                                            | 1 (3%)                              | 3 (5%)              | .35       | .554 |
| Changed my life                               | 5 (17%)                                           | 12 (40%)                            | 17 (28%)            | 4.0       | .045 |

The first question asked was “How do you define or describe heart failure?”.

Shortness of breath or not being able to breathe was verbalized 43% of the time in each group. There was no significant difference between the groups ($p = 1.0$). Weakness was described more in the physician office group (33.3%) as opposed to the HF Clinic group (13.3%) and was found to approach significance ($p = .063$).

Pain was also described by 20% of the HF group and 27% in the physician office as the definition of HF with no significant differences between the groups ($p = .542$).
The second question asked was “What does heart failure mean to you?”. Fifty three percent of the subjects in the physician office group and 30% in the HF Clinic group answered “slowing down”, with no significant differences between the groups ($p = .554$). The verbalization of doing less or can’t do as much was about equal in the two groups, 30% in the HF Clinic group and 33.3% in the physician office group with no significant difference ($p = .19$). There was a significant difference in the responses “changed my life” ($p = .042$) with the HF Clinic group responding as such 40% (12) of the time and the physician office group 17% (5) of the time.

### E. Summary

Demographic and health related demographic data showed significant differences between the two groups. Physical QOL was not significantly different between the two groups. Emotional QOL as measured by the role emotional SF-36v2 sub-scale score showed significant difference between the two treatment groups. Self care resources showed significant difference between the two treatment groups. Verbalization of HF “changed my life” was higher in the physician office group.
V. Discussion

This chapter will discuss the conclusions and implications of the research results. Demographic results and the results of the research questions will be discussed.

A. Results

Demographics

This sample is specific to the population surveyed and may not represent the overall population of HF patients. Based on the study results, the patients being managed in the heart failure (HF) clinic were significantly younger than those patients being managed in the physician practice group. Based on age range the youngest subject in the study was in the HF clinic and the oldest subject was in the physician practice group. Compared to a study of Medicare beneficiaries in the county in which the HF clinic was located, this study group had fewer subjects over the age of 80 than the Medicare study (Wellenius, Bateson, Murray, & Schwartz, 2005). The reported mean age of patients in this study group was lower than the mean age in the Acute Decompensated Heart Failure National Registry (ADHERE) database at 75.1 (ADHERE Registry, 2004). The rate of subjects over the age of 75 was lower in the HF clinic group and higher in the physician office group than the ADHERE database at 47%. The percentage of subjects under age 50 was lower in the physician practice group and higher in the HF clinic group. This emphasizes the disparity in ages between the groups. One possible reason for this disparity is that younger patients may be seeking more aggressive treatment available at the HF clinic.

Gender was not significantly different between the two groups and compared to
the ADHERE database (52% males and 48% females). This sample included more males and less females than the ADHERE database (ADHERE Registry, 2004). One reason for this disparity might be the convenience sampling used in this study.

The subjects in this study were predominately Caucasian. There was no significant difference between the Caucasian and African American groups, but the HF clinic group had more African American subjects than the physician practice group. It is published that approximately 23% of patients with HF are African American (Klein et al., 2003). In the population studied the percentage of African Americans in the physician practices was below this benchmark, but was higher in the HF clinic group. This may be attributed to the larger catchment area the clinic serves. Compared to the ADHERE database data the total population in this study had a higher percentage of Caucasian subjects (15% higher than in the ADHERE database) and a lower percentage of African American subjects (8% lower than in the ADHERE database) which indicated that this population is not equivalent to the ADHERE database norms. There were no Asian or Hispanic subjects in this convenience sample. The American Heart Association statistics state that 2.7% of male and 1.6% of female Hispanics are diagnosed with HF (2006 Heart and Stroke Statistical Update, 2005) and the ADHERE database HF benchmarks three percent Hispanics and one percent Asians (ADHERE Registry, 2004). Because this was a convenience sample, the lack of Hispanic and Asian subjects can be partially attributed to the convenience population and represented the demographics of the community in which the study was conducted.

The HF clinic group included more subjects who had completed higher education
(graduated two or four year college) and this finding was significant. The physician office group had a larger number of subjects at both extremes in education. Eleven had not completed a high school education and four of the subjects had completed graduate or post-graduate school. This disparity also continued in overall higher education with a higher percentage of subjects in the HF clinic group completing high school or post high school education. This inquiry did not have a follow-up survey question. An assumption might be made that subjects education could effect the ability to seek innovative medical care outside of their immediate geographical area. Subjects in the HF clinic group were better educated at both the high school and post high school levels. In summary they were better educated and thus may have better able to seek out additional treatment locations and treatments.

This finding could relate to the distance question. The subjects in the HF clinic group traveled a significantly higher number of miles to appointments. The physician office subjects traveled less miles to an office appointment. Number of miles traveled to appointments were almost double for HF clinic subjects with 150 being the most miles traveled for the HF clinic group. The HF clinic group were younger and possibly not as dependent on transportation to appointments making their increased travel distance manageable.

The length of HF diagnosis between the two groups in this study was not significant. The average length of HF diagnosis from initial onset to death in the literature is five years (2006 Heart and Stroke Statistical Update, 2005). Both groups exceeded this length of time and ranges were almost identical. Although the HF clinic
group had a higher acuity and a more severe physiological response to the disease, length of disease was not significantly different. There was the possibility of memory error as the question “How long have you known of your HF diagnosis?”, was answered by the subjects based on their recollection. Another possible contributing factor to question error was that subjects (23%) related pain to their HF diagnosis which could possibly confuse their HF diagnosis with myocardial infarction diagnosis.

The HF clinic had more subject hospitalizations in the past year, but the difference between the two groups was not significant. There was a wide range in the number of hospitalizations with the HF clinic having a higher number of hospital visits than the physician office group. The HF clinic group was sicker with an overall lower EF which could contribute to HF decompensation. While the literature supports the position that disease specific clinics decrease the number of hospitalizations per year (Hershberger et al., 2001) this premise is not supported with this study’s subject group.

While the number of emergency room visits was also higher in the HF clinic group, there was not a significant difference between the two groups. The range in the number of visits was greater in the HF clinic group. This could be due to the younger age, higher acuity of problems requiring treatment for acute decompensation, and co-morbidity problems.

The number of phone calls for health services in the past 12 months was higher in the HF clinic group. The range of phone calls was greater in the HF clinic group. There was no follow-up inquiry for this question in the survey to investigate the reasons for the calls (development of new or increasing symptoms, weight gain, medication
adjustment, or clarification of instructions).

There was not a significant difference in the mean number of physician/clinic visits per year between the two groups although the HF clinic group did have a slightly higher number of visits and the range was greater. This may be attributed to the age of the subjects, need for adjustments in therapy, and acuity of illness. The total number of physicians seen by patients was the same in both groups.

The initial ejection fraction (EF) was lower by almost half in the HF clinic group. This was a highly significant difference between the groups. The HF clinic group was not only younger, but their cardiac status was more compromised at the initiation of HF treatment. EF the HF clinic group decreased more since their initial visit. This would indicate that even with aggressive treatment in either setting, EF as a measure of cardiac function continues to decrease over time. In this study the EF was documented in 100% of the medical records. In the ADHERE database the EF was only documented 85% of the time (ADHERE Registry, 2004).

This self report of medications that the patient was taking versus information about medications the patient was on from the medical record differed in number in both groups. In the total sample, the medical record recorded one to five more medications listed than the self report of subjects. The HF clinic group had a higher number of discrepancies meaning the subject self report of medications taken and the medical record report of what the patient was taking were not consistent. Both groups showed discrepancies between self report and the medical record. In some cases there were as many as five medications that were not self reported by the patient but were listed on
the medical record. This could have an effect on the patient outcome in two ways. The patient could be taking medications that the health care provider is not aware of which could lead to adverse drug interactions. It is also possible that the patient may not be taking all medications prescribed by the health care provider and the treatment outcome may be altered. The importance of medication reconciliation in the outpatient setting is a high priority in overall care. The Joint Commission on Accreditation of Healthcare Organizations 2006 National Patient Safety Goals specifically addresses medication reconciliation in all health care settings. The findings in this study highlight the opportunity for error in this setting.

The category of HF medications was assigned by the researcher after review of the list of patient medications based on the American College of Cardiology and the American Heart Association (AHA) guidelines (Hunt et al., 2001). There was no significant difference in beta blocker use between the two groups and the percentages of both groups exceeded the 77% benchmark in the AHA statistics (2006 Heart and Stroke Statistical Update, 2005) and 74% in the ADHERE database (ADHERE Registry, 2004). Prescription of angiotensin receptor blockers (ARB’s) was significantly different between the two groups as was the prescription of angiotensin converting enzyme (ACE) inhibitors. When the two medication groups are combined and the subject is either on an ARB or ACE inhibitor, the overall prescription rate in the private physician office group and in the HF group is congruent with the AHA statistics for HF (2006 Heart and Stroke Statistical Update, 2005) and the ADHERE database at 68% (ADHERE Registry, 2004). This could indicate that the guidelines are known and being
implemented in these treatment settings.

Diuretic use is a mainstay of therapy with patients with HF. Overall diuretic use was documented in the ADHERE database subjects 88% of the time. In this study the percentage was slightly lower. The specific use of potassium sparing diuretics was higher in this study in both groups in contrast to the ADHERE database (7%) with the HF clinic significantly higher. This would indicate a tendency to adhere to the latest HF guidelines regarding diuretic therapy. This form of diuretic also necessitates closer monitoring of electrolytes and fluid status which correlates with the increased number of clinic visits and phone calls.

Aspirin prescription was higher in the private physician practice group than the HF clinic group. There was a significant difference between the two groups. Aspirin or some form of anticoagulation is recommended in the American College of Cardiology/American Heart Association guidelines when atrial fibrillation or mechanical valve replacement is present. While aspirin is not a Class I recommendation (there is evidence that treatment is beneficial, useful, and effective), cardiovascular guidelines advocate the administration of aspirin (Hunt et al., 2001). Both groups had a higher percentage of aspirin use than in the ADHERE database (ADHERE Registry, 2004).

A review of the co-morbid conditions in the subjects showed a significant difference with some diagnoses. Cardiomyopathy was significantly different between the two groups with a rate of almost 3:1 in the HF clinic group when compared to the physician office group. Causes for cardiomyopathy may differ between the two groups due to age. Drug abuse and viral myocarditis/endocarditis can contribute to the
diagnosis in younger patients while coronary artery disease and hypertension are often identified as the cause in older patients. The disparity in rate may be due in part to the younger age of subjects in the HF clinic group and the inclination to seek out additional treatment options.

Coronary artery disease was significantly different between the two groups with the private physician practice having a higher incidence. The percentage in the HF clinic group was lower than in the ADHERE database, while the private physician practice group was higher. Myocardial infarction or acute coronary syndrome was significantly different between the two groups with the physician office group having a higher percentage of subjects with this diagnosis. The HF clinic group had a lower percentage than in the ADHERE database and the physician office group had a higher percentage. There was a significant difference between the two groups regarding angina. In the physician office group a higher percentage of subjects had a history of angina and in the HF clinic group the percentage of angina was much lower. This could be a documentation issue regarding past medical history on the medical record (ADHERE Registry, 2004). Age could also be a factor. The older age in the physician office group could explain the increased incidence of coronary artery related disease in this group.

There was not a significant difference in hypertension diagnosis between the two groups and hypertension was higher in both treatment groups than the ADHERE database (ADHERE Registry, 2004).

The presence of dysrhythmias was significantly different between the two groups. The physician office group had more documented dysrhythmia diagnoses. The
presence of an internal cardiac defibrillator (ICD) was significantly higher in the HF clinic group. Four times as many patients had ICDs in the HF clinic group than the private physician practice group. The overall percentage was slightly higher than in the ADHERE database. The presence of a pacemaker was not significantly different between the two groups, but the HF clinic group had a higher percentage of devices. Atrial fibrillation/flutter was not significantly different between the two study groups but was found to be present at a higher rate than in the ADHERE database (ADHERE Registry, 2004). While fewer dysrhythmias were found in the HF clinic, more device treatment with ICDs and pacemakers was initiated for those dysrhythmias, hence more aggressive treatment.

A diagnosis of diabetes was not significantly different between the two study groups but was found at a higher percentage in both groups than in the ADHERE database at 44%. Sleep disorders was not a co-morbid condition included on the past medical history list. Due to the initial number of subjects indicating sleep problems, the question was asked of each subsequent subject. This condition was found in about 25% of the subjects, but no significant difference was found between the two groups.

There was a significant difference in the documentation of the New York Heart Association (NYHA) classification and the type of HF between the two groups. These findings may be skewed because of documentation inconsistencies. The HF clinic group medical records showed a markedly higher percentage in the documentation of this information. This may in part be due to the standardized forms used for each visit. There is a designated place for documentation of NYHA classification and HF type on
the form. The private physician office documentation was obtained via dictated progress notes with no specific format.

There were significant differences in demographics between the two groups. Age, marital status, education and travel distance to appointment were found to be different between the two groups. Health related demographics were also significantly different. The HF clinic group was younger, sicker, had poorer heart function at the initiation of treatment and with treatment, had less dysrhythmias but more aggressive device treatment for the dysrhythmias identified, and had a higher incidence of cardiomyopathy as a cause of HF.

**Research Question 1**

Research question number one asked: Does health related QOL differ among patients with HF who are receiving medical outpatient care in two different clinical settings: a multi-disciplinary (nursing, medicine, pharmacy, physical therapy, social work, nutrition) disease specific HF clinic and physician run private practices as measured by the Medical Outcomes Study Short Form 36v2 Health Survey (SF-36v2) using the Physical Component Summary Scale (PCS) and the Mental Component Summary Scale (MCS)?

There were no significant differences between the two groups in the two SF-36v2 summary scores and seven of the eight sub-scores. Physical status as a measure of physical functioning and well-being is measured by the PCS summary score and was rated the same in both groups. Both group scores in this study were slightly higher than the norm SF-36v2 data for HF patients. This could indicate a slightly higher physical
status due to subject age and their ability to provide self care activities. The MCS summary score, measuring social and role disability due to emotional problems, showed no significant difference between the two groups, however both groups scored slightly lower than the norm SF-36v2 data for HF patients (Ware et al., 2000). This could indicate a slight problem with social interactions and role activities due to health, specifically because of HF limitations. Both group summary scores were slightly different than the SF-36v2 norms, but virtually equal indicating no differences in physical or mental functioning between the two groups.

Comparing the eight study sub-score results with the norms from the SF-36v2 norm based data for HF, the study sub-scores were all lower than the norms except for role physical which was equivalent (Ware et al., 2000). The role-emotional sub-score was significantly different between the two groups. This score measures a problem with work or other daily activities as a result of emotional problems.

The HF clinic group scored significantly lower than the physician office group. This means that the subjects in this group were experiencing problems in completing self care activities at home or job responsibilities at work due to emotional issues related to HF. This could encompass financial worries, work productivity issues, or attendance issues. The HF clinic group could have scored lower due to the overall younger age of this subject group. The HF clinic group is predominantly of working age and work related issues would be more prevalent in this group.

The Jenkinson, Jenkinson, Sheppard, Layte, and Peterson (1997) study used the SF-36 in patients with HF receiving an experimental angiotensin converting enzyme
(ACE) inhibitor. The tool was administered before initiation of treatment and at four weeks. All of the summary and sub-scores in this study were lower than in the Jenkinson et al. (1997) study and the SF-36v2 HF data norms indicating that the QOL was lower in this population.

Differences in this sub-score between the groups may be attributed to the differences in ages of the two groups. Being younger, the HF clinic group may have more issues with work such as attendance and productivity. Being older, the physician office group may have more issues with daily activities such as driving and shopping. Although emotional diagnoses were not initially tabulated, a second review of the data was conducted and two subjects in the physician office group and three subjects in the HF clinic group had a documented diagnosis of depression on the medical record. Subject generated medical history did not list depression diagnoses in either group. A review of the medication lists revealed that seven subjects in the physician office group and five subjects in the HF clinic group were prescribed antidepressants. This disparity in listed diagnosis and medication treatment in the medical record indicates a need for medication diagnosis reconciliation.

The various SF-36v2 sub-scores in both groups indicated a poorer health related QOL when compared to the HF norm. There were no significant differences in overall physical or mental health related QOL between the two groups, although the demographics in the two groups were significantly different. There was a significant difference in the role-emotional sub-score related to work, daily activities, and emotional problems with potential age related issues in both groups.
Research Question 2

Research Question 2: Does disease specific QOL differ among patients with HF who are receiving medical outpatient care in two different clinical settings: a multi-disciplinary disease specific HF clinic and physician run private practices as measured by the Minnesota Living with Heart Failure Questionnaire (MLHFQ) total score, physical sub-score, and emotional sub-score? There was no significant difference in the total MLHFQ score, or the physical or emotional sub-scores between the two groups.

The MLHFQ total scores in this study were comparable to other HF studies using this tool at baseline (many of the studies administered the tool at baseline and at a designated time in the future). Rector’s initial study (Rector, Kubo et al., 1987) with HF patients reported a MLHFQ total score of 34. The subjects in this study were congruent with demographics in the Rector et al. (1987) study, but the EF was slightly lower indicating a slightly worse cardiac status. Ni et al. (2000), in a HF clinic setting, obtained a slightly higher total score. The sample was congruent with this study’s demographics (age, gender, education, ethnicity) and was sensitive to changes in QOL due to program interventions at the HF clinic. Riegel’s study (Riegel et al., 2003) comparing gender differences in a general HF population had a higher MLHFQ total score than in this study. Correlations due to gender were not compared in this study. There was congruence in age, EF, and martial status. Bennet had a much higher total score in the female HF population (S. J. Bennett, Baker, & Huster, 1998). Although demographics of other published studies were equivalent to the demographics in this study, scores of the MLHFQ in this study were higher indicating a poorer disease specific QOL. The higher
rating of disease specific QOL in this sample may be attributed to subject age, current EF, education, level of information, and relationship with healthcare provider.

There was no significant difference between the two groups in the physical dimension sub-score with a difference of only .5 between the scores. The physical dimension sub-score of the MLHFQ correlated with the SF-36v2 PCS summary score.

The physical dimension sub-scores in the Ni et al. (2000) and the Riegel study (2003) were all higher than the individual groups and overall study mean indicating a poorer disease specific QOL. The lower physical dimension sub-scores in this study (indicates a poor physical disease specific QOL) could be related to the lower age, lower current EF, subject co-morbidities, and gender.

There was no significant difference between the two groups in the emotional dimension sub-score. The emotional dimension sub-score correlated with the MCS summary score of the SV-36v2. The emotional dimension sub-score in the Ni et al. (2000) study and the Riegel et al. (2003) study were only slightly higher than in this study indicating the scores in this study are congruent with other studies. The importance of emotional QOL in patients with HF affects all aspects of daily life whether at work or at home and should be incorporated into treatment plans. The lower emotional dimension sub-scores in this study could be due to the convenience sample, subject age, number of co-morbidities, and level of family and healthcare provider support.

The disease specific QOL scores showed no significant difference between the two treatment locations. The physical and emotional sub-scores of the MLHFQ
correlated with the SF-36v2 scores. Disease specific QOL was not different in the two treatment locations.

**Research Question 3**

Are there differences in self care resources of patients with HF who are receiving medical outpatient care in two different clinical settings, a multi-disciplinary disease specific HF clinic and physician run private practices as measured by the Self Care Resource Inventory (SCRI) and the sub-scales Self Care Resource Inventory Needs (SCRIN) and Self Care Resource Inventory Availability (SCRIA) scores?

The study results indicated a significant difference between the two groups in three of the four sub-scores. The SCRIN measures what the patient needs to help them deal with their illness and get better. The SCRIA measures what the patient has available to them to deal with their illness. The internal sub-score measures factors that make the individual unique such as hope and future orientation. The external sub-score measures those factors that are separate from the individual such as social support and health care provider support.

The internal and external SCRIN sub-scores measured what the subjects need to help them deal with their HF. There was a significant difference between the two groups in both the external and internal sub-scores. The HF clinic group scores indicated that this group had fewer unmet needs. The number of HF clinic appointments over a 12 month period was greater than the number of physician office visits which can contribute to meeting the subject’s internal needs of hope, knowledge of HF, and treatment options. External needs could be met by HF clinic support, HF information,
and social support. The HF clinic group was younger, more educated, more hopeful, and had more of a future orientation. The physician office group had more identified needs, some of which are not being met. This group was older and had less of a future orientation.

External SCRIA sub-scores were significantly different between the two groups. The HF clinic group score indicates that this group had fewer needs and more of these needs or concerns were being met. The physician office group scores indicate that they had more identified needs and some were not being met. The HF group felt empowered to get their needs met, possibly due to the younger age of this group. They are able to obtain support from family and friends to accomplish this. When asked “Which person helps you at home the most to manage your HF?” spouse (wife or husband) was the most frequent answer in both groups. Wife was the most frequent answer to this question and this relates to the sample having a high percentage of males. One fourth of the subjects in both groups indicated “me” as the person that helped most to manage their HF. The scores of the physician office group indicate that support to meet their needs varies which leads to unmet needs. This group had fewer office visits, were older, and had less of a future orientation.

External SCRIA sub-scores also measure those factors which are separate from the individual such as social support and health care provider support and if those concerns are being met. The number of phone calls within a 12 month period was not significantly different between the two groups but the HF clinic group had a larger mean number and a larger range of calls. HF clinic subjects more readily called the clinic with
questions and concerns, had 24 hour access to both physicians and nurses, had more verbalized questions regarding their status, and got more direction and information regarding their HF diagnosis. The physician office group are older and may need more family support for daily activities.

While health related and disease specific QOL measures showed little differences between the two treatment locations, self care resources, what the individual needs and what is available to deal with their illness was significantly different. The importance of self care resources should be assessed by the health care provider to assist in meeting both the physical and emotional needs of the patient. Including this information in initial histories and individual visit questions can affect HF care.

Descriptive Questions

Words used to describe how the subjects defined HF and what it means were similar in both groups. The most common HF symptom, shortness of breath was the term used most frequently.

The most notable phrase from the question responses was “changed my life”. There was a higher use of this phrase in the physician office group. Although the HF clinic group was younger and sicker it appears they were better able to adapt to changes in their life from HF. They adjusted to changes in physical status more easily. They perceived more support from both healthcare personnel and family/friends. The physician office group were older and had the opportunity to experience more loss. The changes in their life due to HF became more profound as they reflected on the number of activities they once were able to participate in and now cannot because of physical
limitations. Being able to play a round of golf, mow the yard, dance, shop at the local mall, or attend grandchildren sports events were all examples of activities that subjects were once able to do, and now were missing from their life.

In conjunction with the phrase changed my life, the terms cannot and slowed down were common themes in the subject responses. In many of the responses use of the word "can’t" was repetitive. The subjects associated their daily life with what HF meant to them and many of the responses were negative in the phrases verbalized from the point of what they couldn’t now do compared to what they were able to do in the past.

B. Significance to Nursing

The different care settings for the patient with HF affects the delivery of care. Research findings have shown decreased admission rates and decreased costs with disease specific HF clinic patient management (Harrison, Toman, & Logan, 1998; Paul, 2000; Rich et al., 1995; Rich et al., 1993). With decreased lengths of stay in acute care settings, the patient, in collaboration with their identified primary care provider must assume an active role in maintaining health and disease management. The different levels of health care providers (physician, nurse, advanced practice nurse, physician assistant) who provide medical management of a chronic illness such as HF can influence the care the patient receives.

Nurses can affect the quality of care the patient with HF receives. Whether the nurse is the primary care giver as with an advanced practice nurse or adjunct care giver in the office, clinic, hospital, or home, the nurse can affect how the patient views,
accepts, and manages their chronic disease on a daily basis. The personal interaction with the nurse at the beginning of the office/clinic visit can identify those self care resources that need to be addressed. After hour phone calls being answered by a nurse is another important aspect of care. The nurse can play an important role in continuity of care. This can influence the subsequent financial and emotional effect on the health care system.

From a financial aspect, the benefits of cost-effective care are evident. The health care system needs to address the increased cost and benefits in relation to the medical care setting chosen and its effect on patient QOL. While the financial ramifications of HF care from the third party payer aspect is important ("Humana CHF program cuts costs, admissions," 1998; Mark, 1997; Philbin & Roerden, 1997; Rich, 1999) research also needs to address the patient’s QOL perspective. What has not been clearly addressed in the literature is the impact of the different medical management settings on the patient’s self-reported QOL. QOL assessments are important outcome measures in clinical research trials (Dracup et al., 1992; Konstam, 2001; Packa, 1989; Tandon, Stander, & Schwarz, 1989). Prior to this study, research had not been conducted comparing QOL measurement as an additional outcome measure for different treatment locations.

In this study there were no significant differences in health related or disease related QOL between the groups in the two treatment locations. Although this finding showed no differences, it is important for inclusion in the literature about the measurement of QOL in those locations. Studies directly comparing QOL in different
treatment locations have not been conducted, therefore the findings of this study add to nursing knowledge. The monetary comparisons between treatment locations in prior studies show a marked positive financial effect for the disease specific management treatment location. This study has shown that QOL is not effected by the treatment location and that disease specific management locations can be cost-effective and maintain an adequate level of patient QOL.

Although this study sample was small, it indicates that health care provided in these two different treatment locations have similar endpoints when measuring QOL. Because of the small sample size these results may not be easily generalized to other samples.

Use of the MLHFQ and the SF-36v2 tools are well documented in the literature in the HF population. This study adds to that body of literature. Use of the SCRI tool is limited in the literature and therefore the results of this study will add to this literature.

C. Limitations of the Results/Study

Several issues related to the sample may limit the generalization of results. Not all medically managed HF situations were studied. This study chose two of many possible scenarios, an existing disease specific HF clinic based in a university setting and private physician practices in a non university setting. Other possible settings that could be studied would include: general family practice offices, internal medicine practices not specializing in cardiology, emergent settings (emergency department, urgent care settings) with patients who do not have a primary physician, hospitals for acute care management, home care, or an advanced practice nurse setting. While the
private physician practice is one of the more traditional methods of HF medical management, the clinic setting is now more mainstream. Published research focused on the above listed settings in isolation (Harrison et al., 1998; Paul, 2000; Rauh, Schwabauer, Enger, & Moran, 1999; Shah et al., 1998). This study compared two settings most commonly utilized by patients with HF, a disease specific HF clinic and private physician office.

Only one heart failure clinic treatment location was included. In this geographical area there are only two designated heart failure clinics and both clinics were approached regarding this study. Only one clinic allowed data collection to proceed. The second HF clinic stated that their patients were already involved in multiple research studies and an additional study at this time would be detrimental to patient care. There were many private physician offices with cardiology specialities in the geographical area. The two physician practices chosen for this study are established practices in their community.

The study population is small although sufficient power was reached. A convenience sample was obtained and this may be reflective of the total patient load of each treatment location. The study was done via face to face interviews. This had the advantage of not having any missed data as a review was conducted prior to the completion of the interview. A larger sample may have been obtained using a mailed questionnaire packet. This method can result in missing data thus the increased sample size may affect the results because of missing data.

In comparing these treatment locations to current national benchmarks, it is
encouraging to validate that HF medication guidelines are being implemented. With this study not all database indicators were studied. It would be important to include those indicators (smoking cessation, initial and ongoing laboratory assessments, antioxidant therapy, documentation of hospital discharge instruction, weight, fluid management, and sodium restriction) in any future data collection.

Another limitation is the lack of standardization of the definition and composition of the HF clinic setting. Clinics have varied staffing, settings, resources, access to experimental and non-experimental interventions, and protocol management. Because of this, the HF clinic cannot be generalized from setting to setting without looking at the individual clinics in order to determine consistency.

Using a physician run private practice also has limitations. While all physicians completed medical rotations, there are differences in advanced education and practices. Education can vary from physicians completing an internal medicine residency to physicians completing specialized cardiology fellowships. Other differences in physician practices could include size of practice, number of additional physicians in the practice, disease management expertise, office hours, availability of interventional cardiology (coronary angioplasty, coronary stents) within the practice, in-office diagnostic testing, types of ancillary staff, and number of office staff. The physician practices studied in this research included two private physician practices with a primary cardiology specialty, in a non university, non teaching setting. The physician office environments and components were comparable.

An additional limitation is sample size. While the sample is representative of the
HF population, it is not a representative percentage of the HF population known to exist. Because of the small sample size, the results of this study may have limited application.

D. Future Directions

It would be important for this study to be replicated with a larger samples size using multiple treatment locations (home health, hospice, family practitioners, nurse practitioner clinics). An additional study that would correlate QOL measures in patients with HF to the nursing education levels in the different treatment locations could be beneficial in determining the value of advance practice nurses in HF settings.

Additional questions that could have been surveyed include: time spent in the office/clinic appointment, listing of other HF guideline interventions (smoking cessation, weight management, fluid management, dietary sodium restrictions), how the subject received information about the HF clinic (referring physician, nurse, family/friend recommendation, advertisement), work history/status, and drug and alcohol (including smoking) history. Mental health components (emotional health history, medication history) could be added to the medical history section.

Further research on self care resources is also needed. Questions concerning met and unmet needs of the patient with HF should be investigated. How information is obtained regarding patient issues and concerns is another area of further research. While this study recorded the number of phone calls for issues/problems, further information regarding time of day of the phone call, who the patient talked to (nurse, physician, answering service), and whether the issue/problem was resolved could be investigated.
While the SF-36v2 was easy to administer, using the shorter SF-12 is a consideration in any subsequent studies. Having only 12 questions to answer is an advantage to subjects. The SF-12 reproduces the eight sub-scales and physical and mental summary scores using less questions and fewer levels. For large group studies these differences are not significant. If a smaller sample size is anticipated the SF-36v2 may be the more precise instrument for health related QOL.

E. Summary

Although there were few significant differences in QOL measures in this study, future studies could clarify the differences identified and expand on the results of this study.

Important findings from this research focus on the differences found between these two groups. HF clinic patients were found to be younger and had poorer heart function at initiation of HF treatment and with ongoing HF treatment. This group was better educated, traveled longer distances to appointments, had a higher incidence of cardiomyopathy, and more device treatment for identified dysrhythmias. The physician office group was older, less educated, and had a higher incidence of coronary artery disease and myocardial infarction. This study identified that the differences in demographics and cardiac status between the two groups affect where HF medical care is located.

Health related physical QOL and disease specific QOL were not significantly different between the two groups. Mental health QOL as measured by the role-emotional sub-score of the SF-36v2 was significantly different between the two groups.
The HF clinic group had utilized medical resources at a higher level (clinic visits, phone calls) than those in the physician office group. Self care resources were significantly different between the two groups and should be studied further. The study findings indicate that both locations are delivering quality, appropriate care HF care and that QOL is not effected by treatment location.
Appendixes
Appendix A: MINNESOTA LIVING WITH HEART FAILURE QUESTIONNAIRE

These questions concern how your heart failure (heart condition) has prevented you from living as you wanted during the last month. The items listed below describe different ways some people are affected. If you are sure an item does not apply to you or is not related to your heart failure then circle 0 (No) and go on to the next item. If an item does apply to you, then circle the number rating how much it prevented you from living as you wanted. Remember to think about ONLY THE LAST MONTH.

<table>
<thead>
<tr>
<th>Did your heart failure prevent you from living as you wanted during the last month by:</th>
<th>No</th>
<th>Very Little</th>
<th></th>
<th>Very Much</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Causing swelling in your ankles, legs, etc?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>2. Making your working around the house or yard difficult?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>3. Making your relating to or doing things with your friends or family difficult?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>4. Making you sit or lie down to rest during the day?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>5. Making you tired, fatigued, or low on energy?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>6. Making your working to earn a living difficult?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>7. Making your walking about or climbing stairs difficult?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>8. Making you short of breath?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>9. Making your sleeping well at night difficult?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>10. Making you eat less of the foods you like?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>11. Making your going places away from home difficult?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Question</td>
<td>No</td>
<td>Very Little</td>
<td>Little</td>
<td>Moderate</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>----</td>
<td>-------------</td>
<td>--------</td>
<td>----------</td>
</tr>
<tr>
<td>Did your heart failure prevent you from living as you wanted during the last month by:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. Making your sexual activities difficult?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>13. Making your recreational pastimes, sports, or hobbies difficult?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>14. Making it difficult for you to concentrate or remember things?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>15. Giving you side effects from medications?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>16. Making you worry?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>17. Making you feel depressed?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>18. Costing you money for medical care?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>19. Making you feel a loss of self-control in your life?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>20. Making you stay in a hospital?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>21. Making you feel you are a burden to your family or friends?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

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Appendix B: SF-36v2 Health Questionnaire

Instructions for Completing the Questionnaire
Please answer every question. Some questions may look like others, but each one is different. Please take the time to read and answer each question carefully by filling in the bubble or circle that best describes your answer.

EXAMPLE
This is for your review. DO not answer this question. The questionnaire begins with the section Your Health in General below.
For each question you will be asked to fill in a bubble or circle in each line:

1. How strongly do you agree or disagree with each of the following statements?

<table>
<thead>
<tr>
<th>Strongly agree</th>
<th>Agree</th>
<th>Uncertain</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>&quot;</td>
<td>&quot;</td>
<td>&quot;</td>
<td>&quot;</td>
<td>&quot;</td>
</tr>
<tr>
<td>a) I enjoy listening to music</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b) I enjoy reading magazines</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Please begin answering the questions below now.

<table>
<thead>
<tr>
<th>Your Health in General</th>
</tr>
</thead>
</table>

1. In general, would you say your health is:

<table>
<thead>
<tr>
<th>Excellent</th>
<th>Very Good</th>
<th>Good</th>
<th>Fair</th>
<th>Poor</th>
</tr>
</thead>
<tbody>
<tr>
<td>&quot;</td>
<td>&quot;</td>
<td>&quot;</td>
<td>&quot;</td>
<td>&quot;</td>
</tr>
</tbody>
</table>

2. Compared to one year ago, how would you rate your health in general now?

<table>
<thead>
<tr>
<th>Much better now than one year ago</th>
<th>Somewhat better now than one year ago</th>
<th>About the same as one year ago</th>
<th>Somewhat worse now than one year ago</th>
<th>Much worse now than one year ago</th>
</tr>
</thead>
<tbody>
<tr>
<td>&quot;</td>
<td>&quot;</td>
<td>&quot;</td>
<td>&quot;</td>
<td>&quot;</td>
</tr>
</tbody>
</table>
3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? Is so, How much?

<table>
<thead>
<tr>
<th>Activity Description</th>
<th>Yes, Limited a lot</th>
<th>Yes, Limited a little</th>
<th>No, not limited at all</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b) Moderate activities, such as moving a table pushing a vacuum cleaner, bowling, or playing golf</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c) Lifting or carrying groceries</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>d) Climbing several flights of stairs</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>e) Climbing one flight of stairs</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>f) Bending, kneeling, or stooping</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>g) Walking more than a mile</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>h) Walking several hundred yards</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>i) Walking one hundred yards</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>j) Bathing or dressing yourself</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

<table>
<thead>
<tr>
<th>Problem Description</th>
<th>All of the time</th>
<th>Most of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Cut down on the amount of time you spent on work or other activities</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b) Accomplished less than you would like</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c) Were limited in the kind of work or other activities</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>d) Had difficulty performing the work or other activities (for example, it took extra time)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
5. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

<table>
<thead>
<tr>
<th>Problem Description</th>
<th>All of the time</th>
<th>Most of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Cut down on the amount of time you spent on work or other activities</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b) Accomplished less than you would like</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c) Did work or other activities less carefully than usual</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

<table>
<thead>
<tr>
<th>Extent of Interference</th>
<th>Not at all</th>
<th>Slightly</th>
<th>Moderately</th>
<th>Quite a bit</th>
<th>Extremely</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

7. How much bodily pain have you had during the past 4 weeks?

<table>
<thead>
<tr>
<th>Severity of Pain</th>
<th>None</th>
<th>Very mild</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
<th>Very Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

<table>
<thead>
<tr>
<th>Extent of Interference</th>
<th>Not at all</th>
<th>A little bit</th>
<th>Moderately</th>
<th>Quite a bit</th>
<th>Extremely</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks:

<table>
<thead>
<tr>
<th>Question</th>
<th>All of the time</th>
<th>Most of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) did you feel full of life?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b) have you been very nervous?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c) have you felt so down in the dumps that nothing could cheer you up?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>d) have you felt calm and peaceful?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>e) did you have a lot of energy?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>f) have you felt downhearted &amp; depressed?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>g) did you feel worn out?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>h) have you been a happy?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>i) did you feel tired?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
10. **During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc)?**

<table>
<thead>
<tr>
<th></th>
<th>All of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>11. How TRUE or FALSE is each of the following statements for you?</strong></td>
<td>&quot;</td>
<td>&quot;</td>
<td>&quot;</td>
<td>&quot;</td>
</tr>
<tr>
<td>a) I seem to get sick a little easier than other people</td>
<td>&quot;</td>
<td>&quot;</td>
<td>&quot;</td>
<td>&quot;</td>
</tr>
<tr>
<td>b) I am as healthy as anybody I know</td>
<td>&quot;</td>
<td>&quot;</td>
<td>&quot;</td>
<td>&quot;</td>
</tr>
<tr>
<td>c) I expect my health to get worse</td>
<td>&quot;</td>
<td>&quot;</td>
<td>&quot;</td>
<td>&quot;</td>
</tr>
<tr>
<td>d) My health is excellent</td>
<td>&quot;</td>
<td>&quot;</td>
<td>&quot;</td>
<td>&quot;</td>
</tr>
</tbody>
</table>

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Appendix C: Self Care Resource Inventory  
Directions: We are interested in the things or “resources” that may be helpful to you in dealing with your illness. First, you are asked to rate each resource in terms of how much you need it to help you deal with your illness and get better. Second, you are asked to rate each resource in terms of how much is available to you. Rate your responses for each from 0 (none) to 4 (a lot). Circle the number that best represents how you feel as you rate each “resource”. There are no right or wrong answers, so complete each item as honestly as you can. Be sure that you circle one number in each column on every line.

<table>
<thead>
<tr>
<th></th>
<th>Amount I Need</th>
<th>Amount I Have</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>None</td>
<td>A Lot</td>
</tr>
<tr>
<td></td>
<td>0 1 2 3 4</td>
<td>0 1 2 3 4</td>
</tr>
<tr>
<td>1. Emotional support from my family</td>
<td>0 1 2 3 4</td>
<td>0 1 2 3 4</td>
</tr>
<tr>
<td>2. Control over my daily activities</td>
<td>0 1 2 3 4</td>
<td>0 1 2 3 4</td>
</tr>
<tr>
<td>3. Information about my illness and treatment</td>
<td>0 1 2 3 4</td>
<td>0 1 2 3 4</td>
</tr>
<tr>
<td>4. Spiritual strength</td>
<td>0 1 2 3 4</td>
<td>0 1 2 3 4</td>
</tr>
<tr>
<td>5. Someone who can make me laugh</td>
<td>0 1 2 3 4</td>
<td>0 1 2 3 4</td>
</tr>
<tr>
<td>6. Feeling good about myself</td>
<td>0 1 2 3 4</td>
<td>0 1 2 3 4</td>
</tr>
<tr>
<td>7. A good relationship with my health care providers</td>
<td>0 1 2 3 4</td>
<td>0 1 2 3 4</td>
</tr>
<tr>
<td>8. Control over my plan of care</td>
<td>0 1 2 3 4</td>
<td>0 1 2 3 4</td>
</tr>
<tr>
<td>9. Having the skill to do the things that will help me get better</td>
<td>0 1 2 3 4</td>
<td>0 1 2 3 4</td>
</tr>
<tr>
<td>10. Setting goals that I can reach</td>
<td>0 1 2 3 4</td>
<td>0 1 2 3 4</td>
</tr>
<tr>
<td>11. Assistance with my usual family responsibilities</td>
<td>0 1 2 3 4</td>
<td>0 1 2 3 4</td>
</tr>
<tr>
<td></td>
<td>Amount I Need</td>
<td>Amount I Have</td>
</tr>
<tr>
<td>---</td>
<td>---------------</td>
<td>---------------</td>
</tr>
<tr>
<td></td>
<td>None A Lot</td>
<td>None A Lot</td>
</tr>
<tr>
<td>12. The will to live</td>
<td>0 1 2 3 4</td>
<td>0 1 2 3 4</td>
</tr>
<tr>
<td>13. Being able to laugh</td>
<td>0 1 2 3 4</td>
<td>0 1 2 3 4</td>
</tr>
<tr>
<td>14. Financial resources to take care of myself</td>
<td>0 1 2 3 4</td>
<td>0 1 2 3 4</td>
</tr>
<tr>
<td>15. Emotional support from friends</td>
<td>0 1 2 3 4</td>
<td>0 1 2 3 4</td>
</tr>
<tr>
<td>16. Someone to help me do things that I cannot do myself</td>
<td>0 1 2 3 4</td>
<td>0 1 2 3 4</td>
</tr>
<tr>
<td>17. Feeling that my life has meaning</td>
<td>0 1 2 3 4</td>
<td>0 1 2 3 4</td>
</tr>
<tr>
<td>18. Someone to teach me how to care for myself</td>
<td>0 1 2 3 4</td>
<td>0 1 2 3 4</td>
</tr>
<tr>
<td>19. Emotional strength</td>
<td>0 1 2 3 4</td>
<td>0 1 2 3 4</td>
</tr>
<tr>
<td>20. Assistance so I can do my work or usual activities</td>
<td>0 1 2 3 4</td>
<td>0 1 2 3 4</td>
</tr>
<tr>
<td>21. A positive view of myself</td>
<td>0 1 2 3 4</td>
<td>0 1 2 3 4</td>
</tr>
<tr>
<td>22. Good personal appearance</td>
<td>0 1 2 3 4</td>
<td>0 1 2 3 4</td>
</tr>
<tr>
<td>23. Knowing others respect me</td>
<td>0 1 2 3 4</td>
<td>0 1 2 3 4</td>
</tr>
<tr>
<td>24. Reaching goals that I set</td>
<td>0 1 2 3 4</td>
<td>0 1 2 3 4</td>
</tr>
<tr>
<td>25. Knowing how to care for myself</td>
<td>0 1 2 3 4</td>
<td>0 1 2 3 4</td>
</tr>
<tr>
<td>Item</td>
<td>Amount I Need</td>
<td>Amount I Have</td>
</tr>
<tr>
<td>---------------------------------------------------------------</td>
<td>--------------</td>
<td>---------------</td>
</tr>
<tr>
<td></td>
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<td>A Lot</td>
</tr>
<tr>
<td>26. Hope for the future</td>
<td>0 1 2 3 4</td>
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</tr>
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<td>27. An intimate relationship</td>
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<td>28. Energy to do activities</td>
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<td>29. Willingness to try new roles</td>
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</tr>
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<td>30. Desire to set new goals</td>
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</tr>
<tr>
<td>31. Someone to confide in</td>
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<td></td>
</tr>
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<td>32. Prayer</td>
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<td>33. Financial resources to take care of my family</td>
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<td>34. A close friend</td>
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<td>35. Religious activities</td>
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Copyright 1994 Linda S. Baas
Appendix D: Permission letter to use Minnesota Living with Heart Failure Questionnaire

October 8, 2001

Ms. Janet Bischoff
80 Fernwood Avenue
Wheeling, WV 26003

Re: Copyright License Agreement
Minnesota Living With Heart Failure
U/M Docket 94019

Dear Ms. Bischoff,

We appreciate your decision to use the Minnesota Living With Heart Failure Questionnaire. Enclosed is your fully signed copy of the copyright license agreement.

Thank you for using the agreement and good luck on your dissertation.

Please call me if there are any questions. I can be reached at 612-624-9568, by fax at 612-624-6554, or via email at hilde017@tc.umn.edu.

Best regards,

[Signature]
James W. Hildebrand
Software Licensing Associate
JWH/rm

Enclosure
Appendix E: Permission letter to use Short Form-36 version 2

Subj. Single User Non-Commercial License Agreement Date: 11/19/2001 1:06:06 PM Eastern Standard Time

From: kmcbride@qualitymetric.com (Kathy M. McBride) To: jlbphd@aol.com

Monday, November 19, 2001

Janet Bischof Student
Duquesne University
80 Fernwood Avenue
Wheeling, WV 26003
United States

Regarding your project: Dissertation document for Ph. D. in Nursing schoolwork

Dear Janet:

I am pleased to grant you permission to use and reproduce the U.S. English versions of the SF-36v2(r) Health Survey(s), subject to the following terms and conditions:

Permission to use the U.S. English versions of the SF-36v2(r) is granted royalty free for individual research and institutional non-commercial use. This permission does not extend to reproduction or transmission of the instrument(s), scoring algorithm(s), and/or normative data on a computer network, Intranet, Internet server. It also does not extend to those wishing to re-sell, sublicense, or otherwise distribute the survey forms or scoring algorithms as part of their product or service offerings (whether or not a fee is charged). Such use requires a special license, and interested parties should write license@qmetric.com for more information.

This permission to use is for the U.S. English version only. Information and permission to use the non-U.S. English translations of the SF-36v2(r) can be obtained from the International Quality of Life Assessment (IQOLA) project. Please direct your inquiries to info@iqola.org.

Please know that we have added you to our mailing list and encourage you to visit our websites, Wt.Wv.qmetric.com and www.amthealthy.com, for the most up-to-date information on our scientific products and services.

Sincerely,

John E. Ware, Jr., Ph.D. Chief Executive Officer QualityMetric Incorporated

Executive Director, Health Assessment Lab
Appendix F: Permission letter to use the Self Care Resource Inventory

Janet Bischof, RN, MN
80 Fernwood Avenue
Wheeling, WV 26003

June 25, 2004

Dear Janet:

I am pleased that you are interested in using my tool, the Self Care Resource Inventory, in your dissertation research. I am willing to share the tool and the scoring system for the instrument. There is no fee for the use of the instrument, but do know that I hold the copyright for it and that should be included with any written discussion of the instrument.

My only request is that you share the raw data with me so that I can maintain a data bank for the purpose of further developing psychometrics of the tool. I only request that I be given subject age and gender along with the SCRI item scores. Please delete any identifying information about the subject.

I wish you well in your research endeavors and would be happy to discuss the SCRI with you anytime.

Sincerely,

[Signature]

Linda S. Baas, PhD, RN
Associate Professor and Director of Acute Care Graduate Program.
Appendix G: Patient Demographic Questionnaire

Patient Demographic Questionnaire

Study ID # ___________

Please verbally complete the following questions:

Full name ________________________________________________________

Where is this interview taking place ____________________________________

Today’s Date: Month ______________ Day _____________ Year ____________

Who is currently the president of the United States? _________________
Patient Demographic Questionnaire  Study ID # ____________

Please answer the following questions to the best of your ability:

1. **Age** : __________ years

2. **Gender** (check one)
   - _____ Male
   - _____ Female

3. **Education** (check one)
   - _____ less than 8 years of school
   - _____ less than 12 years of high school
   - _____ graduated high school
   - _____ vocational/tech school education
   - _____ graduated from a 2 year college
   - _____ graduated from a 4 year college
   - _____ graduate school
   - _____ post graduate classes

4. **Race/Ethnicity** (check one)
   - _____ Asian
   - _____ Black - African American
   - _____ Hispanic
   - _____ White
   - _____ Other __________________

5. **Marital Status** (check one)
   - _____ Single
   - _____ Living with partner
   - _____ Married
   - _____ Married living apart
   - _____ Widow/Widower
   - _____ Divorced
   - _____ Separated

6. **Number of Children** __________
   - _____ Number of Females _____ Number of Males
7. Please answer all medical conditions that apply to you

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<tr>
<td>Other</td>
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</tr>
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</table>

8. How long have you known of your Heart Failure diagnosis? ___________ years

9. In the past 12 months, how many times have you stayed in the hospital overnight? ________
   Specifically for Heart Failure? ___________

   Number of days in hospital with last hospital admission? ___________

10. How many Emergency room visits for Heart Failure in the past 12 months have you had? ___________
Study ID # ____________

11. How many physician or clinic visits for HF have you had in the past 12 months_____
How many phone calls for problems?___________

12. For all your health care needs, how many physicians do you see?
   _____ 1
   _____ 2
   _____ 3
   _____ 4
   _____ 5
   _____ more than 5

13. Which person helps you at home the most to manage with your Heart Failure?

14. Who do you call first if you develop problems with your Heart Failure (for example, increased weight gain, shortness of breath, swelling of feet or legs)? ________________

15. Would you please list the medications you are currently taking?

<table>
<thead>
<tr>
<th>Medication</th>
<th>Dosage (ie mg, units, grams)</th>
<th>Frequency How many times a day</th>
<th>Do you take the medication as the physician ordered? Yes or No</th>
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<tbody>
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</tbody>
</table>
16. When you have an appointment for your heart failure - which health care personnel do you routinely see? (Check all that apply)
   _____ Cardiac rehab personnel
   _____ Cardiologist
   _____ Dietician
   _____ Nurse Practitioner
   _____ Occupational Therapist
   _____ Pharmacist
   _____ Physical therapist
   _____ Physician
   _____ Physician Assistant
   _____ Psychologist
   _____ Registered Nurse
   _____ Social Worker

17. Where were you first diagnosed with Heart Failure?
   _____ Hospital
   _____ Physician office
   _____ Clinic office
   _____ Emergency Room

18. How many miles do you travel to keep this appointment?
   ____________________
19. How do you define or describe heart failure?

20. Did you ever not receive a medication or treatment because your insurance would not pay for it?  _____ Yes  _____ No  
What was it?

21. What does heart failure mean to you?

22. Is there any other information you consider important?
Appendix H: Pilot Study Letter and Questions

80 Fernwood Avenue
Wheeling, WV 26003
June 6, 2003

This research is in conjunction with Janet Bischof’s dissertation at Duquesne University entitled “A comparison of the Adult Heart Failure Patient’s Quality of Life when managed in different medical settings: A Heart Failure Clinic and a Cardiology Practice”. I have selected the four surveys to be used in my research and have some questions about their use in my research.

Participation in the testing of these surveys will take no more than an hour of your time. There is no risk associated with participation and you are assured confidentiality. Your return of the completed survey indicates your consent to participate in this pilot study.

Enclosed you will find a copy of the surveys to be reviewed. These surveys are intended to be completed by patients who have a diagnosis of heart failure. I am not interested in the content of the answers. I am interested in the process and ease of completing the surveys. Please read the following instructions prior to completing the surveys.

Instructions:
1. When you are ready to start completing the questionnaire please mark the time that you start. For example 10:15 am
2. Answer the questions on all pages. Again your answers are not as important as your ease in completing the questions.
3. If you have concerns about words used, instructions, or unclear questions - please feel free to write on the surveys and indicate your problems.
4. When you are finished with the survey indicate the time you finished. For example 10:45 am.
5. Then, please take a few minutes to complete the questions about the “look” of the surveys.

When you have completed the survey and questions - please return them to Leah Martin or by mail using the enclosed self-addressed stamped envelope.

Your review of these surveys will assist in my research efforts and allow the patients that participate in this research to have clear, easy to follow surveys to complete. Your participation is greatly appreciated.

Sincerely
Janet Bischof RN, MS, CCRN, CNA
Doctoral Student Duquesne University
Pilot Study Questions

1. Age of reviewer ______________ years

2. Time you started reviewing the surveys __________________

3. Time you completed reviewing the surveys __________________

4. Were you able to read the size of print without problem? _____ Yes _____ No
   Comments:

5. Did shading or coloring of every other question make it easier to read and answer the questions? _____ Yes _____ No
   Comments:

6. Is the white paper the surveys are printed on make it easy to read?
   _____ Yes _____ No
   Comments:

7. Does having the pages printed front and back make it harder to complete the questions? _____ Yes _____ No
   Comments:

Reminder: You may write on the surveys if there are particular questions you did not understand or instructions that were unclear.
Appendix I: Medical Chart Questionnaire

MEDICAL CHART REVIEW (to be completed by the researcher)

Study ID # ____________

EF%

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<th>initial %</th>
<th>Date</th>
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<tr>
<td>current %</td>
<td>Date</td>
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Echo Results:

Cardiac Cath results:

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<th>NYHA Classification</th>
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<tr>
<td>_____ II</td>
<td>_____ Diastolic</td>
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<td>_____ III</td>
<td>_____ Combination</td>
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<tr>
<td>_____ IV</td>
<td>_____ Undetermined</td>
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# of documented visits in past 12 months ________________

number of calls ________________

Medical profile from chart

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<th>Dosage (ie mg, units, grams)</th>
<th>Frequency</th>
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<td>How many times a day</td>
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<tr>
<td>Medication</td>
<td>Dosage (ie mg, units, grams)</td>
<td>Frequency How many times a day</td>
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**Past medical History**

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<td>Lung problems</td>
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<td>CVA (Stroke)</td>
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<td>Hypertension (high blood pressure)</td>
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<td>Cardiomyopathy</td>
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<td>MI (heart attack)</td>
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<tr>
<td>Dysrhythmias</td>
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<td>Number of years</td>
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</tr>
<tr>
<td>Other</td>
<td></td>
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</tbody>
</table>

If LBBB - pacemaker?

Date first seem in clinic or physician office _________________

Date interviewed _________________

Primary physician _________________

Are you using a HF protocol or guideline
  ____ clinic specific
  ____ office specific
  ____ ACC guidelines
  ____ HSA guidelines

Failed treatments:

Insurance company:

Referral to clinic or physician office from ______________________
Appendix J: Sample Size Comparisons from Previous Heart Failure Studies

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<td>23.28</td>
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<td>20.34</td>
<td>129</td>
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</table>

1 MLHFQ - Minnesota Living with Heart Failure Questionnaire
2 SD - standard deviation
3 SF-36 Short Form 36
Appendix K: Patient Information Brochure

PRIMARY INVESTIGATOR

Janet Bischof, Registered Nurse, is a doctoral student at Duquesne University in Pittsburgh, PA. This study is in fulfillment of requirements for a PhD in Nursing. Janet resides in Wheeling, WV. Her prior nursing experience includes nursing care in Coronary Care Units, Critical Care Units and step-down or Teleretry Units. Janet also has experience in nursing management and nursing education. She is currently working in a hospital in western Ohio in the Nursing Education Department.

If you have questions regarding this study, you may call Janet at home: (304) 342-8453.

PURPOSE OF THE STUDY

To obtain information about how you think Heart Failure affects your daily life.

THE STUDY

This study will involve a one-time commitment of approximately forty (40) minutes.

You will be answering four (4) questionnaires:

1. The Minnesota Living with Heart Failure Questionnaire
2. The SF-36
3. The Self Care Resource Inventory questionnaire
4. A general questionnaire about you personally

Everything you need to complete the questionnaire will be supplied—the questionnaires and a pencil.

You will be asked to sign a CONSENT regarding participation in this research.

STUDY TIME FRAME

This study will gather information starting in the spring months of 2005 and end in the summer of 2005.

The investigator, Janet, will be present on the premises on various days to gather the data/information after your normally scheduled appointment. If Janet is present on your appointment day, you will be asked by the staff during your appointment, if you would like to participate. You may answer YES or NO to participation. There are no detrimental outcomes if you choose not to participate.

RESULTS

If you would like a summary of the research findings, a pre-paid postcard will be provided for your request.

CONFIDENTIALITY

At no time will your name or full address be included in the data or on the questionnaire. You will be assigned STUDY IDENTIFICATION NUMBER (ID NUMBER). This ID number will be used to identify your information.

This study has been reviewed by the Institutional Review Board (IRB) committee at Duquesne University and the committee has given permission to proceed with the study. This committee reviews all research studies being conducted by students or employees.
Appendix L: Duquesne University IRB Approval Letter

DUQUESNE UNIVERSITY
INSTITUTIONAL REVIEW BOARD
424 RANGOS BUILDING ◆ PITTSBURGH, PA 15282-0202

March 11, 2005

Ms. Janet Bischof
80 Perrwood Avenue
Wheeling WV 26003

Re: “A comparison of the adult heart failure heart patient’s quality of life when managed in different medical settings: A heart failure clinic and a physician practice”
Protocol #05-25

Dear Ms. Bischof:

Thank you for submitting your research proposal.

Based upon the recommendation of IRB member, Dr. Linda Goodfellow and HIPAA Officer, Dr. Joan Kiel, along with my own review, I have determined that your research proposal is consistent with the requirements of the appropriate sections of the 45-Cod of Federal Regulations-46, known as the federal Common Rule. The intended research poses no greater than minimal risk to human subjects. In addition it is HIPAA compliant. Consequently, under rules 46.101 and 46.110, your proposed research is approved on an expedited basis.

In accordance with federal guidelines, the IRB stamps consent forms with an approval date and one year expiration date. This stamp appears on the front page of the consent form, which is enclosed with this letter. You should use it as the original for your copies. Please remember that there should be two copies with original signatures, one for you and one for the subject.

This approval must be renewed in one year as part of the IRB’s continuing review. You will need to submit a progress report to the IRB in response to a questionnaire that we will send. In addition, if you are still utilizing your consent form, you will need to have it approved for another year’s use.

If, prior to the annual review, you propose any changes in your procedure or consent process, you must inform the IRB of these changes and wait for approval before implementing them. In addition, if any procedural complications or adverse effects on subjects are discovered before the annual review, they immediately must be reported to the IRB Chair before proceeding with the study.
Certificate of Successful Completion of
An Approved Continuing Education Activity
Cine-Med, Inc. does hereby certify that

Janet Bischof
80 Fernwood Avenue,
Wheeling, WV 26003

Successfully Completed

Human Participant Protections Education for Research Teams

Sponsored by the National Cancer Institute
National Institutes of Health

Date of Completion  October 24, 2003
Contact Hours  1.5

Brian Mozelak  October 27, 2003
Director, Continuing Medical Education

This activity has been approved by the Maryland Nurses Association, which is accredited as an approver of continuing education in nursing by the American Nurses Credentialing Center's Commisions on Accreditation.
Appendix N: West Penn Allegheny Health System IRB Approval Letter

July 18, 2005

Janet Bischof, RN
Duquesne University

RE: RC # 3834 A Comparison of the Adult Patient with Heart Failure’s Quality of Life When Managed in Different Medical Settings: A Heart Failure Clinic and a Physician Practice

Dear Ms. Bischof:
The Institutional Review Board (IRB) of Allegheny General Hospital is in receipt of the above-referenced protocol.

The IRB has reviewed the information and determined that the above-referenced protocol is approved. A copy of the stamped approved Informed consent (dated July 18, 2005) is attached for your use.

This protocol has been reviewed via the “expedited review” process and approved on its scientific, safety, ethical and socio-economic merits, and approved in accordance with Institutional, Federal and State regulations by the IRB. It is the responsibility of the investigator to obtain any other necessary approvals prior to implementation of the research (AGH and/or ASKR).

Your approved protocol will be subject to review within one year from the date of initial review by the IRB.

Sincerely,

Matthew R. Quigley MD
Chairman
Institutional Review Board
MRQ/c

cc: Department Chairperson
Administrative Vice President
Certificate of Completion

The Allegheny General Hospital Institutional Review Board

Certifies that

Janet Bischof

Completed the Human Subject Research Education Video series and passed the written test with a score of 80% or greater.

October 26, 2004

Date

**Education Certification is valid for 3 years

[Signature]

Research Compliance Specialist
Appendix P: Informed Consent Documents

Duquesne University
School of Nursing

Title: A comparison of the Adult Heart Failure Patient’s Quality of Life when managed in different medical settings: A Heart Failure Clinic and a Physician Practice

Principal Investigator:
Janet Bischof RN, MS, CCRN, CNA
Student, Duquesne University School of Nursing
80 Fernwood Avenue
Wheeling, WV 26003
Home (304)242-8453

Advisor:
Dr. Kathleen Sekula PhD, APRN
628 College Hall
School of Nursing
Duquesne University
Pittsburgh PA 15282
Work (412) 396-4865

Source of Support:
This study is being performed as partial fulfillment of the Requirements for the doctoral degree in Nursing at Duquesne University, Pittsburgh, PA

Purpose:
You are being asked to participate in a research project that seeks to study quality of life measures in the heart failure group. The study is trying to determine how you think heart failure has changed your daily life. You will be asked to answer paper and pencil surveys that will take approximately 40 minutes of your time to complete.

Subjects:
You are being invited to take part in this research study because you have already been diagnosed with heart failure. People invited to join in this study must be over the age of 18, currently receiving treatment for heart failure, and have the ability to read and write English.

The investigators are committed to comply with the basic principles of the NIH guidelines on inclusion of women and minorities in research, and will make every effort to enroll subjects into the study from both sexes, all minority groups, and age levels.

Procedures to be Performed:
If you decide to take part in this research study, you will be asked to complete 4 written questionnaires: The Minnesota Living with Health Failure Questionnaire, the Short Form-36 version 2 survey, the Self Care Resource Inventory questionnaire, and a general questionnaire about you personally. Confidentiality will be maintained and at no time will the participants names be recorded.
Risks:
The risks of this study involve sharing of personal medical and social information. There are no physical risks involved. You will be promptly notified, if during this research study, any new information develops which may cause you to change your mind about continuing to participate.

Benefits:
The benefits of this study involve the ability to share collected information with other health care workers to better provide care to heart failure patients.

Alternate Procedures:
What treatments or procedures are available if I decide not to participate in this study:
If you decide not to participate in this study, you will continue to receive heart failure medical care in your current setting.

Costs:
Neither you nor your insurance provider will be charge for the costs of any portion of this study.

Payment:
There will be no monetary compensation for completing the surveys this research study. I have been fully informed by the researcher and I understand fully, that in the event of any physical injury, or injuries resulting from research procedure or protocols to which I have voluntarily and knowingly agreed to participate in, that no monetary compensation or free medical treatment will be made available to me by Allegheny General Hospital or Allegheny-Singer Research Institute.

Confidentiality:
Any information about you obtained from this research will be kept as confidential (private) as possible. All record related to your involvement in this research will be stored in a locked file cabinet at the researcher’s home. Your identify on these records will be indicated by a case number rather than by your name, and the information linking these case numbers will be kept separate from the research records. You will not be identified by name in any publication of the research results.

In 1996 the government passed a law known as The Health Insurance Portability and Accountability act (HIPAA), Public Law 104-191. This privacy law, among other things will improve how your health care information is protected and kept confidential when it is used or disclosed with others. This includes both your medical records and insurance information as well as other personal health information. This consent form describes to you how information about you may be used or disclosed (released) if you are in a research study. It is important that you read this carefully.

In order to participate in this research study you must permit (allow) certain research records to be made about you in addition to the usual records the hospital and doctors create about your medical treatment. These research records will contain private medical and other information, which is protected by law. The researchers will only create the minimum amount of research records necessary to carry out the research.

Types of research records that may be shared/copied is:
- Tissue Samples
- Medical Records - a review of you medical record in the clinic/office
- Lab Results
- Other (specify)

In addition to using these research records to carry out the research and, perhaps, to treat you, the researchers will share portions of these research records to third parties involved in the research study. The third parties, who receive research information, may further share the information about you in accordance
with their policies, practices, and what the law requires. However, some third parties, (such as the Sponsor) may not need to follow their privacy law. To the best of our knowledge, a complete and accurate description of who the third parties are and how they will use or disclose the information are as follows:

<table>
<thead>
<tr>
<th>Third Party</th>
<th>Purpose</th>
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<tbody>
<tr>
<td>Allegheny-Singer Research Institute</td>
<td>May share this signed consent form and records that identify you for purposes related to this research and for publication.</td>
</tr>
<tr>
<td>Duquesne University</td>
<td></td>
</tr>
</tbody>
</table>

The release of information described above will be the minimum necessary to abide by the law complete the research, and perhaps, publish the research.

Unlike your medical records, you will not have access to research records made about you during the study. However, these will be available at the end of the study. Although every effort will be made to keep research records about you private, complete confidentiality cannot be guaranteed. Such research records may be subject to subpoena or court order. The researcher has set up safeguards to keep private information about you confidential.

There is no expiration for this Authorization unless you revoke (cancel) it. You may revoke this Authorization by writing to the Principal Investigator. If you revoke your Authorization, you will also be removed from the study. Revoking your Authorization only affects the use and sharing of your information after the written request is received. Any information obtained prior to receiving the written request may be used to maintain integrity of the study (for example account for reporting of side effect, sending information to the FDA for studies it regulates.

This research will involve the recording of current medical information from your current medical record. The information will be recorded will be limited to the information concerning the purpose of this study. Your identify on these records will be indicated by a case number rather than by your name, and the information linking these case numbers will be kept separate from the research records. You will not be identified by name in any publication of the research results.

If you choose not to sign this Authorization, you will not be permitted to participate in this research study. In order to participate in this study, you must agree to the use and disclosure of your information with the groups above. Upon completion of the study or if you withdraw from the study at any time, the research records about you will be kept by the researcher(s) and all of the information provided above will continue to apply to your research records.

You give permission that your research records can be used and disclosed as described.

Voluntary Participation
Your participation in this research study is completely voluntary. Whether or not you provide your consent for participation in this research study will have no affect on your current or future relationship with your health care provider or health care insurance provider.

Inquires
If you have any questions or concerns regarding the research study, you may contact the principal investigator as listed on page 1 or the Allegheny Singer Research Institute at (412) 359-3156.

Right to Withdraw:
You are under no obligation to participate in this research study. You are free to withdraw your consent to participate at any time. To formally withdraw your consent for participation in this research study you may
stop completing the questionnaires and document withdrawal from study on the last page. Your decision to withdraw will have no affect on your current or future relationship with your current medical provider or insurance provider.

**Summary of Results:**
A one page summary of results of this research study will be supplied to you at no cost, upon request.

**Voluntary Consent:**
I have read the above statements and understand what is being requested of me. I also understand that my participation is voluntary and that I am free to withdraw my consent at any time, for any reason. All of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by the researchers as listed on the first page of this form.

By signing this form, I agree that I am willing to participate in the research study. A copy of this consent form will be given to me.

I understand that should I have any further questions about my participation in this study, I may call Dr. Paul Richer, Chair of the Duquense University Institutional Review Board (412-396-6326) or the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh (412-578-8570).

__________________________________    ______________
Participant’s Signature    Date

I certify that I have explained the nature and purpose of this research study to the above-named individual and I have discussed the potential benefits and possible risks of study participation. Any questions the individual has about this study have been answered, and we will always be available to address future questions as they arise.

__________________________________
Printed name of Person Obtaining Consent    Role in Research Study

__________________________________    ______________
Signature of Person Obtaining Consent    Date
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Duquesne University
School of Nursing

Title: A comparison of the Adult Heart Failure Patient's Quality of Life when managed in different medical settings: A Heart Failure Clinic and a Physician Practice

Principal Investigator:
Janet Bischof, RN, MS, CCRN, CNA
Student, Duquesne University School of Nursing
80 Fernwood Avenue
Wheeling, WV 26003
Home (304) 242-2453

Advisor:
Dr. Kathleen Schula PhD, APRN
524 Fisher Hall
School of Nursing
Duquesne University
Pittsburgh PA 15282
Work (412) 396-4865

Source of Support:
This study is being performed as partial fulfillment of the requirements for the doctoral degree in Nursing at Duquesne University, Pittsburgh, PA.

Purpose:
You are being asked to participate in a research project that seeks to study quality of life measures in the heart failure group. The study is trying to determine how you think heart failure has changed your daily life. You will be asked to answer paper and pencil surveys that will take approximately 40 minutes of your time to complete.

Subjects:
You are being invited to take part in this research study because you have already been diagnosed with heart failure. People invited to join in this study must be over the age of 18, currently receiving treatment for heart failure, and have the ability to read and write English.

The investigators are committed to comply with the basic principles of the NIH guidelines on inclusion of women and minorities in research, and will make every effort to enroll subjects into the study from both sexes, all minority groups, and age levels.

Procedures to be Performed:
If you decide to take part in this research study, you will be asked to complete 4 written questionnaires: The Minnesota Living with Heart Failure Questionnaire, the Short Form-36 survey, the Self Care Resource Inventory questionnaire, and a general questionnaire about you personally. Confidentiality will be maintained and at no time will your name be recorded.
Risks:
The risks of this study involve sharing of personal medical and social information. There are no physical risks involved. You will be promptly notified, if during this research study, any new information develops which may cause you to change your mind about continuing to participate.

Benefits:
The benefits of this study involve the ability to share collected information with other healthcare workers to better provide care to heart failure patients.

Alternate Procedures:
What treatments or procedures are available if I decide not to participate in this study?
If you decide not to participate in this study, you will continue to receive heart failure medical care in your current setting.

Costs:
Neither you nor your insurance provider will be charged for the costs of any portion of this study.

Payment:
There will be no monetary compensation for completing the surveys in this research study. I have been fully informed by the researcher and understand fully, that in the event of any physical injury, or injuries resulting from research procedure or protocols to which I have voluntarily and knowingly agreed to participate in, that no monetary compensation or free medical treatment will be made available to me by Allegheny General Hospital or Allegheny-Singer Research Institute.

Confidentiality:
Any information about you obtained from this research will be kept as confidential (private) as possible. All records related to your involvement in this research will be stored in a locked file cabinet at the researcher's home. Your identity on these records will be indicated by a case number rather than by your name, and the information linking these case numbers will be kept separate from the research records. You will not be identified by name in any publication of the research results.

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Types of research records that may be shared/copied is:

- [ ] Tissue Samples
- [X] Medical Records - a review of your medical record in the clinic/office
- [ ] Lab Results
- [ ] Other (specify)
In addition to using these research records to carry out the research and, perhaps, to treat you, the researchers will share portions of these research records to third parties involved in the research study. The third parties, who receive research information, may further share the information about you in accordance with their policies, practices, and what the law requires. However, some third parties, (such as the Sponsor) may not need to follow the privacy law. To the best of our knowledge, a complete and accurate description of who the third parties are and how they will use or disclose the information are as follows:

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<td>Duquesne University</td>
<td></td>
</tr>
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<td>Allegheny General Hospital</td>
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</table>

The release of information described above will be the minimum necessary to abide by the law, complete the research, and perhaps, publish the research.

Unlike your medical records, you will not have access to research records made about you during the study. However, these will be available at the end of the study. Although every effort will be made to keep research records about you private, complete confidentiality cannot be guaranteed. Such research records may be subject to subpoena or court order. The researcher has set up safeguards to keep private information about you confidential.

There is no expiration for this Authorization unless you revoke (cancel) it. You may revoke this Authorization by writing to the Principal Investigator. If you revoke your Authorization, you will also be removed from the study. Revoking your Authorization only affects the use and sharing of your information after the written request is received. Any information obtained prior to receiving the written request may be used to maintain integrity of the study (for example account for reporting of side effect, sending information to the FDA for studies it regulates).

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If you choose not to sign this Authorization, you will not be permitted to participate in this research study. In order to participate in this study, you must agree to the use and disclosure of your information with the groups above. Upon completion of the study or if you withdraw from the study at any time, the research records about you will be kept by the researcher(s) and all of the information provided above will continue to apply to your research records.

You give permission that your research records can be used and disclosed as described.

**Voluntary Participation**
Your participation in this research study is completely voluntary. Whether or not you provide your consent for participation in this research study will have no affect on your current or future relationship with your health care provider or health care insurance provider.

**Inquires**
If you have any questions or concerns regarding the research study, you may contact the principal investigator as listed on page 1 or the Allegheny Singer Research Institute at (412) 359-3156.
In addition to using these research records to carry out the research and, perhaps, to treat you, the researchers will share portions of these research records to third parties involved in the research study. The third parties, who receive research information, may further share the information about you in accordance with their policies, practices, and what the law requires. However, some third parties, such as the Sponsor, may not need to follow the privacy law. To the best of our knowledge, a complete and accurate description of who the third parties are and how they will use or disclose the information are as follows:

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You give permission that your research records can be used and disclosed as described.

Voluntary Participation
Your participation in this research study is completely voluntary. Whether or not you provide your consent for participation in this research study will have no effect on your current or future relationship with your health care provider or health care insurance provider.

Inquiries
If you have any questions or concerns regarding the research study, you may contact the principal investigator as listed on page 1 or the Allegheny Singer Research Institute at (412) 359-3156.
Right to Withdraw:
You are under no obligation to participate in this research study. You are free to withdraw your consent to participate at any time. To formally withdraw your consent for participation in this research study you may stop completing the questionnaires and notify the investigator of your withdrawal. Your decision to withdraw will have no affect on your current or future relationship with your current medical provider or insurance provider.

Summary of Results:
A one page summary of results of this research study will be supplied to you at no cost, upon request.

Voluntary Consent:
I have read the above statements and understand what is being requested of me. I also understand that my participation is voluntary and that I am free to withdraw my consent at any time, for any reason. All of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by the researcher as listed on the first page of this form.

By signing this form, I agree that I am willing to participate in the research study. A copy of this consent form will be given to me.

I understand that should I have any further questions about my participation in this study, I may call Dr. Paul Risher, Chair of the Duquesne University Institutional Review Board (412-396-6326) or the Allegheny-Singer Research Institute office (412-396-3156).

______________________________
Participant's Signature

______________________________
Date

I certify that I have explained the nature and purpose of this research study to the above-named individual and I have discussed the potential benefits and possible risks of study participation. Any questions the individual has about this study have been answered, and we will always be available to address future questions as they arise.

______________________________
Printed name of Person Obtaining Consent

______________________________
Role in Research Study

______________________________
Signature of Person Obtaining Consent

______________________________
Date
References


*European Journal of Cancer, 31A*(Suppl 6), S2-7.


Baas, L. S. (1992). *The relationship amoung self-care knowledge, self-care resources, activity level and life satisfaction in persons three to six months after a*
myocardial infarction. Unpublished Dissertation, The University of Texas at Austin, Austin, Texas.


(WHOQOL) instrument [see comments]. *Journal of Clinical Epidemiology, 53*(1), 1-12.


are valid measures of health-related quality of life in heart failure. *Journal of Cardiac Failure, 5*(2), 85-91.


College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Revise the 1995 Guidelines for the Evaluation and Management of Heart Failure): Developed in Collaboration With the International Society for Heart and Lung Transplantation; Endorsed by the Heart Failure Society of America. *Circulation, 104*(24), 2996-3007.


Kellum, J. A. (2001). *Critical Care Medicine, 29*(8), 1526-1531.


than training involving a major muscle mass in chronic heart failure patients.


